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CHAPTER 6

THE INDIAN GOVERNMENT AND THE PHARMACEUTICAL INDUSTRY

As indicated in Chapter 5, the Government of India plays an important role in the regulation of the pharmaceutical industry. An experienced Marketing Manager of one major European company described India as a "unique market", because of the plethora of controls (1); the effects of these laws formed a central subject in most of the interviews held in India. The laws are particularly unpopular with the foreign companies and the Chairman of the industry association which represents such companies, characterised them as follows:

"The pharmaceutical industry tops the list of industries in the country that are tightly controlled, regulated and legislated upon. There are at least 7 Ministries and Departments... concerned with the control and regulation of the pharmaceutical industry. In addition to these, there are controls, regulations and legislations to enforce them at State level.

No wonder, then, that there are inevitable delays in decision-making at every point of control. The cumulative impact of such delays is staggering in terms of slow-down in the pace of growth and consequent loss of production, employment and revenue to the national exchequer.

Clearly there is urgent need to move away from a period of excessive or counter-productive controls to an era of vigorous and healthy growth." (2)

As Dutt Gupta states here, there are many Ministries involved in the regulation of the industry. The Ministry of Petroleum, Chemicals and Fertilisers (PCF) has primary responsibility (3), and it is supported by other official bodies, such as the DGTD and the CSIR (4).

(1) Interview, Europe, January, 1981.
(3) Others include Health, Commerce, Finance and Industry.
(4) In the late 1970s, the Government re-established the Drugs and Pharmaceuticals Development Council, a semi-autonomous advisory body. Bazaz (1980) p75 and SCRIP, 3 March, 1979. The Council has 25 members, including representatives of Government and Public and
Equally, the Government is convinced of the need to regulate the industry, explaining that:

"In a country like India where the average technical knowledge of the consumer is rather low and technical guidance for him is scarce, the role of the Government becomes highly important." (5)

6.1 LEGISLATION AND THE PHARMACEUTICAL INDUSTRY

The nature of state control may be understood by reviewing the major laws which are peculiar to the pharmaceutical industry and those which affect productive industry as a whole.

In the mid-1970s, the Government instigated a comprehensive enquiry, which resulted in wide-ranging legislation affecting the pharmaceutical industry. Nevertheless, the drug regulatory system is, essentially, an inheritance from colonial times. The Drugs and Cosmetics Act, passed in 1940, was adopted after Independence as the principal Act to regulate the import, manufacture, distribution and sale of drugs (6).

The pharmaceutical industry has been of much interest to the authorities in India and at various times they have established several enquiries. The first of these was the 1930-31 Committee, chaired by Lt.Col.R.N.Chopra (7), proposed the establishment of (central) Government and State Pharmacy Councils, improved testing and private Sector industry.

(5) Hathi (1975) p162.
(6) It is now used, together with many other laws which refer specifically to drugs, passed by the colonial or independent administrations. Such laws are described, briefly, in Bazaz (1980) p21-33.
(7) It was set up after the 'Quinine Fraud' of the 1920s, when extremely substandard tablets were sold to the public. Enquiries were made, throughout the country, into the production and distribution of drugs and the report was submitted in 1931.
control legislation, and a comprehensive Act, to apply to the whole of India. The Committee's recommendations were included in the 1940 Drugs and Cosmetics Act (8).

The Chopra Committee was followed, after Independence, by the 1953-54 (Bhatia) Pharmaceutical Enquiry Committee, which had wide-ranging terms of reference, including the structure of ownership, as well as the efficacy of drug manufacture and distribution (9). Its 212 recommendations were equally comprehensive; they included the advice that all manufacturers should produce "as many fine chemicals and drugs starting from basic chemicals and/or intermediates... as possible" §No.1, that the supply of raw materials should be coordinated by the Government §No.2, that Public Sector penicillin production should be greatly expanded §No.10 (and No.11), and that the Government should assist companies to build production plants which would otherwise be uneconomic because of the low demand §No.39. The Foreign Sector was the particular subject of several recommendations. Such units should be required to produce bulk pharmaceuticals starting from raw materials, but they would be allowed imports in the meantime §No.37. Foreign companies would be allowed only to set up factories to manufacture products not already manufactured in sufficient quantities §No.40; foreign collaboration would not be allowed

(9) "(i) To study the working of the existing pharmaceutical manufacturing concerns in India with special reference to the demand... quality... the cost of production... efficiency of the processes... whether the product is made from imported intermediates and penultimate products or from basic raw materials and chemicals, (ii) To study the operations of foreign... concerns... The extent and tie-up between the... Indian concerns with foreign companies, (iii) To recommend steps to encourage the manufacture of important drugs which are imported... (iv) To enquire into the scheme of distribution... [and] (v) All ancillary matters connected with the above." Bhatia (1954) p2-3.
for cosmetics and should be allowed for pharmaceuticals, only if the drugs to be produced were essential and the process involved bulk drug manufacture §No.45. "Firms with 100 per cent foreign capital... should not be permitted" §No.49 (10). The Committee added that:

"We wish to sound a note of caution, however, that unless these recommendations are implemented in toto the desired results may not be achieved." (11)

In fact, very few of the recommendations were enacted. During the late 1950s, the Government encouraged foreign collaboration (12), and failed to enforce bulk drug production, whilst "some of the firms did tend to undertake the manufacture of bulk drugs [but] they came across several difficulties, due to lack of technology, basic chemicals etc." (13)

Over the next two decades, a dozen further committees reported on various aspects of the industry (14), before the next comprehensive enquiry was held in the mid-1970s. As a result of these inquiries, and in accordance with its wider industrial policy, the Government of India has passed a variety of regulations which affect the pharmaceutical industry, either uniquely, or together with other industries. These are briefly described in Appendices 6.1 and 6.2.

6.2 THE 1970s: PUBLIC DEBATE AND THE PHARMACEUTICAL INDUSTRY

In the early 1970s, the purpose and performance of the Indian pharmaceutical industry became a matter of increasing concern, upon which the Government was finally forced to act:

(12) See Chapter 1 and Rajadhyksha (1973) p33.
(14) These are listed in Jayaraman (1980a) p63-69.
"The functioning and growth of the Drugs and Pharmaceutical Industry in India over the past few years were engaging the attention of Government for quite sometime [sic], particularly with a view to finding out ways and means to meet the growing requirements and broad social objectives before the country. Questions about the performance of the Public Sector units, multi-national firms' gaining stronghold in this field, prices of locally produced medicines, etc. were raised in the Parliament." (15)

In April, 1974, the Government of India established a Committee, under Jaisukhlal Hathi, to investigate the industry. Its specific terms of reference were as follows:

"(i) To enquire into the progress made by the industry and the status achieved by it,
(ii) To recommend measures necessary for ensuring that the Public Sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development,
(iii) To make recommendations for promoting the rapid growth of the drugs industry and, particularly, of the Indian and Small Scale Industries Sector. In making its recommendations the Committee will keep in view the need for a balanced regional dispersal of the industry.
(iv) To examine the present arrangements for the flow of new technology into the industry, and make recommendations therefor [sic],
(v) To recommend measures for effective quality control of drugs, and for rendering assistance to Small-Scale units in this regard,
(vi) To examine the measures taken so far to reduce the prices of drugs for the consumer, and to recommend such further measures as may be necessary to rationalise the prices of basic

drugs and formulations,

(vii) To recommend measures for providing essential drugs and common house-hold remedies to the general public, especially in the rural areas, and

(viii) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially in the Small-Scale Sector." (16)

On the surface, these terms seemed rather innocuous, and the Foreign Sector did not feel unduly threatened (17). In fact, the Report of the Hathi Committee led to a vigorous debate, which continues up to the present day. The Government also formulated the 1978 New Drug Policy and the 1979 DPCO from the Hathi Recommendations.

The Report of the Hathi Committee is a large document; it covers some 275, closely-printed, pages and contains a wealth of numerical data, information and opinion. It also includes many recommendations, which range from trivial exhortations (18), to some which would greatly change the nature of the Indian pharmaceutical industry. Amongst the latter were:

(17) Almost a year later, during the month in which the Committee actually reported, SCRIP was of the opinion that "in making its recommendations, the Committee is expected to emphasise: the need for balanced dispersal of the industry, and the importance of the Public Sector in the manufacture of basic drugs, and in research and development. It is understood that American and multinational drug firms operating in the country are likely to be unaffected by the Hathi proposals." SCRIP, 12 April, 1975, p4.
(18) For example: "The Indian sector should maintain an effective dialogue with the medical profession regarding their products." (p104); "There is a need for increased productivity in a rationalised manner of all that we produce now and diversification of production to cater to national needs on a priority basis." (p167); and, "No Inspector should be posted by a State Government unless he has been trained." (p201).
(i) The proposal to establish a National Drug Authority (NDA), which would exercise control over pharmaceutical production and distribution (19),

(ii) The TNCs in India were described as: "a powerful damper on the challenge of our achieving the technological goals of self-sufficiency and self-reliance." (20) The Committee recommended, by a majority decision, that: "the multinational firms should be taken over, forthwith." (21)

(iii) The prevailing system of price control "[did] not appear to have contributed materially to the emergence of a product or price pattern which [was] more in consonance with social needs or national objectives." The Committee proposed an alternative system of control, whereby companies would be limited in their overall profit levels (22), and

(iv) The Committee decided that "Brand Names should be abolished in a phased manner." (23)

Of these recommendations, the establishment of the NDA was by far the most drastic. All private producers felt this to be a threat, as it would remove much of their freedom. However, as the OPPI spokesmen were quick to point out, the establishment of a

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(19) Individual companies would be told what to produce and in what quantities; all international collaboration would be arranged by the NDA. Government workers in "primary health centres, post offices and public distribution agencies [would be] used for economic distribution." The NDA is discussed on p84-85 of the Hathi Report.
(20) Hathi (1975) p96.
(22) One further suggestion was that the leading producers, who "account for, say, 60% of the sales, would have fixed prices." Price control is discussed in Hathi (1975) p180-188.
(23) Hathi (1975) p257. They identified 13 drugs which should be sold only under generic names immediately, and suggested that others should be added later.
supra-governmental body might also pose a threat to the state establishment in that:

"... the NDA is to be free from day-to-day Governmental interferences. It is also not clear what would be the role of the NDA in relation to Government and Parliament (which are the supreme policy planning bodies in the country) and what kind of control Government and Parliament would exercise over the NDA. If the Government is not to abrogate to the NDA its responsibilities for laying down the policies and priorities concerning the industry, then such a functional body is bound to be a needless intermediary between the Government and Parliament, on the one hand, and the industry on the other, serving as a brake at every stage and causing needless delays over matters that need urgent attention." (24)

In practice:

"The NDA was not even seriously considered. The Ministry was not willing to forego the existing advantage and, even the Small-Scale industry, all [producers] have benefited from the status quo too much to risk anything... and the medical profession is not against the status quo." (25)

In the event, the issue of nationalisation attracted the most attention and it dominated the period between the publication of the Hathi Committee Report and the Government decisions on the recommendations, some three years later. This debate, as described by Zoya (26), demonstrates the apparent interests of those affected by nationalisation. Those who would be most affected included the Government, members of the medical profession, and the pharmaceutical manufacturers.

The opinions of the industry itself were voiced by its own organisations. The private companies are represented, primarily, by

(25) Interview, B.V. Rangarao, New Delhi, April, 1981.
(26) Zoya (1976) and Hasan (1980) are the same writer. The latter paper is a slightly updated and amended version of sections of the original PhD thesis.
two trade bodies, OPPI (The Organisation of Pharmaceutical Producers of India) (27), and IDMA (The Indian Drug Manufacturers' Association) (28). Other trade associations have pharmaceutical sections, and they comment, usually in conjunction with OPPI or IDMA, on matters of common interest (29).

Understandably, the call for foreign companies to be nationalised was received differently by the various industry Sectors. OPPI led the opposition, arguing that, if the foreign companies were to withdraw, the country would face difficulties in the supply of quality drugs and in the introduction of new technology (30). OPPI maintained that the foreign companies were serving the needs of the country, and that there was no real distinction between the Foreign and Indian Sectors:

"It is important to recognise that all units, irrespective of their base of ownership, are in fact Indian; they operate in India, are operated by Indians, for the people of India, and are subject to the laws and regulations of India." (31)

(27) "OPPI is an association of pharmaceutical manufacturers representing companies that account for 40 per cent of the country's pharmaceutical production and 60 per cent of exports and R&D" OPPI (1982) p4. Although a very few OPPI members are Indian-owned, the great majority are foreign companies and OPPI is usually taken to represent the views of the Foreign Sector. See, for example, Hasan (1980), footnote 39, p242.
(28) IDMA represents the Indian Sector; until the early 1970s, it was mainly confined to the Small-Scale companies, but it now has members from the small, medium and large companies. Interview, Managing Director, Small-Scale company, Bangalore, June, 1981 and I.A. Alva, Secretary, IDMA, Bombay, April, 1981. Although IDMA represents the Indian companies, it does not always enjoy an harmonious relationship with the Government: "Discussion [with the IDMA] gave us the impression that there is little rapport between Government and these sectors of the industry." Hathi (1975) p94.
(29) These include, AIMO (The All-India Manufacturers' Association), ICMA (The Indian Chemical Manufacturers' Association) and the All-India Chemists' and Druggists' Association.
(31) OPPI (1976) p5, emphasis in the original. This argument by the foreign companies recurs; see, for example, Special Correspondent (1976) p500.
The reaction of the Indian companies was mixed. Hasan reports that two large Indian companies, Alembic and Sarabhai, were against the takeover of the foreign pharmaceutical companies (32). She ascribes this to the fact that they could compete with the Foreign Sector, but they may also have been responding to the minority view, expressed within the Hathi Committee, that the same arguments for nationalising the foreign companies could also be advanced against the larger Indian companies (33). The Small-Scale Sector also opposed the proposed nationalisation, fearing that it would result in a state monopoly, which would take over their business of supplying drugs to the Government health services (34).

However, most of the private Indian companies (35), supported the proposed take-over. They argued that they had the necessary technical capacity to produce good quality drugs, and they requested State support:

"The IDMA campaign carried definite nationalist overtones. They conveniently assumed that nationalisation and nationalism were synonymous, implying that those who supported foreign companies were anti-national... the small companies could not develop without state protection against the competition of foreign capital and big Indian companies. As a result, they were often compelled to adopt an overtly nationalist position." (36)

The Government decisions on this issue were made, in 1978, during the imposition of the "State of Emergency", when policies could be pursued without fear of criticism in Parliament or in the press. In the event, the Government seemed to adopt OPPI's analysis, in

(33) Hathi (1975) p98.
stating that it rejected nationalisation because of the possible disruption to production. Hasan also suggests that: “the Government preferred not to disturb the status quo, so as to be able to encourage the flow of foreign aid and capital required for bolstering the sagging economy.” (37)

In 1977, the Janata Government replaced that of the Congress Party, but followed a similar line on the question of nationalisation. The recommendations of the Hathi Committee, in this respect at least, were much diluted. The decisions on the whole of the Hathi Report were published in March, 1978, as the New Drug Policy, and again induced further controversy. The New Drug Policy adopted many of the recommendations of the Hathi Committee, but the Government also 'improved' (38), on many of the details. The 'broad objectives' of the policy included the following:

(i) To develop self-reliance in drug technology,
(ii) To provide a leadership role for the Public sector,
(iii) To reduce imports,
(iv) To encourage the growth of the Indian sector,
(v) To "ensure that drugs are available in abundance to meet the health needs of our people",

(37) Hasan (1980) p248. Indeed, Hasan quotes the opinion of K.D. Malaviya, the Minister for Petroleum, Chemicals and Fertilisers, that: "A doctrinaire position on nationalisation was contrary to the spirit of the new economic environment as it would cause uncertainty in the private sector." Financial Express, 7 May, 1976, quoted by Hasan (1980) p251. One official in the same Ministry observed that: "nationalisation of the industry could offend the Western countries, particularly the United States, whom the Indian Government would not like to alienate." Interview, March, 1976, by Hasan, quoted in Hasan (1980) p251.
(38) The term used by Bahuguna, the Minister of Petroleum, Chemicals and Fertilisers, in answering questions on the new Drug Policy, Rajya Sabha, Unstarred Question No.1412, 7 August, 1978.
(vi) To control drug prices,
(vii) To monitor quality and prevent malpractices,
(viii) To offer incentives for R&D, and
(ix) "To provide other parameters to control, regulate and rejuvenate the industry as a whole, with particular reference to containing and channelizing the activity of foreign companies in accord with national objectives and priorities." (39)

The main differences from the recommendations of the Hathi Committee are shown in Table 6.1. The decisions on the method of price control were formally issued as the Drugs Price Control Order [DPCO] (1979) and other measures were implemented in a piecemeal fashion, as and when other laws could be suitably modified (40). The DPCO (1979) controls the price of every formulation sold in India and gives the Government power to control the price of bulk drugs. Drugs are placed in one of four categories, according to their supposed therapeutic value. Further details of the DPCO (1979) are given in Appendix 6.3.

As might be expected, the reaction of the companies to the new regulations was mixed, with the foreign companies speaking out against almost all of the New Drug Policy and the DPCO (1979) (41). OPP submitted a 24-page note to the Minister for Petroleum Chemicals

(40) Aiyar (1978b).
(41) Orville Freeman, a prominent USA businessman and commentator on Indian commercial affairs, is quoted as believing that "The situation in this industry is hopeless. If the policy statement that was laid on the table of the Indian Parliament is implemented a whole lot of US drug companies will leave. There will be a sharp drop in their research and development effort and the consumer will suffer. In my opinion, the policy is a deliberate attempt to drive out the foreign companies." "Freeman Sees No Future for Alien Drug Cos. in India", Economic Times, 15 September, 1978.
and Fertilisers, criticising many aspects of the new rules (42). This document stressed the need to have:

"More and more production of drugs... avoid shortage of drugs... optimum utilisation of existing installed capacities... encourage new investment... encourage the drug industry to introduce new drugs which have proved their superiority and efficacy in other parts of the world..." (43)

OPPI made little reference to the aspirations of the different sectors, referring, where possible, to the "drug industry" as a whole. It criticised the degree of control which the Government was trying to exert, and warned that:

"Such discriminatory treatment to drug industry is definitely acting as a damper to new investment and this may lead to further shortages of vital and essential drugs in future." (44)

In marked contrast to such reactions, the Indian companies considered the New Drug Policy largely favourable to their prospects. IDMA's memorandum, submitted in June 1978, made much more of the roles which the different sectors could play:

"We are in agreement with the broad objectives of the New Drug Policy... However, so far as providing a leadership role to the public sector is concerned, we feel that the public sector should act like a big brother and help the Indian sector to grow in the larger interests of the country." (45)

(42) OPPI (1980).
(43) OPPI (1980) pl.
(45) IDMA (1978) p329. Modi also saw some "points in the Policy which are very favourable for the growth [of the Indian sector]," but he criticised other aspects. Modi (1978) p683. Bhai Mohan Singh was attracted by the degree of regulation which the New Drug Policy promised. He refers to "the pragmatic and rational Drug Policy which at [last] has been produced... thereby putting an end to great deal of Adhocism [sic] that has prevailed for several years resulting in many contradictory interpretations and policies." Singh (1978) p45. These broadly correspond to the reservations which IDMA expressed and are considered below. The All-India Manufacturers' Association, speaking mainly for the Indian
<table>
<thead>
<tr>
<th>The Recommendations of The Hathi Committee (page nos. in Hathi (1975))</th>
<th>New Drug Policy (page nos. in NDP (1978))</th>
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<tbody>
<tr>
<td>1. Foreign Companies should produce, rather than import, bulk drugs within 3 years of introducing a new formulation (p104-107)</td>
<td>Period reduced to 2 years. New licences only for 'high technology' bulk drugs from the basic stage. Bulk Drug formulations ratio to be less than 1:5 (p7-12)</td>
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<td>2. A general recommendation to encourage R&amp;D. Suggested that the Public Sector spend 5% of turnover on R&amp;D. (p70)</td>
<td>R&amp;D expenditure levels laid down for foreign companies, but not for the Public Sector. (p19)</td>
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<td>3. Exemption from price control for bulk drugs which do not use imported material or whose sales are less than Rs25 lakhs per annum. A selective system of price control on formulations, using the concept of leader prices for a few products. (p186-188)</td>
<td>All bulk drugs and 8 'critical intermediates' subject to price control. Complex formulation price control, with certain exemptions for drugs discovered in India. The onus on Public units to provide low-priced drugs for health services. (p13-17)</td>
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<td>4. The establishment of a National Drug Authority with comprehensive powers. (p84-85)</td>
<td>A system of statutory bodies with much-reduced powers, to monitor drug production and distribution and to advise the Government. (p18-19)</td>
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<tr>
<td>5. Foreign companies to be taken over forthwith. If that was not acceptable to the Government, foreign companies should be made to bring their equity holdings below 40% at once, with eventual dilution to 26% (p104)</td>
<td>FERA 'core sector' activity redefined; foreign companies with suitable technology would be allowed equity holdings above 40% (p8).</td>
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<tr>
<td>6. A general move towards generic, rather than brand names for drugs. Brand names for 13 drugs to be withdrawn immediately (p257). (p257)</td>
<td>Brand names for 5 drugs withdrawn. All new, single-ingredient drugs to be sold under generic names. The policy to be under constant review. (p19,24)</td>
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In the four years following the publication of the New Drug Policy, there was considerable controversy about its terms. The principal target for the OPPI and IDMA attacks was the Government,
which they tried to influence both directly, and also indirectly by appealing to the medical and para-medical professions and to the English-speaking, upper-middle class.

The most conspicuous attempts to influence the Government were by direct approach. Almost every issue of the bi-monthly 'OPPI Bulletin' gives an account of a letter, telegram or memorandum sent to the Government, or of a delegation meeting a Government Minister (46). IDMA also use such methods, but their volume of output seems to be less (47).

There were other, less direct forms of persuasion. The foreign companies, in particular, have given, and still give, financial aid to the Central and State Governments, particularly in times of natural disaster (48). Articles are written in English-language newspapers and journals by members of OPPI's staff, or by 'independent' writers, using OPPI material (49). The foreign companies, in

 Sector, also welcomed much of the New Drug Policy. However, it recognised that a threat came, not only from the foreign companies, but also from the large Public Sector. It suggested that equal preference should be given to the Indian, Small-Scale and Public Sectors, whilst also repeating many of the IDMA and OPPI criticisms.

(46) These are also described in the OPPI Annual reports, OPPI (1981) p3-20 and OPPI (1982) p3-19. When Mrs.Gandhi returned to power, OPPI sent a telegram to: "assure you of our unqualified and unstinting support to rapidly increase production and eliminate shortages." Mrs.Gandhi thanked them for their good wishes. Both messages are quoted in OPPI Bulletin No.1/80, January/February, 1980, p1.
(48) Hasan (1980) p253. The companies, themselves, hail decisions to build factories outside the major cities as evidence of their sense of social responsibility. For example, see "Glaxo Helps Develop Backward Areas", OPPI Bulletin No.5/80, September/October, 1980, p2.
(49) Nair (1979) is an example of the former (Nair is Communication Manager of OPPI).; Anon. (1980) is an example of the latter.
particular, have developed a close relationship with the medical doctors who, they claim, prefer their products to those of the Indian companies (50). OPPI supports the post-graduate medical education programmes of the specialist medical associations, and also prepares information which it circulates to General Practitioners (51).

Other methods are less well-documented, and remain the subject of assertion by various critics. Drug companies are said to give large, clandestine, donations to political parties (52), and to give jobs, preferentially, to the relatives of Government officials (53). There have also been reports that K.R.Ganesh, a prominent official in the Ministry of Petroleum and Chemicals in the mid-1970s, was pressured into resigning: "in view of his insistence on the acceptance of the Hathi Committee recommendations." (54)

In the main, communication between the private companies and the

Similarly, OPPI met "senior economic/financial journalists... on 23 August, 1980 for an in-depth discussion of the current position and problems of the pharmaceutical industry... The objective of the meeting was not to seek publicity but to produce understanding and appreciation of the industry position and problems." OPPI Bulletin No.4/80, July/August, 1980, p2. The most ambitious of this type of action was a series of meetings held in 1981 on the "Cost-Benefit of Price Control". It was organised by the Institute of Cost and Works Accountants of India, in cooperation with the trade bodies for the pharmaceutical, cement, sugar and fertilisers industries. See "National Debate on Cost-Benefit of Price Control", OPPI Bulletin No.1/81, January/February, 1981, p5 and Shah (1981), Narasimhan (1981) and Mehta (1981).
(51) OPPI (1980a) p9-11. The debate is, occasionally, taken outside the national boundaries, especially through the pages of SCRIP, much of whose information is supplied by companies in India. Finally, in 1981, the OPPI President, S.K.Bhattacharya, attacked the policies of the Indian Government during a meeting of UNIDO "Govt. Spokesman Rebuts OPPI Charges", Economic Times, 20 January, 1981.
(52) Interview, A University Lecturer, New Delhi, April, 1981.
(53) Interview, Managing Director of an Indian company, Bombay, April, 1981.
Government arises from the initiative of the companies, in response to Government legislation. However, the Government has also made its views known on various occasions (55). Perhaps the most widely-publicised incident came in May, 1981, when the Indian Prime Minister berated the practices of foreign drug companies during her speech at WHO Headquarters (56). Mrs. Gandhi called for a "health revolution in less developed countries to wipe out diseases and provide basic health care", but instigated no new action on her return to India. The Government is also in regular contact with the various UN agencies. Indian workers are frequent contributors to UNIDO, WHO and UNCTAD monographs on pharmaceutical production and distribution (57).

Amongst other interested groups, the medical doctors and pharmacists have expressed their views, particularly on the phasing out of brand names. The trades unions, and other employees' organisations, are most vocal on the pharmaceutical industry levels of pay and conditions of work (58).

(55) In 1978, for example, the Indian Minister of Finance assured the Swiss Minister of Public Economy that the Swiss pharmaceutical companies in India would not be adversely affected by the new Drug Policy. SCRIP, 27 May, 1978, p22.
(56) "PM Lashes out at Drug Cartels", Economic Times, 7 May, 1981.
(57) For Government participation in UNIDO's programmes, see "Govt. Spokesman Rebuts OPPI charges", Economic Times, 20 January, 1981 and "... One of the Most Advanced Countries", SCRIP, 29 July & 3 August, 1981, p15. The Hathi Committee referred to a UN document, which had influenced their views on the foreign companies (Hathi (1975) p94-95). However, the work of the UN agencies can also provide excuses for doing nothing; for example, the Maharashtra Minister of Public Affairs claimed that: "there was no reason to curb multinationals, because they were already guided by the United Nations on how they should behave in host countries." Free Press Journal, 13 January, 1975, quoted by Hasan (1980) p253.
(58) However, there is one instance of a group criticising the commercial practices of their employer. The Central Committee of Glaxo Employees' Unions submitted a memorandum to the Government, accusing the company of 13 malpractices. Statement by Janeshwar Mishra, Minister of State for Petroleum, Chemicals and Fertilisers, quoted in IDMA Bulletin, IX (22), p288, May, 1978.
Many supporters of the private pharmaceutical companies claim to find it difficult to understand why they should be criticised. They see the TNCs, in particular, as bringing:

"direct and immediately perceptible advantages such as transfer of advanced technology, transmission of managerial skills, increase of employment potential and... at least two other significant contributions made by MNCs... the reduction of morbidity and mortality rates and considerable savings in medical care costs." (59).

From this viewpoint, the function of the pharmaceutical companies should be to produce as many drugs as possible, with a minimum of Government controls. Thus, attempts are frequently made to steer the debate away from questions of ownership and the usefulness of the drugs actually being produced. This is most succinctly illustrated by a quotation from a past President of OPPI:

"Unrealistic politico-ideological dogmas should not and cannot override clear economic considerations. Every impediment to production, whether it be industry or agriculture, must be removed. Licensing must be simplified and all controls, which impede production and thus create shortages and black marketing, must be removed." (60)

The word 'pragmatic' has become a favourite amongst the industry spokesmen who urge the Government to adopt 'pragmatic policies' and, themselves, claim to seek 'pragmatic solutions' to current difficulties (61).

Amongst the many regulations contained in the New Drug Policy, three have received particular attention; (i) brand and generic nam-

(60) Brigadier B.S. Bhagat, quoted in "Government Constraints Serious Hindrance to Indian Development", SCRIP, 11 April, 1974, p3. Similarly, the Hathi Committee found that OPPI was willing to increase the production of bulk drugs if the Government would not impose "any conditions". Hathi (1975) p94.
ing of drugs, (ii) price control, and (iii) licensing. For various reasons, the great majority of the private companies agree in their views on the first two issues, but the foreign and Indian companies differ over the third. The debates over these issues are described in Appendix 6.4.

6.3 THE CONDITION OF THE INDIAN PHARMACEUTICAL INDUSTRY: SOME INDICATORS

The preamble to the New Drug Policy listed nine "broad objectives" for the new regulations. The fifth of these was "that drugs are available in abundance to meet the needs of our people." There was no indication that this was considered pre-eminent and, indeed, the policy makes little mention of the ways in which drugs should be used to meet health needs. In practice, other criteria receive more attention, whilst questions about the use of drugs often seem to be regarded as self-evident. This may be illustrated by reference to two features of the Indian pharmaceutical industry. Firstly, production is, almost always, described in terms of the sales value of the drugs. In this way inflation serves not only to magnify any increase in the volume of production but, more seriously, the type and use of products is given only secondary consideration (62). Secondly, the Government Ministry with principal responsibility for the pharmaceutical industry is not the Ministry of Health, but the Ministry of Petroleum, Chemicals and Fertilisers.

(62) This is not an original observation; it has been made by such as Gaitonde (1978) p12, Hathi (1975) p55, Special Correspondent (1976) p500 and, perhaps most pithily, by ICSSR and ICMR, quoted in Chapter 5. However, the practice continues, largely as a result of the convenience of having a unidimensional variable as an apparent indicator of success.
In addition to these features of overall organisation, the political system in India is such that the aspirations of the individual private companies must be taken into account. If the companies consider their activities to be unremunerative, then they will not continue them; in contrast, the Indian Public Sector units have little freedom of choice, and are forced to operate under the prevailing conditions. Consequently, matters such as profitability cannot be considered irrelevant as long as the technical capabilities of the private companies are still thought to be necessary.

The four Subsections below relate both to the availability of important medicines at 'reasonable' prices, as well as to the aspirations of the private companies and the consequences of their activities.

6.3.1 Financial Results

Before the introduction of price control, the prices of Indian drugs were considered to be high (63). However, since the 1970s, this has been reversed, to the extent that the prices of formulations are now believed to be: "amongst the lowest in the world." (64)

The extent to which drug prices have been controlled may be

(63) For example, see UNCTAD (1977) p32; Lall (1974) p163; and, Kidron (1965) p251. However, it is difficult to find authoritative evidence; Kidron relies on the opinion of a "Russian Committee of experts" and on information on two drugs supplied to an American Senate Committee.
(64) OPPI (1977) p5. This was also the conclusion of an Indian Government Tariff Commission, whose findings are quoted in Hathi (1975) p174. The Marketing Manager of a large European company confirmed this and said that if the prices in India were to influence the prices which his company could charge world-wide, then it might withdraw from that country. Interview, Europe, January, 1981.
illustrated by comparing the rise in the index of drug prices with that of all commodities. Mody quotes a series which has, as its base, prices in the year 1952-53 at 100. By 1960-61, drug prices were still at about 100, but the index for all commodities had risen to nearly 125. By the end of 1967, the drug price index had risen to 123, but the index for all commodities exceeded 200 (65).

However, this apparent success must be viewed with some reservations. Firstly, as Y.K. Hamied has shown, the system of controlling prices by 'mark-ups' is both a disincentive to the manufacturer to cut costs and, also, discriminates against formulations with a small amount of active ingredient (66). Secondly, whilst the average cost of drugs may be controlled, there are also considerable variations within the prices of individual drugs. The patient, hampered by not knowing the possibilities for substitution, and restricted to the drugs listed on the doctor's prescription, has only a limited ability to compare prices (67). Thirdly, the Government insistence on manufacture within India may have led to prices being higher than they would otherwise have been (68). Yet, it seems certain that

(65) Mody (1968) p8. A similar trend is seen in the 1970s and it illustrates the effects of the 1970 DPCO. Taking the base year as 1970-71, the drug price index had risen to about 135 by the end of 1980, but the index for all commodities was greater than 256. OPPI (1981a) p5.
(67) The Small-Scale companies are, in any case, exempt from comprehensive price control, and charge what the market will bear. Soon after the introduction of the DPCO (1970), Agarwal et al found that, if one company had a monopoly in the production of a certain drug, price control seemed to be less effective. Agarwal et al (1972) p2288.
(68) Two reports have compared the prices of some bulk drugs available in the world market, with the cost of the same drug manufactured in India. Both suggest that, for some drugs at least, indigenous manufacture may be excessively costly. Rangarao (1975), Table 14, p30-31 and UNCTAD (1977) p28. This may be one explanation for the findings of an Australian Government report,
Government legislation has been the main reason why drug prices have not risen more steeply, rather than any marked reduction in the cost of manufacture (69).

In one survey, Desai asked several pharmaceutical manufacturers why they were unable to increase their output or to reduce costs. The results are reproduced in Table 6.2. Although this survey is, by now, rather dated, its findings seem to confirm observations made in 1981.

Problems with raw materials figure prominently in Desai's survey (70), and the system of canalisation has been one way in which the Government has attempted to reduce raw materials costs. According to the Government, canalisation:

(i) Checks the possible over-pricing of drugs by some companies,
(ii) Assists the Small-Scale manufacturers in the procurement of raw materials,
(iii) Obtains drugs at lower prices, as a result of bulking imports, and
(iv) Regulates imports, so as not adversely to affect indi-

which found that the price which Pfizer charged for one drug in India was 56 per cent of the equivalent cost in Australia but, in contrast, another drug cost more than six times as much. Ralph (1979) p183. (69) The costs of production, especially for bulk drugs are said to be high; equipment and raw materials must often be imported, whilst technology transfer agreements result in fees and royalty charges. Jayaraman (1980a) p75; Hathi (1975) p174; Special Correspondent (1976) p497; and, Bazaz (1980) p8. (70) Deo (1977) p143, also refers to the high cost of importing bulk drugs.
<table>
<thead>
<tr>
<th>Obstacles Named by Companies to the Expansion of Output and Cost Reduction in the Indian Pharmaceutical Industry</th>
<th>Ave. Rank of Obstacle</th>
<th>% of Companies citing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Expanding Output</td>
<td>Cost Reduction</td>
</tr>
<tr>
<td>Restriction on import of materials</td>
<td>2.7</td>
<td>1.6</td>
</tr>
<tr>
<td>Non-Availability of materials</td>
<td>2.7</td>
<td>2.0</td>
</tr>
<tr>
<td>Poor quality materials</td>
<td>4.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Restrictions on importing equipment</td>
<td>1.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Non-Availability of equipment</td>
<td>5.3</td>
<td>4.8</td>
</tr>
<tr>
<td>Poor quality of equipment</td>
<td>6.6</td>
<td>5.7</td>
</tr>
<tr>
<td>Restrictions on import of technology</td>
<td>6.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Technical difficulties with installed capacity</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Industrial Licencing</td>
<td>2.0</td>
<td>4.5</td>
</tr>
<tr>
<td>Non-availability of labour</td>
<td>13.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Low labour productivity</td>
<td>6.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Fuel problems</td>
<td>15.0</td>
<td>14.0</td>
</tr>
<tr>
<td>Lack of demand</td>
<td>3.5</td>
<td>3.3</td>
</tr>
<tr>
<td>Shortage of finance</td>
<td>6.7</td>
<td>11.0</td>
</tr>
</tbody>
</table>

**NOTE:** The sample size is not given; from the third and fourth columns of figures, it would seem to be 13 companies. "Here the low value of obstacle indicates high rank and a high percentage of companies indicate that the obstacle is widely spread."

**SOURCE:** Desai (1970).
P.C. Sethi, of the Ministry of Petroleum, Chemicals and Fertilisers, claimed that canalisation "has resulted in decreases in the prices of some drugs." (72) However, other commentators have been less enthusiastic about the benefits of canalisation. Jayaraman claims that it is "doubtful whether the pooled price has enabled the consumer to get drugs cheaper... [the private companies] appear to be perturbed over the sharp deterioration in the supply schedule of imports effected by the canalising agencies." (73)

It is frequently stated that the costs of raw materials in India are relatively high (74). Furthermore, the costs of some items has increased to a far greater extent than those of others. OPPI compiled data on "cost escalations" for 11 common raw materials for the period February, 1979 to June, 1980. Lactose, for example, had increased in price by 44 per cent and chloroform by 51 per cent; in contrast, the price of sugar had risen by 500 per cent, and four other items had more than doubled in price (75). Some, mainly

(72) "Indian Govt. Claims Canalisation Does Reduce Drug Import Costs", SCRIP, 28 January, 1981, p9. Veerendra Patil had also stated in the Lok Sabha, during the previous year, that canalisation had reduced the cost of some 'essential drugs', because the canalised price had been maintained at a relatively low level, whilst the average price of imports had risen more sharply. Statement, Lok Sabha, 17 June, 1980. Further cost data are included in Lok Sabha, Answer to Starred Question No.427, 16 December, 1980.
(75) OPPI (1981a) p4. Presumably the 11 items were selected for their high price rises. Such rapid increases are frequently cited by critics of the Government's pricing regulations; they claim that the drug prices allowed cannot take account of such rapid cost increases.
foreign, manufacturers claimed that production costs were further increased by the necessity of introducing 'extra' purification steps, although others claimed that they did not find this necessary (76). One further report illustrates the way in which other costs have risen. The cost of wages and electricity have both increased significantly faster than the average drug prices. This is shown in Table 6.3.

Table 6.3
The Variation in some Cost Indices in the Indian Pharmaceutical Industry: 1970-77

<table>
<thead>
<tr>
<th>Year</th>
<th>Wages</th>
<th>Electricity</th>
<th>Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970-71</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>71-72</td>
<td>123</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>72-73</td>
<td>144</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>73-74</td>
<td>176</td>
<td>127</td>
<td>100</td>
</tr>
<tr>
<td>74-75</td>
<td>226</td>
<td>135</td>
<td>150</td>
</tr>
<tr>
<td>75-76</td>
<td>251</td>
<td>169</td>
<td>150</td>
</tr>
<tr>
<td>76-77</td>
<td>279</td>
<td>210</td>
<td>#</td>
</tr>
</tbody>
</table>

NOTE: # - Illegible in source.

SOURCE: AIMO (1978)

OPPI has vehemently denied that drugs with generic names would be cheaper than those sold under brand names (77). However, other commentators disagree (78) whilst Ghosh supports the OPPI assertion with data for 8 drugs sold under both brand and generic names (79).

(76) The costs of raw materials have often increased sharply. One newspaper report quotes figures supplied by "A purchase Manager of a leading drug company" for the price rises of some 20 chemical and packing materials. In the course of 12 months, some had risen by as much as 100 per cent. "Drug R&D goes to Waste", Business Standard, 12 May, 1981.

(77) "As price control applies equally to generics and brand, there is no question of drugs becoming cheaper if brand names are abolished.", OPPI Bulletin No.1/81, January/February, 1981, p.18.

(78) For example, "Prices are often influenced by the use of brand names...", ICSSR and ICMR (1981) p183.

The pharmaceutical industry sees the stringent controls on prices as the main cause of its declining profitability. In 1975, Rangarao could write that "The Industry's profitability has been very high... The earning rates represent twice the average earning rates from the entire industrial sector." (80) However, only a few years later, Jayaraman referred to "dwindling profitability" (81), and Alva produced figures which showed that the average industry profit had fallen from 15.5 per cent of turnover in 1969-70, to 5.0 per cent of turnover in 1976 (82).

The largest profits amongst the pharmaceutical companies are still, on the whole, realised by the foreign companies, and the industry remains one of the most profitable in India. However, it is no longer as conspicuously profitable as it had been in the 1950s and 1960s. OPPI reproduces three tables, which compare the profitability, expressed in various ways, of a range of industries. In each case, the pharmaceutical industry was about the tenth ranked (83).

Studies in other countries, mentioned in Chapter 2, have identified transfer prices as one possible cause of apparently low profits declared by TNCs in host countries (84). Over the years, there has been some limited evidence of transfer pricing in India (85) but, more recently, the practice seems to have declined. Lall claimed

(81) Jayaraman (1980a) p76.
(83) OPPI (1981a) p3-4.
(84) Funds are transferred to the parent company by paying for supplies at inflated rates.
(85) For example, Agarwal et al (1972) p2288, and Badami (1968) p13, who, like writers in other countries, finds evidence of excessive prices being charged by Hoffman LaRoche for Librium and Valium.
that the Government had largely ignored the problem (86), but also refers to the policy of the Indian Government in limiting severely the flow of imports (87). This strict control has minimised the possibility of transfer pricing, as companies usually have to supply detailed information before imports are allowed (88). The level of profitability declared by the subsidiaries of TNCs, and other companies with foreign collaboration, may also be affected by the financial costs of technology transfer. These include royalties and technical fees, whilst dividends may also be paid abroad (89). Rangarao concludes that there has been a net outflow of foreign exchange as a result of investment by foreign pharmaceutical companies (90).

For the pharmaceutical manufacturers: "the question of finance becomes all-important when one considers [the necessary investment to meet planned targets of drug production]... The industry must be allowed to make adequate profits to plough back and to encourage public participation." (91) Many commentators have described the current low level of investment as a direct consequence of the price control legislation (92). The rate of new investment in the industry has

(86) Lall (1974) p166.
(88) The main difficulty in controlling transfer pricing occurs when there is only one source of supply and an appropriate 'market price' cannot be determined. Rangarao (1975) p30. The Managing Director of one Indian company revealed that they were planning to make a drug which had, hitherto, been made in India only by one foreign company. This foreign firm purchased an essential intermediate from a supplier in the UK, through its parent company, for which it paid Rs6 per kg. to its Head Office. The Indian company claimed to have been quoted a price of Rs2.4 per kg. by the same supplier. Interview, Bombay, May, 1981.
(89) Further details are given in UNCTAD (1977) p30-32.
(92) For example, Venkateswaran (1980); Bhattacharya (1981) p3-4; Jayaraman (1980a) p74,76; and, "Stress on Growth Oriented Drug Policy", Economic Times, 3 April, 1980, which quotes a speech made by S.Pillai, the Chairman of Pfizer, India.
decreased markedly whilst, for some of the more important drugs in Categories I and II, the low mark-up seems to have led a few companies to discontinue production (93), and other reports claim that over one-third of drugs are sold at 'unprofitable' prices (94).

The cost of imported drugs is rising steadily, although the proportion of imports, relative to production, is decreasing. The types of drugs imported cover a similar range to indigenous production; Table 6.4 shows the value of drug imports according to therapeutic category.

<table>
<thead>
<tr>
<th>TABLE 6.4 The Import of Bulk Drugs to India: 1974-77</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Rupees Crores)</td>
</tr>
<tr>
<td>1974-75</td>
</tr>
<tr>
<td>Antibiotics</td>
</tr>
<tr>
<td>Antimalarials</td>
</tr>
<tr>
<td>Anaesthetics/Analgesics</td>
</tr>
<tr>
<td>Sulphas</td>
</tr>
<tr>
<td>Hormones/Steroids</td>
</tr>
<tr>
<td>Vitamins</td>
</tr>
<tr>
<td>Anti-TB</td>
</tr>
<tr>
<td>Tranquilisers</td>
</tr>
<tr>
<td>Anti-amoebias</td>
</tr>
<tr>
<td>Anti-diabetic</td>
</tr>
<tr>
<td>Anti-hypertensives</td>
</tr>
<tr>
<td>Diuretics</td>
</tr>
<tr>
<td>Drug Intermediates</td>
</tr>
<tr>
<td>Others</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

SOURCE: Tata Economic Consultancy Services (1978)

(93) Khorakiwala (1980) reports a decline in the production levels of several 'essential drugs'.
Many of the drugs are imported because the techniques of manufacture are not yet known in India, or because the scale of demand renders local production particularly uneconomic (95). However, there are also many drugs which are both produced in India, and also imported (96) and OPPI is vociferous in its criticism of this practice (97). The main explanation would seem to be that, although the private companies have the technical ability to manufacture more of such drugs, they consider the financial returns, and the Government regulations, unfavourable (98).

Finally, the export of drugs, like other methods of earning foreign exchange, is highly regarded in India. The Government has established an Export Promotion Council for Chemicals and Pharmaceuticals (99). Awards are given to companies which export large amounts (100), and licences are sometimes granted on the condition that a company exports a certain proportion of its output (101).

(95) See, for example, Hathi (1975) p20-22, 46.
(96) Some examples are given in "Imports by CPC of Selected Canalised Bulk Drugs and their Indigenous Production Thereof", OPPI Bulletin No.1/81, January/February, 1981, p12-14, which quotes Government data. Data for other selected drugs are given below.
(97) For example, "Imports are going up; there are several examples where bulk drugs can be, and are, being locally produced but imports are still permitted. Why should this be allowed?", in "OPPI Delegation Meets Mr.Veerendra Patil, Submits Memorandum", OPPI Bulletin No.3/80, May/June, 1980, p1, and "drugs we can easily make in our country are being imported" in "Drugs, Are We Planning for Shortages?", a 'Public Information Advertisement', reproduced in OPPI (1981b) p8.
(98) In addition, the Public Sector companies, in particular, may take up licences, yet be unable to produce an equivalent amount of drugs.
(99) Called CHEMEXCIL, its work is described in Bazaz (1980) p7-8.
(101) This was one of the conditions quoted in the Letter of Intent, issued to Glaxo for Salbutamol. See "Glaxo India Issues Statement on Salbutamol", SCRIP, 13 July, 1981, p14. There has long been a system of incentives for firms which export; Adarkar (1968) describes some of the conditions in 1968.
The majority of drug exports are the products of the Indian companies; the share of the foreign companies was only 13.5 per cent in 1974, and had declined to 10.4 per cent by 1977 (102). As with imports, the exported drugs cover a wide range of therapeutic groups, as is shown in Table 6.5.

### TABLE 6.5
The Export of Pharmaceuticals from India: 1975-77
(Rupees Lakhs)

<table>
<thead>
<tr>
<th></th>
<th>1975-76 (Actual)</th>
<th>1976-77 (Estimated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Patent and Proprietary&quot;</td>
<td>249.6</td>
<td>278.3</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>241.4</td>
<td>239.9</td>
</tr>
<tr>
<td>Anti-malarials</td>
<td>77.1</td>
<td>72.2</td>
</tr>
<tr>
<td>Anaesthetics/Analgesics</td>
<td>37.2</td>
<td>36.2</td>
</tr>
<tr>
<td>Menthol</td>
<td>0.2</td>
<td>34.5</td>
</tr>
<tr>
<td>Anti-dysentries</td>
<td>15.0</td>
<td>34.6</td>
</tr>
<tr>
<td>Tonics, Blood purifiers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emulsions &amp; Appetisers</td>
<td>10.2</td>
<td>17.9</td>
</tr>
<tr>
<td>Vitamins</td>
<td>1.8</td>
<td>13.9</td>
</tr>
<tr>
<td>Alkaloids</td>
<td>6.8</td>
<td>1.1</td>
</tr>
<tr>
<td>Sulphas</td>
<td>0.3</td>
<td>10.9</td>
</tr>
<tr>
<td>Antidiabetics</td>
<td>-</td>
<td>10.3</td>
</tr>
<tr>
<td>Others</td>
<td>1953.0</td>
<td>2021.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2592.6</strong></td>
<td><strong>2781.8</strong></td>
</tr>
</tbody>
</table>

**NOTE:** The large entry for 'Others' is not explained. These figures represent Formulations and Bulk Drugs; in 1976-77, Medicinal Castor Oil and Medicinal Herbs accounted for a further Rs5200 lakhs (Alva (1978) pS24.)

**SOURCE:** Tata Economic Consultancy Services (1978)

The drugs are sold to a variety of countries, with particularly large amounts going to the Public Health services in Sri Lanka, Tanzania, The People's Republic of China, Libya and Mauritius (103).

The encouragement given to exports may be criticised on several
grounds with Rangarao seeing it as helping the foreign companies:

"... a vicious circle... a blessing in disguise to the foreign firms who produce drugs in India from over-priced imported ingredients [using] cheaper manpower... This export qualifies the foreign firm for an export subsidy from the government and an import entitlement, which is again used for importing over-priced ingredients." (104)

Perhaps more important, is the fact that the Government encourages companies to export drugs which are in short supply in India and which must be imported to compensate. The net effect on the flow of foreign exchange is, at best, questionable, whilst the reports of shortages of many important drugs reflects the preoccupation of the Government with the financial results of the industry, at the expense of meeting health needs.

6.3.2 Industrial Indicators

There is ample evidence that the workers associated with the Indian pharmaceutical industry have considerable skills. This extends over the range of activities, from fundamental R&D to the design, construction and operation of sophisticated plant. The foreign companies are now satisfied that Indian contractors are able to construct new plants (105), whilst both foreign and Indian companies employ Indian engineers to interpret and implement technology transfer material (106). Similarly, Indian equipment and raw

(104) Rangarao (1975) p38.
(105) Interview, Managing Director, USA Company, Bombay, May, 1981.
(106) "The relatively high proportion of pure technical collaboration agreements... suggests that the Indian industry possesses some measure of the infrastructure and technical capability required for discovering better methods of transfer and bargaining in the direction of "unpackaging" the technology transfer...", UNCTAD (1977), p15. Government regulations have developed in response; for example: "the laws on effluent disposal are [amongst] the toughest anywhere." Interview, Production Manager, European company, Europe, January, 1981.
materials producers have progressed from the position in the mid-1960s, when the industry was "mostly dependent on imports of basic raw materials." (107)

The Hathi Committee acknowledged that:

"Several instances can be quoted to show [how] the vast resources of the multinational corporations secured for the country the kind of production and the type of technology which otherwise would not have been available." (108)

This flow of knowledge has not been confined within formal agreements, but has been spread when employees of the companies in India join other manufacturers. However, the Hathi Committee also concluded that the continuing flow of information had been less than might have been expected:

"The claim that flow of technology from parent foreign firms on a continuing basis is ensured because of foreign equity holdings is not valid... Rarely new and novel technology is permitted to flow either free or even on payment. Most technologies that flow from parent foreign firms into their Indian subsidiaries are in fact well established all over the world for the last 15-20 years and could as well have been imported into the country without taking recourse to equity participation." (109)

With this basis of technical ability, it might appear that the pharmaceutical industry is well-equipped to expand production, gradually increasing its output relative to the growth of the population. Various estimates have been made of the potential for this expansion

(107) Badami (1968) p13. Although, as indicated in Chapter 5, the quality of such goods is frequently criticised.
(108) Hathi (1975) p97. The apologists for the foreign companies have been quick to make similar points; see, for example, Jayaraman (1980a) p59, 71, and Anon (1980) p2.
(109) Hathi (1975) p95, emphasis in the original. Similarly, an UNCTAD report declared that: "foreign technology was allowed to substitute for indigenous technology, rather than being an impetus to Indian industry." UNCTAD (1977) p28. Alva (1978) p522, claimed that Indian companies had been able to make many of the more important drugs only after the Patent Law had been relaxed in 1970.
In addition to the figures produced by Government planners, Y.K. Hamied has attempted to estimate drug production and consumption in the year 2000 (111). He estimated that drug consumption could exceed Rs13,000 crore by 2000, and that per capita consumption would rise from Rs14, in 1980, to Rs76, at constant prices (112). There are several reasons why this expansion will be difficult to achieve and, also, why it will be insufficient to meet the nation's health needs. The difficulties to be faced encompass organisational and structural considerations.

The part played by industrial licensing illustrates some of the problems. The Government seems firmly wedded to the concept of industrial licences, yet there is abundant evidence to indicate that the system is failing to meet the objectives. There are three quantities which are relevant to industrial licensing; the capacity licenced by the Government, the capacity installed by the company, and the actual production. If these are expressed on the same basis, such as tonnes per annum, their magnitude should be approximately equal if the Government's planning method is to work. This is rarely the case and one recent Indian Government report found that:

"In the organised sector, capacity utilisation is only 75% for bulk drugs and 80% for formulations and in the small-scale sector, capacity utilisation is even lower." (113)

(110) Although the contention of this writer is that they are pointless exercises, this is discussed further, below, and in the concluding chapter.
(112) This represents a tenfold rise in total output over the two decades. These figures are included in the reports which are cited in the last footnote.
(113) "Indian Pharmaceutical Industry Inefficient, says Foreign Trade Official", SCRIP, 30 March, 1981, p12.
These figures are for all pharmaceutical production, but the production of a particular drug may be much lower (114). Whilst many plants operate well below capacity, it has been estimated that: "over 25 per cent of the output is derived from capacity established in excess of licenced capacity." (115) The Hathi Committee found examples of bulk drug production which were as much as 900 per cent in excess of licenced capacities (116).

Modi has suggested that it is mainly the foreign companies which have produced drugs in excess of their licenced capacity, whilst the Indian companies have under-produced (117). This would seem to be confirmed by other reports (118), but the Hathi Committee also found evidence of over-production by Indian companies (119).

This situation has arisen from a combination of semantic and historical reasons, aggravated by the bureaucratic machinery which the Government has built to control industrial production. Firstly, it is difficult to define what is meant by 'capacity' in the production of pharmaceuticals. Unlike many industries, including other forms of chemical production, there is a relatively small amount of

(114) Bazaz gives data on production against installed capacities for some 90 important drugs (Bazaz (1980) p14-16). Rangarao indicates that capacity utilisation was below 15 per cent for thiacetazone (an important anti-TB drug), amidopyrin, vitamin B2, hydrochlorothiazide and for all anti-leprotic drugs. Rangarao (1975) p17.
(116) Hathi (1975) p144.
(118) Such as "Drug Firms Exceeding Licenced Production in India", SCRP, 13 September, 1973, p2; Lok Sabha, Answer to Starred Question No.600, 3 April, 1979; "Drugs Output to be Regularised", Financial Express, 4 April, 1979; and, "Excess Bulk Drug Production in India by Foreign Companies", SCRP, 27 July, 1981, p12.
(119) The list given by Hathi (1975) p144, of companies which had produced excess bulk drugs, includes three wholly Indian-owned companies, and a further five with foreign equity below 50 per cent.
plant dedicated to the manufacture of any single product. Capacity has to be defined according to the way in which drug production can be scheduled to use the available equipment. Furthermore, development work might lead to enhanced yields and, therefore, more production than had originally been anticipated (120).

Secondly, many companies had installed plant and started to produce drugs before the introduction of the 1951 IDRA. They are not limited by licences, so that their overall production may exceed the capacities licenced since 1951 (121). At other times, the Government has been excessively anxious to encourage:

"... speedy industrialisation and the training of young men who will run the new industry in the future. Any offer is welcome if these two aims are fulfilled." (122)

Many such offers have been accepted, although the companies have subsequently failed to implement the licences (123). Companies which fail to produce at the licenced levels face only minimal punishments (124).

In addition, the Government may take several years to decide whether to issue a licence, and the company equally long to implement it (125). Whilst such an application is pending, the Government is

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(120) A point emphasised by Jayaraman (1980a) p69,71,74.
(121) Aiyar (1978b) and Interview, K.V.Ramanthan, Ministry, Petroleum, Chemicals and Fertilisers, New Delhi, May, 1981. On various occasions since 1951, companies have been granted a licence which specified the capacity for the combined production of several different drugs. They have chosen to vary the product-mix to suit sales prospects. Hathi (1975) p99.
(123) "Drug Prices", Hindusthan Times, 9 August, 1980; "Default in Drugs", Economic Times, 5 August, 1980; and, "The Reason Why", Free Press Journal, 16 August, 1980. According to these reports, the reasons included revised cost calculations, which made the process seem uneconomic, and 'pre-emptive' applications by companies anxious to secure the right to produce.
(125) Glaxo's application to produce salbutamol is just one such
unwilling to issue other licences.

Production at variance with the licenced levels causes difficulties: shortfalls mean that planned targets are not reached, whilst excessive production costs: "too much foreign exchange, and the foreign companies make more profits, which they repatriate with dividends and other ways." (126) The Government has announced various plans to "tap the idle capacity" (127), or to "regularise the excess capacity" (128). These are hampered by, amongst other things, the wider industrial policy of the Government, which asserts the immutability of licences, once issued (129).

The Government of India is also committed to enforcing equity dilution, in line with the use of "high technology". However, it is finding it difficult to achieve a consensus on what is meant by this phrase and various commentators have pointed out the weakness of leaving such a decision to the bureaucrats (130). Others have argued that it should be that which is "hard to get... [and] hard to develop in a short time." (131), or that it should also include difficult formulation activities (132). The Government claims to be aware of these difficulties, but has yet to publish its guidelines [1982] (133).

example.
(126) Interview, K.V.Ramanathan, Ministry of Petroleum, Chemicals and Fertilisers, New Delhi, May, 1981.
(127) "Idle Capacity to be tapped", Business Standard, 12 May, 1981.
(128) Lok Sabha, Answer to Unstarred Question No.1081, 24 February, 1981.
(129) Lok Sabha, Answer to Unstarred Question No.110, 25 November, 1980.
(130) For example, Gaitonde (1978) p22.
(132) Interview, Managing Director, USA company, Bombay, May, 1981.
(133) Interview, K.G.Ramanathan, Joint Ventures Secretary, Ministry of Commerce, New Delhi, May, 1981.
The expansion of pharmaceutical production is further hampered by the inimical structure of Indian industry. In particular, the chemical industry, as a whole, is small relative to the pharmaceutical industry, and was "almost non-existent" at Independence (134). Significant growth has been achieved since then, but the chemical industry remains relatively small. In the major pharmaceutical producing countries, the value of pharmaceuticals is, typically, around one-tenth of the total value of chemicals (135); in India, this ratio is nearer to one-third (136). The result is that indigenous supplies of raw materials may be expensive and erratic (137), whilst imported goods still represent a relatively large proportion of the total raw materials used by the industry (138).

Pharmaceutical production is linked, directly or indirectly, with several other industries. These include dyestuffs, pesticides, plastics, synthetic fibres and rubber chemicals, which also use the products of the heavy chemical industry, and which rely on the production of packaging materials, machinery and equipment, glass and ceramics, which also feed the pharmaceutical industry. Each of these is, also, relatively small, and there is only limited scope for symbiosis (139).

Perhaps the most obvious and most serious effect of having a

(134) Hathi (1975) p162.
(136) Rangarao attributes this disparity to the different levels of profitability within the chemical industry; economies of scale are even more powerful in the heavier chemical industries. Rangarao (1975) p33. Even at this level, the Indian chemical industry is larger than that in most LDCs. Rahman et al (1970) p494.
(138) One writer has estimated that 70 per cent of all raw materials need to be imported, whether as bulk drugs or other, less complex, chemicals. Special Correspondent (1976) p498.
small chemical industry, is the frequent shortage of raw materials and other inputs. Drug shortages are frequently attributed to the non-availability of chemicals (140), of packing materials (141), and of power (142). In part, this is exacerbated by the fact that the chemical processes have usually been designed in the West, where the cost and availability of raw materials are markedly different. Several writers have suggested that the Indian industry should develop processes to suit the raw materials which it has in relative abundance, especially plant and animal materials, and to increase the use of chemicals derived from coal, rather than petroleum (143).

It is highly unlikely that the present system of R&D has the means, or the orientation, to develop important new techniques. Not only do the research programmes of the companies rely on small budgets (144), but it also, it is claimed, their programmes do not aim at the important problems (145). R&D programmes in the Public Sector


(141) A strike in the aluminium industry led to a shortage of packing foil, "Drugs Shortage", Financial Express, 20 June, 1980.

(142) Hamied (1980) p11 and "Drug Prices", Hindusthan Times, 9 August, 1980. The latter also reports that "widespread labour unrest" was a cause of drug shortages.

(143) For biological materials, see Mehta (1968) p2 and Rangarao (1975) p43. Hamied (1980) p9, and Hathi (1975) p146f, also discuss the need to consider the use of coal-based chemicals.

(144) Consuming a much lower proportion of a much lower sales turnover than the large companies in the West. The Managing Director of one Indian company claimed that the position was made worse by the practice of the foreign companies "to count everything [eg Quality Control expenditure] as R&D", thereby inflating the apparent R&D expenditure for tax and cosmetic purposes. Interview, Bombay, May, 1981.

(145) ICSSR and ICMR (1981) p184. There is an understandable desire by Indian scientists to pursue the same sort of programmes as their contemporaries in the West: "Prof.Menon [Secretary, Department of Science and Technology, Government of India] em-
companies are frequently criticised for their failure to coordinate the work of the different public bodies (146). In addition, R&D is further hampered by the conspicuous lack of communication between industrial and academic workers (147). The research programmes of the educational establishments rarely prove useful to industry.

Finally, the economics of production do not seem to favour the scale of expansion envisaged by Hamied. For a variety of reasons, Jayaraman doubts "whether any substantial investment in the capital-intensive sphere of bulk drug production would be forthcoming..." (148) The size of the Indian market works against bulk drug production, especially those processes which use fermentation. In Europe and USA, most penicillin plants have an annual output of at least 4,000 MMU, whilst the largest plant in India produces only 100 MMU per annum. Similarly, the largest Indian tetracycline plant has an output of about 50 tonnes per annum, whilst most plants in the West are at least ten times that size (149).

If any substantial expansion does occur under the present system, it seems inevitable that it will encourage a growth in the number of Small-Scale companies. This, in turn, is likely to give

phased that we should not be satisfied with 'intermediate' or 'appropriate' technology only for solving problems but develop understanding and capability at the very frontiers of modern science." "R&D Infrastructure", OPPI Bulletin No.3/80, May/June, 1980, p6.
(146) For example, Jayaraman (1977) p10. Gaitonde, amongst others, has suggested a way in which this could be improved. Gaitonde (1978) p28.
(147) Described by Rangarao (1975) p38; UNCTAD (1977); and, Deo (1977) p141.
(149) Both examples are taken from "Indian Industry Inefficient, says Foreign Trade Official", SCRIP, 30 March, 1981, p12. The position was confirmed in interviews with the Production Managers of two large European companies, Bombay, May, 1981.
rise to problems of poor quality drugs (150), as Small-Scale companies find it difficult to install the necessary Quality Control equipment, whilst maintaining their capital expenditure below the Government limits for such companies (151). Despite suggestions that Small-Scale companies should share facilities, the Quality Control Manager of one Small-Scale company knew of no instances where this had been done (152).

6.3.3 Social Factors

Statements by the Government, and others, have asserted that social benefits would flow from the establishment of a pharmaceutical industry in India. In the light of such beliefs, it is instructive to examine the way in which the pharmaceutical industry has, in fact, developed, with respect to three factors; the employment provided, regional location, and the extent of national self-reliance.

Employment in the pharmaceutical industry has grown significantly since the 1954 Bhatia report found that a total of some 30,000 people were employed in various 'organised' companies (153). By the 1960s, this had risen to around 60,000 (154), reaching a figure of 65,000 by 1976 (155). By 1982, OPPI estimated that 100,000 people were employed in the organised Sector, with another 50,000 working in

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(150) There is ample evidence of substandard drugs being produced by Small-Scale companies; for example, Agarwal et al (1972); Lall (1974) p169; Datey (1975); Rangarao (1975) p21f; and, Hamied (1980) p10.
(152) Interview, Bangalore, July, 1981.
Small-Scale companies. Furthermore, some 500,000 workers were employed in the distributive trades, and 200,000 in ancillary industries (156). Thus, the total number of people finding direct or indirect employment through the Indian pharmaceutical industry is about 850,000, or approximately 0.1 per cent of the total population (157). However, no large private company claimed to be seeking ways to create more employment, whilst a Spokesman for the Public Sector IDPL suggested that ways were being sought further to automate existing plant (158).

Some commentators describe the: "wages and working conditions offered by the industry to its employees [as] among the best in the country." (159) In 1982, the lowest-paid employee of the large American company, Pfizer, was paid approximately Rs850 (about $100) per month (160), a fact which the company, at least, thought worthy of advertising. Other writers apparently consider that employment legislation has become biased towards the workers:

"Our labour has learnt international slogans and is copying systems and practices of highly developed Western countries so far as wages and rights and privileges of labour are concerned. The Governments, both at the Centre and in the States, have gone out of their way to pacify labour and enacted legislation of which the sole purpose seems to be to control employers without putting a check on the harmful activities of labour leaders and labour itself." (161)

(157) One report has estimated that a further 225,000 jobs might be provided, if the increased production envisaged in the Sixth Five-Year plan were achieved. "... And The Outlook Through to 1982-83", SCRIP, 17 June, 1978, p16-17.
(158) Interview, Chemical Engineer, IDPL, Rishikesh, April, 1981.
(159) Jayaraman (1980a) p81
Not only is the pharmaceutical industry able to create only a relatively small number of jobs, but they are also concentrated in a few areas. The Bhatia Committee found that the majority of the industry was located in the urban areas, and that people there had better access to drugs (162). Some twenty years later, the Hathi Committee came to similar conclusions:

"The drug industry is concentrated in three states, namely Maharashtra, Gujarat and West Bengal. Quite a few drug units... are operating in Andhra Pradesh. Karnataka has also, of late, been attracting a few drug manufacturing units... Even in these states, the industry is concentrated in one or two large metropolitan cities... Unless the Central and State Governments work in unison, it will be difficult to achieve any measure of success towards the goal of rational dispersal of the industry in different regions." (163)

The Hathi Committee recommended that the Government should act to stop this concentration (164). Various cash subsidies were announced, which one industry commentator considered "adequate" (165), and new units, or expansions, were forbidden in Bombay (166). Companies reported that they found some advantages when locating in industrially less-developed areas, including lower wage rates and the: "less-explosive political background of the workers" (167). However, there were also disadvantages, such as difficulties in obtaining spare parts, electric power and ancillary supplies, and in attracting a competent and experienced managerial force (168). Some new plants are being built in rural areas, but this is more a result

(166) Interview, Production Manager, European company, Europe, January, 1981.
(167) Interviews, European companies, Bombay and Maharashtra, April, 1981.
(168) Interview, Production Manager, European company, Maharashtra, April, 1981.
of the fact that permission is not granted for extensions to urban sites, rather than any positive aspects of such areas. Despite pressure and various inducements, the pharmaceutical industry still remains concentrated in a few cities.

The provisions of the 1973 FERA, and the 1978 New Drug Policy, sought to limit foreign ownership in the pharmaceutical industry. It was envisaged that the foreign equity should be reduced:

"Government financial and public sector institutions should aim to acquire 66% of the balance equity, the rest being disinvested in favour of Indian investors, preference in the latter case being given to Indian employees of such companies. If this is not an enlightened social control, I would like to know what is." (169)

In fact, such equity dilution has made little difference to the control within foreign companies. The Hathi Committee found that foreign control was exercised whenever the holdings of the foreign principal were greater than the biggest single Indian holding (170), whilst Singh is only one of the many commentators to point out the apparent anomaly that a company with nearly 40 per cent foreign holdings is treated exactly the same as a wholly Indian-owned company (171). There have been some indications that the Foreign Sector, as a whole, no longer sells the most drugs (172), but it seems, instead, that there is a greater concentration in the market power of the top foreign and Indian companies, whilst some foreign companies may now be less important (173).

There are several factors which limit the desirability of swift,

(169) Bahuguna (1978) p36.
(170) Hathi (1975) p96,98.
(171) Singh (1978) p47.
drastic, action against the foreign companies. Jayaraman claims that: "any measure that seeks to shut the door to the inflow of new technology from abroad is certainly not in the national interest, much less in the interests of the nation's sick." (174) Other commentators have written of the impetus which foreign companies give to domestic competitors (175). One particular difficulty, is that the Foreign Sector holds a disproportionate share in the production of certain types of drugs. This was recognised by the Hathi Committee, from the production data for 1973 (176), which revealed that: "some multi-national units hold an almost mono-polistic position in this country in regard to the supply of life-saving drug formulations such as Methyldopa, Indomethacin, Furosemide, Prenylamine lactate, gentamycin sulphate, diphenylhydantoin etc." (177). Recent data, relating to the production of various therapeutic groups by foreign companies, is given in Table 6.6.

6.3.4 Medical Effects

There is good reason to be concerned with some of the medical results of the way in which pharmaceutical production is organised in India. The impression of this writer is that it is quite inadequate to meet the health needs of India's population, either now, or in the foreseeable future. However, there are a few encouraging signs. The Government is adamant that clinical trials are not carried out in India using drugs banned for such purposes in other countries (178).

(175) "Role of Multinationals", Financial Express, 22 May, 1980.
(177) Hathi (1975) p90.
(178) "Drugs Controller on Clinical Trials of New Drugs", Presidential Address by S.S.Gothoskar, Drugs Controller, India, at the 31st Conference of the Indian Pharmaceutical Congress Association, Baroda, 27 December, 1979. Quoted in OPPI Bulletin No.1/80,
TABLE 6.6
The Share of Foreign Companies in the Production of Bulk Pharmaceuticals in India, According to Therapeutic Groups: 1978-79
(All financial data in Rs Cr)

<table>
<thead>
<tr>
<th>Production</th>
<th>Foreign Firms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>% of total</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>61.0</td>
</tr>
<tr>
<td>Anti-rheumatics/analgesics</td>
<td>24.0</td>
</tr>
<tr>
<td>Vitamins</td>
<td>21.0</td>
</tr>
<tr>
<td>Sulphas</td>
<td>18.0</td>
</tr>
<tr>
<td>Anti-TB</td>
<td>9.0</td>
</tr>
<tr>
<td>Steroids/hormones</td>
<td>9.6</td>
</tr>
<tr>
<td>Anti-amoebics</td>
<td>6.0</td>
</tr>
<tr>
<td>Anti-malarials</td>
<td>4.0</td>
</tr>
<tr>
<td>Anti-diabetics</td>
<td>3.0</td>
</tr>
<tr>
<td>Others</td>
<td>44.4</td>
</tr>
<tr>
<td>Total</td>
<td>200.0</td>
</tr>
</tbody>
</table>

SOURCE: Jayaraman (1980a) p67

This might have been expected in a country with large, slow-moving, bureaucratic organisations. There are few other causes for optimism.

In the three decades after Independence, it was found that drugs new to India were frequently introduced only after many years of use in their countries of origin (179). Only six new drugs had been introduced to India between the 1978 New Drug Policy and mid-1981, and none of these was a single ingredient drug (180). Several January/February, 1980, p6-7, and "No Drug Trials at Human Risk", Financial Express, 16 February, 1980.

(179) Rangarao lists the dates of production, abroad and in India, for several important drugs; they vary by as much as 18 years. Rangarao (1975) p1, 12, 17. Similarly, an UNCTAD report found that: "The most recent of the newly-introduced compounds is one decade old and the oldest nearly three decades old. UNCTAD (1977) p39. These two sources imply that this is an indication of the duplicity of the foreign companies, although Jayaraman (1980a) p74 claims it to be a failure of the Indian bureaucratic process.

(180) Single ingredient drugs would not be allowed to have brand names. Interview, S.S. Gothoskar, Drugs Controller, India, New Delhi, May, 1981. The General Manager of one European company
commentators have suggested that this slow flow of new products is not a grave disadvantage. The Hathi Committee found, for example, that many new drugs had only "marginal differences" (181).

One result of the large number of pharmaceutical companies in India has been a confusing multiplicity in the number of formulations. About 400 different bulk drugs are available (182), but no-one can be certain about the number of formulations. Various writers have estimated 15,000 (183), "more than 20,000" (184), "as many as 30,000" (185), "as many as 40,000" (186), or, even, "about 50,000" (187). For example, there are 66 different formulations of analgin, 74 of phenyl butazone and as many as 90 of phenobarbitone (188).

The sales of drugs, according to therapeutic groups, are shown in Table 6.7. Various commentators have criticised the apparent imbalance of such sales, compared to the disease pattern in India. Rangarao berates the industry which: "operates on the exploitation of markets existing and created... [The] volume of sales is pushed up with promises of health and protection against sickness through proteins, vitamin preparations and tonics." (189) An UNCTAD report came

confirmed that the insistence on generic names for new, single-ingredient, drugs was the main reason why more new drugs had not been brought in. Interview, Bombay, March, 1981. (181) Hathi (1975) p60. Similarly, Gaitonde writes that many were 'me-too' drugs. Gaitonde (1978) p29.
(183) Francis (n.d.).
(184) Ghosh (1981a) and "Drug Prices", Hindusthan Times, 9 August, 1980.
(185) "Drug Prices", Times of India, 30 August, 1980 and "Dr Arole Flays Philosophy of Drug Industry", Times of India, 4 March, 1980.
(186) "In India: Drug Categorisation for Price Fixing Proposed", SCRIP, 14 November, 1974, p7.
(189) Rangarao (1975) p35. Gaitonde (1978) p8 writes in similar vein, of the: "vitamins, tonics, health restoratives and enzyme
### TABLE 6.7
The Sales and Market Shares of The Major Drugs in India, According to Therapeutic Group: 1978

<table>
<thead>
<tr>
<th>Group</th>
<th>Sales (Rs crores)</th>
<th>Market Share %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic Antibiotics</td>
<td>90.40</td>
<td>19.0</td>
</tr>
<tr>
<td>Vitamins</td>
<td>51.31</td>
<td>10.8</td>
</tr>
<tr>
<td>Cough &amp; Cold Preps</td>
<td>21.64</td>
<td>4.5</td>
</tr>
<tr>
<td>Tonics</td>
<td>21.40</td>
<td>4.5</td>
</tr>
<tr>
<td>Anti-anaemics</td>
<td>21.17</td>
<td>4.4</td>
</tr>
<tr>
<td>Anti-parasitics</td>
<td>18.65</td>
<td>3.7</td>
</tr>
<tr>
<td>Analgesics</td>
<td>17.58</td>
<td>3.2</td>
</tr>
<tr>
<td>Anti-rheumatics</td>
<td>15.04</td>
<td>3.2</td>
</tr>
<tr>
<td>&quot;Health Restorers&quot;</td>
<td>12.67</td>
<td>2.7</td>
</tr>
<tr>
<td>Anti-diarrhoeals</td>
<td>12.64</td>
<td>2.7</td>
</tr>
<tr>
<td>Antacids</td>
<td>12.05</td>
<td>2.5</td>
</tr>
<tr>
<td>Systemic corticosteroids</td>
<td>10.18</td>
<td>2.1</td>
</tr>
<tr>
<td>Sex hormones</td>
<td>9.88</td>
<td>2.1</td>
</tr>
<tr>
<td>Anti-TB</td>
<td>9.29</td>
<td>1.9</td>
</tr>
<tr>
<td>Enzymes</td>
<td>9.27</td>
<td>1.9</td>
</tr>
<tr>
<td>Topical corticosteroids</td>
<td>8.83</td>
<td>1.9</td>
</tr>
<tr>
<td>Anti-spasmodics</td>
<td>8.07</td>
<td>1.7</td>
</tr>
<tr>
<td>Anti-asthmatics</td>
<td>7.80</td>
<td>1.6</td>
</tr>
<tr>
<td>Mineral supplements</td>
<td>7.76</td>
<td>1.6</td>
</tr>
<tr>
<td>Anti-bacterials</td>
<td>7.33</td>
<td>1.5</td>
</tr>
<tr>
<td>Others</td>
<td>103.81</td>
<td>21.8</td>
</tr>
<tr>
<td>Total</td>
<td>476.78</td>
<td>100.0</td>
</tr>
</tbody>
</table>


to a similar conclusion:

"It seems then, that in the planning of drug production, the pattern of diseases is not given enough attention. Instead, transnational corporations have transferred technologies for the manufacture of products that are suited to the disease patterns of the Western world to meet the demand originating from the well-to-do consumers in India. This has occurred because these... "branded" products earn a much higher profit margin than the generic products required by the poor." (190)
In more recent years, the problem has been further aggravated by the reaction of some companies to the 1979 DPCO; they have preferred to manufacture the more profitable, but less important Category IV preparations (191). Drug companies are acutely aware of the advantages of selling their products profitably rather than, necessarily, of producing drugs in accordance with the medical needs of the country (192). The great majority of the information on drugs which reaches medical doctors is supplied by the companies themselves; the Hathi Committee drew attention to the need for an independent information sheet: “to keep the medical profession... well-informed about new drugs and also to popularise the generic names.” (193)

Not only does the overall production pattern seem medically unbalanced but there would also appear to be many unnecessary drugs marketed. The 1954 Bhatia Committee had recommended that drugs containing combinations of active ingredients should, in general, be proscribed (194). However, some two decades later, many “irrational” formulations were found (195). Many such drugs have been found to be of “no therapeutic value”, and removed from the market by the Government (196).

and a deficit for the important drugs.
(192) See the comments of senior Glaxo Managers, quoted by Thakore (1981), especially p30,32. See, also, Lall (1974) p166. The market power of the well-known companies encourages elaborate copies. This writer was shown an excellent fake of a Roussel label, kept by Drugs Controller of Karnataka, July, 1981.
(194) Bhatia (1954) p205.
(195) Special Correspondent (1976) p498; this had been encouraged, in part, by the regulations of the New Drug Policy, which allowed brand names for combination drugs. “Disturbing Trends”, Financial Express, 1 September, 1980.
At the same time, it is possible that efficacious drugs are used more than is necessary. As well as the possible side-effects, drug-resistant disease strains have developed (197), whilst some writers have asserted that: "the doctor and the drugs producer join hands to over-medicalise health care." (198)

Only about one-quarter of India's population has any regular access to modern drugs and there are very frequent reports that drugs are not available even to those who can afford them (199). The reasons adduced for these shortages, as mentioned above, include the effects of the DPCO and high costs, which make production uneconomic, shortages of raw materials and other utilities, industrial disputes, and the policies of chemists to stock only profitable lines.

The Government has reacted, firstly, by arguing that drugs only appear to be in short supply and certain brands may be unavailable, yet equivalent formulations can be bought (200). Secondly, 'Monitoring Cells' have been established. State and Zone offices make periodic reports to Central Government and, at the end of each month, the shortages are "looked into immediately." (201) The monitoring

(200) Statements by Veerendra Patil, Minister for Petroleum, Chemicals and Fertilisers, Lok Sabha, 17 June, 1980 and 7 August, 1980, and, "Shortage of Drugs", Economic Times, 5 February, 1981. This argument presupposes that the patient is aware of the alternative brand names for the formulation marked on the prescription.
cells have not been found effective (202).

Evidence such as this might suggest that some method of selecting "Essential Drugs" might be advisable and such ideas are not new in India. The 1954 Bhatia Committee drew up a list of 192 drugs, insecticides, disinfectants and 'medicinal foods', "whose production should be encouraged." (203) Similar selections were made by the 1966 Committee on Essential Drugs (204), and the 1975 Hathi Committee listed 117 drugs "extensively used and... essential for medical practice." (205) All this is in addition to the WHO list, which was issued as a basis for 'Essential Drugs' lists to be drawn up by individual countries (206). Certainly India has the technology to produce a large proportion of these important drugs (207), yet it is often found that production falls short of the targets (208).

At the basic levels of health care, very few drugs are needed. Gaitonde claimed that the WHO list: "can be reduced, in the context of Indian conditions, to not more than about 15-20 drugs." (209) He mentioned 14 drugs, most of which are also included in a list of

(204) Reported in Jayaraman (1980a) p65.
(205) Hathi (1975) p259-265. Various States have also drawn up such lists: "Harmful Drugs Termed Essential", Pharmatimes 12 (12), December, 1980, p19. This describes an 'Essential Drugs' list, drawn up by the State of Tamil Nadu, containing various drugs which another Government Committee had termed 'harmful'.
(206) WHO (1977b).
(207) B.B.Gaitonde claimed that India had the technology to make "at least 150 basic drugs; which covers almost all essential drugs." Interview, B.B.Gaitonde, WHO, New Delhi, May, 1981. OPPI (1977) p19-20 lists 21 drugs and late intermediates for which the technologies are well-known in India and which, also, use a high proportion of indigenous raw materials.
(208) Hathi (1975) p41,63.
"Essential drugs Needed at the Community Level", compiled by the ICSSR and ICMR. These are listed in Table 6.8.

**TABLE 6.8**

A Proposed List of "Essential Drugs Needed at the Community Level" in India

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>Analgesic, Antipyretic, in rheumatic arthritis etc.</td>
</tr>
<tr>
<td>Chloroquine</td>
<td>Malaria, amoebiasis, giardiasis, tape worm infestation, lepra reaction etc.</td>
</tr>
<tr>
<td>Sulphonamides</td>
<td>Bacillary dysentry, urinary tract infection, meningococcal meningitis, chancroid, trachoma and inclusion conjunctivitis etc.</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>TB, urinary tract infections, meningitis, bacteriemia and bacterial endocarditis, respiratory tract infection.</td>
</tr>
<tr>
<td>Penicillin</td>
<td>Respiratory tract infection, rheumatic fever, meningitis, osteomyelitis, otitis media etc.</td>
</tr>
<tr>
<td>Isoniazid (INH)</td>
<td>TB</td>
</tr>
<tr>
<td>Thiacetazone</td>
<td>TB</td>
</tr>
<tr>
<td>Dapsone (DDS)</td>
<td>Leptospirosis, P. falciparum (malaria)</td>
</tr>
<tr>
<td>Piperazine</td>
<td>Roundworm or threadworm infestation.</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>Anti-helmintic.</td>
</tr>
<tr>
<td>Di-iodohydroxyquinoline</td>
<td>Amoebiasis</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Intestinal and hepatic amoebiasis, trichomoniasis, giardiasis etc.</td>
</tr>
<tr>
<td>Ferrous Sulphate</td>
<td>Iron deficiency anaemia.</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Vitamin A deficiency, prophylaxis etc.</td>
</tr>
<tr>
<td>Vitamin B complex</td>
<td>Generalised avitaminosis B, or deficiency of any vitamins of B-complex group as in prophylaxis.</td>
</tr>
<tr>
<td>Thiocarbamazine</td>
<td>Filariasis</td>
</tr>
<tr>
<td>Sulphur Ointment</td>
<td>Scabies, psoriasis, ring worm infestation, lupus erythematosus etc.</td>
</tr>
<tr>
<td>Oral Rehydration Salts</td>
<td>Dehydration</td>
</tr>
</tbody>
</table>


Some data relating to these drugs in the years 1977-78 and 1979-80, have been presented in Table 6.9 and Table 6.10 (210). It

(210) The 'requirements', listed in Table 6.10, are Government figures, based on the sales of previous years. Certainly this is one basis and, for many drugs which are used for a variety of conditions, little else is possible. However, two sample calculations show the weakness of such estimates when there are alternative means of calculating drug requirements. These are presented...
will be seen that, in almost every case, production lags well behind both the estimated requirements and the licenced capacity. Moreover, several drugs are exported, even though they must then also be imported (211).

\[
\text{TABLE 6.9}
\]

Some Data Relating to the Production, Import and Export of Selected Important Drugs in India: 1977-78

<table>
<thead>
<tr>
<th>Drug</th>
<th>Licenced Capacity (tonnes)</th>
<th>Production (tonnes)</th>
<th>Imports (tonnes)</th>
<th>Imports (Rs lakhs)</th>
<th>Exports (Rs '000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>1860</td>
<td>982</td>
<td>238</td>
<td>41</td>
<td>6</td>
</tr>
<tr>
<td>Chloroquine</td>
<td>156</td>
<td>37</td>
<td>335</td>
<td>869</td>
<td>#</td>
</tr>
<tr>
<td>Sulphamethoxazole</td>
<td>29</td>
<td>16</td>
<td>58</td>
<td>135</td>
<td>#</td>
</tr>
<tr>
<td>Sulphadiazine</td>
<td>390</td>
<td>62</td>
<td>#</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>Sulphadimidine</td>
<td>1000</td>
<td>452@</td>
<td>24</td>
<td>6</td>
<td>#</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>257</td>
<td>200</td>
<td>29</td>
<td>95</td>
<td>1077</td>
</tr>
<tr>
<td>Penicillin (MMU)</td>
<td>454</td>
<td>315</td>
<td>22</td>
<td>29</td>
<td>2747</td>
</tr>
<tr>
<td>INH</td>
<td>539</td>
<td>78</td>
<td>11@</td>
<td>23@</td>
<td>#</td>
</tr>
<tr>
<td>Thiacetazone</td>
<td>153</td>
<td>24</td>
<td>#</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>DDS</td>
<td>38</td>
<td>17</td>
<td>1</td>
<td>83</td>
<td>#</td>
</tr>
<tr>
<td>Piperazine</td>
<td>165</td>
<td>110</td>
<td>258@</td>
<td>23</td>
<td>#</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>3</td>
<td>#</td>
<td>9</td>
<td>#</td>
<td>19</td>
</tr>
<tr>
<td>Di-iodohyd.quin</td>
<td>561</td>
<td>111</td>
<td>#</td>
<td>#</td>
<td>545</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>137</td>
<td>23</td>
<td>31</td>
<td>79</td>
<td>#</td>
</tr>
<tr>
<td>Vitamin A (MMU)</td>
<td>45</td>
<td>50</td>
<td>16</td>
<td>#</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>120</td>
<td>35</td>
<td>56</td>
<td>120</td>
<td>&amp;</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>50</td>
<td>#</td>
<td>42</td>
<td>139</td>
<td>0.5</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>24</td>
<td>8</td>
<td>16</td>
<td>60</td>
<td>11</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>55</td>
<td>31</td>
</tr>
</tbody>
</table>

NOTES: 
# - data unavailable or assumed to be negligible
@ - data markedly inconsistent between different sources.
& - Included in Rs300,000 of Vitamin B complex.

SOURCES: Compiled by the author from data released by the Ministry of Petroleum, Chemicals and Fertilisers.

Such figures illustrate the poverty of Government planning in the pharmaceutical industry, and the illogicality of industry in Appendix 6.5. (211) Admittedly the value of the exports is relatively low, but the Government is trying to increase this trade, through the Export Promotion Council.
### TABLE 6.10
Some Data Relating to the Production, Import and Export of Selected Important Drugs in India: 1979-80

<table>
<thead>
<tr>
<th>Drug</th>
<th>Licence Capacity (tonnes)</th>
<th>Requirement (tonnes)</th>
<th>Production (tonnes)</th>
<th>Imports (Rs lakhs)</th>
<th>Exports (Rs'000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>2160</td>
<td>1500</td>
<td>996</td>
<td>296</td>
<td>47</td>
</tr>
<tr>
<td>Chloroquine</td>
<td>176</td>
<td>250</td>
<td>35</td>
<td>53</td>
<td>146</td>
</tr>
<tr>
<td>Sulphamethoxazole</td>
<td>#</td>
<td>90</td>
<td>30</td>
<td>64</td>
<td>155</td>
</tr>
<tr>
<td>Sulphadiazine</td>
<td>#</td>
<td>200</td>
<td>51</td>
<td>171</td>
<td>136</td>
</tr>
<tr>
<td>Sulphadimidine</td>
<td>#</td>
<td>450</td>
<td>513</td>
<td>#</td>
<td>*</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>337</td>
<td>300</td>
<td>220</td>
<td>73</td>
<td>274</td>
</tr>
<tr>
<td>Penicillin (MMU)</td>
<td>530</td>
<td>350</td>
<td>327</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>Thiacetazone</td>
<td>153</td>
<td>40</td>
<td>13</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>DDS</td>
<td>38</td>
<td>28</td>
<td>16</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Piperazine</td>
<td>165</td>
<td>240</td>
<td>87</td>
<td>167</td>
<td>#</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>#</td>
<td>20</td>
<td>#</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>Di-iodohyd.quin</td>
<td>22</td>
<td>300@</td>
<td>12</td>
<td>#</td>
<td>1036@</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>165</td>
<td>90</td>
<td>94</td>
<td>#</td>
<td>#</td>
</tr>
<tr>
<td>Vitamin A (MMU)</td>
<td>75</td>
<td>100</td>
<td>59</td>
<td>42</td>
<td>80</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>#</td>
<td>100</td>
<td>49</td>
<td>59</td>
<td>152</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>#</td>
<td>40</td>
<td>#</td>
<td>25</td>
<td>#</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>#</td>
<td>30</td>
<td>7</td>
<td>21</td>
<td>#</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>#</td>
<td>0.25</td>
<td>0.1</td>
<td>#</td>
<td>#</td>
</tr>
</tbody>
</table>

NOTES: # - data unavailable or assumed to be negligible
* - Rs6.7 Million worth of 'sulpha drugs' were exported.
@ - data refers to 'Halogenated oxy-quinolines'.
& - Rs774,000 worth of 'Vitamin B complex' exported.

SOURCES: As for Table 6.9.

celebrations that the total drug sales have increased. Several points can be made here, although their further analysis is outside the scope of this study. Firstly, the Indian medical profession is both powerful and heavily-influenced by Western exemplars. (Its relationship to the pharmaceutical industry is discussed in Chapter 3.) The immutability of the present structure of drug usage being determined by the medical profession seems to be taken for granted, despite its evident failure (212).

(212) Even the Hathi Committee seemed to accept the status quo in
Secondly, there is a lack of effective pharmaceutical research. This relates not simply to the low level of fundamental research into the discovery of new drugs but, more seriously, there is relatively little investigation of the real drug needs of the population (213). Moreover, there is a tendency to expect drugs to cure all manner of conditions. Thus, the Hathi Committee found that the drugs to treat malnutrition were not "entirely satisfactory" (214), whilst Hamied suggested that a priority in research should be for "drugs for improvement of memory, intelligence and personality." (215)

Finally, the respective roles of allopathic medicine, and the unani, ayurvedic and homeopathic systems, is yet to be worked out (216). Recently, the Government has given increasing support to the non-allopathic systems, which are used by the majority of the Indian population (217), yet many still consider the funds to be insufficient (218). There is little integration of the various systems, which involve fundamentally different approaches (219).

The literature contains periodic reports about the efficacy of new herbal drugs (220), and recommends that: "any production by village communities for their own use (eg cultivation of herbs) should

this respect, warning of: "self-medication of drugs which is not desirable." Hathi (1975) p100.
(213) "There is no comprehensive Health Atlas of India. The statistics available are those of the government hospitals in urban areas where protected water supplies and other health precautions are provided and from the death records in which the diseases are not properly identified." Rangarao (1975) p36.
(214) Hathi (1975) p93.
(217) Lok Sabha, Answer to Unstarred Question No.2598, 8 March, 1979.
(219) Interview, B.V.Rangarao, New Delhi, April, 1981.
(220) For example, "Indian News in Brief", SCRIP, 16 September, 1978, p23.
be encouraged." (221) Up to now, there is little indication that any effective action is being undertaken in support.

(221) ICSSR and ICMR (1981) p182.
COMPANY CASE STUDY 1: TECHNOLOGY TRANSFER BY CIBA-GEIGY

As has been shown in Chapter 2, the great majority of the world's pharmaceuticals is produced by transnational corporations (TNCs). Most of these companies have their headquarters in the industrialised nations of Western Europe, USA and Japan.

In contrast with many other forms of manufacturing, most of the technology transfer in the pharmaceutical industry takes place within the boundaries of these corporations, when they establish subsidiaries in other parts of the world. Know-how may also be transmitted from the parent company to associates in other countries. When domestic pharmaceutical companies develop alongside the TNC subsidiaries, they are frequently influenced both by the techniques which the TNCs have introduced and by Government regulations, drawn up in reaction to the activities of the foreign companies.

For these reasons, it is important to consider the role of the large TNCs in technology transfer. One of the largest pharmaceutical producers in the world is the Swiss-based company, Ciba-Geigy AG. In 1977, this company was 4th in the world rankings for pharmaceutical sales (1). It is recognised as one of the important innovators, both in terms of discovering and introducing new drugs and in the development of management and planning systems. Therefore, whilst there are considerable variations amongst the large TNCs, it might be expected that the experiences of Ciba-Geigy will give some indications of the ways in which such companies view technology transfer, how they

(1) UNCTC (1979) p113.
effect such transfer, and how company strategy has evolved, with its effect on the LDCs.

Many factors affect whether a company decides to transfer technology and the techniques it selects. These have been discussed in general terms in Chapter 2 and are equally relevant in the case of Ciba-Geigy. In any particular case, however, there are additional influences, about which it is difficult to generalise. This can be illustrated by case studies of the experiences of Ciba-Geigy in Indonesia and India, the countries described in Chapters 4, 5 and 6. The purpose of this chapter is threefold. Firstly, to investigate what has led the company to transfer technology (2). Secondly, to examine the extent of technology transfer, in terms of the production processes which have been established as well as the parallel projects, of a less-obviously commercial nature, which the company has undertaken in the country. Thirdly, to describe how the company has gone about technology transfer (3). After an introduction to some of the features of the company as a whole, the main body of this chapter is concerned with the pharmaceutical operations of Ciba-Geigy in Indonesia and India. The final section considers recent general developments in the company (4).

(2) These considerations include the history and internal organisation of the company, as well as events in the potential host country.
(3) Including, how internal systems have evolved to optimise this process, both in the short-term considerations of project management and, also, in the longer-term methods by which the company seeks to plan its future on a global scale.
(4) A series of interviews was held at company Headquarters in January, 1981, in the Indian subsidiary between February and May, 1981, and at the Indonesian subsidiary between July and October, 1981. Unless indicated otherwise, the material for this chapter is taken from these interviews, or from unpublished company documents.
7.1 HISTORY AND ORGANISATION

The company of Ciba-Geigy was created in 1970 by the merger of two concerns, CIBA Ltd and JR Geigy SA, both of which had a long and distinct tradition. Both companies were situated in the Swiss city of Basel, and both had taken the decision to embark on the manufacture of synthetic dyestuffs and, thereby, enter the world of industrial chemistry, in 1859.

Geigy dates from the the 18th Century, when it was a trading company dealing in the 'colonial' goods of chemicals, dyes and drugs processed from plant materials. By the end of that century and in the early decades of the 19th Century, the development of the steam engine and the power loom gave an impetus to the growth of the textile industry; Geigy responded by concentrating on dyestuffs. The company grew, went public in 1901 and, during the 20th Century, entered other fields of manufacture. These included textile chemicals in the 1920s, agrochemicals in the 1930s and the establishment of a pharmaceutical division in 1938.

CIBA developed from a small silk-dyeing business, established soon after W.H.Perkin had discovered the first coal dye in 1856. By 1884, it was large enough to be converted into a limited liability. Registered as the 'Society of Chemical Industry in Basel', it became so widely known by the acronym 'CIBA' that, in 1945, this was adopted as the official name. The company presented its first pharmaceutical products at the Paris Exhibition of 1889 and later diversified into such fields as textile chemicals, cosmetics, plastics, epoxy resins, animal health and hygiene, photochemicals and electronic technology.

In the period immediately following the Second World War, both
companies experienced an unprecedented demand for their products; growth was swift and international. Thus, few had anticipated the next step in the companies' development, when they merged at the end of the 1960s to form the company Ciba-Geigy.

There were many characteristics of size, specialisation and organisation which had to be considered in such a move. The product ranges of the two companies, summarised in Appendix 7.1, seemed particularly complementary. The proposals for the merger met significant opposition, both from within the companies and outside, especially in the USA, where the plans had to be negotiated through the Anti-Trust laws. This was eventually achieved in 1970 (5).

Together with the other large chemical companies, Sandoz and Hoffmann LaRoche, which are also based in Basel, Ciba-Geigy plays an important part in the economic prosperity of Switzerland. The country has a relative dearth of natural resources and the chemical industry has specialised in original high-quality chemicals, which make a significant contribution to Swiss exports, comprising about 20 per cent of the total. Ciba-Geigy contributes about one third of this, or 7 per cent of the total Swiss exports (6). In the late 1970s, some 98 per cent of company sales were outside Switzerland (7).

The company's products are now sold throughout the world and various subsidiaries and associated companies have been established.
in 56 different countries. The company has continued to produce the wide range of goods which CIBA and Geigy manufactured at the time of the merger, but has not diversified into other fields. The sales of the group in terms of location and operating sectors are shown in Tables 7.1 and 7.2. It will be seen that sales of pharmaceuticals represent about 27 per cent of the group's total, whilst the sales of all sectors in Asia comprise about 10 per cent of the total. Around 20 per cent of pharmaceutical sales are made in LDCs (8).

### TABLE 7.1
Global Sales of the Ciba-Geigy Group of Companies by Operating Sector: 1976-1980
(Millions of Swiss Francs (a))

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyestuffs and Chemicals</td>
<td>2,045</td>
<td>1,974</td>
<td>1,718</td>
<td>1,859</td>
<td>2,007</td>
<td>17</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>2,689</td>
<td>2,806</td>
<td>2,559</td>
<td>2,729</td>
<td>3,213</td>
<td>27</td>
</tr>
<tr>
<td>Agricultural Products</td>
<td>2,282</td>
<td>2,469</td>
<td>2,083</td>
<td>2,242</td>
<td>2,683</td>
<td>22</td>
</tr>
<tr>
<td>Plastics and Additives</td>
<td>1,609</td>
<td>1,780</td>
<td>1,636</td>
<td>1,989</td>
<td>2,345</td>
<td>20</td>
</tr>
<tr>
<td>Airwick (c)</td>
<td>389</td>
<td>387</td>
<td>389</td>
<td>468</td>
<td>617</td>
<td>5</td>
</tr>
<tr>
<td>Ilford (d) and Electronic eqpt.</td>
<td>474</td>
<td>525</td>
<td>547</td>
<td>604</td>
<td>1,049</td>
<td>9</td>
</tr>
<tr>
<td>TOTAL</td>
<td>9,488</td>
<td>9,941</td>
<td>8,932</td>
<td>9,891</td>
<td>11,914</td>
<td>100</td>
</tr>
</tbody>
</table>

NOTES: (a) Based on actual sales figures expressed in Swiss Francs  
(b) A period of significant change in the value of the Swiss Franc.  
(c) Includes a wide range of household items.  
(d) Mainly photochemicals.  


The 1980 sales of the Indian company amounted to some Rs610

TABLE 7.2
The Geographical Distribution of Sales by the Ciba-Geigy Group of Companies: 1976-1980
(Percentages, based on the actual sales figures expressed in Swiss Francs.)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>45</td>
<td>46</td>
<td>47</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>N.America</td>
<td>29</td>
<td>26</td>
<td>24</td>
<td>24</td>
<td>26</td>
</tr>
<tr>
<td>Latin America</td>
<td>10</td>
<td>11</td>
<td>10</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Asia</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>11</td>
<td>9(a)</td>
</tr>
<tr>
<td>Africa, Australia and Oceania</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

NOTE: (a) The Annual Report for 1980 identifies this fall in sales in Asia as largely the result of currency fluctuations in Japan.


million, of which pharmaceutical sales were about Rs190 million. This is approximately equivalent to SwFr130 Million and SwFr40 Million respectively, so that total sales in India represent about 1.1 per cent of the group's total, and pharmaceutical sales about 1.2 per cent of the group's pharmaceutical sales. Pharmaceutical sales in Indonesia represent about SwFr18 Million, or 0.6 per cent of group pharmaceutical sales.

Capital is invested for a variety of reasons, including production, research and development and technical infrastructure. The geographical distribution of this expenditure is shown in Table 7.3, whilst the distribution of employment is shown in Table 7.4.

Group activity is controlled by means of a 'three-dimensional structure', consisting of:
### TABLE 7.3
The Geographical Distribution of Capital Expenditure by the Ciba-Geigy Group: 1976-1980 (Millions of Swiss Francs)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>274</td>
<td>228</td>
<td>190</td>
<td>237</td>
<td>352</td>
<td>41</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>180</td>
<td>159</td>
<td>141</td>
<td>165</td>
<td>246</td>
<td>29</td>
</tr>
<tr>
<td>N. America</td>
<td>140</td>
<td>153</td>
<td>136</td>
<td>118</td>
<td>133</td>
<td>16</td>
</tr>
<tr>
<td>Latin America</td>
<td>35</td>
<td>63</td>
<td>54</td>
<td>30</td>
<td>88</td>
<td>10</td>
</tr>
<tr>
<td>Asia</td>
<td>32</td>
<td>18</td>
<td>18</td>
<td>28</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>Africa, Australia and Oceania</td>
<td>18</td>
<td>19</td>
<td>15</td>
<td>20</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>679</td>
<td>640</td>
<td>554</td>
<td>598</td>
<td>853</td>
<td>100</td>
</tr>
</tbody>
</table>

**SOURCE:** Company Reports (1977-1981)

### TABLE 7.4
The Number of People Employed by the Ciba-Geigy Group of Companies by Geographical Region: 1976-1980

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>21,275</td>
<td>21,202</td>
<td>21,320</td>
<td>21,534</td>
<td>22,892</td>
<td>28</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>28,203</td>
<td>27,663</td>
<td>25,511</td>
<td>28,047</td>
<td>27,921</td>
<td>35</td>
</tr>
<tr>
<td>N. America</td>
<td>11,440</td>
<td>11,290</td>
<td>12,119</td>
<td>15,150</td>
<td>14,771</td>
<td>18</td>
</tr>
<tr>
<td>Latin America</td>
<td>6,785</td>
<td>6,970</td>
<td>7,116</td>
<td>7,555</td>
<td>7,706</td>
<td>10</td>
</tr>
<tr>
<td>Asia</td>
<td>4,832</td>
<td>5,072</td>
<td>5,515</td>
<td>6,150</td>
<td>5,985</td>
<td>7</td>
</tr>
<tr>
<td>Africa, Australia and Oceania</td>
<td>1,820</td>
<td>1,883</td>
<td>1,713</td>
<td>1,787</td>
<td>1,909</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>74,355</td>
<td>74,080</td>
<td>75,294</td>
<td>80,223</td>
<td>81,184</td>
<td>100</td>
</tr>
</tbody>
</table>

**SOURCE:** Company Reports (1977-1981)
(i) FUNCTIONS, which include Legal Affairs, Finance, Technology, Marketing, Research and Development and the like,
(ii) DIVISIONS, Dyestuffs, Pharmaceuticals and so on, and
(iii) REGIONS under the headings (a) North America, (b) West Europe, (c) Latin America, (d) Africa/Near East, (e) East Europe/Indian Sub-Continent, and (f) Far East, Australasia and Oceania.

The Pharmaceutical Division manufactures about 200 active ingredients, in 300 preparations, for sale around the world. The majority may be divided into four categories:

(i) Products for the treatment of cardiovascular disease,
(ii) Anti-rheumatic and other anti-inflammatory preparations,
(iii) Psychotropic and neurotropic drugs, and
(iv) Anti-infective agents.

Between them, these products account for around three-quarters of total pharmaceutical sales. The remainder comprises a large number of other products, with relatively low sales.

7.2 PHARMACEUTICAL ACTIVITY

Whilst many of the Ciba-Geigy anti-infective drugs, and some of the other products outside these four categories, are widely used in tropical countries, drugs in the first three groups do not realise high sales in such countries (9). Ciba-Geigy carries out significant research into 'tropical diseases' (10) but, like all TNCs, does not

(9) This does not mean that the conditions which they are designed to treat do not exist in industrially less developed countries, but that the perceived need for other products is greater, and sales of such drugs higher.
(10) For an account of Ciba-Geigy's R&D into 'tropical diseases', see Behrman (1980).
concentrate its R&D effort in this area. Therefore, the company does not have a particular need to sell in LDCs because of its product range but, rather, hopes to sell a more or less standard selection of drugs for a wide range of diseases.

Interviews at Basel confirmed that Ciba-Geigy follow the general strategy of technology transfer outlined in Chapter 2. The economies of scale and other considerations of control and hygiene have led the company to centralise production as far as possible. When they have established factories overseas it has usually been in response to direct or indirect pressure by the host Government, rather than as a result of corporate financial evaluations. Consequently, a large proportion of the pharmaceutical production is carried out at factories within Basel and at the nearby sites of Schweizerhalle (Canton Basel-Rural) and Stein (Canton Aargau). Ciba-Geigy, like most TNCs, uses the latest production techniques in its home country factories. These include microprocessor and computer control, minimal operator involvement with products or intermediates, and tight control over the ingredients used in formulations. Much of the equipment used in both primary and secondary production is dedicated to particular products.

By the end of 1979, some 20 production plants had been established in LDCs. Together, these factories produced about 35 per cent of the Division's output, and involved a total of some 2,500 jobs (11).

(11) These figures somewhat exaggerate the level of activity in LDCs, as very little bulk production is undertaken; production processes usually involve the formulation of active ingredients manufactured in Western Europe.
7.3 CIBA-GEIGY IN INDIA

Ciba-Geigy has been particularly active in India. The CIBA and Geigy companies have had long histories of involvement there, which date from the latter years of the 19th Century, when the first CIBA dyestuffs were made available in India through trading companies. In 1928, CIBA (India) Ltd was established. It operated as importer and a marketing concern until 1958, when a factory was established at Bhandup for pharmaceutical manufacture (12). In 1960, the manufacturing facilities were reinforced by the establishment of a joint venture with Atul, an Indian company, to form CIBATUL at Valsad in the state of Gujarat. This plant synthesises the bulk material for the production of sulphonamides, an important part of the production range of the Bhandup factory. In 1963, the company took the unusual step of establishing the large CIBA Research Centre at Goregaon, on the outskirts of Bombay. Five years later, it built a pesticides factory in Goa, in which a pharmaceutical intermediate is also produced.

By the early 1970s, Geigy had also established factories for manufacturing pharmaceuticals in India, although they had not been as heavily involved as CIBA (13). By 1948, Geigy had negotiated with the Amalgamated Chemical and Dyestuffs Corporation (ACDC) of India to import finished goods. In the mid-1950s, Geigy established a joint venture with the Indian company, Sarabhai, to form Suhrid-Geigy, which manufactured pharmaceutical bulk material in Baroda, Gujarat. During the 1960s, Suhrid-Geigy expanded its facilities to another site at Ranoli, also in Gujarat and, by 1972, had started its own

(12) At that time, Bhandup was just outside Bombay but it now forms a suburb of that city.
(13) This reflects the relative importance which the two companies placed on pharmaceuticals.
pharmaceutical formulation at that site.

When the two parent companies merged in 1970, moves were made to amalgamate their subsidiaries around the world. The Indian companies were re-organised in 1974 and CIBA of India assumed the title of Ciba-Geigy of India Ltd. However, under the 1973 Foreign Exchange Regulation Act, Ciba-Geigy of India was not permitted to market the Geigy line of products (14). This was prohibited on the grounds that Suhrid-Geigy was an 'Indian' company, by virtue of its shareholding distribution, whilst Ciba-Geigy was a 'Foreign' company. For a short time, the Geigy range was manufactured under licence by Suhrid-Geigy but the contract was dissolved in 1975, and the India company later changed its name to SG Chemicals. In 1979, Ciba-Geigy opened a formulation factory at Kandla, in Gujarat, to formulate products for export. The chronology of the operations in India is summarised in Appendix 7.2 and the locations of the principal sites illustrated in Figure 7.1. Ciba-Geigy of India now has its headquarters in the centre of Bombay, from where it coordinates all operations of the Pharmaceutical, Dyestuffs, Plastics and Additives, Agricultural and Consumer Products Divisions.

7.3.1 Bhandup

The factors which led CIBA to establish this plant in 1958 are an example of the indirect pressures to begin local production which a host Government can exert on a foreign company (15). As the industrial licensing policy of the Indian Government then stood, CIBA was classed as an 'Established Importer'; it could import finished goods

(14) Although similar moves were allowed in every other country.
(15) Geigy also began local manufacture for similar reasons.
FIGURE 7.1  THE LOCATION OF CIBA-GEIGY INSTALLATIONS IN INDIA.

at a level based on historic sales. Once it began local manufacture, however, it became an 'Actual User'. As such, it was granted a licence to import raw materials to meet the market requirements and paid a lower duty. Given the great potential for selling pharmaceuticals in India at that time, this was a marked advantage.

It was a natural choice to site the factory at Bhandup, near to the Head Office in Bombay. The advantages included the proximity of the port for imported material and equipment, and a wide range of other suppliers of machinery, materials and services. Municipal supplies of water, power and sewage disposal were also available. As the pharmaceutical industry in India is centred on Bombay, the company experienced little difficulty in recruiting workers with the required skills; wage rates were somewhat higher than might be paid in other parts of the country, but the extra cost was considered insignificant when compared to the other advantages of the site.

The Bhandup factory was one of the first to be established overseas by CIBA and the company had not developed many of the techniques for technology transfer and assessment which it now employs. As the Indian company had not built up its own engineering department, the design of the Bhandup factory was carried out in Basel and based on the existing machinery used in Europe, which the Indian authorities allowed to be imported.

In later years, the factory has expanded to include equipment for chemical production, in accordance with the Government of India's requirements for more bulk drug manufacture. Chemical production at Bhandup includes the conversion of some sulpha drug intermediates, supplied by CIBATUL, and the manufacture of drugs from bulk material
bought from other suppliers in India. The Indian subsidiary manufactures a wide range of formulations, and concentrates on five main product groups:

(i) Steroids (12 products),
(ii) Sulphonamides (5 products),
(iii) Antihistamines/diuretics (5 products),
(iv) Anti-diarrhoeals (2 major products), and
(v) Anti-hypertensives (2 major products).

These drugs are sold in various dosage forms (16). The production of bulk drugs is listed in Appendix 7.3, whilst the value of pharmaceutical production by Ciba-Geigy of India is summarised in Table 7.5.

<table>
<thead>
<tr>
<th>FORMULATIONS</th>
<th>1979</th>
<th>1983</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actual</td>
<td>Estimated</td>
</tr>
<tr>
<td>Local</td>
<td>150.2</td>
<td>214.7</td>
</tr>
<tr>
<td>Export</td>
<td>14.0</td>
<td>49.1</td>
</tr>
<tr>
<td>BULK DRUGS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To local Third Party</td>
<td>8.4</td>
<td>10.3</td>
</tr>
<tr>
<td>Export</td>
<td>3.5</td>
<td>3.0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>176.1</td>
<td>277.1</td>
</tr>
</tbody>
</table>

BASIS: Local Sales - Retail Prices, excluding excise duty
Exports - current F.O.B. Prices

With the Indian company being well-established by the 1980s, the initiative to introduce a new drug arises when a potential market for

(16) For further information on the products sold by Ciba-Geigy of India, see Hathi (1975) p119-120. Very few new products have been introduced since this report was compiled.
a product, known to be in the Ciba-Geigy range elsewhere, is identified by the subsidiary. The parent company will then send enough information to enable a more detailed feasibility study of the technical and commercial potential to be made. Nevertheless, the information transmitted at this stage does not give all the manufacturing details necessary for full production. Should the feasibility studies seem promising, an application is made to the Indian Government for a manufacturing licence. If the conditions imposed by the Government are acceptable both to the Indian company and to the parent company in Switzerland, further information is given to the subsidiary (17).

The potential for local production is then considered by the Ciba-Geigy Development Technology Department in Bombay. The raw materials to be used and the suggested equipment are compared with the materials which are available in India and the equipment which is already installed in the factory. Chemical production processes may be tried in the laboratory and pilot plants, and the yield compared to the results quoted by the parent company (18).

Chemical production processes at Bhandup are usually somewhat more labour-intensive than in Basel. The scale may be several times smaller, using manual or semi-automatic equipment, whereas the

(17) These instructions include layout drawings and equipment list, flow-sheet drawings, safety instructions, detailed manufacturing steps, materials balance sheet, and the specifications and methods of testing for the raw materials, intermediates and final product.

(18) It was suggested that yields were sometimes found to be up to 15 per cent less than those quoted by the parent company; one possible cause for this was be the relative impurity of locally available chemicals (interview, Ciba-Geigy, Bombay, March, 1981). In such circumstances, the economic feasibility might have to be reassessed or minor changes made to the process, for example, by using a different solvent.
process in Europe might be fully-automated (19). This is influenced by the Government of India's industrial policy, which has prohibited the import of machinery (20). Chemical processes must also be adapted to take account of environmental factors, but the pharmaceutical processes usually require few changes, to take account of the smaller scale and different equipment.

Unlike the pharmaceutical factory, the chemical plant is not air-conditioned and the temperature and humidity are both much higher than in Switzerland. In particular, the ambient temperature of cooling water is greater, which necessitates longer cooling times, or the use of a cooler medium (21), in the vessel jacket.

Although some 1,250 people are employed at Bhandup, the lower labour costs have not led the company to introduce formulation techniques which are notably more labour-intensive than those used in Europe. A company representative stated that the ability of the Indian workers is different from those in Europe, and a larger number of personnel would also lead to organisational difficulties and increased potential for labour disruption (22).

In addition to its pharmaceutical products, the Bhandup factory

(19) Examples of such adaptation include the use of manual hoists for transferring materials, where a pump or pneumatic conveying system had been introduced in the West, and in control systems, where the rate of temperature change of a vigorous reaction might be monitored automatically in Switzerland but by an operator in India.

(20) A company spokesman identified this as one reason why they had experienced difficulty in introducing certain dosage forms into India. For example, the manufacture of sustained release tablets, which had been developed in the parent company, using Swiss and German machinery, had proved problematical on Indian machinery. Interview, Ciba-Geigy, Bombay, April, 1981.

(21) Such as refrigerant, whereas cooling water is adequate in Switzerland.

(22) Interview, Ciba-Geigy, Bombay, March, 1981.
also makes some consumer goods. Further details of the plant are included in Appendix 7.4

7.3.2 CIBATUL

Unlike the Bhandup factory, which started as a formulation unit and had expanded later to include chemical production, the CIBATUL factory originated as a chemical plant. CIBA had first made contact with the Indian company, Atul in the early 1950s, when the company produced three bulk drugs under licence for CIBA (23). By 1958, CIBA had identified an increased market for its sulphonamide drugs (24). It sought permission from the Government to open a chemical factory which could manufacture these drugs for formulation elsewhere in the company. The Government was unwilling to allow such expansion to be wholly owned by CIBA and this gave the impetus to the founding, in 1960, of CIBATUL. The company is a joint venture, with shares originally being held by the Indian company, Atul (65 per cent), CIBA of India (30 per cent) and CIBA of Basel (5 per cent) (25).

(23) Atul is one of the better-known family companies in India. See, for example, the obituary of Kasturbha Lalbhai, Eastern Economist, 74 (4), 25 January, 1981, p164. Atul, itself, produces a variety of different chemicals, and also has joint ventures with an American company and a UK company, which occupy adjacent sites to the CIBATUL factory.
(24) Sulphonamides are not antibiotics but are used in a somewhat similar way, as antibacterials, in clinical practice. Although they are much less efficacious on a weight-for-weight basis, they are generally cheaper. The drugs are all derived from the compound sulphanilamide, which was originally synthesised in 1908 in the investigation of new dyes for cloth. The antibacterial potency was recognised as early as 1917, but it was not until 1932 that clinical trials were carried out. The sulpha drugs were introduced into common medical practice during the 1930s and formed a valuable part of the medical arsenal, particularly during the Second World War when members of the armed forces from temperate countries were stationed in tropical climates. See Fisher and Christie (1975) p223-227; Parish (1979) p269-271; and, Reuben and Burstall (1978) p352,353.
(25) The shares held by the CIBA parent company and subsidiary have now been transferred to the Ciba-Geigy companies in India and
Production at CIBATUL began in 1966, with the commissioning of a plant to manufacture two CIBA resins, Urea-formaldehyde and Melamine-formaldehyde; bulk pharmaceuticals were introduced two years later, with a sulpha drugs intermediates plant. This sulpha plant was one of the first pharmaceutical chemical plants to be built by CIBA in a foreign country. Great care was taken over the planning and preparation of the project; the success of the technical operation has meant that the methods introduced then have become something of a model for later projects and, for this reason, it is considered at some length here.

CIBA had begun to produce sulpha drugs in 1939 and could, therefore, base the planning for CIBATUL on some 20 years of experience in development and production. With the advent of the antibiotics, however, sulpha drugs became relatively less important to the company. Production took place on several sites, notably the CIBA factory in Grimsby, UK, and a variety of synthesis routes had developed to take account of local factors (26). The plant at CIBATUL was to be built on virgin land. The design had, therefore, some degree of flexibility in equipment installation, but was restricted by the raw materials which could be supplied in India (27).

Basel at the same levels.
(26) Such as raw materials cost, availability and quality, and the equipment available.
(27) During the late 1950s, the total requirement of sulpha drugs in India was about 1,500 tonnes per year, and it was initially estimated that the CIBATUL factory would produce about one third of this quantity. A reassessment was made by the Marketing Department during the planning stage (1960-1963), when IDPL began production of sulpha drugs; this resulted in the actual installed capacity being 240 tonnes per year. However, since 1970, the demand of Ciba-Geigy of India has varied between 300 and 400 tonnes per year and expansions have been made. The production in 1979 was about 350t. Over 90 per cent, by value, of CIBATUL's output is bulk drugs for Ciba-Geigy in Bombay, although CIBATUL is an independent entity and it also produces some bulk material for other formulators within India, and for export.
Design and Operation of the Chemical Plant at CIBATUL

The Chemical Production Department in Basel decided that the plant should be designed to carry out the total synthesis of all the sulpha intermediates from aniline, using a common route and a multipurpose conversion plant. The chemical synthesis route is illustrated in Figure 7.2.

Many of the processes used by CIBA at that time had to be modified to fit this general scheme and it was necessary to carry out a significant amount of development work to determine the reaction conditions. This work involved some twenty chemists working in Grimsby and Basel. It had been hoped to decrease the number of solvents used (28), but it was still found necessary to use three. All the reactions and unit operations eventually selected for CIBATUL were relatively safe and straightforward to carry out. In a few cases, a safe process was adopted, even though a higher yield might have been obtained by a somewhat riskier or more difficult process.

Whilst the process development work was going on, the building design and its feasibility were considered, with contractors helping to establish the project timetable. Atul selected a site beside its own factory; amongst the attractive features, were good access, and the nearby sea which, besides giving a cool breeze, could absorb some effluent. The site had some basic facilities (29), and so CIBATUL had no immediate need to duplicate them. The interested contractors were soon reduced to two and the company eventually selected a

(28) To facilitate materials purchasing and the use of multipurpose plant.
(29) Such as water purification, power generation and effluent treatment, provided by Atul.
'R' represents the appropriate cyclic compound for the required product. For example, sulphamerazine is produced by reacting 2-amino-4-methyl-pyrimidine with ASC and hydrolysing the resulting compound.

THE REACTION SCHEME FOR THE PRODUCTION OF SULPHONAMIDE DRUGS AT CIBATUL.

British-based concern, with a subsidiary in Bombay, which was relatively experienced in this sort of plant and had a competent staff of expatriate and Indian engineers. This company assumed somewhat more responsibility than might have been the case for a project in Europe (30).

Feasibility studies in Basel suggested that the optimum batch size would be around 1,000 kg, which implied a reactor size of 10m³ and made the plant the largest pharma-chemical plant in India at that time. It was decided to install modern techniques of chemical processing, which included systems for continuous reactions, crystallisation, filtration, drying and distillation. In particular, this was the first time that continuous crystallisation had been used in India (31). Equipment was selected on the basis of laboratory and pilot plant trials in Basel and Grimsby, and all the equipment was imported from Europe, after discussions with a wide range of suppliers. Finally, extensive tests and inspections were carried out in Grimsby or Basel before export (32). The capital cost of the project was estimated to be around SwFr18 million and the proportion to be paid by CIBA (33), was used to purchase the equipment. Further details of the project cost and the equipment are included in Appen-

(30) The division of responsibility depends both on the nature of the project and the country, and also on the individual relationship between the contractor and the client.
(31) Whilst continuous systems are frequently more economical than batch processing, the control and maintenance of equipment is often more difficult. It was very important to ensure that the equipment was in good working order, that control systems were efficient, and that the production personnel were well-trained to operate the processes themselves.
(32) The company was careful to establish a good supply of spare parts against future mechanical failure. As an example of the scale of this inventory, standby pumps were purchased at a rate of one for every two pumps actually installed.
(33) Which totalled 35 per cent, or some SwFr6 million.
The environmental conditions had some effect. For example, chutes were used instead of pneumatic lines to convey solids. The operation of pumps is also difficult, as the teflon stator seals tend to distort at temperatures above 40°C. Rubber seals perform better but the maintenance of pumps is a continuing problem in hot countries; therefore pumps were eliminated, as far as possible, by arranging pipework for gravity flow. The main use of pumps was to fill head tanks above the reactors.

Process control was not the most sophisticated available, as the company used air-operated, rather than electronic, systems. As the main contractor was relatively inexperienced with control systems, it was agreed that an instrument engineer from Basel should supervise their installation and the training of local staff in their operation and maintenance.

By 1965, the project team had completed the basic design, placed orders for the equipment, and selected subcontractors for the specialised installations. The contractors moved onto the site to start the civil work and the majority of the equipment was installed during the next two years. At the same time, a Swiss Project Leader was selected and during the period 1965-1970, he spent about 80 per cent of his time on CIBATUL business, both in Europe and in India. He was much involved in discussions on layout, necessitated by local factors, and he had to see to the modification of the drawings and flow sheets prepared by the design team and the contractor. Nevertheless, some mistakes were made, although it was possible to correct them all later (34).
Whilst equipment was being installed, production staff were recruited and trained, and discussions were held with potential suppliers of raw materials. Some of the qualified personnel joined the company from Atul, but over 80 per cent were relatively inexperienced engineers and chemists who came from all over India. Local semi-skilled and unskilled labour was recruited from the surrounding villages (35).

As CIBA placed great importance on the training of the staff, a training programme was devised which involved the senior CIBATUL personnel spending time in Europe. Further details of this training programme are included in Appendix 7.5. By 1964, the senior Indian staff for CIBATUL had already been recruited and, after initial familiarisation with the processes, they played a full part in the running of the training programme.

Although laboratory and pilot plant work had been performed in Europe during the plant design stage, it was now necessary to carry out further pilot plant work on site. This had the dual function of assessing potential suppliers of raw materials, and enabling Indian staff to carry out the processes under controlled conditions. Suitable equipment for this work was found in the Bhandup factory and in the Atul plant, since much of it had already been used for the production of some of the sulpha drug intermediates.

(34) Examples include the location of a sight glass too close to the floor, misplaced supports for a fluidized bed dryer, which forced the flanges out of perfect alignment. and the pipework on a distillation column being installed in such a way that access to the control platform was denied during operations. (35) During the construction phase, there was a large number of labouring jobs but numbers fell as the plant was commissioned and production started.
The Swiss Project Leader and his assistants from CIBA had experience of commissioning plants in other countries. They were determined to avoid some of the potential pitfalls by initiating an extensive programme of mechanical commissioning (36). When the mechanical commissioning was complete, the overall performance of the plant could be checked and this was done in two distinct stages. Initially, water was used to test the pumps, reactor systems, and the like, and to familiarise the production staff with the operation of the equipment (37). Then the plant was used to produce trial batches and, eventually, begin full production. The first phase included the intermediate ASC, and one of the bulk drugs. The second stage added two further bulk drugs, and others were introduced in later years (see Appendix 7.5). With the plant operating on a continuous basis, it was necessary to introduce a 24-hour shift system.

During the introduction of the chemical processes, the responsibility was gradually handed over to the local production staff. As this proceeded, the project team withdrew but was available on site to effect any minor modifications and to give advice and assistance.

(36) To some extent, this activity is also the responsibility of the contractor and the degree of responsibility of each party has to be negotiated. In this case, the contractor was required to do relatively little; the Project Leader was concerned to see that the plant was checked to the standards he, himself, demanded. In subsequent Ciba-Geigy projects, the contractor has played a larger part, but this depends on the nature of the plant and the experience of the parties. The programme of mechanical commissioning involved pressure and vacuum testing, lubrication, calibration and cleaning; the latter including the removal of rust and welding residue. This required a range of services, such as electricity, compressed air and steam; further details are included in Appendix 7.5.

(37) For example, pumps were run continuously for 24 hours to recycle water and reactors half-full of water stirred for a similar period. During the latter operation, it was found that the gears and drive of some of the reactor agitators were out of true alignment and excessive frictional heat was generated.
until the plant worked at the optimum level.

The Performance of CIBATUL

In the 15 or so years since the handing over of the sulpha plant, there have been relatively few serious problems (38). Sulpha drugs have continued to sell well and the capacity has been expanded to 320 tonnes per annum. In 1980, an application was made to the Government to increase the capacity of the plant further to 700 tonnes per annum (39). Such new capital expenditure would be financed by CIBATUL itself, rather than by further investment by Ciba-Geigy in Basel or India.

When interviewed in 1981, a CIBATUL spokesman reported that the company had experienced no particular difficulties through being located in Gujarat, rather than Bombay (where an office is maintained to arrange commercial matters, such as insurance, banking and the clearance of goods through the docks). Transport by road and rail to Bombay is of a relatively high standard, whilst technical problems had been minimised by establishing a comprehensive selection of spare parts and the careful ordering of raw materials. When the plant had opened, about 35 per cent of the equipment and raw materials were of Indian origin; by 1980, this figure had risen to 90 per cent (40). The company has achieved attractive financial results, which are summarised in Table 7.6

(38) One difficulty had been anticipated. The important intermediate, ASC, is highly corrosive, and by 1981, the company had decided to build a new plant in a separate building for the manufacture of this material.
(40) Interview, CIBATUL, Valsad, April, 1981.
TABLE 7.6
(Lakhs of Rupees)

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<td>Revenue</td>
<td>414.30</td>
<td>507.42</td>
<td>759.30</td>
<td>1,008.10</td>
<td>1,081.64</td>
<td>1,449.12</td>
</tr>
<tr>
<td>Gross Profit</td>
<td>90.76</td>
<td>101.63</td>
<td>172.94</td>
<td>165.58</td>
<td>159.63</td>
<td>171.61</td>
</tr>
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<td>Depreciation</td>
<td>39.34</td>
<td>37.03</td>
<td>43.27</td>
<td>47.55</td>
<td>38.64</td>
<td>34.97</td>
</tr>
<tr>
<td>Taxation</td>
<td>-</td>
<td>-</td>
<td>71.40</td>
<td>60.32</td>
<td>58.24</td>
<td>78.50</td>
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<tr>
<td>Net Profit</td>
<td>51.42</td>
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<td>58.27</td>
<td>57.71</td>
<td>62.75</td>
<td>58.14</td>
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<tr>
<td>Dividends</td>
<td>-</td>
<td>-</td>
<td>17.00</td>
<td>36.00</td>
<td>36.00</td>
<td>36.00</td>
</tr>
<tr>
<td>Profit Retained</td>
<td>51.42</td>
<td>64.60</td>
<td>41.27</td>
<td>21.71</td>
<td>26.75</td>
<td>22.14</td>
</tr>
</tbody>
</table>


7.3.3 Research and Development Centre, Goregaon

In 1963, CIBA opened a large Research Centre at Goregaon on the northern outskirts of Bombay. This venture is extremely unusual, as the other Ciba-Geigy pharmaceutical research centres are located in the USA, Switzerland and the UK, and few other companies have developed significant R&D departments in LDCs (41). With hindsight, it is unlikely that Ciba-Geigy would repeat the decision to build their research centre, and it is instructive to consider the factors in the late 1950s and early 1960s which influenced their decision then.

Firstly, the future business potential of India was seen to be very high. At that time, the structural nature of poverty and

(41) For example, Hoechst has a Research and Development department adjoining its production site in Bombay. This is probably the next biggest commercial centre for pharmaceutical research in India, but it is much smaller than the Ciba-Geigy enterprise.
underdevelopment was not well understood; India had achieved Independence in 1948 and it was widely expected that, with the constraints of colonialism removed, it would soon convert its natural resources and indigenous ability into significant economic growth. The President of CIBA, Robert Käppeli, had visited India and he was very impressed both with the efforts made by the country and with the Prime Minister, Jawaharlal Nehru (42).

Secondly, India at that time could be classified as a 'sellers' market'. The sales realised by companies, particularly those manufacturing consumer goods, were high, and the business climate was considered to be favourable. At the same time, however, India suffered severe foreign exchange difficulties and restricted the amount of revenue which TNCs could repatriate. CIBA had amassed significant capital reserves in India and, with the development of the CIBATUL project, had no need to spend these on further production facilities.

These two considerations led to the decision to build a Research Centre which, it was hoped, would make use of the company's financial resources and the pool of Indian scientific personnel, many of whom had furthered their studies in USA or Europe. Käppeli saw this as a means of converting the surplus revenue of: "the Indian business... into a quasi-intangible economic asset whose fructification entails no outflow of foreign exchange." (43) The drugs discovered in India could be used throughout the CIBA organisation, enabling Indian profits to be converted into a non-monetary, transferable, form. Thus, Käppeli thought, the Centre would be of benefit both to India, and to CIBA as a whole.

(42) Käppeli (1965).
(43) Käppeli (1965) p131.
This idea was attractive both to others in the company and to the Indian Government. The project went ahead at great speed; the Centre was opened on 21 March, 1963 by Nehru, himself, some three years after the formal conception of the idea.

All of the Centre's equipment was exported through Basel. The initial cost was Rs3 crores and annual costs have subsequently risen to a level of about Rs2.5 crores (44). The company now runs a complex of some 30 buildings including 80 separate air-conditioned laboratories, an animal house, library, offices, utilities, canteen and a housing colony. By 1967, there were 230 senior staff at the centre; 117 were qualified to BSc level, with a further 28 holding doctorates (45). Further training of scientific staff includes a scheme whereby one chemist each year visits Basel for between 3 and 6 months and biologists visit somewhat more frequently.

Originally the programme at Goregaon mirrored the work in Basel. More recently, however, a degree of specialisation has occurred, based on the Centre's own assessment of its capabilities and in conjunction with the other company research institutions. Somewhat predictably, the Goregaon Centre now concentrates on the search for drugs against 'tropical diseases' in a programme which is partly funded by WHO (46). About 8 per cent of all the Ciba-Geigy personnel engaged in research work are stationed at Goregaon, but, because of the differences in wage rates, this represents no more than 1.5 per

(44) Personal Communication, Dr.B.Wenger, Pharmapolitik, Ciba-Geigy, Basel, April, 1983.
(45) In the early 1980s, the total personnel strength was 275, of which about 150 were degree holders. Interview, Goregaon, February, 1981.
(46) However: "The WHO funds are minimal...more precisely the programme is in collaboration with WHO." Personal Communication, Dr.B.Wenger, April, 1983.
cent of the company's total expenditure on research staff, worldwide. The major discoveries made at the centre have been:

(i) An anti-depressant drug, Sintamil, which has been marketed in India since March, 1982. This dates from the early years when work was carried out into the central nervous system.
(iii) A neuroleptic drug.
(iv) A product which can be used in the control of hookworm. It is also very active against schistosomiasis and has some application in the treatment of filariasis. By April, 1983, both this drug and the neuroleptic product mentioned above had been registered in India.
(v) A drug which may have potential in the treatment of diabetes (this programme is at an early stage).

In addition, Rhesus monkey models for fertility and epilepsy research have also been developed (47).

7.3.4 Goa

During the 1960s, CIBA became interested in the potential of the newly-independent territory of Goa as a site for production (48). The Government of India identified it as a 'Backward Territory' and encouraged manufacturing industry to go there by such incentives as tax holidays and cash subsidies for capital investment. In 1972,

(47) For further information on the activity of the Goregaon Centre, see "Swiss Contribution to Tropical Medicine", OPPI Bulletin No.3/80, May/June, 1980, p6-8.
(48) Unlike the majority of India, which had been a British colony, Goa was held by Portugal and entered the Indian Union in 1961, some 13 years after the rest of the country.
CIBA took advantage of this by building a plant, near the capital Panaji, to manufacture organo-phosphoric agrochemicals, which had been denoted a 'Priority' activity, thereby entitling the company to other Government facilities. The Goa factory is not financially very important to Ciba-Geigy of India, but the way in which it was established further illustrates the range of disciplines which can be involved in technology transfer.

The first stages of pharmaceutical production began in 1974, with the cultivation of diascorea tubers in the area around the village of Valpoi, some 50 km inland from the agrochemical plant. Diascora is processed to produce di-hydro-isoandrosterone acetate (DA), which is an intermediate in the production of all Ciba-Geigy's range of steroids. Such use of diascorea has been known for many years and most countries have relied on naturally available, wild tubers.

In India, diascorea is found growing on land over 1,200m above sea level. However, as natural resources were depleted, Ciba-Geigy was denied permission to harvest enough for their needs and, instead, decided to develop plantations in Goa. This was the first time that diascorea had been cultivated so near to sea level and the project required careful management by a team of agriculturalists and botanists.

By 1981, the company was able to grow diascorea on five separate farms. The area of cultivated land has risen to a total of 70 hectares and the production of the tubers is now at the rate of 100 tonnes per annum. The progress of this development is illustrated in Table 7.7.
### TABLE 7.7
The Production of Diascorea Tuber by Ciba-Geigy in Goa: 1976-1983

<table>
<thead>
<tr>
<th>Year</th>
<th>Area under Cultivation (Hectares)</th>
<th>Production of Tuber (Tonnes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1976</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>1977</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>1978</td>
<td>49</td>
<td>23</td>
</tr>
<tr>
<td>1979</td>
<td>59</td>
<td>31</td>
</tr>
<tr>
<td>1980</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>1981</td>
<td>68</td>
<td>100 (a)</td>
</tr>
<tr>
<td>1982</td>
<td>(b)</td>
<td>150 (a)</td>
</tr>
<tr>
<td>1983</td>
<td>(b)</td>
<td>200 (a)</td>
</tr>
</tbody>
</table>

**NOTES:**

The first species to be cultivated here was the *Diascorea floribunda*, which has a high yield and takes 3 years to mature. *Diascorea composita* is now planted to the same extent: this species is easier to harvest but has a lower yield.

(a) - Planned  
(b) - To be decided

**SOURCE:** Ciba-Geigy of India, Goa, April, 1981.

The annual rainfall around Valpoi is about 5000mm per year, which is twice the minimum required for *diascorea* cultivation. However, this is concentrated in the four months of the monsoon and the company has had to install a pump spray system to irrigate the crop during the remainder of the year. The farms employ over 300 labourers, two-thirds women, who work a six day week. For most of the workforce, this represents the first experience of formal employment, but the company reports little difficulty in introducing the necessary discipline.

The harvested tubers are chopped and minced and laid out in the
sun to ferment and to dry. After some days, the product is transported to the agrochemicals plant, where equipment is reserved for further processing. This entails hydrolysis with dilute hydrochloric acid, neutralisation with calcium hydroxide, filtration and drying in the sun to give DA. This intermediate is transported by road to the factory at Bhandup, where further conversion is carried out to give the steroidal products.

In an article in the company's house magazine, M.D. Nair of Ciba-Geigy of India described this project. He stated that:

"It exemplifies Ciba-Geigy's approach to the problems of the Third World. It is in harmony with an area of highest natural priority. It is serving to develop a valuable primary resource. It helps to equalize the country's balance of payments by substituting imports and creating exports. It is generating employment among the unskilled rural poor, uplifting the economy of an underdeveloped area and training the population in modern agricultural methods. Its technology, in conformity with the local scene, is - to use the vogue word - 'appropriate'. And it does not pollute." (49)

Towards the end of the 1970s, the company became interested in developing manufacturing facilities at Goa. This was partly because it could not gain permission to expand the Bhandup site but also because Goa offered various advantages; these included Government financial incentives and the likelihood that industrial licenses would be easier to obtain. Labour wages are somewhat lower, although the gap is decreasing, and workers' organisations have not yet developed to the same extent as in Bombay. The supply of water and power are more reliable than in the Bombay region. Power is also cheaper, to the extent that, at the end of 1980, it was available at Rs0.22 per kwh in Goa, compared with Rs0.40 per kwh at Bhandup.

(49) Nair (1979).
The disadvantages in Goa were seen to be the relative lack of skilled technicians and the difficulty of persuading managerial executives to leave Bombay. It was expected that these could be overcome and, by 1981, plans had been developed to expand the facilities to process diascorea, as a first step towards significant pharmaceutical manufacture in Goa. The company also hopes to begin the chemical manufacture and formulation of rifampicin on the same site (50).

7.3.5 Kandla

The most recent factory to be built by Ciba-Geigy of India is at Kandla in north-west Gujarat. During the mid-1960s, the Government of India established two 'Free Trade Zones', in order to promote export-orientated manufacture; one is at Santa Cruz in Bombay for the manufacture of electronic equipment, and the other is the Kandla Free Trade Zone (KAFTZ). Companies investing in these regions may import machinery and raw materials without restriction, provided that all the products are exported and that the foreign exchange thereby earned is at least 40 per cent higher than that spent in importation (51).

Ciba-Geigy became interested in investing in KAFTZ during 1978, when the USSR had approached the parent company with a view to obtaining the product rifampicin (52). This could not be arranged through Switzerland, but the Indian company was able to meet the order by establishing a manufacturing unit at KAFTZ. This was

(52) Sold by Ciba-Geigy under the trade-name 'Rimactane'.
achieved very quickly and trade with the USSR continued, the turnover in 1981 being of the order of Rs100 million. Approximately 3 tonnes of active material, imported from Basel, are formulated into 20 million capsules, sold as 250,000 packages (53). The design and construction of this unit, which employs about 50 people, was financed and carried out by Ciba-Geigy of India. The investment proposals were reviewed by the parent company, which also gave assistance in the purchase of equipment.

By 1983, the company had also introduced the manufacture of toothpaste and pesticides at Kandla. All production is intended for export to the USSR.

7.3.6 The Development of Ciba-Geigy of India

Whilst it is not possible to expand on the commercial position of Ciba-Geigy of India, it can be seen from this description of their technical capacity and from Chapters 5 and 6, that Ciba-Geigy is one of the largest and most successful pharmaceutical manufacturers in India. The Pharmaceutical Division is not only the largest sector, in terms of sales and employment, but also, until recently, has contributed a relatively high profit. This rate of profit has shown a sharp decline, however, and in 1978 and 1980 the Pharmaceutical Division made a trading loss. Selected financial results over the period 1968-1980 are shown in Table 7.8

The pharmaceutical business in India is particularly important

TABLE 7.8
(Millions of Rupees)

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
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<th></th>
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<th></th>
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<tbody>
<tr>
<td>SALES</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ciba-Geigy of India</td>
<td>122.7</td>
<td>158.8</td>
<td>232.3</td>
<td>364.3</td>
<td>436.0</td>
<td>548.9</td>
<td>715.0</td>
<td>610.9</td>
</tr>
<tr>
<td>of which Pharma</td>
<td>52.3</td>
<td>66.6</td>
<td>103.4</td>
<td>136.7</td>
<td>167.3</td>
<td>174.2</td>
<td>233.9</td>
<td>191.2</td>
</tr>
<tr>
<td>in India</td>
<td>51.0</td>
<td>64.8</td>
<td>101.0</td>
<td>133.5</td>
<td>166.4</td>
<td>167.3</td>
<td>216.5</td>
<td>139.4</td>
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<tr>
<td>export</td>
<td>1.3</td>
<td>1.8</td>
<td>2.4</td>
<td>3.2</td>
<td>0.8</td>
<td>7.0</td>
<td>17.4</td>
<td>51.8</td>
</tr>
<tr>
<td>PRE-TAX PROFIT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharma</td>
<td>13.5</td>
<td>13.1</td>
<td>12.5</td>
<td>9.7</td>
<td>9.2</td>
<td>(4.1)</td>
<td>13.7</td>
<td>(1.9)</td>
</tr>
<tr>
<td>as % of Sales</td>
<td>26</td>
<td>20</td>
<td>12</td>
<td>7</td>
<td>6</td>
<td>(2)</td>
<td>6</td>
<td>(1)</td>
</tr>
<tr>
<td>CAPITAL EXPENDITURE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Company</td>
<td>4.0</td>
<td>12.4</td>
<td>12.9</td>
<td>6.7</td>
<td>13.0</td>
<td>14.6</td>
<td>31.9</td>
<td>58.1</td>
</tr>
<tr>
<td>of which Pharma</td>
<td>1.2</td>
<td>2.4</td>
<td>3.9</td>
<td>5.3</td>
<td>4.7</td>
<td>6.7</td>
<td>12.0</td>
<td>15.0</td>
</tr>
<tr>
<td>PRE-TAX DIVIDENDS</td>
<td>2.6</td>
<td>2.6</td>
<td>3.2</td>
<td>3.8</td>
<td>4.8</td>
<td>7.2</td>
<td>7.2</td>
<td>9.0</td>
</tr>
<tr>
<td>TO BASEL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EQUITY</td>
<td>32.5</td>
<td>32.5</td>
<td>48.8</td>
<td>48.8</td>
<td>61.8</td>
<td>92.6</td>
<td>92.6</td>
<td>138.9</td>
</tr>
<tr>
<td>OF WHICH CIBA-GEIGY</td>
<td>21.1</td>
<td>21.1</td>
<td>31.7</td>
<td>31.7</td>
<td>40.1</td>
<td>60.2</td>
<td>60.2</td>
<td>90.3</td>
</tr>
</tbody>
</table>


to Ciba-Geigy. With the introduction of the Foreign Exchange Regulation Act in 1973, the level of foreign shareholdings allowed in a foreign company is decided by the nature of the business. Ciba-Geigy's trading operations (54) are not regarded as 'core' activities. On the other hand, pharmaceutical manufacturing is a priority area, and the company is careful to maintain this activity at a relatively high level. Other points in favour of the company being allowed to maintain a relatively high foreign shareholding include the sophisticated technology used, the large export business, and the

(54) Such as buying and selling dyestuffs and the consumer products, like toothpaste. For recent decisions on equity holdings within Ciba-Geigy of India see Financial Times, 26 January, 1983. Ciba-Geigy has been allowed to retain 51% of equity but it must meet an export obligation of 10% of turnover.
significant investment in research and development.

Ciba-Geigy products are promoted in India by much the same methods as they are in the West. By 1981, the company ran a field force of about 190 representatives, who use promotional material prepared at Head Office, in Bombay, with the assistance of the central Marketing Division in Basel (55). The company uses an independent distribution network which covers the whole country, with depots in almost every State (56).

Drug prices are very tightly controlled, and some of the regulations of the New Drug Policy (57) are considered unacceptable by many Foreign companies. Ciba-Geigy, like most TNCs in India, has introduced very few new products since the mid-1970s (58).

Ciba-Geigy has also developed its technical capacity, alongside its commercial ability. It now operates an Engineering Section, with some twenty experienced graduates, which is capable of designing and installing major modifications to existing plant and coordinating the construction of new installations, such as the Kandla venture. The Quality Control Department has also developed the skills, experience and equipment to be given responsibility by Basel for the local release of all products (59). Whilst the company is generally able

(55) There are approximately 140,000 registered medical doctors in India; Ciba-Geigy sales representatives visit about 70,000 to 80,000 of these, concentrating on those doctors who write the largest numbers of prescriptions. This is reinforced, as in Europe, by direct mailing of favourable journal articles and other promotional material. Interview, Ciba-Geigy, Bombay, May, 1981.
(56) The exceptions are in the north-east of the country.
(57) Such as the requirement to offer 50 per cent of bulk production to a non-associated formulator.
(58) In 1982, it registered the anti-depressant product it had discovered at Goregaon. This was the first new product for several years.
(59) It is, however, required annually to send samples of each active ingredient to Basel, together with an analytical report. An
to buy the necessary equipment in India, certain sophisticated items have not been obtainable until relatively recently. For example, Ciba-Geigy of India did not possess High Pressure Liquid Chromatography (HPLC) apparatus in mid-1981, although it intended to introduce this soon. The workforce in the factory was reported to have a satisfactory awareness of the need for hygiene, and clean and safe methods of working (60).

Raw materials are bought from a variety of indigenous sources and very little material has to be imported. Whilst local manufacturers produce material to the legally required standards, these often do not meet the specifications required by Basel (61). Ciba-Geigy products are manufactured to meet a wide range of specifications; some of these are stipulated by the Indian Government (62), whilst others are company requirements. Appendix 7.6 illustrates, by way of example, the tests to be performed on a particular sulpha drug.

It might seem that there are several factors which could induce Ciba-Geigy to transfer more of its manufacturing to the Indian factories. These include the technical capability of the local organisation, lower wage rates and the assistance which might be expected from a Government eager to stimulate export activity. In practice,

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(60) Although some difficulties arose in old buildings which did not comply with modern concepts of what constitutes good working conditions. Interview, Quality Control Manager, Ciba-Geigy, Bombay, March, 1981.

(61) Which are developed in accordance with raw materials available in Europe from manufacturers with sophisticated equipment. In such cases, Ciba-Geigy of India has to explore many potential suppliers and discuss the results with the central Quality Control department in Basel.

(62) Under the Drugs and Cosmetics Act, 1940.
however, there are many reasons why this has not happened. Labour costs comprise a relatively small proportion of production costs and the differences in the abilities of workers make comparison difficult. One employee in Basel explained the situation, somewhat caustically, as follows:

"Wage rates may only be a quarter of what they are [in Europe] but you need four people to do the work of one... and then they need a supervisor... and they all join a union and go on strike." (63)

Raw material costs are frequently higher and the quality lower, whilst municipal services, such as power and water, are less reliable. Products made in India are less attractive on the international market than those produced in Europe and, in any case, it would be illogical to divert production away from the large factories in Europe and decrease their economies of scale. Although direct comparisons of cost are, therefore, difficult, some data relating to production at Bhandup are included in Appendix 7.7. Ciba-Geigy of India employs some 3,000 people in its different divisions and sites, and their distribution is summarised in Table 7.9.

Like most large companies, Ciba-Geigy rewards its employees with both wages, and a substantial amount of other benefits (64). These social benefits include a provident fund, 'gratuities', medical and maternity benefits, and injury and accident insurance (65). Executive staff also enjoy a pension fund. The cost to the company of direct and indirect personnel expenses is summarised in Table 7.10.

(64) This is another reason why comparison of wage rates is difficult.
(65) Which covers field staff whether or not they are on duty.
TABLE 7.9
The Number of People Employed by Ciba-Geigy of India: March 1981

<table>
<thead>
<tr>
<th>Budget Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. DIVISIONS</td>
</tr>
<tr>
<td><strong>Pharmaceutical Division</strong></td>
</tr>
<tr>
<td>Research</td>
</tr>
<tr>
<td>Manufacturing at Bhandup - Workers</td>
</tr>
<tr>
<td>- Staff</td>
</tr>
<tr>
<td>Marketing, including medical</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
</tr>
<tr>
<td><strong>Other Divisions</strong></td>
</tr>
<tr>
<td><strong>Total in Divisions</strong></td>
</tr>
<tr>
<td><strong>2. FUNCTIONS</strong></td>
</tr>
<tr>
<td>Corporate Management</td>
</tr>
<tr>
<td>Finance</td>
</tr>
<tr>
<td>Administration</td>
</tr>
<tr>
<td>Technical-Head Office</td>
</tr>
<tr>
<td>- Bhandup workers</td>
</tr>
<tr>
<td>- staff</td>
</tr>
<tr>
<td>- Goa workers</td>
</tr>
<tr>
<td>- staff</td>
</tr>
<tr>
<td>- Kandla workers</td>
</tr>
<tr>
<td>- staff</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
</tr>
<tr>
<td>Extras - Casual workers at Bhandup</td>
</tr>
</tbody>
</table>

NOTES: Total Executive Strength = 274
Only one employee, the Deputy Managing Director, is now an expatriate.
The actual Kandla strength is some 41 workers and 7 'staff'.


Tables 7.9 and 7.10 have been compiled on the basis of budget estimates, rather than actual figures. This has been done to give a more accurate reflection of the normal level of activity, which would not have been shown by the real results for the period described. During 1980 and 1981 the company was hit by a strike which seriously
### TABLE 7.10
Personnel Expenses of Ciba-Geigy of India: 1981
(Thousands of Rupees: Budget for 1981)

<table>
<thead>
<tr>
<th>DIRECT EXPENSES</th>
<th>62,100</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Wages/salaries, bonus, gratuity, House Rent Allowance, Leave Travel Allowance)</td>
<td></td>
</tr>
<tr>
<td>EXPENSES FOR 'SOCIAL CONTRIBUTION'</td>
<td>7,720</td>
</tr>
<tr>
<td>(Provident Fund, Employees' State Insurance Scheme, Medical Expenses)</td>
<td></td>
</tr>
<tr>
<td>TOTAL PERSONNEL EXPENSES</td>
<td>69,820</td>
</tr>
</tbody>
</table>

**NOTE:** Mean Annual Expenses per worker = approx. Rs23,000
(= approx. $2,750)

**SOURCE:** Ciba-Geigy of India, May, 1981.

affected operations. In January, 1980, employees at the Bhandup factory put forward their demands for the level of bonus to be paid and also called for a special "Silver Jubilee" bonus. The management refused, on the grounds that the levels demanded were outside those specified in the labour laws (66). The workers responded by initiating a 'go-slow' and later intensified their actions. During the latter phase, the management claimed that products were deliberately mislabelled and adulterated; they locked the workers out on 15 November, 1980 (67). By June, 1981, there was no indication of the dispute being settled. Several Ciba-Geigy drugs had disappeared from the market and company turnover had been halved (68).

(66) "Ciba-Geigy Invites You to be the Judge", company advertisement in the Free Press Journal, 18 February, 1980.
(67) Notice of the lock out was placed in the Indian Express, 31 October, 1980. See, also, "Ciba-Geigy Lock Out from 15 Nov.", Economic Times, 6 November, 1980.
7.4 CIBA-GEIGY IN INDONESIA.

The establishment of the company in Indonesia comes a generation later than the evolution of CIBA and Geigy in India. By the time the first factory was built in Indonesia, the parent companies had already merged. Detailed methods to assess investments had also been derived, so that a study of the activities in Indonesia provides an interesting contrast to the scale and methods used in India. It also gives some indication of the way in which technology transfer techniques have been developed by Ciba-Geigy.

CIBA products, imported and distributed by one of the large Dutch trading companies, were available in Indonesia from the 1930s. This was halted by the Second World War and by the Indonesian fight for independence. Although the Dutch traders subsequently tried to re-establish themselves in the newly-independent Indonesia, they were unable to regain their past position and were ejected at the end of the 1950s. From then onwards, CIBA and Geigy products have been handled by Indonesian companies (69).

In 1968, the prevailing economic climate induced CIBA to employ a representative in Jakarta. By the end of 1969, he had recruited three other employees whose function was to analyse the sales figures returned by the distributor, to coordinate with the sales field force and to compile a rolling forecast for the future import requirements of finished goods. At that time, Geigy, with its smaller volume of pharmaceutical business, did not have employees in Indonesia and,

Dr. B. Wenger, March, 1983.
(69) CIBA, for example, had used a general wholesaler until 1967, when the business was switched to a company which specialised in pharmaceutical products.
until 1973, the importation of its products was handled by a local wholesaler.

During 1968, the Government of Indonesia introduced its Foreign Investment Act, which required foreign companies to state their intentions. As the possibility of a merger between the two companies was developing, Geigy, with the smaller pharmaceutical business, decided to reserve its position on investment. CIBA, on the other hand, was encouraged by conditions and by the local representative, who reported enthusiastically to Basel. Accordingly, a project outline for production facilities was submitted to the Government and approved by the Indonesian President on 27 December, 1968.

As with other pharmaceutical TNCs, Ciba-Geigy would prefer to operate a wholly-owned subsidiary, rather than initiate a joint venture, which it would only choose in a country where the business environment was particularly 'difficult' (70). In Indonesia, however, the FIA did not allow wholly foreign-owned companies, so CIBA had to find a local partner to take 10 per cent of the shares. These were taken by the Indonesian distributor of CIBA's products, PT Dos Ni Roha, which has provided no technical and only limited commercial input to the project.

By the late 1960s, CIBA had developed a process of investment appraisal which has subsequently been adopted by Ciba-Geigy. The objective of the scheme, which had seen little substantial change by the beginning of the 1980s, is firstly to submit documentation to senior management as a basis for the effective allocation of investment reserves and secondly to establish the sequence of project

elaboration and decision stages. The process consists of three planning stages, which lead to the compilation of documents on which decisions must be taken. This is shown schematically in Figure 7.3.

FIGURE 7.3
A Schematic Representation of the Project Appraisal Process used by CIBA-GEIGY

<table>
<thead>
<tr>
<th>Planning Stages</th>
<th>Decision Stages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate Plan (Project Idea)</td>
<td>Investment Proposal (IP)</td>
</tr>
<tr>
<td>Project Elaboration</td>
<td>(Possibility of Pre-Project (PP) leading to further elaboration)</td>
</tr>
<tr>
<td>Implementation</td>
<td>Final Project (FP)</td>
</tr>
<tr>
<td></td>
<td>Final Report (FR)</td>
</tr>
</tbody>
</table>

The Investment Proposal is essentially a commercial document which sets out the justification for the project and indicates some of the financial implications; it has little technical content. This document is prepared within the Pharmaceutical Division, on the basis of marketing estimates, and after discussions with the Pharmaceutical Production Department (PPK) and the Central Engineering Service (ZID). Costs are estimated to within 30 per cent.

The Investment Proposal is appraised by senior management. If it is passed, the project becomes the responsibility of ZID, which begins to prepare the Final Project. Originally it was intended to prepare one or more 'Pre-Projects', as a matter of course, to facilitate the making of further decisions, but this is now omitted, unless
there are alternatives which must be examined more closely.

The Final Project restates the project in much greater detail, with the technical aspects emphasised. It includes updated marketing forecasts, corrected equipment lists, layout, flowsheets, energy requirements and so on. It is expected to be costed to within 10 per cent of the actual price. For a pharmaceutical plant, it is compiled in Basel by ZID in conjunction with PPK, the prospective user (71). Finally, a report on the progress of the project is compiled within two years of installation. Further details of the Ciba-Geigy appraisal system are included in Appendix 7.8, and the timetable for the Indonesian project is shown in Appendix 7.9.

Whilst the Final Project for the Indonesian factory was being compiled, ZID had already begun to consider potential sites. In accordance with the prevailing industrial climate in Indonesia it had been decided to open a pharmaceutical formulation factory but also to include facilities for chemical manufacture, as required by law. The plans for the merger of CIBA and Geigy were, by then, well advanced, and it was clear that the project should take into account the manufacture of the Geigy line of products, as well as those of CIBA.

7.4.1 Pharmaceutical Production

Potential sites in Indonesia were assessed in terms of a number of factors, which included natural features (72), and matters of

(71) The time required for the various stages of this process can vary considerably between projects. In the case of Indonesia, the Investment Proposal was submitted in March, 1969 and the Final Project in July, 1971. This is somewhat faster than usual, one result of the conditions in Indonesia at that time.
(72) Such as the lie of the land and water quality.
infrastructure (73). ZID has developed a checklist to facilitate such evaluation and its contents are summarised in Appendix 7.10.

A site for the Indonesian factory was found some 27 km from the centre of Jakarta, in the direction of Bogor, and where many other foreign companies have subsequently built factories. The site selected by CIBA was found to belong to about thirty different individuals and, in some cases, the legal ownership was not clearly defined. As a result, it took some eighteen months to purchase the land (74). Throughout this period and the subsequent construction phase, relationships with Government officials were reported, by the company, to be satisfactory (75).

Contact had also been made by the Jakarta office with a firm of expatriate architects who had an office in that city. Although they had no particular experience with pharmaceutical factories, they had little difficulty in translating the general requirements for the factory, determined in Basel, to suit the area (76). Local knowledge was considered to be more relevant and it was estimated that, in this project, 80 to 90 per cent of the architectural work was done by this company in Jakarta. This proportion has decreased to about 30 to 40 per cent in subsequent Ciba-Geigy projects because the central Architects' Department in Basel now has greater experience of designing factories for tropical conditions.

(73) Such as proximity to the commercial centre (in this case, Jakarta) and municipal supplies of utilities.
(74) The delay arose, primarily, from the need to establish who was the owner, rather than from negotiating the price.
(75) Although it was said to be frequently difficult to find who was the relevant official for a particular matter of business. Interviews, Ciba-Geigy, Basel, January, 1981.
(76) Such factories are not so specialised that they cannot be designed by architects who have only general experience.
Locally-based engineering consultants suggested the names of about ten potential contractors. On the basis of bids, several were rejected and the others were assessed by ZID personnel, who visited the offices to discuss the project with engineers and other employees. Factors other than cost were considered important; the Basel personnel were also looking for a company in which they could have confidence. The contractor eventually chosen was persuaded to recalculate his bid and this was accepted, despite the fact that it was still only the third cheapest (77). This contractor was made responsible for the overall development of the site and for building the main structures; specialist work, such as electrical installations, air conditioning and ventilation were sub-contracted. The preparatory work to level the site and establish access, which involved constructing a bridge from the main road over a large stream, was carried out by the Indonesian Army (78).

Whilst the buildings were being erected and the equipment installed, five Swiss employees were based in Jakarta. They included civil and mechanical engineers, and technical staff from the Production Department. In this respect, the project organisation was similar to that required if the plant was being built in, for example, West Germany or France. However, there were some major differences; for example, water quality was a constant problem (79), and a water treatment plant had to be installed.

Communication with Basel was difficult, as there was then no

(77) It had originally been the most expensive of those selected for further appraisal.
(78) The Corps of Sappers was required to earn one-third of its costs by such work.
(79) As in many tropical countries.
direct telephone link. This was not seen as a major problem, because the project team was experienced, and most of the problems had to be solved locally. On the other hand, the team reported certain advantages from their standpoint; for example, the contractor was found to be more 'flexible' so that when the work was dropping behind schedule an extra night shift could be introduced.

With practically no pharmaceutical equipment being produced in Indonesia, the company chose to import machinery from Western Europe. Although this was significantly more expensive than that available from Eastern Europe, it was expected to last longer, require less maintenance, and would also be familiar to the expatriate Managers who would initially operate the plant (80).

The majority of specialist materials of construction had to be imported, mostly from Australia. This included roofing, high quality pipes, electrical materials and water treatment equipment. On the other hand, cement, which is usually in short supply in India, was readily available in Indonesia. Only one major item of equipment, a steam generator, was bought locally, but this presented several problems in operation, as the rivets were generally not of the expected standard. Eventually the company substituted an imported item.

There was also a large range of infrastructural facilities which, it might be expected, would have been provided by the local authority in a more industrially developed country, but which had to

(80) Duty-free importation had been granted in principle but duty was, in fact, levied on certain items which came into the purview of some Government departments which had not specifically granted this exemption. It also proved difficult to release some items from the docks; the company adopted the practice of painting the corners of their crates blue, to ease identification.
be established by the company in Indonesia. For example, although there is now a fire brigade based some 3 km from the factory, a site fire brigade was trained and a pool built to store water. Other services installed by the company include refrigeration, air conditioning, steam and electricity generation, water supply and treatment, and sewage treatment. The company has three 250 kVA diesel generators, and one of these is dedicated to supplying the air conditioning system. There are now two steam boilers; one supplies steam at 5 to 6 bar (81), and the second generates steam at 8 bar, which is used for the chemical production and in a Ciba-Geigy dyestuffs plant, on an adjacent site. A deep well was sunk on the site to supply water for all requirements; by 1981, these totalled some 4,000 m³ per month. The company also installed what is thought to be the first large-scale effluent treatment plant in Indonesia.

In buying raw materials, Ciba-Geigy follows the pattern of most of the large foreign companies described in Chapter 4. All active ingredients are shipped out by the parent company; most of them are produced in Basel (82). The parent company also ships out the majority of the other chemicals used by the plant (83). Ciba-Geigy of Indonesia buys other ingredients locally, after they have been imported by other companies.

The first commercial production batch was made in April, 1973,

(81) Most of which is throttled down to 2 bar for pharmaceutical production.
(82) Exceptions are those products of Zyma and some others, such as rifampicin, which is no longer produced at Basel, but in the company's plants in UK and Italy.
(83) These include pharmaceutical grade sugar, although Ciba-Geigy does not make many syrups and has a relatively low consumption of around 7 tonnes per annum. Other large companies in Indonesia, with significant production of syrups, might use around 50 tonnes per annum.
about six months ahead of schedule. The plant was officially opened in July of that year by President Soeharto, with the Chairman of Ciba-Geigy, and the Head of the Pharmaceutical Division also in attendance. The capital cost was some SwFr9.1 million, which was slightly lower than had been estimated by the second Pre-Project. Since going into operation, production at the pharmaceutical plant has increased steadily. Neither sterile liquids, nor powders are made at this site, but all the other common dosage forms are produced.

By 1979, the factory was producing nearly 3 million packs per year; further details are included in Appendix 7.11. The main therapeutic groups include; intestinal antiseptics, antibiotics, sulphonamides, mucosal decongestants, spasmyotics, analgesics, beta-blockers, and anti-rheumatics.

As indicated in Chapter 4, the main difficulties in achieving pharmaceutical good manufacturing practice (GMP) arise from the climate (84), and from the ability of the workforce. It has proved difficult to introduce certain operations, such as coating and spray granulation, because of the humidity. Whilst such problems can be solved (85), the solution is likely to be very expensive. One engineer in the company estimated that air-conditioning equipment represented about 10 per cent of the total capital investment; the product area has to be maintained at less than 65 per cent relative humidity, and must be even lower for certain operations, like filling hard capsules.

(84) Particularly the humidity.
(85) By introducing full air-conditioning.
Many of the employees come from poor environments and had to be trained in the hygiene requirements employed by the company (86). Non-skilled staff are recruited from the immediate locality and transported to the factory by works' bus or given a transport allowance. Graduate staff, of whom there are thirty, are recruited from all over Indonesia. It has been difficult to find pharmacists, accountants, medical doctors and engineers of the right experience and salary requirements, although this has gradually become easier with the general development of the industry in Indonesia (87).

As was indicated in the case of India, it is very difficult to compare the costs of production in this factory with those in others. Some indication of the costs of the various components are included in Appendix 7.12.

As in any pharmaceutical plant, a particularly important department is Quality Control. The Indonesian QC department employs 8 people and is responsible for the testing and quarantining of all raw materials and finished products before release (88). The staff are all Indonesians; the Department Head holds a PhD in pharmacy and the remainder are graduates of the Academy of Analytical Chemistry. Most of the imported active ingredients and excipients are fully analysed and packed in airtight, sterile containers in Basel. In such cases, the Indonesian Quality Control department merely checks the identity

(86) The company performs medical examinations on its workers each year; these include vaccinations, X-rays, and blood counts.
(87) Most workers are given only on-the-job training, but middle management also receives some training at institutions in Indonesia or, occasionally, overseas. Department Heads have received experience in Ciba-Geigy factories in Basel and in other subsidiaries of the group, particularly in Cairo and the Philippines.
(88) In-process control is carried out by the Production department.
of the contents, unless the container appears to be damaged in any way.

Ciba-Geigy of Indonesia had hoped to buy wheat starch from Australia; the first two consignments were of suitable quality but the third, and subsequent batches, were contaminated. Another foreign company had used locally-available cassava starch, decontaminated using gamma radiation, but the Ciba-Geigy parent company decided that the cassava starch would change the medical characteristics of its products and did not give permission for its use. Wheat starch is now bought in Switzerland and exported to Indonesia (89).

It was originally intended to buy laboratory instruments from a European firm, with which the parent company was familiar. However, it was found that maintenance facilities had not been developed in Indonesia. The company has, instead, purchased instruments from a Japanese manufacturer able to provide good servicing facilities (90).

The Indonesian subsidiary is classed in the 'yellow' category by the Quality Control department in Basel. This means that it has the authority to release products on the basis of its own analysis, although one sample a year of each product must be sent to Basel to

(89) The Quality Control department is also responsible for checking the quality of the water supply and air. This is not found to present any particular technical difficulties. In order to carry out analytical tests, the department has a well-stocked, modern laboratory with a wide range of equipment. This includes a spectrophotometer, pH meter with titration apparatus, polarimeter, disintegration and dissolution rate apparatus, viscometer and equipment for gas and liquid chromatography. Some of the equipment was not envisaged when the factory was opened, but has been introduced later as the parent company developed analytical methods based on more sophisticated tests which the subsidiary has been required to duplicate.

(90) Ciba-Geigy of Indonesia planned to introduce equipment for infra-red and ultra-violet spectroscopy in 1982.
be checked. New products are put in the 'red' category and samples of the first five batches are sent to Basel, which determines whether or not the batch may be released (91).

Ciba-Geigy does not produce ampoules of sterile liquid in Indonesia (92). Instead, in 1975, a contract was negotiated with a local company which had the necessary equipment. Initially, four products were made by this company but this has now been reduced to one. Two were withdrawn when the active ingredient was banned in the USA, for medical reasons which Ciba-Geigy considered justified and a third, which was not selling well, has also been taken off the market (93).

7.4.2 Chemical Production.

One of the requirements, made by the Indonesian Government when the original investment plans were approved, was that Ciba-Geigy should introduce the production of at least one bulk active material within five years of beginning operations. The company decided to produce rifampicin, a drug which plays an important part in the treatment of tuberculosis, and permission was readily granted by the Indonesian Government.

(91) The Quality Control department in Indonesia also undertakes some development work. Extreme conditions of heat and humidity are simulated to examine potential methods of formulation and packaging. Initially, all products were sold in expensive aluminium foil, which gives better protection to the drug. However, stability tests have now shown the possibility of selling some, but not all, products in the less-expensive blister packs.

(92) This possibility was considered at the pre-project stage but rejected because the high capital cost, in the region of SwFr1.5 million, was not justified by the relatively low production requirements.

(93) The Indonesian company now produces around 100,000 ampoules per year for Ciba-Geigy. Its facilities are regularly inspected by technical staff to ensure the quality.
The plant was designed in Basel and details added with the aid of an architect, based in Jakarta. It was required to produce only sufficient quantities for the company’s own use, since the costs of production were expected to be too high for selling to other formulators. There was also no need to introduce an elaborate reaction sequence which would increase the cost of production. These requirements have resulted in the construction of a small plant, with a total capacity of 1200 kg per annum, in which only the final reaction step is carried out.

Rifampicin is produced by a condensation reaction between a solid and a liquid intermediate in an acetone and ethyl acetate solvent mixture. Some of the solvent is removed by vacuum distillation, and rifampicin crystals formed by cooling the mixture to -15°C. The solid is separated in a pressure filter, washed with cold acetone, and dried at 60°C under vacuum. The mother liquor is collected and later destroyed by burning, whilst the distillate is sold to another company. The plant, made entirely from equipment imported from Switzerland, produces about 5kg of product in each batch; it is illustrated in Figure 7.4.

Unlike the pharmaceutical factory, which operates from 0730 to 1600 hrs each working day, the chemical plant operates continuously. It is run by a total staff of five, which includes a Manager who is present during the day. Each batch takes about 22 hours to complete and the plant is, therefore, operated on a 24-hour cycle, with the same operation being carried out at a similar time each day. The reaction stage, which is technically the most complex, is performed in the first shift, which has two operators (94).

(94) The more straightforward operations are carried out in the

SOURCE: Original
The Manager of the plant had no previous experience of chemical production, and as rifampicin is no longer made by Ciba-Geigy in Basel, a visit was arranged to the plant in Italy. There, the scale is somewhat different to that in Indonesia, since it produces about 5,000 kg per annum, using the whole reaction sequence. A further sophistication is that a 'second crop' is recovered from the mother liquors in the final stage, whereas these liquors are destroyed in Indonesia. Despite these differences, the Plant Manager considered the visit to be a most valuable experience (95). During the commissioning of the plant, a member of the Italian production department assisted the general project team. Together with the Chemical Plant Manager, he was able to recruit and train the four operators, none of whom had any previous relevant experience (96). There have been relatively few problems encountered during the operation of the plant, and those which did arise were of a straightforward, technical nature and were solved by the personnel on site (97).

The process is now operating successfully and the annual production has risen steadily to a level of about 800 kg per annum in 1980.

(95) Interview, Plant Manager, Jakarta, August, 1981.
(96) Even to the extent of working in pharmaceutical production.
(97) Firstly, the filtration of the solid was initially difficult. It was found that the filter bag, although the same as that used in Italy, did not work well at the smaller scale. The company was able to arrange a different source of supply and this has proved satisfactory. Secondly, the bulk density of the product was too great and thus it did not have the required characteristics for the formulation processes. This arose because the reactor was being cooled too quickly to induce the required crystallisation characteristics. This operation now takes some nine hours and a suitable product is obtained. Finally, it was initially difficult to adjust the amounts of reactant added to give the required pH. This resulted in an unsatisfactory crystal form and the necessity of extra washings in the filter. This difficulty has been overcome by the careful weighing of ingredients.
However, the company makes little attempt to determine the real costs of this operation. Calculations are made on the basis of the transfer price and quantities of raw materials, compared to the weight of product, but no attempt is made to estimate depreciation, labour costs and utility requirements. Some further details of this project are included in Appendix 7.13.

7.4.3 The Development of Ciba-Geigy in Indonesia

It has sometimes been suggested that the pharmaceutical industry presents good opportunities for cooperative action amongst companies in technical matters. These might include sharing the use of expensive equipment for laboratory tests or for maintenance, and the pooling of service facilities (98), to serve several plants in the same area. Indonesia has a high potential for such action; many large foreign companies built their factories at a similar period, and a dozen or so of these are located within a few kilometres of each other on the Jakarta-Bogor road.

In practice, there has been very little formal cooperation. Ciba-Geigy, like all the foreign companies, is a member of the trade organisation, which discusses matters of mutual interest, but technical facilities are not shared on a regular and continuing basis. Rather, contact depends on personal relationships between managerial staff, who may allow each other to borrow equipment when breakages occur or arrange plant visits for new or inexperienced staff (99).

(98) Such as a fire brigade, for example.
(99) Ciba-Geigy was one of the first foreign companies to invest in Indonesia and many of the companies which followed sought their advice on how best to meet the Government regulations. More recently, the Government factory, Kimia Farma, has also introduced the chemical manufacture of rifampicin. The processes operated by the two companies are not identical but some limited, informal
As well as the factory on the outskirts of Jakarta, Ciba-Geigy has an office in the centre of the city, to coordinate the commercial operations and marketing. Ciba-Geigy employs a field force of about 100 representatives, advertises in medical journals, uses direct mailings and sponsors symposia (100).

In the early 1970s, Indonesia was regarded as a 'sellers' market' but it has, subsequently, become much more competitive. One indication of this is that the company maintains separate field forces for the products in the Ciba, Geigy and Zyma ranges. In general, each representative promotes one range although, in the outlying areas, the total product range is handled by one individual. There are some 14,000 registered medical doctors in Indonesia and Ciba-Geigy maintains contact with approximately 6,000.

The majority of the sales are made in the two main islands of Java and Sumatra, as shown in Table 7.11 The distribution of representatives mirrors this pattern, with the greatest concentration being in Jakarta and other parts of Java (101).

Ciba-Geigy products, in common with those of the other foreign companies, are highly-priced, relative both to those of the locally-owned companies and, also, when compared with the levels of income. The Marketing Manager of the company estimates that the products are sold only to the (unofficial) socio-economic 'A' and 'B' class consumers, whose income is above an average of Rp450,000 per month (102), discussions have been held.

(100) It had been possible to advertise over-the-counter products on television, but this was banned in 1981. Ciba-Geigy does not have a large OTC range and its principal products are well-known, so it was not affected as severely as some other companies.
(101) Representatives are stationed only on the five main islands but make periodic visits to the other islands.
(102) Interview, Ciba-Geigy, Jakarta, September, 1981.
TABLE 7.11
The Geographical Distribution of Pharmaceutical Sales by Ciba-Geigy, Indonesia

<table>
<thead>
<tr>
<th>Region</th>
<th>Approx. % of Total Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. JAVA</td>
<td></td>
</tr>
<tr>
<td>Jakarta</td>
<td>35</td>
</tr>
<tr>
<td>East Java</td>
<td>20</td>
</tr>
<tr>
<td>West Java</td>
<td>10</td>
</tr>
<tr>
<td>Central Java</td>
<td>10</td>
</tr>
<tr>
<td>Sub Total</td>
<td>75</td>
</tr>
<tr>
<td>2. SUMATRA</td>
<td></td>
</tr>
<tr>
<td>North Sumatra</td>
<td>10</td>
</tr>
<tr>
<td>Central Sumatra</td>
<td>7</td>
</tr>
<tr>
<td>South Sumatra</td>
<td>7</td>
</tr>
<tr>
<td>Sub Total</td>
<td>24</td>
</tr>
<tr>
<td>3. OTHERS</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100</td>
</tr>
</tbody>
</table>

SOURCE: Ciba-Geigy of Indonesia, August, 1981

and who comprise about 1.7 per cent of the total population.

Ciba-Geigy sells about 60 of its total range of 200 products in Indonesia. These include the best-sellers from around the world, but sales figures in Indonesia reflect the nature of morbidity in that country. The best selling drugs are:

(i) 'Entero-Vioform' (The generic name of the active ingredient is clioquinol): an intestinal antiseptic, which accounts for some 30 per cent of total sales.
(ii) 'Rimactane' (rifampicin): an anti-infective (including TB and leprosy treatment).
(iii) 'Voltaren' (sodium diclofenac): an anti-rheumatic drug.
(iv) 'Otrivine' (xylometazoline hydrochloride): a nasal
decongestant.

(v) 'Trasicor' (oxprenolol hydrochloride): a beta-blocker (103).

In contrast to the stagnant situation in India, the Indonesian company has introduced three new drugs during the last five years. These include a drug to treat leprosy, sold as a soft capsule; the Government granted permission for this important product to be imported in finished form.

The Pharmaceutical Division of Ciba-Geigy, Indonesia now employs nearly 300 people. The distribution of personnel in the different functions is indicated in Table 7.12, in which the total includes two expatriates. There was a relatively large number of expatriates employed in the early 1970s, when the factory was being constructed and commissioned. Amongst others, they filled the important roles of Production Manager, Quality Control Manager, and Finance Director. The number of expatriates increased slightly in 1973, when the subsidiaries of Ciba and Geigy merged in Indonesia, but has subsequently decreased as Indonesian staff have now been found to fill most of the managerial positions (104). The variation in the number of expatriates in the subsidiary is shown in Table 7.13.

Although the sales of Ciba-Geigy in Indonesia have steadily increased, the profit is such that no dividends have been returned to Basel. The subsidiary is not quoted on the Stock Exchange, and only limited financial results are available. These are displayed in Table 7.14.

(103) Interview, Marketing Manager, Jakarta, August, 1981.
(104) The two expatriates employed in 1981 filled the positions of General Manager and Finance Controller; all production staff were Indonesian.
### TABLE 7.12
Personnel employed by the Pharmaceutical Division of Ciba-Geigy, Indonesia: 1981

<table>
<thead>
<tr>
<th>Department</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing CIBA (a)</td>
<td>36</td>
</tr>
<tr>
<td>Marketing GEIGY (a)</td>
<td>32</td>
</tr>
<tr>
<td>Marketing ZYMA (a)</td>
<td>26</td>
</tr>
<tr>
<td>Marketing (general)</td>
<td>19</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>113</strong></td>
</tr>
<tr>
<td>Medical</td>
<td>5</td>
</tr>
<tr>
<td>Commercial Administration</td>
<td>3</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>8</strong></td>
</tr>
<tr>
<td>Management</td>
<td>15</td>
</tr>
<tr>
<td>Production Planning</td>
<td>5</td>
</tr>
<tr>
<td>Kitchen, Canteen</td>
<td>5</td>
</tr>
<tr>
<td>General factory services</td>
<td>5</td>
</tr>
<tr>
<td>Personnel</td>
<td>4</td>
</tr>
<tr>
<td>Printing/Packaging Development</td>
<td>4</td>
</tr>
<tr>
<td>Material handling</td>
<td>6</td>
</tr>
<tr>
<td>Quality Control</td>
<td>8</td>
</tr>
<tr>
<td>Utilities</td>
<td>10</td>
</tr>
<tr>
<td>Workshop</td>
<td>13</td>
</tr>
<tr>
<td>Production</td>
<td>11</td>
</tr>
<tr>
<td>Packaging</td>
<td>41</td>
</tr>
<tr>
<td>Chemical Production</td>
<td>5</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>132</strong></td>
</tr>
<tr>
<td>Administration and finance</td>
<td>36</td>
</tr>
<tr>
<td>Temporary Workers</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>294</strong></td>
</tr>
</tbody>
</table>

**NOTE:** (a) Field Force
The security staff, gardeners and most canteen workers are contract employees - not Ciba-Geigy staff.

**SOURCE:** Ciba-Geigy of Indonesia, August, 1981.

By the end of the 1970s, the subsidiary in Indonesia had achieved a considerable degree of autonomy. The organisation has a self-administering, local structure which decides short-term details and expenditure within a limited budget (105).
TABLE 7.13
The Number of Expatriates working in the Pharmaceutical Division, or in General Administration, Ciba-Geigy, Indonesia: 1969-1981

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969</td>
<td>2</td>
<td>1975</td>
<td>7</td>
</tr>
<tr>
<td>70</td>
<td>6</td>
<td>76</td>
<td>7</td>
</tr>
<tr>
<td>71</td>
<td>7</td>
<td>77</td>
<td>7</td>
</tr>
<tr>
<td>72</td>
<td>7</td>
<td>78</td>
<td>5</td>
</tr>
<tr>
<td>73</td>
<td>9</td>
<td>79</td>
<td>5</td>
</tr>
<tr>
<td>74</td>
<td>7</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>81</td>
<td>2</td>
</tr>
</tbody>
</table>

SOURCE: Ciba-Geigy of Indonesia, Jakarta, August, 1981.

7.4.4 Other Ciba-Geigy Activities in Indonesia

In the same period as it was building its factories, Ciba-Geigy initiated several projects which were not directly related to their own production facilities. These include:

(i) Participation in the Government family planning scheme,
(ii) Assistance in training pharmacists,
(iii) Establishing a training school for laboratory technicians, and
(iv) Initiating a TB eradication programme, together with the

(105) Larger expenditure is controlled by the parent company and assessed by means of documentation transferred between the two countries and by periodic visits in both directions. For example, in the Marketing Department, which has the greatest degree of regular personal contact, staff from Basel visit, on average, two or three times each year; further periodic visits are made by specialists for particular product ranges. Regional meetings are held in the Far East, or in Basel, and two or three people from the Indonesian company visit Switzerland each year. This pattern is repeated, at a lower frequency, in the other departments.
TABLE 7.14
The Financial Results of the Pharmaceutical Division of Ciba-Geigy, Indonesia: 1977-1980
(Millions of Rupiah)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>#</td>
<td>2,504</td>
<td>3,151</td>
<td>4,815</td>
<td>6,276</td>
</tr>
<tr>
<td>Promotional Expenditure</td>
<td>#</td>
<td>176</td>
<td>248</td>
<td>486</td>
<td>576</td>
</tr>
<tr>
<td>Capital Expenditure</td>
<td>2,699</td>
<td>86</td>
<td>82</td>
<td>85</td>
<td>266</td>
</tr>
<tr>
<td>Dividend to Basel</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Share Capital (300 shares)</td>
<td>1,241</td>
<td>1,241</td>
<td>1,241</td>
<td>1,241</td>
<td>1,241</td>
</tr>
</tbody>
</table>

NOTE: # - Item not available

SOURCE: Ciba-Geigy of Indonesia, Jakarta, August, 1981.

The first of these had a limited life, as far as Ciba-Geigy was concerned. The company's oral contraceptives were introduced in the early 1970s but were withdrawn when the products of other companies proved more effective and popular. The second project forms a small part of a larger programme to assist workers in LDCs throughout the world. The third and fourth items, however, are carried out only in Indonesia, and have been warmly welcomed by the Government.

Ciba-Geigy identified one of the problems found by less developed countries as a relative dearth of middle-level technicians and, after discussions with the Indonesian Ministry of Health, it was agreed that the company could give practical aid by helping to establish a training school for chemical and pharmaceutical laboratory assistants. In an agreement to this effect, signed in August, 1972, Ciba-Geigy provided the know-how for the planning and functioning of
the school, and met the cost of the equipment, such as laboratory instruments, chemicals, glassware and teaching material. The company also recruited two lecturers, from the British subsidiary, who served for an initial period of two years. The Government of Indonesia provided the building and infrastructure.

The school was officially opened in Jakarta in April, 1973, when twelve students were selected from the Government service, throughout the country, and were trained for two years. During this period the expatriate staff selected two outstanding students to continue as lecturers after their departure. Every two years, the most promising student is selected to visit Basel for further training.

When, in November 1974, all the equipment and material was handed over to the Government, the project had cost Ciba-Geigy some SwFr0.9 million, which included initial fixed costs and the subsequent expenses of the two lecturers (106).

The participation of the company in the programme to combat tuberculosis (TB) has been linked with the use of the Ciba-Geigy drugs, rifampicin. The standard treatment for TB had consisted of using the antibiotic, streptomycin, which is much cheaper than rifampicin. However, this requires a lengthy period of treatment, and its use is frequently marred by high patient dropout rates and lower levels of efficacy.

TB is particularly prevalent in Indonesia and the Government, after consultation with WHO officials, invited Ciba-Geigy to initiate

field trials in the country. Some 300 patients in the islands of Malang and Bali were treated and the results were evaluated by sophisticated methods, which included computer calculations and sputum analysis, conducted both locally and at the international reference centre at the Brompton Hospital, London.

Initial results suggested several benefits, despite the higher drug cost. These included, ease of administration, the lower requirements for infrastructure, the success rate of the treatment, and the ability of the patient to lead an active life during treatment (107).

In 1977, the trials were extended to cover some 2,000 patients in seven Provinces, with the drug administered under field conditions. The Government purchases about one-third of Ciba-Geigy's output of rifampicin for this programme, and also for the treatment of leprosy, where it is used in combination with another Ciba-Geigy product.

7.5 THE FUTURE OF TECHNOLOGY TRANSFER BY CIBA-GEIGY: SOME INDICATORS

The actions of Ciba-Geigy in establishing its manufacturing facilities in India and Indonesia took place a decade or more ago. With the recent developments in the pharmaceutical industry (108), this represents an era of technology transfer which has passed. It is of interest, therefore, to examine how the company's policies in technology transfer have developed in the meantime.

In the late 1960s and early 1970s, planning relied mainly on

(108) Especially the emergence of the heightened political debate, described in Chapter 2.
detailed long-term forecasts, which involved the spurious analysis of large amounts of statistical data (109). Ciba-Geigy was significantly affected by economic conditions in the early 1970s. In 1975, its profits decreased by over 60 per cent which meant that, for the first time, it was incapable of funding investment from cash-flow. Together with the fresh attitudes to planning, which had been engendered at the time of the merger, this led to the development of a new approach. The emphasis on detailed calculations shifted to more flexible suggestions of strategy over periods of three years. The company, and each Division, produces an independent 'Leitbild' (110), which suggests a strategy for the future. This includes not only matters of detail (111), but also considerations like the "assumptions on our corporate environment" and internal company concerns of structure and organisation. Whilst it is outside the scope of this work to examine this process further, early indications are that the 'Leitbild' concept will be a powerful tool for the future commercial success of the company (112).

The LDCs have played an increasing part in the company's planning. Since 1972, sales in such countries have increased by an average of 7 per cent per annum, and the number of people employed by the company has also risen. This is shown in Table 7.15. In 1974, the company established a Department with the specific remit to consider Relations with the Third World' and, in the same year, it also

(109) The perils of such practice is shown by the fact that, at the time of the merger in 1969, the companies forecast that the contribution to group sales of dyestuffs and plastics would be 27.2 per cent and 9.8 per cent respectively in 1980. The actual contributions were 16.8 per cent and 19.7 per cent. Quoted by Lorenz (1979).
(110) Literally, 'leading picture'.
(111) Such as types of product to be promoted. For a list of Ciba-Geigy products sold in India and Indonesia, see Appendix 7.17.
(112) Lorenz (1979).
TABLE 7.15
The Distribution of Ciba-Geigy Employees in LDCs, arranged according to the Average Per Capita Income in the Country

<table>
<thead>
<tr>
<th>Per Capita Income ($)</th>
<th>1972 No.</th>
<th>%</th>
<th>1980 No.</th>
<th>%</th>
<th>Increase %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country Group I</td>
<td>&gt; 375</td>
<td>8,935</td>
<td>77</td>
<td>11,372</td>
<td>76</td>
</tr>
<tr>
<td>Country Group II</td>
<td>200-375</td>
<td>444</td>
<td>4</td>
<td>868</td>
<td>6</td>
</tr>
<tr>
<td>Country Group III</td>
<td>&lt; 200</td>
<td>2,246</td>
<td>19</td>
<td>2,738</td>
<td>18</td>
</tr>
<tr>
<td>Total in LDCs</td>
<td></td>
<td>-</td>
<td>11,625</td>
<td>100</td>
<td>14,978</td>
</tr>
<tr>
<td>Total in Ciba-Geigy Group</td>
<td></td>
<td>-</td>
<td>71,136</td>
<td>81,184</td>
<td>14</td>
</tr>
</tbody>
</table>


published its 'Corporate Policy for Third World Countries'. This document, which was revised in 1980, attempts to interpret general corporate priorities in the special environment of the industrially less developed countries. Further details are given in Appendix 7.16.

H.P.Koechlin, the Head of the Department, summarised the document in the Ciba-Geigy Journal:

"While we have to realise short, as well as long, -term profit, necessary for the continued existence of the enterprise now, as before, we are prepared to take into account the special conditions prevailing in developing countries and to accept greater risks there. The aim, in any case, remains the same: to further the positive effects of our activities in the Third World and to avoid negative ones. For now, more than ever, the company can prosper long-term in a market only if the country itself prospers." (113)

Koechlin emphasised some of the benefits which he saw coming from Ciba-Geigy's operations in LDCs; they included the employment gen-

erated and the availability of products, such as agrochemicals and pharmaceuticals which: "correspond largely to host country requirements." (114) Technology transfer is identified as a particularly relevant area of concern and is described as: "not a one-time transaction, of course, but a matter of ongoing collaboration, and it usually involves investment, too." (115)

Ciba-Geigy has initiated a number of projects, such as the school for laboratory workers in Jakarta, which do not have a direct commercial relationship to the company. In 1979, the company emphasised the separation of such activity from its commercial interests by establishing the 'Ciba-Geigy Foundation for Cooperation with Developing Countries.' This body has a budget to finance projects of its own, makes donations to projects of outside organisations, and puts specialists at the disposal of LDCs, various UN bodies, the Swiss Government and private organisations (116).

Although the company has had relatively little contact with UNCTAD and UNIDO it has, on several occasions, cooperated with the WHO. Such cooperation has included the secondment of technical experts to projects in LDCs and participation in research programmes for the discovery of drugs to combat 'tropical diseases'. During the latter part of the 1970s, the large Swiss companies acted in concert with the WHO to introduce a special range of products to be sold under generic names, at low cost, to the poorest countries of the world (117).

(116) One year earlier, the employees of the company had established the 'Ciba-Geigy Employees' Society for Development Aid'. Subscriptions by members of this society are matched by the company.
(117) Wassermann (1979). See, also, Melrose (1982b) p162f, espe-
In addition, Ciba-Geigy has adopted a rather brave and relatively unusual response to the various criticisms made of the transnational pharmaceutical industry. It has declared:

"A much more open policy through linking its activities with the environment at its scene of operation, adopting policies to meet criticisms, initiating disclosure and inviting critics and pressure groups to view our internal operations." (118)

Arguably, the cooperation from the company which has yielded the material for much of this study is one result of this new policy.

Whilst such moves have attracted favourable attention to Ciba-Geigy, the company has also been criticised over two products which it has withdrawn in the West but continued to sell in other countries. The first product is a combination of amidopyrine and allobarbitone which is sold, under the name 'Cibalgin', as a general analgesic and anti-pyretic. This was found to have adverse side-effects and was subsequently withdrawn in several European countries and the USA. However, the company continued to sell it in Asia and Africa and this practice was criticised when a patient suffered from particularly virulent side-effects after taking the product in Mozambique (119).

A second substance, clioquinol, has attracted much more widespread attention and is the subject of continuing debate. Clioquinol has been used for over forty years to combat intestinal infections and Ciba-Geigy sells it in two different formulations, 'Entero-Vioform' and 'Mexaform'.

From the 1950s onwards, a disease called SMON (120), which leads to sensory and motor disturbances and visual disorders, was identified, particularly in Japan. By 1970, several thousand cases had been diagnosed and concentrated research undertaken to establish the cause. One potential factor was identified as clioquinol (121), and proceedings were taken against Ciba-Geigy and two Japanese companies which also sold the drug.

Ciba-Geigy eventually accepted a legal settlement in 1978 when they acknowledged that clioquinol had a causal relationship with SMON, and that they had a responsibility to compensate victims. Payments of between $40,000 and $100,000 were made to several patients, the amount depending on the severity of the complaint (122).

The drug has been banned in the USA, Norway, Sweden, Denmark and New Zealand and is strictly controlled in most other countries in Western Europe. However, by 1981, it was still freely available and actively promoted in most LDCs, where diarrhoeal diseases are much more prevalent. It was readily obtainable, for example, in all the ASEAN nations, where its availability and presentation was examined by the International Organisation of Consumers' Unions in 1980. Samples of 20 different brands of clioquinol, formulated by different companies, were bought between March and April of that year. All except one were readily available over the counter, although some

(120) Subacute Myelo-Optic Neuropathy.
(121) Even though 15 per cent of the SMON sufferers had not taken the drug
(122) However: "Ciba-Geigy has acknowledged a causal relationship because this was a condition for a settlement according to Japanese law. We did this because otherwise the victims would have had to wait for years if instead of a settlement one would have had to wait for the court's decision. But there is no [proof] as yet regarding a causal relationship." Personal Communication, Dr. B. Wenger, March, 1983.
were, nominally, to be sold on prescription only. It was found that, even in the same formulation of clioquinol sold by Ciba-Geigy in different countries, the indications for use and warnings were not identical (123). Products containing clioquinol represent around one third of Ciba-Geigy's pharmaceutical sales in Indonesia. When interviewed in 1981, a company spokesman said that Ciba-Geigy had no plans to withdraw the product and he argued that the pattern of usage in Indonesia is different to that in Japan and that the benefits outweighed the possible side-effects (124).

The Ministry of Health in Indonesia is fully aware of the debate about clioquinol, but it has made no move to ban its use (125). It seems unlikely that the adverse publicity from other countries has damaged the position of Ciba-Geigy in Indonesia in the eyes of the Government authorities, or of the majority of the affluent consumers who buy its products.

The use of clioquinol, and its promotion by Ciba-Geigy, continued to attract much controversy. Both Muller (126), and Balasubrahmanyan (127), claimed that clioquinol was ineffective against nonspecific diarrhoea, although the company promoted it for that purpose. Both these writers described the various campaigns against Ciba-Geigy for continuing to promote clioquinol; Balasubrahmanyan states that "a campaign against [Entero-Vioform] has begun in Indonesia... on August 12 [1982]... soon after the Health Minister announced that the drug was still 'needed' in that country." (128)

(123) Sim (1980).
(124) Interview, Marketing Manager, Jakarta, September, 1981.
(125) Interview, Ministry POM, Jakarta, September, 1981.
(127) Balasubrahmanyan (1982).
(128) Balasubrahmanyan (1982) p1642. For an early example of the opposition to the use of clioquinol in India, see "Toxic Effects",...
By the end of 1982, Ciba-Geigy had announced a new policy on the control of diarrhoeal diseases (129). It declared that it had been necessary to reassess the role of drugs to combat diarrhoea and, in particular, conceded that the use of oral rehydration salts (ORS) was a safe and effective treatment for acute diarrhoea in all age groups.

Ciba-Geigy declared that it would: "actively promote the benefits of oral rehydration and will also help national/international authorities to expand the use of this therapy." In contrast, clioquinol was acknowledged to be of very little use, and the company declared its unequivocal resolve to: "phase-out clioquinol-containing oral preparations from its product range on a world-wide scale... during the coming three to five years."

---

letter from Drs. Dandiya, Bapna and Patni, to Times of India, 30 June, 1977. The Government of India considered banning the import of 'halogenated oxyquinolines' in 1981, but decided against such a move as "the toxic effects had not been observed in India, although the drugs had been used for many years." However, manufacturers were required to give more information on possible side-effects. Press Release, Press Information Bureau, Government of India, New Delhi, 8 January, 1981.

COMPANY CASE-STUDY 2: THE ASTRA-IDL JOINT VENTURE, INDIA

Between the two extremes of the very large pharmaceutical transnational and the tiny domestic enterprise there is a variety of other companies. For example, some transnationals fully deserve such a description, because they manufacture in many countries. However, their international behaviour is of a degree less than the largest companies because they concentrate on particular types of country, with relatively little undertaken in others (1). On the other hand, there are domestic companies which, for one reason or another, remain at that level. They do not establish overseas operations, other than a small volume of sales through agents, yet nor do they achieve what they consider a satisfactory share in the domestic market (2).

The subject of this chapter is a joint venture between two companies which lie within this middle ground of the international pharmaceutical industry. Although the initiative came from one partner, both companies eventually decided that a joint venture might give them the potential for significant corporate development. Within this chapter there is a description of the two companies involved in this venture and their position in the early 1970s, when the project was begun, the way contact was made between them and how their plans developed.

(1) In particular, there are several companies which operate marketing operations throughout the world yet produce their drugs almost exclusively in the industrially developed nations. They regard production in the LDCs as an activity which requires an institutional corporate structure.
(2) Frequently their national market is dominated by transnationals.
8.1 IDL AND MIT

The parent company of the Indian partner is IDL Chemicals Ltd (3). It is based in Hyderabad, where it was founded in 1961, primarily to produce detonators. By 1965, it had negotiated its first technical collaboration with a foreign company when an agreement was signed with the Kemplex company of Hungary, under which know-how was to be provided for a wider range of detonators (4). By the mid-1960s, the company had already achieved an important position in this field (5). Throughout the 1960s and early 1970s, IDL gradually broadened its range of activities. It began to manufacture both standard and safety fuses and, in 1969, established a plant at Rourkela for the production of slurry explosives (6).

Whilst such moves strengthened the position of the company in the Indian explosives market, they did not satisfy the directors, who sought to diversify into other activities. During the 1970s, agreements were signed with several foreign companies and, by the end of 1976, the company operations included the breeding of milch cows, seed cultivation, and the manufacture of agrochemicals and pharmaceuticals. The Swedish company, Nitro-Nobel bought 40 per cent of the shares in the early 1970s (7).

(3) IDL stands for Indian Detonators Ltd, reflecting the original interests of the company.
(4) "Astra-IDL; a new pharmaceutical venture", an undated leaflet produced by the two companies.
(5) Until the early 1950s, the Indian explosives market had been controlled by Indian Explosives Limited, a subsidiary of the British company, ICI; from the mid-1960s, IDL and IEL together dominated the market. Hermele (1980) p26.
(6) This was achieved with technical assistance from Atlas Chemicals Industry of USA and the agreement was continued when Atlas subsequently merged with Dow Chemicals, another large USA company with a wide range of manufacturing interests. "Astra-IDL; a new pharmaceutical venture".
(7) This was the maximum equity level permitted by the Indian Government.
The pharmaceutical division of IDL was also acquired in this period. Mysore Industrial and Testing Laboratories (MIT) had been established as a state-owned enterprise in the colonial period, when it served as a simple chemical laboratory, and produced tinctures and other standard medical supplies for local state hospitals. This function had hardly changed by the end of the 1960s, when MIT was controlled by the State of Karnataka (8). By 1972, IDL had purchased nearly 70 per cent of the shares in the company and, two years later, MIT was amalgamated with IDL.

Whilst MIT had remained a State-owned enterprise, it had done little to promote its very limited range of drugs. Now it began to function as a private company, marketing its products to potential prescribers. Until 1970, the products were distributed only within the home State of Karnataka but IDL decided to sell drugs in most of the southern, western and northern regions of India (9). In 1976, sales by IDL amounted to some Rs163 million, of which MIT contributed Rs145 lakhs (9 per cent). Further details are given in Table 8.1.

By 1976, the old management of MIT had been almost completely replaced by relatively young and enthusiastic personnel, many of whom had worked for large TNCs in the important Bombay region. They were ambitious to expand the operations of MIT, but faced various constraints. The company was small and, more importantly, did not have the potential to make great advances itself. It did not have suffi-

(8) By then, it played a much smaller role in the State health services, whose needs were now supplied by the larger Government and private factories.
(9) A field force of some 66 representatives, supported by 9 sales promotion supervisors and 3 regional managers promoted the company's products to about 16,000 of the 150,000 doctors registered in India.
TABLE 8.1
(Rs lakhs)

<table>
<thead>
<tr>
<th>Year</th>
<th>IDL Total Sales</th>
<th>of which MIT Sales</th>
<th>IDL Pre-Tax Profit</th>
<th>IDL Net Fixed Assets</th>
<th>IDL Total Net Worth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1962</td>
<td>14</td>
<td>-</td>
<td>2</td>
<td>0.1</td>
<td>0.2</td>
</tr>
<tr>
<td>1966</td>
<td>218</td>
<td>-</td>
<td>41</td>
<td>91</td>
<td>20</td>
</tr>
<tr>
<td>1970</td>
<td>345</td>
<td>52</td>
<td>69</td>
<td>227</td>
<td>122</td>
</tr>
<tr>
<td>1974</td>
<td>826</td>
<td>43</td>
<td>130</td>
<td>399</td>
<td>336</td>
</tr>
<tr>
<td>1976</td>
<td>1627</td>
<td>145</td>
<td>282</td>
<td>565</td>
<td>569</td>
</tr>
<tr>
<td>1978</td>
<td>2476</td>
<td>150</td>
<td>330</td>
<td>758</td>
<td>660</td>
</tr>
<tr>
<td>1980</td>
<td>2762</td>
<td>223</td>
<td>275</td>
<td>1027</td>
<td>546</td>
</tr>
<tr>
<td>1981</td>
<td>3352</td>
<td>377</td>
<td>417</td>
<td>1042</td>
<td>-</td>
</tr>
</tbody>
</table>

NOTE: (a) Year ending 30th June

icient research effort to develop any new products of its own. Being relatively new as a commercial operation, it had not established a reputation to help its sales promotion to medical doctors. Instead, the company explored the possibility of collaborating with a foreign company which might be able to offer know-how for new products and which, equally importantly, would have a foreign name to attract the attention of prescribers. The first agreement was signed with the British company, Stuarts, which had only a limited presence in India (10). MIT also approached the foreign collaborators of IDL, first Atlas and later Dow, both of which had limited interests in pharmaceuticals (11).

(10) MIT formulated some Stuarts' products under licence but were unable to negotiate the purchase of more complete manufacturing details. This agreement was dissolved when ICI took over Stuarts and then attempted to buy MIT from IDL, their competitors in the explosives field. IDL refused the offer.
(11) Some technical collaboration was arranged but it gave only a limited boost to MIT and was discontinued in 1976, when IDL became involved with Nitro-Nobel.
MIT, continuing to seek collaboration with a foreign partner, approached Nitro-Nobel for assistance on several occasions in the mid-1970s, when IDL was negotiating with the Swedish company. Through Nitro-Nobel, contact was made with AB Astra of Sweden and, eventually, this led to the joint venture described below.

8.2 AB ASTRA

Astra is the largest pharmaceutical company in Scandinavia and one of the largest in Europe (12). However, until the joint venture with IDL/MIT it had not manufactured in an LDC, other than in a long-established subsidiary in Argentina (13).

Astra started to manufacture in 1914, with a cardiovascular drug, 'Digitotal' (14). The growth of the company accelerated during the First World War, which interrupted the normal methods of drug import and enabled Astra to expand without substantial foreign competition. By the end of 1917, Astra employed over 200 people (15).

(12) In 1977, its sales placed it 34th in the world and 16th in Europe. UNCTC (1979) p110-111. Astra was founded in 1913 by 424 shareholders. Most were pharmacists and doctors and together they subscribed a share capital of Skr350,000. This was one of the first such undertakings in Sweden, as the law had previously reserved pharmaceutical production for individual pharmacists, and the balance had been met by imported products. Astra Digest (House magazine) December, 1973, p3.

(13) It maintained only a relatively small representation in most LDCs through a regional marketing organisation.

(14) A chemist who had previously been head of Pharmaceutical Production at CIBA in Switzerland joined the company and production expanded rapidly under his guidance. Dunning et al (1981) p186-189.

(15) Astra expected further expansion in the coming decades. In fact, the company found the 1920s somewhat traumatic; at the end of the war the shares were purchased by another Swedish firm with the objective of developing a major domestic company modelled on their larger European rivals. They invested heavily in expanded production facilities but unstable market conditions and strong foreign competition forced the company almost to bankruptcy. It was rescued only by substantial Government assistance which resulted, in 1924, in the company being returned to private ownership.
During the 1930s and 1940s, the company increased its sales substantially, both in Sweden and abroad. It also began to lay the foundations for future success by starting its own research programmes. This research has been particularly successful and the company has identified two reasons why this should be so (16). Firstly, unlike many European companies, which concentrated their efforts on chemical synthesis, from an early date Astra was also concerned with the biological and medical results of their work. Secondly, Astra was able to develop good relationships with hospitals and universities, because Swedish law contains an unusual facility whereby research workers in such bodies can remain free from commercial ties, yet still receive royalties for their inventions (17).

This policy paid very handsome dividends in the 1940s with the discovery of lignocaine, (sold by Astra as 'Xylocaine'), a versatile local anaesthetic (18). The product was eventually launched in 1948. Acceptance of the new drug in dental and medical fields exceeded all expectations and it has now become the leading local anaesthetic for a wide range of applications (19).

(16) As with the previous chapter, most of the material on which this case study is based has been obtained from interviews or from unpublished company documents. References are given only when the source document may be available to others.

(17) Astra recruited what was, at that time, a relatively large number or research scientists and also sponsored work in independent organisations. Burstall et al (1981) p187.

(18) It was discovered in 1943 by two chemists at Stockholm University who were, ironically, performing their research "under certain obligations to another Swedish pharmaceutical company." Astra Digest, December, 1973, p4-5. When this rival failed to grasp the opportunity, the discoverers turned to Astra, who signed a commercial agreement without yet recognising the financial potential of lignocaine. Clinical trials were carried out, although they were hampered by the difficulty in producing adequate quantities of the active ingredient. Whereas the chemical synthesis was relatively easy, it proved difficult to obtain sufficient quantities of meta-xylidine, an important raw material.

The company thrived during the Second World War. Once again, the restrictions on international trade boosted the sales by domestic companies, whilst chemical manufacturers were also encouraged to find synthetic substitutes for natural products no longer available. Astra expanded its research activities, gradually developing a range of new products, whilst sales also increased at a remarkable rate (20).

Astra has also developed internationally, although within particular regions of the world. The first overseas contacts were made as early as 1926, when goods were exported to Finland and Colombia. In the 1930s, an over-capacity in production facilities led to the establishment of sales subsidiaries in Latvia, Norway, Finland and Brazil (21). During the Second World War, the difficulties of international trade induced the company to establish a manufacturing subsidiary in Argentina, where cattle glands were processed for subsequent conversion into hormonal products. After the war, further subsidiaries were founded in a wide range of countries (further details are given in Appendix 8.1).

By 1960, Astra had fourteen subsidiaries and a further fifty licensees or agents around the world (22). However, the priorities of the company may be seen by the fact that, with the exception of Argentina, Colombia, Mexico and Brazil, the subsidiaries were all located in Europe, North America and Australia. Astra did not have a single subsidiary in Africa or Asia and marketed its drugs through

(20) In the twenty-five years since 1947, the year before Xylocaine was launched, the sales revenue of Astra has increased by a factor of 33.
(21) Serious investigations were also made into the commercial possibilities in other countries, such as Egypt and India.
agents in these continents (23). Table 8.2 illustrates the growth in sales and the number of employees between 1950 and 1980. Group sales, and the number of employees, continued to grow until the mid 1970s, whilst Sweden declined, both as a market and as the hub of corporate activity.

**TABLE 8.2**


(Financial results in Millions of Swedish Kroner)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
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<td>181</td>
<td>525</td>
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<td>Of which</td>
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<tr>
<td>In Sweden</td>
<td></td>
<td></td>
<td>330</td>
<td>444</td>
<td>622</td>
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<tr>
<td>as % of total</td>
<td></td>
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<td>63</td>
<td>52</td>
<td>42</td>
<td>28</td>
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<td>Total</td>
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<td>4525</td>
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<td>as % of total</td>
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<td>71</td>
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<td>56</td>
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SOURCE: Astra Company Reports

During the 1960s and 1970s, the company was faced with some difficult choices, in order to remain profitable. Growth, as always, would be seen as an indicator of their success, but the most fruitful directions for growth were not clear. Firstly, in the 1950s and 1960s, with Xylocaine as its only internationally-known drug, Astra had diversified outside pharmaceuticals. They began to manufacture in related chemical fields such as nutritional, 'sports' (Astra produced a wax for use on skis), agricultural products, and corrosion-

(23) The 1976 Annual Report shows a very similar picture, with fifteen subsidiaries, now called 'Group Companies', listed. The only differences to the 1960 position is the disappearance of the subsidiary in Italy, where Astra products are now sold through an agent, the conversion of the Colombian subsidiary into a company in which Astra holds only 20 per cent of the shares, and the establishment, in 1975, of a group company in Japan.
proof paints. However, these activities had never represented more than about one-quarter of group sales and had attracted proportionately much less of the company's research expenditure. After experiencing a variety of technical and bureaucratic difficulties in the non-pharmaceutical fields, Astra decided to restructure its operations. In the Annual Reports of 1977 and 1978, the President of Astra, Ulf Widengren, spoke of the major growth potential being inside pharmaceuticals, rather than outside, and reported that most of the non-pharmaceutical operations had been sold off during 1978 (24).

The second field in which Astra might have looked for expansion was in the development of drugs in therapeutic classes new to them. Local anaesthetics remained one of the most important product groups (25), and in 1976, sales of this group represented some 23 per cent of the company's pharmaceutical sales. Astra, however, did not limit itself to that field. High-selling products had been developed in other groups, such as cardiovascular preparations (21 per cent of total pharmaceutical sales), anti-asthma agents (10 per cent), antibiotics (9 per cent), gastro-intestinal preparations (4 per cent) and psycho-pharmacological agents (4 per cent). Cardiovascular preparations accounted for the most rapid growth and, within two years, was to become the largest selling group (26).

The use made by Astra of its research funds had proved very profitable in many ways (27). Efforts were underway to introduce more

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(25) Astra had strengthened its position with the introduction of 'Duranest' to supplement Xylocaine.
(27) The 'Astra Digest' of December, 1975 could report that Astra
new products into the lucrative markets around the world. At the same time, Astra's research organisation had developed in ways which, perhaps, made it difficult for the company to diversify into new fields. For example, the close links with academic institutions had led to the establishment of three Swedish research centres, in Södertälje (the company headquarters), Lund and Göteborg. Each centre, concentrating on only a few groups of products, had developed techniques best suited for such drugs but had done little work in other therapeutic categories. Expansion into another field required, therefore, a large investment in terms of equipment, the recruitment of more workers and, most significantly, the development of new techniques with which the company was relatively unfamiliar.

The third potential area of growth could be termed "territorial" and it includes both the level of corporate activity and spatial expansion. The largest companies employ their own marketing force for the great majority of the countries where they sell drugs, because this is generally regarded as being the most profitable. Astra, however, had not developed its international operations to this extent, and it was only in the Nordic countries and in other countries where it had established subsidiaries where this pattern was followed. Eventually, Astra decided to develop licensing and marketing agreements with several large companies (28).

ranked "fourteenth among world's introducers of new drugs." Astra Digest, December, 1975, p2. This referred to the number of new markets into which a drug was introduced, rather than the number of new products discovered.
(28) For example, by 1976, Astra had developed a broad spectrum antibiotic, 'Penglobe'. It decided to organise the international sales of this product in cooperation with the USA company, Pfizer and Beecham of the UK. A company spokesman explained that: "In some countries, the three companies will vie for the market in keen competition with each other, while in other countries, the company with the greatest marketing resources and most fully established organisation will dominate the market." Astra Digest, Sep-
In 1975, Astra strengthened its marketing operations by establishing a joint venture company with Fujisawa of Japan (29). During the 1970s, it also established new subsidiaries in Austria, Belgium and Spain. However, Astra was uncertain about its role in the LDCs. Firstly, its products might not sell well in such countries. Secondly, as Chapter 2 has described, the pharmaceutical industry was emerging into the limelight of international debate. One result was that more countries were now demanding greater financial commitment from TNCs and some measure of local production. This was particularly true of the large countries, whose markets which would be most attractive to Astra.

During this period, Astra declared its 'Product Supply Policy', which was described in the house magazine, and which declared an opposition to large-scale manufacturing overseas:

> Our goods supply policy calls for a large synthesis plant in Södertälje...The next step is ensuring that we have sufficient formulation capabilities, which should be concentrated - we have already decided - to as few plants as possible...As far as packing is concerned, we feel it is important to have facilities close to, or in, each market...The ultimate objective is thus total production concentrated on Sweden, formulation and packaging in Australia and packaging in West Germany, Holland and England. Of course there are exceptions to every rule...” (30)

November, 1976, p3. Astra also licensed some of its products to other manufacturers. However, this was becoming a less attractive proposition because the inventor might lose its patent rights to the product, which was a serious hardship as the cost of drug research soared and new products were particularly important to the future development of any company. Cross-licensing, whereby production and marketing rights are exchanged, was regarded more favourably and one such agreement had been signed with Ciba-Geigy (Burstein et al (1981) p189). By a variety of such arrangements, Aptin, a cardio-vascular product, was sold in some 80 different countries by 1979 (information provided by the Bugli Company, Sweden to accompany a new issue of Astra shares).

(29) Astra Digest, October, 1975, p3.
At the same time, the company realised that the vast populations of the LDCs represented a huge potential market. The company belief, that there should be no large Astra establishment outside the most valuable markets, was beginning to be questioned. It was in this environment that M. Varadarajan, the Managing Director of IDL, first approached Astra.

8.3 THE FIRST CONTACTS BETWEEN ASTRA AND IDL

When IDL sought to expand its pharmaceutical operations, it contacted its foreign collaborators, Nitro-Nobel. The Swedish company did not, itself, manufacture pharmaceuticals but was able to arrange a meeting between Astra and IDL in the offices of its parent company, Kema Nobel. The common factor in all these companies was the giant Wallenberg group, the leading Swedish financial organisation. Wallenberg has large shareholdings in many of the big Swedish companies and is, for example, the largest single shareholder in SKF, Saab and Alfa-Laval (31). One further link was that Ulf Widengren, who became President of Astra in 1977, had previously been the Managing Director of Barnängen, a subsidiary of Kema Nobel and the two companies enjoyed a close relationship (32).

(31) The Wallenberg group holds 25 per cent of the Kema Nobel shares and 72 per cent of Nitro-Nobel. In Astra, it controls 27 per cent of the votes, whilst the next biggest shareholder is the state with 10 per cent and no other shareholder has more than 5 per cent. Hermele (1980) p27 and Hermele, private communication, October, 1980.

(32) The first contacts between IDL and Astra had been made in 1973 and 1974. Astra and IDL discussed the possibility of collaboration, but this did not progress beyond a very general exploration of the Indian business climate. By March, 1976, Widengren was becoming involved in Astra's activities. Whilst reviewing the operations of the company, he again raised the possibility of collaboration with IDL but again the idea was not taken up by senior management. However, it was learned that Varadarajan and another MIT manager were planning to visit Sweden in the June of that year. It was decided that the possibility of collaboration should
On the 16 June, 1976, a meeting was held between the IDL representatives and some of the Astra senior managers. It resulted in the informal agreement that the potential for collaboration should be explored further. Astra delegated responsibility for this next stage to its Senior Vice-President in charge of International Relations, Hans Hellström. Other company employees with suitable experience were also co-opted and the first action they took was to send a questionnaire to MIT (33). The management Sub-Committee under Hellström needed to familiarise itself with the details of the pharmaceutical industry in India and to gain ideas of the role that Astra and IDL might play. The questionnaire was divided into three sections, which covered:

(i) General questions relating to India, the pharmaceutical industry and the 'medical environment',
(ii) IDL's ideas on possible collaboration, and
(iii) Detailed questions relating to a joint venture company.

The replies to this questionnaire, which is summarised in Appendix 8.2, illustrate the extent to which Astra was unfamiliar with operations in India. For example, the company did not have a copy of the Hathi Report. It needed to ask whether the proposed joint company "would belong to the organised or small-scale sector." (question 11), if there were "any rules and regulations for the production of pharmaceuticals issued by any Government body." (question 14) and about the "most recent news on the abolition of brand names."

(33) Up to this point, Astra had had relatively little contact with India. Their leading product, Xylocaine, had been licensed to Suhrid-Geigy, on the initiative of Geigy. A few more products were licensed to a Small-Scale unit, Cosme Farma, based in Panajim, the capital of Goa.
(question 20).

Whilst there was no reason for the Astra management to be familiar with such details already, and they might have been able to find out such information from the Indian Government (34), it was clearly helpful to have the guidance of MIT. This feature was emphasised by other questions which necessitated a more evaluative judgement. These included "the attitude towards foreign participation" (question 10) and the "availability of suitable labour" [implying, of course, suitable skills at 'reasonable' wage rates] (question 18) (35). The enthusiasm of IDL was seen, when they replied as early as August, 1976 with a compilation of some 80 pages (36).

The first visit by Astra employees to India was made in September, 1976. Two leading members of the Sub-Committee met Nitro-Nobel personnel and travelled to IDL headquarters in Hyderabad, MIT at Bangalore, to the important manufacturing centre of Bombay, and to the capital, Delhi. Together with MIT, they discussed the potential for selling Astra products in India.

As a result of all these contacts, the Astra team decided that they had a firm basis on which to develop ideas of cooperation. It was realised, however, that the senior management of Astra would

(34) For example, from the European offices of the Indian Investment Centre.
(35) At the same time, the Astra team sought to familiarise itself with the possibilities by reading several documents about India and other LDCs produced by business consultants and trade journals.
(36) Contacts between the companies were further developed in the same month by another IDL visit to Sweden. On this occasion, Varadarajan was accompanied by MIT staff and by an American consultant who was employed as a scientific adviser to the Indian Government. The latter was able to give Astra a Western perspective of Indian industry in general, and the organisation of IDL in particular.
approach the project with much caution (37), and it was necessary to emphasise the favourable circumstances of the proposed Indian venture. Accordingly, the project was discussed on many occasions by the Astra senior management and the Sub-Committee also produced a document to clarify the important issues and options available to Astra:

"When estimating the MIT-ASTRA project, the following factors are probably the most important ones: The realistic conventional alternative to establishment according to the proposed MIT-ASTRA model is to abstain from organised activity in India until the import and establishment policies of the country have been liberalised?! In spite of the uncertainty of available data it is evident that the project does not constitute a financial risk of any importance. The MIT offer means a unique opportunity to establish ourselves in a market with great future potential, but with profit transfer possibilities that are new to us and difficult to estimate. The crucial question is to what extent we in Sweden are prepared to engage capacity for the out-of-routine package of activities in India, which partly derives from pronounced demands by the authorities and partly is designed to take care of the profit possibilities outside our sale of specialities in India. Only if we accept the transfer of activities and technical know-how basically according to the requests by the Indian Government and if we are also prepared to adjust our own engagements to new activities, partially yet unknown, fitting into the sketched MIT-ASTRA model, is the MIT-ASTRA project feasible." (38)

This document reflected the structure of the questionnaire, covering "India as a market for pharmaceuticals", possibilities for an "Astra establishment in India" and "Special commitments and profit possibilities." India was described as a: "manufacturer's

(37) Only three years previously, the company had explored the potential for establishing a subsidiary in Indonesia but concluded that Astra was not suited for such a venture. Astra was also in the early stages of establishing itself in Nigeria, where it was experiencing some difficulty.
market...everything that can be manufactured...is sold with a small but guaranteed profit...The market is expanding rapidly and the future potential [sic] of the market is of a completely different size than the scale reported today." (39)

The tone of this document was generally optimistic compared with, for example, the publications of OPPI in India and the attitude of most TNCs to the 1975 Hathi Report. The document went on to explain that Astra was faced with a choice between three alternatives:

1. Maintenance of the status quo, which involved direct sales of bulk material to Small-Scale companies such as Cosme Farma. The disadvantage of this was that local manufacture of the same products by domestic companies would lead to a ban on the import of the Astra brands.

2. The licensing of individual products to relatively large Indian companies. Whereas this would give, in the short-term, a higher income than alternative 1, it would involve Astra in continuing technical assistance to the licensee as well as loss of control over the use of the product.

3. The third alternative, which the document went on to explore more fully, was the establishment of a joint venture, in which Astra would have a minority holding under the requirements of Indian law.

In financial terms, the third option would realise an income

(39) One feature of the market was said to be that: "price increases are granted when costs increase and when the tied-up capital is increased. [Indian business practices are] closer to the European way of thinking than in most other Asian countries."
somewhere between that from the first two alternatives. As in alternative 2, royalties would accrue, but the venture would need continuing technical and commercial assistance. Furthermore, long-term capital would be tied up. However, this alternative offered several other advantages. These were in part financial, in the form of dividends and the possibilities of low-priced raw materials and cheaper formulation of Astra products for export from India. The Sub-Committee also expected that other advantages might accrue, although they did not describe them in the document. For example, a venture in India would be the first of its kind by Astra. Once the first step had been taken, the company would be better placed to consider other projects in LDCs. Any subsequent projects in LDCs might make use of Indian technicians, paid at a lower rate than Europeans, and more familiar with labour-intensive manufacture in tropical conditions (40).

The document went on to suggest the form of a possible agreement with IDL. The MIT division would become a separate company and invite Astra as part-owner. Astra and IDL would have equal shareholdings, of between 26 per cent and 28.5 per cent, with the remainder open to the public. The estimated share capital was Rs20 million and new premises would be built on a greenfield site, some 20km outside Bangalore. This is, substantially, what happened (41).

The Sub-Committee's 'Guide for Critics' went on to describe the current activities of MIT:

(40) Interviews, Södertälje, October, 1980.
(41) Although some of the early ideas proved unacceptable to Astra. For example, IDL had hoped to use part of the new site to manufacture pesticides. The Astra technicians refused to consider such a scheme, because of the dangers of contamination.
"The present production, which only consists of formulation, is carried out [in] old-fashioned premises and with equipment which, on the whole, looks like Sweden 40s and 50s. The working discipline and the skills seem satisfactory."

Several Astra products were identified for possible production in India, with the Government requirement to introduce synthesis being emphasised. It might also be possible to manufacture other intermediates or bulk drugs for export, either to Astra in Sweden, or elsewhere (42).

These ideas were presented to the Astra senior management in November, 1976. The Board asked the Sub-Committee to develop their ideas and to keep the top management informed of the progress. This decision was communicated to Varadarajan during December, 1976, in a letter which proposed the bases for the development of the project. The size of the financial commitment had concerned the Astra executives and the total initial share capital was now suggested as being Rs10 million, rather than Rs20 million. The new venture would manufacture a range of products, including the current MIT drugs and the leading Astra products in several therapeutic categories. The principal product would be Xylocaine, which would be manufactured in a variety of forms (43). The letter to Varadarajan described the

(42) For example, at that time, Astra used approximately 120 tonnes per year of psyllium husk, which was converted into a laxative, 'Lunelax'. The raw material was imported from India by a German company which processed it for sale to Astra. The new venture might be able to short-circuit this process and reduce costs.

(43) These included injectable solutions for medical work, cartridges for dental practice and 'semi-solid' jellies and ointments for topical applications. The promotion of 'xylocaine' and the companies latest local anaesthetic, 'Citanest', in India, was to be a major activity of the new company. Marketing personnel identified the Indian health care infrastructure as being both particularly suitable for the use of local anaesthesia and also a discipline which had been somewhat neglected.
Astra drugs and suggested the timing of their introduction (44).

Technical matters were generally seen as subordinate to economic considerations, although the difficult syntheses of two of the drugs were emphasised. In one case, the drug was popular and its early introduction was recommended to allow time for any production problems to be solved. For the other drugs, the relatively low sales volume expected led Astra to suggest that they should import the bulk drug as long as they were allowed to do so, and whilst sales increased. Larger requirements would then justify the greater technical input required when local synthesis was eventually introduced. Astra had also recognised the weakness of the data on which the sales estimates were based. They now provided more data, such as manufacturing and raw materials costs, for further calculations. Information was also given on the registration in India of some of the Astra drugs (45).

The design of the production facilities was also discussed in the letter. The project was divided into two sections, the formulation factory and the bulk synthesis plant. For the formulation factory: "Astra Sweden's participation as we see it today will be to partly guide the Indian project team as well as plan in detail for the specific Astra parts of the formulation plant." (46)

(44) On the whole, the schedule was developed in terms of commercial factors. It would be impossible to launch all products simultaneously and those products with the widest commercial appeal were to be introduced first, with the more specialised drugs to follow.
(45) For example, jectofer, an iron compound and Xylocaine had long been registered in India. However, 'Bricanyl' (terbutaline sulphate, an anti-asthmatic agent) and a different formulation of jectofer were in the process of being registered. This was being arranged by Cosme Farma. Other Astra products had not previously been considered for India.
(46) This was estimated to cost between SwKr0.6 million and SwKr0.7 million (about Rs300,000). These costs would be met from
For the chemical factory, Astra recommended that a multipurpose synthesis plant, based on 1,000 litre vessels, should be built to accommodate company requirements for the first five to seven years. It was suggested that Astra could send drawings of a 4,000 litre plant, a size with which they were more familiar, and the MIT technicians could adapt this to the smaller scale. It was agreed that Astra should charge for the design work and the cost for this part would be in the region of SwKr0.1 million (47).

A covering letter was sent with the same information to the MIT offices. In this, Hellström stated that the MIT manager who had previously visited Astra had: "worked in close contact with our technicians and created a deep understanding in all circles within Astra for the Indian project in general and for MIT people in particular." Nevertheless, he emphasised that: "our technicians were less satisfied with the administrative way in which the architects wanted to run the construction work." When interviewed in 1980, Hellström explained that the Indian procedure seemed to involve continuous decision making and modifications as the factory was being con-

the working capital of the new joint venture company. This technical work would be performed between 1977 and 1980 when, it was hoped, the plant would be commissioned.

(47) One product, 'Bacampicillin', required special equipment and a further SwKr0.1 million would be needed to prepare the drawings for this. The psyllium husk would also be prepared in a separate building, and drawings for this could be provided at a cost of some SwKr0.02 million. The production capacity of the new venture would be developed further by the exchange of information on the manufacturing processes for synthesis and formulation. This could be done by the exchange of documents describing the techniques and by the visits of Indian personnel to Sweden to observe the processes there. It was suggested that two technicians should see the formulation activity, each staying one month, and that one person should spend about one month in Sweden for each synthesis to be introduced. The cost in Sweden, excluding the salaries and travelling expenses, would be about SwKr0.01 million each man month.
structured. The Swedish technicians preferred more details to be specified before construction started.

Astra also affirmed its wish to sign a royalty agreement for bulk materials which would be "as favourable as possible." They suggested a 5 per cent return over a five to ten year period. Finally, the export component of the joint venture was discussed, since this was known to be a feature which would be important to the Government. Astra listed four substances which they currently imported from elsewhere and indicated the price they paid for these, in the hope that they could be acquired more cheaply in India.

8.4 DEVELOPING THE PROJECT

During 1977, both companies worked towards agreeing the basic ideas of the joint venture. From the outset, they had to consider the likely response of the Indian Government (48). Astra employees reported later that they were somewhat nonplussed by the debate over the Hathi Report. They relied on the opinion of IDL/MIT, which continued to be optimistic.

With the Hathi Report in mind, the companies recognised that their application should contain proposals for the production of bulk drugs, exports, and some R&D. The Government would also scrutinise the financial aspects of any agreement, especially, the levels of royalty payments, and Astra's equity holdings (49).

(48) The Hathi Committee had reported in 1975 but the Government decisions on the recommendations were not published until March, 1978. Many of these decisions would be crucial to the success of the project, not least that on the Hathi recommendation that the industry should be nationalised. See Chapters 5 and 6.
(49) Most of the Astra products might be regarded as falling in highly-specialised and sophisticated therapeutic areas. However, the companies did not expect that the Indian Government would see this as a disadvantage. Rather, it was expected to be a point in
In April, 1977, Hellström and another leading member of the Sub-Committee, returned to Bangalore to meet the IDL and MIT managements again. They reviewed Astra's expectation of the project and decided that it was important to exchange more financial data, in order to establish the economic feasibility of the various parts of the proposed venture (50). It was necessary to speed up the registration of those products being handled by Cosme Farma, and Astra decided that MIT should approach Cosme Farma to expedite this process.

During the next six months or so, Astra technicians prepared the drawings for the production facilities. They decided, with MIT's guidance, not to install expensive equipment but rather to use labour-intensive techniques. In India, MIT developed the project timetable and, with the aid of the Astra data, reviewed their sales forecast, which they republished in November, 1977. Finally, they recalculated the capital cost of the project (51).

the company's favour, especially when contrasted to the basic range of drugs which MIT sold.

(50) These included the price at which Astra exported Xylocaine to the Far East and the various costs involved in the processing of the psyllium husk.
(51) These developments were facilitated by three further visits. In September and October, Hellström, and two Astra managers, including a senior research scientist, returned to India. They held informal discussions with Government officials in Delhi, Bombay and Bangalore and also revisited MIT's production facility. The scientist's impression of the latter was favourable; he reported that the conditions were poor, but the MIT technicians had a good understanding of GMP requirements. In November, a senior MIT technical manager went to Sweden for further discussions on the factory design. Later in the same month, Hellström returned to India with the senior legal executive in the Astra group. They visited both MIT, and the Bombay offices of a long-established practice of company lawyers. This firm was able to indicate some of the essential elements to be agreed in the formation of a new company and the likely reaction of the Government. The Astra team returned to Sweden, confident that the project was feasible.
The Astra board met on 16 December, 1977, when it considered a favourable report from the Sub-Committee. They decided that Astra should invest in the new company although, by now, the estimated share capital required had risen to Rs20 million. The minutes of that meeting record the intended activities of 'MIT-ASTRA', including the manufacture and development of new products, export of materials to Astra in Sweden and to other companies and: "the recruitment and training of specialists for work with technology transfer to other developing countries...The planned export of MIT-ASTRA's products shall be solely carried out by Astra." (52)

Many details were determined in 1978 and the events of that year illustrate some of the peculiarities of establishing a joint venture in India. The efforts of Astra and IDL were concentrated on two fronts. Firstly, they refined their application to the Indian Government. Secondly, technical staff in both companies became more involved in detailed calculations. These developments are described below.

8.5 ASTRA, IDL, AND THE GOVERNMENT OF INDIA

The new venture needed to obtain the permission of the Government of India in two specific areas; collaboration of an Indian company with a foreign enterprise, and the industrial licenses for the production of the Astra drugs. The applications were

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(52) Astra's increased commitment to the new venture was now recognised by the establishment of an 'Indian task force'. This had a wider scope than the Sub-Committee and included representatives from the technical departments, who had previously been consulted only on certain aspects of the proposal. None of the members of this group worked full-time on the Indian project. The input of the technical staff, in particular, was initially low, but soon increased greatly.
prepared by the IDL/MIT personnel who had much more experience than Astra in such matters. Astra assisted by preparing data for calculations and, later, by responding to the amendments which the Government required. The applications were submitted in early January, 1978, some two months before the publication of the New Drug Policy.

Many of the features of the proposed joint venture were repeated in both applications. The MIT personnel were careful to stress those aspects which they expected would be regarded favourably by the Government and these included:

(i) Foreign Equity: the 'direct' foreign equity would be reduced from 40 per cent (the holding of Nitro-Nobel in IDL) to 25.75 per cent for Astra,

(ii) Astra was "Number One Pharmaceutical Company" in Scandinavia and had a good reputation for research and development,

(iii) The venture was to be: "primarily export-oriented". It was expected to realise some Rs30 million of foreign exchange during the first five years of operation. This would mean a net flow into India of some Rs25 million, when imports and dividends were taken into account.

(iv) Unlike: "normal foreign collaborations seeking first manufacture of formulations, our proposal starts with the manufacture of bulk." The ratio of the values of bulk and formulation production would be only about 1:1.6, much lower than the usual limit of 1:10 proposed by the Government. Six bulk drugs would be manufactured:

Jectofer ('Astrafer') - used to treat iron-deficiency anaemia.

Iso-sorbide di-nitrate (ISDN) - to treat angina

Terbutaline Sulphate ('Bricanyl') - a bronchodilator
Prilocaine ('Citanest') - a local anaesthetic
Lignocaine ('Xylocaine') - a local anaesthetic
"Lunelax substance" - for export to Astra for further processing

(v) The two companies would undertake research in "fields relevant to diseases in developing countries",
(vi) Over 500 people would be employed, compared to the 300 in the current MIT organisation, and
(vii) The drug industry in Karnataka was "deficient" and this proposal would be a significant contributor to help the state achieve its objectives under the Fifth Five Year Plan (53).

"In summary, the advantages of this proposal are:
(a) continuous inflow of latest technology on essential drugs;
(b) export by the Indian joint venture using Astra's global marketing network,
(c) joint research and development programme,
(d) training of Indian personnel, and
(e) availability of Astra's trademark." (54)

The submissions to the Government indicated some of the uses to which the Astra drugs might be put. For example, Astrafer was said to be: "essential in the Indian context, where incidence of iron-deficiency anaemia is extremely high...superior to other forms of therapy in view of its predictable absorption and availability."

Citanest was described as an: "essential drug" (55), and a product "ideally suited for the Indian rural market because it does not need

(53) The companies were able to remind the Government of India that it encouraged new industries to build outside large cities. IDL had acquired a piece of land from the Karnataka Industrial Areas Development Corporation some 20km outside Bangalore.
(54) All quotations in the above passage are taken from "Summary highlights of the proposed joint venture; Astra-IDL Limited", compiled by MIT and enclosed with the applications to the Indian Government.
(55) Although it had not been included in the lists compiled by the Hathi Committee or WHO (1977b).
special storage conditions." However, the first two aspects of this drug which MIT chose to emphasise were that it was a "basic manufacturing proposal" and, ironically, that it would be an: "export-only project to begin with." (56) Similarly, it was emphasised that Astrafer would make use of "sophisticated technology." (57)

By mid-February, 1978, the Government had acknowledged the receipt of these applications. Except for supplying some additional data required by individuals in the Ministry of Industry, the companies now could only wait until their submission was considered.

The long-awaited New Drug Policy was published in March, 1978. There had been much debate and speculation about its contents which Astra, unfamiliar with the Indian industry, had been unable to appreciate in detail. On the other hand, S.V. Raman, now the Chief Executive of MIT, had a wide experience of the Indian drug industry, and was able to interpret the new measures for Astra. It was fortunate for the joint venture that he could fill this role. When interviewed in 1980, Hellström suggested that Astra might not have continued with the project had not Raman reassured them. Many of the regulations in the NDP appeared too restrictive to large-scale, foreign, private enterprise.

The members of OPPI met in Bombay in April, 1978 to discuss the NDP. Raman represented Astra and IDL, and was able to identify those regulations which had a particular bearing on the joint venture. His report to Astra claimed that the MIT management had correctly

(56) This was to be until the drug was registered in India.
(57) All quotations relating to the individual properties of the drugs are taken from "Salient features of the Astra-IDL Industrial Licence Proposal", which formed an annexure to the Industrial Licence application.
anticipated many of the characteristics which would appeal to the Government. There were no elements in the applications for the Industrial Licence or Foreign Collaboration which would be made obsolete by the new bill. Instead, the NDP most affected the large TNCs, whereas the proposed Astra-IDL venture had several features which would be in its favour. Perhaps most importantly, it would count as an 'Indian' company, since the direct foreign equity was less than 40 per cent (58).

The Astra/IDL applications were reviewed by the Government in June, 1978. Hellström, Raman and five other Indian managers of IDL met a large committee of Government representatives in Delhi (59). Ten questions were asked in the first session of the meeting and only one of these concerned the medical properties of the drugs Astra-IDL proposed to manufacture. Even this point (60), was countered by technical and economic arguments. Astra-IDL said that their proposal was for basic manufacture and not merely formulation and that their

(58) This would facilitate the granting of licenses and such matters as the amount of bulk production required (the Government 'guidelines' were now formalised so that Indian companies had to produce bulk drugs with a value at least 10 per cent of the formulations, whereas the 'foreign' companies had to produce at least twice that amount) and the proportion of the bulk production which had to be offered to a 'non-associated formulator' (30 per cent of the output of Indian companies, compared to 50 per cent for foreign companies). The NDP also specified the maximum profit levels which individual companies could realise and it was necessary for the Astra-IDL financial results to be reviewed. However, this was not expected to reveal any serious impediment to the success of the venture.

(59) This committee comprised sixteen people, drawn from every Government department with a direct interest in the proposed venture. These included the Ministry of Chemicals and Fertilisers, the Ministry of Health (represented by the Drugs Controller of India), the Small-Scale Industry Directorate, the Foreign Investment Bureau and the Directorate General of Technical Development. Further details of the group are given in Appendix 8.3.

(60) Which referred to the fact that the drug, Astrafer, was the same as a product already sold in India.
activities would achieve import substitution and make bulk material available to the Small-Scale formulators (61).

The representative of the Small-Scale Industry Directorate objected to the Astra-IDL proposals to manufacture lignocaine. He said that there were "several" Small-Scale units which, together, manufactured nearly 20 tonnes of this drug. They would be: "hit hard if a large-scale manufacturer is licensed." Astra and IDL claimed, in reply, that their proposal was: "adequately justified by other components of the package." They should be allowed to make lignocaine because: (a) unlike other manufacturers, they would earn foreign exchange by exporting bulk lignocaine, (b) they would work towards backwards integration in their production, and (c) "Xylocaine is synonymous with Astra's name the world over and it is only fair that the Astra company in India is permitted to have this product in their range." (62)

The Government decisions were made verbally at that meeting and confirmed in letters from the Ministry of Industry in August, 1978. The new venture was approved, with only a few, relatively minor amendments required. The changes included:

(i) The adjustment of royalty levels to 3 per cent for sales of three bulk drugs within India and 4 per cent for exports. (The initial application had been for rates between 1 per cent and 2 per cent higher and for four bulk drugs.)

(ii) Astra-IDL was allowed to produce lignocaine, and sell it as

(61) These formulators sell the drug as iron sorbitol which is the generic name of the active ingredient in Astrafer.
(62) All quotations in this section are taken from "Minutes of the Screening Committee Meeting", written by an IDL representative.
Xylocaine, (considering "Astra's emotional attachment to Xylocaine and their willingness to earn foreign exchange to finance the import of intermediates.") (63) Astra-IDL were, however, now required to export 50 per cent of the bulk drug, compared to the 20 per cent which had originally been envisaged.

(iii) The manufacture of terbutaline sulphate had to be carried out from a more basic stage and manufacture of ISDN should make exclusive use of indigenous raw material (64).

By this stage, Astra and IDL/MIT had modified the system of payments for services rendered by the two companies before the formation of the merger. The Government agreed that Astra should be paid a lump sum of Rs500,000 (65) for all technical know-how, drawings and designs. The management of MIT and Astra-IDL in the period 1978-81 was to be arranged and paid for by IDL. This was in recognition of the fact that Astra had not received the market price for their services.

The Government stated their intent to grant a composite industrial licence for the six Astra bulk drugs which were to be produced by the joint venture. These are shown in Table 8.3, together with the installed capacities permitted by the Government. In January, 1980, IDL replied to the Government and accepted these conditions (66).

(63) "Minutes of the Screening Committee Meeting..."
(64) The Government also enforced several provisions of the NDP which Astra-IDL had argued against, but had expected to be implemented. These included a requirement to sell terbutaline sulphate, a new single ingredient drug in India, under the generic name, rather than as Bricanyl, the Astra trade-mark.
(65) Approximately SwKr0.25 million.
(66) Further details of the agreement were later defined by the Government. These included the exact stage from which the various syntheses should occur by given dates and the definition of which portion of the bulk output should be offered to non-associated
### TABLE 8.3

<table>
<thead>
<tr>
<th>No.</th>
<th>Generic Name</th>
<th>Item As sold by Astra-IDL</th>
<th>Unit</th>
<th>Installed Annual Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Jectofer</td>
<td>Astrafer</td>
<td>kg</td>
<td>1,500</td>
</tr>
<tr>
<td>2.</td>
<td>Iso-Sorbide Di Nitrate</td>
<td>Not Applicable</td>
<td>kg</td>
<td>500</td>
</tr>
<tr>
<td>3.</td>
<td>Terbutaline Sulphate</td>
<td>Terbutaline Sulphate</td>
<td>kg</td>
<td>100</td>
</tr>
<tr>
<td>4.</td>
<td>Prilocaine</td>
<td>Prilocaine</td>
<td>Tonne</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>Pysillium Husk</td>
<td>Not Applicable</td>
<td>Tonne</td>
<td>250</td>
</tr>
<tr>
<td>6.</td>
<td>Lignocaine</td>
<td>Xylocaine</td>
<td>kg</td>
<td>5,000</td>
</tr>
</tbody>
</table>

**NOTE:** for information on the original Astra drugs introduced to India through ASTRA-IDL, see Appendix 8.7.


#### 8.6 THE TECHNICAL DESIGN AND ECONOMIC IMPLICATIONS

In 1978, technical personnel from the two companies began to discuss the details of the new factory. Differences of opinion soon emerged and the difficulties were later compounded when actual sales figures diverged from forecasts. This led to a major reassessment of the project and the adoption of solutions radically different to those which had originally been envisaged.

Part of the reason for these different approaches by the two companies may lie in the type of factory with which each was familiar. Astra operated formulation and packaging factories in some twelve countries. Most of these were in Northern Europe and North America, with the exceptions of the long-established plants in South formulators. The decisions were communicated to IDL on 9 January, 1980 and accepted by S.V.Raman in a letter dated 16 January, 1980.
America. The most recent factory was the Gårtna plant, some 3 km from the Södertälje headquarters, which contained facilities for making about half of the tablets produced in Södertälje and space for stockpiling raw materials. Site preparation began in April, 1973, and the plant began full-scale operation at the start of 1976. The design and construction of this factory followed the latest company ideas on GMP. Great care was taken to establish hygienic conditions and to see that workers did not come into contact with product dust or solvent. An employees' organisation, which included representatives of the trades unions, was formed and consulted by the company over the work environment and job satisfaction (67). The total cost of the plant amounted to some SwKr87 million (approximately $20 million) (68).

In contrast, MIT operated only one factory. It was built before the Second World War and had not been substantially altered since that time, although more modern machinery had been added. Before the involvement of IDL, the company had not synthesised any chemicals. Those processes which had been subsequently added were not original but copied from elsewhere with minimal adaptation. Wage rates were generally low by Indian standards. Some workers' organisations had been formed, but a senior MIT technical manager, interviewed in 1981, asserted that: "[trades] unions are generally strong...affiliated to political parties and more conscious of rights than responsibilities."

(67) Astra installed a sophisticated ventilation system, which included the use of computerised monitoring of impurity levels.
(68) The Gårtna plant has an annual production capacity of a billion tablets, including the most recent Astra products, Aptin, Bricanyl and Seloken.
At the time of the early contacts between Astra and IDL, the Indian company was concerned that their European partners would react unfavourably to their factory, since many of its features would appear completely unacceptable (69). Despite this, the early reports by Astra's senior technical staff suggested that cooperation with MIT was feasible. When Astra staff had found some unacceptable elements in the MIT practices, the Indian management had readily agreed that they should be corrected. Most of the senior staff had experience in other, larger, companies and were familiar with their standards of GMP. Writing to Astra in March, 1978, MIT stated that:

"The frequent debacles in the market due to quality defects of some of our products in the past are not likely to recur in the modern plant and with the excellent manufacturing practices envisaged."

Few of the managers, however, had designed a factory of the size required for the new venture.

During 1977, MIT engaged the services of an Indian architect. With the aid of process data provided by Astra and the guidance of MIT technicians, he produced a draft design for the new factory. This was left incomplete in many ways, and included several errors, but Astra considered it both a positive indication of indigenous capabilities and a suitable basis on which to start work.

The first comprehensive exchange of views by technical personnel took place in January, 1978. A five-man team from Sweden, consisting (69) For example, the raw materials storage shed had a floor formed of ceramic tiles laid directly onto an earth floor. One of the main rooms was drained by a gully passing through a hole in the outer wall. At night this allowed cockroaches and rodents to come in. Finally, the company had found no satisfactory method of preventing ants entering the building. They had, however, stopped them climbing onto working surfaces by placing the table legs in small tins of paraffin.
a-Background data from India arrives in Sweden
b-Preliminary lay-out from Sweden arrives in India
c-Adjustment in India; new data obtained

KEY
A-Freeze programme (requirements, lay-out etc.)
B-Preliminary tender documents to Sweden
C-Scrutinized and amended documents sent to India
D-Tender documents ready (to contractors and Sweden)
E-Award contracts; construction starts

CONTRAINTS
B₂ before D₁; C₂ before E₁

Adjust for new data

Make preliminary lay-out

Civil & Sanitary document work

Swedish team to India

All other functions document work

Call tenders

Scrutinize

FIGURE 8.1 THE PROJECT TIMETABLE OF THE ASTRA-IOL FACTORY AS SEEN BY ASTRA IN FEBRUARY, 1978
SOURCE: Astra, Södertälje, November, 1980
of an architect, three production managers and an independent consultant, spent ten days in Bangalore. They visited the proposed site for the new factory, met their counterparts in the MIT organisation and reviewed their calculations. Their report criticised much of the work and it caused senior management in the two companies seriously to reconsider both the feasibility of the project as a whole and the way in which it might be carried out.

The burden of the report was that MIT had been over-optimistic. The factory they had envisaged would cost much more than they had estimated to bring it to the Astra GMP standards. The schedule proposed for the plant construction and the introduction of new products was unrealistic. Astra estimated that the cost of the project would be some 50 per cent greater than had been envisaged and that the timetable would also have to be extended by 50 per cent.

These comments were sent to MIT in February of that year, together with a revised timetable (70). In March, 1978, MIT replied, explaining that they had decided to make a fresh technical and economic appraisal evaluation of the project over a period of eight years (71).

IDL now calculated that the project would need a total of some Rs50 million in the initial period. This would comprise:

(70) The latter listed both the timing of important milestones in the project implementation and matters which had to be agreed between the two parties. It is illustrated in Figure 8.1.
(71) This was a somewhat longer period than the earlier forecasts had considered and would give: "sufficient time for the project to become viable after gestation".
Rs36 million - Fixed Capital  
Rs 6 million - Working Capital  
Rs 8 million - Accumulated Losses  

Rs50 million - Total  

They assumed a debt/equity mix of 2 to 3 and, on that basis, the project required equity of some Rs30 million, compared to the Rs20 million estimated in 1977. This meant that Astra's investment, at 25.75 per cent of the equity, would be Rs7.7 million, against the earlier figure of Rs5.2 million.

Varadarajan was reported to be unsure whether the public would now subscribe sufficiently to meet the increased level of public shareholding. MIT explained in their letter that:

"It was, therefore, decided that we should simultaneously attempt an exercise of cutting down the investment to a smaller figure, if necessary by extending the product introductions and market entries to a longer period. This may mean a smaller facility for a start at [the new site]; we may expand after five years when the cash flow commences."

MIT had also re-examined the commercial potential of the Astra drugs which they were hoping to introduce. One of these was Jectofer, which had been included in the application, to the Indian Government, for an Industrial Licence. They now concluded that the level of sales expected did not justify introducing this product. However:

"...for strategic reasons, we decided to keep the product in our Industrial Licence application and push it vigorously. After we get the Industrial Licence for this product, we can review Jectofer afresh, based both on the inputs of indigenous sales and profits as well as indications from you on the possible export potential and forecast for the same."

This change in thinking was not mentioned at the Screening Committee
meeting, held three months later, and the Industrial Licence which was subsequently granted included permission to manufacture jactofer.

The position of psyllium husk was also reviewed. This project had a dual aim. Firstly, the part-processed product might be supplied to Astra at a lower price than they had previously paid. Secondly, Astra-IDL could export material, thereby earning foreign exchange. The original calculations had shown that Astra would benefit if the joint venture could deliver the processed husk at a price below Rs40 per kg. Preliminary design and costing of a plant indicated that this could be achieved for Rs36.10 per kg. However, a senior MIT technician, who visited the psyllium processing plant of a third party whilst visiting Astra, suggested some necessary modifications to the MIT design, which resulted in the estimated cost of production and delivery rising to Rs41.60 per kg. The viability of the project now rested on the ability of Astra-IDL to have the activity described in a different way by the Government of India. If they could persuade the authorities that they were exporting "drugs and pharmaceuticals", rather than "psyllium", they would qualify for a substantial 'export incentive'. The value of this bonus would result in a net gain of Rs7.75 per kg compared to a loss of Rs1.60 per kg without the Government bonus (72).

(72) There were many elements in the project which could not be calculated exactly. In addition to the export incentive bonus, these included the cost of the raw husk, the fluctuation in the exchange rate between the Swedish kronor and Indian rupee, the flexibility which Astra could allow on the price of the intermediate and the success of technical development work carried out in India. Despite these uncertainties, MIT concluded that the project was too important to the whole programme to be omitted. The position of the psyllium husk was discussed again in April, 1978. IDL revealed that they had purchased a large tract of land at Bhiwandi near Bombay, where they intended to set up a factory for explosives manufacture, and suggested that Astra-IDL might lease part of the site for psyllium processing. This would remove the need of transporting some 100 to 200 tonnes per year of husk from
Hellström returned to India in April, 1978, and met Varadarajan. They confirmed the new investment levels required and Varadarajan indicated that he was now confident that Rs15 million could be raised by public issue. The senior Astra technical staff had, meanwhile, considered what should be their role in the project design and implementation. It was decided that IDL should, as far as possible, do this themselves. This was partly in recognition of their ability and, particularly, their knowledge of Indian conditions. At the same time, Astra did not wish to become too heavily involved in detailed work which they could do less efficiently at such a distance.

Astra and IDL decided to adopt labour-intensive techniques wherever feasible. Capital was scarce and people would be employed where this did not compromise hygiene or safety standards. This was considered an adequate guideline for specifying the new machinery and no detailed calculations were made to compare different labour and capital mixes. Rather, the companies agreed on the sort of equipment acceptable and, from that, estimated their labour requirements.

Whilst willing that the detailed calculations should be made in India, Astra staff reserved the right to influence the decisions. This was particularly important as the "Astra" name was to be used as a symbol of good quality in marketing, both in India and overseas. One Astra production manager was given responsibility for the formulation facilities and those items of infrastructure, such as utilities, which affected the whole site. Another was responsible for Bombay to Bangalore and back, and would improve the economics of the project considerably. By the beginning of 1982, IDL was still seeking final Government approval for their explosives manufacture at Bhiwandi (Economic and Political Weekly, 29 January, 1982, p.10). The psyllium plant had, also, not been constructed by that date.
overseeing the design of the synthesis plant. They devised a classification system to indicate the extent to which they wanted to be involved in various aspects of the design:

Class A questions - in which Astra desired to participate to influence the material on which to base a decision and, also, to participate in the decision as such.

Class B questions - for which Astra was prepared to give advice but the decisions were to be taken by the project team in India. The advice could be spontaneous, or when requested, and MIT could add items to Class B.

Class C questions - items where Astra did not wish to be involved.

Whenever possible, Astra would also be consulted on the recruitment of key personnel (73).

As an example of the contents of these lists, it was considered to be a class A matter that: "The fluidised bed dryer should be placed close to an outside wall (risk for dust explosion)" whilst class B included: "Fluidised bed dryer - the filters for exhaust air will crack sooner or later. If it is not acceptable to have the product out in the air [sic] a filter could be included in the duct and, in connection with that, an explosion membrane." (74)

The senior Indian project manager visited Sweden in June, 1978,

(73) Although there was no definite agreement that Astra should approve each appointment, interviews were usually held when Swedish managers visited India. For example, the Quality Assurance manager was appointed when the Astra specialist was in India. The two men were able to discuss their respective responsibilities and the standards which Astra expected.

and the two teams took the opportunity to discuss their design philosophy (75). Most of the Astra products were to be produced according to the latest GMP in the new factory, but the position of terbutaline sulphate would be reviewed. There was a possibility that this might be manufactured in the existing MIT factory if a 'quality audit' by Astra proved favourable.

In July and August, however, the direction of the project had to be changed once again. MIT sales figures were released, which revealed that their actual sales were substantially less than those forecast, and the expected cash flow was not being realised. For a time, it looked as though the project might even be cancelled, but a compromise solution was eventually adopted for the initial production requirements. The existing MIT factory would be refurbished to allow the production of Astra products according to GMP. Any chemical synthesis required would be done in the pilot plant or in the laboratories.

This proposal had both advantages and disadvantages. It would involve the company in immediate expenditure in plant for which they would have limited use after the construction of the new factory. Technical work would be needed for the refurbishment and this would, consequently, delay the development of the new factory. Against this, the Astra products could be launched more quickly, which would result in an improved cash flow and increased marketing potential for the new company. Furthermore, manufacture in the refurbished factory would enable the company to evaluate some practical techniques about which they were unsure. The various alternatives could be evaluated

(75) This was described in an internal Astra memorandum of 21 June, 1978.
through practical experience.

The final decision to undertake the refurbishment was not made until September, 1978. In that month, an Astra Quality Assurance manager visited the MIT factory. He emphasised that much work had to be done to convert the facilities to Astra standards and provided detailed instructions on how this should be achieved. Astra was adamant that they would not have proceeded if his report had been unfavourable (76). The first product to be made was terbutaline sulphate, and it went on sale in India in the second half of 1979. At that time, Astra-IDL had not been officially formed and the drug was sold by MIT, but the package emphasised that it was manufactured with the collaboration of Astra of Sweden.

Similarly, Astra insisted that the sterile liquids production area had to be transformed for the introduction of lignocaine production. Here, the changes required were even more extensive than for tablet production. An Astra process engineer was given responsibility for the introduction of this process (77). When interviewed, in October, 1980, he described some of the features which seemed to con-

(76) Interview with Hellström, Sweden, October, 1980. The first area to be modernised was for the production of tablets. The work included gutting several rooms, improving the surfaces of the floor, wall and ceiling and installing equipment, such as air filters and laminar flow booths for hygienic production. This was completed during the first half of 1979. In June and July of that year, a pharmacist in Astra's tablet production department spent nearly a month supervising the introduction of terbutaline sulphate production, which was achieved relatively smoothly. Some modifications were required. For example, the relative humidity in Bangalore is much higher than in Sweden. This makes it more difficult to form a tablet which does not crumble. Astra and MIT adopted the solution of partially drying the air supply to the process room.

(77) He made three trips to India, in October, 1979 and March and September, 1980. On the latter two occasions he spent two to three weeks supervising the production.
most strongly with practice in Sweden. The climatic conditions were very different; the relative humidity was high but whereas this affected tablet production, it had little affect on the liquid lignocaine formulation. However, the humidity created what he found to be an uncomfortable working environment, yet air conditioning was not to be introduced unless it was necessary for the process. The temperature was also unfavourable; at around 35°C, it was ideal for the growth of harmful micro-organisms. The water supply system had to be sterilised daily, whereas this was done only monthly in Sweden. The batch size was smaller, being only about one-tenth of that used in Sweden (78). The operations were much more labour-intensive but he did not consider that this, in itself, led to any significant deterioration in quality.

This engineer reported his experiences with a semi-automatic vial stoppering process, in order to highlight the relative inexperience of Astra in manufacturing in LDCs. Astra in Sweden had abandoned semi-automatic stoppering for a fully-automated process some ten years previously. Nevertheless, for reasons of cost and machine availability, they used the semi-automatic method in the MIT factory. It was soon found that some of the techniques required, whilst not in themselves difficult, were contrary to current Astra practice. Fortunately, the Astra engineer remembered the methods used in Sweden during the 1960s and the process was successfully introduced. If Astra had been active elsewhere in LDCs, the semi-automatic techniques would have been more familiar.

All formulation processes were eventually to be automated to a

(78) This resulted from the equipment available in the MIT factory and it was planned to use a larger size in the new plant.
level only slightly below that in Sweden, whereas proportionately more people were employed in packaging operations. This sometimes resulted in a label being misaligned on its box, where a machine would have centred it, but the product itself would be medically comparable. Similarly, the packaging material was of an inferior quality to that used in Sweden, but was still acceptable to Astra.

At the same time as the two Astra products were being introduced in the refurbished factory, the MIT personnel prepared the tender documents for the construction of the new factory. The communication between the two companies had followed the patterns indicated in the timetable drawn up in February, 1978 (79), but the schedule fell behind the dates indicated there (80).

As well as the many details to be calculated, the design also had to take account of the location of the factory. Two aspects were particularly important; it was to be outside the important Bombay region and it was also to be built some 20 km away from the centre of Bangalore.

Bangalore offered several advantages. It is situated some 900m above sea level and the climate compares favourably to that in Bombay for pharmaceutical production. It was a growing industrial town and had, in contrast to Bombay, power, land, housing and transport available relatively cheaply. The labour unions were less active than in Bombay. Location in Bombay would have offered different advantages.

It is the centre of the pharmaceutical industry and it is a port. In

(79) See Figure 8.1.
(80) For example, the senior MIT project engineer visited Sweden in June, 1978, but the contract was not actually awarded until March, 1979.
Bangalore, imports cannot be arranged so easily and communication with other large companies and with OPPI is less immediate (81). Although these factors had a bearing on the overall feasibility of the project, there was, however, no real question but that the new factory would be built in, or near, Bangalore. The decision had already been made, effectively, some forty years ago when Mysore State built MIT in Bangalore and it would have been too great an upheaval to establish the plant elsewhere.

By selecting Bangalore, the company had more flexibility in the choice of the site for the new factory. The land which they eventually bought was one of the few large expanses available owned by a single landlord. It had several attractive natural features, such as a gentle slope to aid drainage and easy access to an adequate water supply. Planning permission was readily obtained as both the local Government and the influential local residents were keen to encourage industry. The factory would be situated some 20km from the centre of Bangalore, near enough to obtain the services of specialist tradesmen.

When the companies began the detailed design of the plant, it was evident that it would not be completely straightforward. In their own plants, Astra had developed a hygiene classification system, by which all areas of the formulation factory were placed in one of four classes, according to the type of activity (82). Astra attempted to introduce this system into the new factory, but it was

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(81) Raman, the MIT Chief Executive, made special trips to attend OPPI meetings twice yearly. On other occasions, he visited Bombay on business matters and took the opportunity to attend OPPI meetings then. Interview, Bangalore, June, 1981.

(82) The hygiene class determined such factors as the standard of decoration, who could have access under what circumstances, and the clothing to be worn.
soon found that this could not be achieved without modifications as some of the materials of construction were not available (83).

The companies also found that some components were not available for the production of a terbutaline sulphate preparation. This formulation is used with an inhaler to treat asthmatic conditions and the inhaler valves are a specialist item not made in India. The company could apply for a licence to import these from the United Kingdom but the amounts which Astra-IDL required (84) would result in a prohibitively high unit cost. By 1981, the company had not reached a definite decision about this preparation.

The unavailability of some materials also made the design of the chemical syntheses difficult. One important raw material in the preparation of lignocaine is meta-xylidine. This is a noxious material which resembles aniline in its toxic effects, and it has relatively little use elsewhere in the chemical industry. When Astra first produced lignocaine in the 1940s, they had found difficulties in obtaining sufficient supplies of this material and they now found the same problem in India. The production method used in the refurbished plant made it necessary to purify the meta-xylidine, but it was hoped that the larger quantities used in the new plant would be sufficient to induce a supplier to offer a better quality. By 1981, this had not been the case and a purification step had to be included. Similarly, one of the solvents used by Astra was not

(83) For example, Astra in Sweden used PVC to coat the walls and floors in the areas where the hygiene requirements were most strict. This provided an unbroken surface which was easy to clean. However, PVC could not be obtained easily in India. A compromise solution was derived whereby the walls were plastered and then coated with epoxy paint.

(84) The company expected to produce about 20,000 inhalers per year.
readily available and the new plant had to be designed to use a substitute (85).

It was also necessary to install equipment to provide services for the new factory. The electricity supply, taken from the main high tension line to a local aerodrome, was based on a 750 kVA load at the site of the new company (86). In practice, Astra-IDL found it necessary to install a standby generator to ensure reliable power for the chemical synthesis and formulation factories. The existing MIT factory was on the outskirts of the city and had a reliable source of towns water. This service did not extend to the new site, where water was obtained by sinking several wells (87). Steam was to be raised by means of a coal-fired boiler; the old MIT factory used oil, but coal was more economical for the steam load envisaged here. Nitrogen and compressed air were also required. The utility provisions for the two sites are summarised in Table 8.4 The Indian Government required that Indian equipment should be bought whenever possible. Astra technical staff reported that this resulted in the use of machinery which, in their view, had a relatively poor finish but which seemed to have an adequate performance (88). The design also involved some changes from the standards of operator safety and comfort expected in Northern Europe. The following examples

(85) The change of solvent meant that some evaluative work had to be performed by scientists in Sweden. Some further details of the lignocaine and terbutaline sulphate syntheses are included in Appendix 8.4.
(86) This has several advantages. Firstly, voltage fluctuations are less common than in the low tension lines. Secondly, power cuts are less frequent in high tension sources and usually some warning is given by the authorities.
(87) Although the company had not made extensive attempts to determine the reliability of the supply, the Technical Manager reported in 1981 that it seemed adequate. Interview, Bangalore, June, 1981.
(88) Interview, Sweden, October, 1981.
A Comparison of the Utilities at the MIT and Astra-IDL factories, Bangalore.

<table>
<thead>
<tr>
<th>UTILITY</th>
<th>MIT Site (old Factory)</th>
<th>ASTRA-IDL Site (new Factory)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td>Towns water available up to 25 m³/day. Cost Rs1.68/m³ up to 100 m³, then Rs2.50/m³.</td>
<td>Taken from wells using two pumps. Up to 400 m³/day. Tax between 0.75 - 2.5 paisa per m³ (depending on use to which water is put). Payable to local authority.</td>
</tr>
<tr>
<td>ELECTRICITY</td>
<td>Low Tension Supply. No restriction. Cost Rs0.445/kWh.</td>
<td>H.T. Supply. Rs0.27/kWh plus charge of Rs16,500 per month for 750 KVA supply.</td>
</tr>
<tr>
<td>STEAM</td>
<td>Oil-fired boiler. 1,000 kg/hr at 10 bar.</td>
<td>Coal-fired boiler. 3,000 kg/hr at 10 bar.</td>
</tr>
<tr>
<td>NITROGEN</td>
<td>7 cylinders, each of 0.2 m³ of nitrogen at 150 bar.</td>
<td>14 such cylinders.</td>
</tr>
<tr>
<td>COMPRESSED AIR</td>
<td>17m³/hr available.</td>
<td>60m³/hr available.</td>
</tr>
</tbody>
</table>

SOURCE: MIT, July, 1981

illustrate this:

(i) Mechanical handling in the synthesis plant was minimised. Drums and sacks of raw materials were to be manhandled and poured into reactor vessels through the manholes.

(ii) Control systems in the synthesis plant were somewhat rudimentary. For example, the automatic monitoring of vessels was minimised and no remotely operated valves were installed. Control systems were pneumatic rather than electronic.

(iii) Air-conditioning is a particularly expensive item. It was decided to limit air-conditioning to those rooms in the formulation factory where the process required low humidity or cool air. In other rooms, the workers would have only fans.

(iv) Wages were to be very different from those paid in Sweden.
Table 8.5 shows the rates in the MIT factory during July, 1981 and these were to be the basis for the new factory.

### TABLE 8.5
Wages Paid at the MIT Factory in Bangalore; 1981

<table>
<thead>
<tr>
<th>Function</th>
<th>Wage (Rs/Month)</th>
<th>Approx. Equivalent ($/month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine Operator</td>
<td>700</td>
<td>81</td>
</tr>
<tr>
<td>Graduate Engineer (2 years exp.)</td>
<td>1,500</td>
<td>170</td>
</tr>
<tr>
<td>Graduate Engineer (10 years exp.)</td>
<td>3,000</td>
<td>350</td>
</tr>
<tr>
<td>Stenographer</td>
<td>1,000</td>
<td>120</td>
</tr>
<tr>
<td>Assistant Chemist</td>
<td>850</td>
<td>98</td>
</tr>
<tr>
<td>Senior Chemist</td>
<td>1,200</td>
<td>140</td>
</tr>
<tr>
<td>Marketing Representative (Field Staff)</td>
<td>900</td>
<td>100</td>
</tr>
</tbody>
</table>

**SOURCE: MIT July, 1981**

The employment levels for the new factory were also estimated in this period (89). Table 8.6 shows the employment levels in the MIT factory in 1981 (90), and the levels expected in the new factory, (a) estimated by the senior Swedish technician in February, 1979 and, (b) calculated by an Indian engineer in 1981, less than a year before production was due to start (91).

By the end of 1978, the basic design of the new factory was (89) Although, with sales and, therefore, the future of the joint venture being somewhat uncertain, it was not possible to calculate these exactly.
(90) They had changed relatively little in the previous five years.
(91) The last set of figures is for the first phase of production at the new site and envisages expansion as further processes are added.
TABLE 8.6
Employment in the MIT factory, July, 1981, and the estimated levels of employment in the new Astra-IDL factory

<table>
<thead>
<tr>
<th></th>
<th>(a)</th>
<th>(b)</th>
<th>(c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance</td>
<td>5</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Quality Control</td>
<td>12</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Formulation Production</td>
<td>90</td>
<td>21</td>
<td>117</td>
</tr>
<tr>
<td>Formulation Development</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Chemical Production</td>
<td>7</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Stores</td>
<td>9</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Purchasing</td>
<td>*</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Security, Transport, Gardeners etc.</td>
<td>*</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>126</td>
<td>82</td>
<td>193</td>
</tr>
</tbody>
</table>

NOTE: (a) - Estimated early 1979 by a Swedish technician for the whole factory.
(b) - Estimated mid-1981 by an Indian technician for the first stage of operations.
(c) - Actual levels in the MIT factory, July, 1981.
* - Not estimated

SOURCE: (a) - Astra, October, 1980
(b) - MIT, July, 1981
(c) - MIT, July, 1981

complete and agreed by the two companies. Bids were invited from contractors for the construction of the factory. Whereas the joint venture had previously relied on the local knowledge of MIT and IDL, it was now the international experience of Astra which came to the fore. The technical managers realised that it was important that their Indian counterparts should not only have the Astra GMP requirements in writing, but should also see some other modern factories in India. They contacted some of the large TNCs in Bombay and were able to arrange visits to two factories belonging to French and Swiss com-
panies (92). The contract for the construction of the chemical plant was eventually awarded to Tata Consulting Engineers, based in Bombay (93).

The foundation stone was laid in April, 1979 (94). By October of that year, work had begun to clear the site, the civil construction being sub-contracted to another Bombay company, Pheroze Kudianwala. Astra had no control over the construction methods, which were very labour-intensive, according to the general Indian habit. For example, no cranes were used, and the large items were erected by means of ropes, pulleys, bamboo scaffolding and human effort. Families camped on the site during the construction and all members provided labour. Men were paid Rs8 per day (around $1) and women Rs6 (75 cents). Children on the site were expected to work, although this was nominally illegal and, officially, they were not paid (95).

(92) The visit to the French company was reported to be particularly valuable. Their factory had been built only a few years previously and it was admired by the Astra personnel. Astra were able to contact the architect, and he subsequently designed the Astra-IDL factory.
(93) They are a very large company, part of the huge Tata group, which has interests in most heavy manufacturing and construction sectors. IDL/MIT knew of their excellent reputation, but the Astra technicians were concerned that the company did not have sufficient experience in constructing pharmaceutical manufacturing factories. The MIT personnel might need to spend unnecessary time checking details and discussing the design with Tata. However, Astra did not know any other consultant and accepted the advice of their partners.
(94) Astra being represented by Hellström and a member of the Astra board.
(95) Towards the end of 1979 the project suffered a minor setback against which it had been practically impossible to guard. MIT had selected a chemical engineer to be in charge of the design of the chemical synthesis plant. He had established a good understanding with Astra personnel and, at the end of 1977, travelled to Sweden to meet them and discuss the design. IDL had inserted a term in his contract that he should not leave the company within two years of any foreign travel. Exactly two years later he left. In the event, his work was continued by other MIT engineers with his Swedish counterpart clearing up uncertainties through written communications. The Astra chemical engineer had returned to India shortly before his Indian colleague left the company. They had,
Construction on the new site continued throughout 1980 and 1981 and production began early in 1982. The factory was officially opened on 15 February, 1982 by the Prime Minister of Sweden. The Chief Guest at the ceremony was Govind Narain, the Governor of Karnataka, with Gundu Rao, the State's Chief Minister, also being present.

During the latter stages of construction, the company had taken further decisions about the role of the new plant. The first phase of operation would involve bulk production of a few MIT products and the Astra drugs, terbutaline sulphate and lignocaine. Formulation would be restricted to the production of vials of injectable lignocaine. Once production was fully established, the old MIT factory would be closed. Formulation of the other drugs would be contracted out to other manufacturers in the region (96).

The capital cost of the first phase was some Rs31.5 million. This sum was raised by the equity capital of the two partners and by loans from State financial institutions, made at preferential rates. Further details are shown in Table 8.7

It had also been necessary to train the people who would operate the new factory. Some of the existing MIT employees had been with the company for many years. As they had become used to the standards of the old factory, it was thought unlikely that they would be successfully converted to the GMP requirements in the new factory. On the other hand, some workers were expected to adapt without undue

again, visited the factories of other large companies in Bombay. On this occasion they were accompanied by personnel from Tata, who found the visit instructive. Interview, Astra chemical engineer, October, 1980.

(96) Astra-IDL was able to do this as it counted as an 'Indian' company. Further expansion of the new factory would include the installation of facilities for other dosage forms.
### TABLE 8.7
Sources of Finance for the First Phase of the Astra–IDL project.
(Rs millions)

<table>
<thead>
<tr>
<th>Source</th>
<th>Amount (Rs millions)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. EQUITY CAPITAL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Astra</td>
<td>5.15</td>
<td>25.75%</td>
</tr>
<tr>
<td>IDL</td>
<td>5.15</td>
<td>25.75%</td>
</tr>
<tr>
<td>Public</td>
<td>9.70</td>
<td>48.50%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>20.00</td>
<td>100</td>
</tr>
<tr>
<td><strong>2. LOANS FROM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Astra and IDL (a)</td>
<td>2.57</td>
<td></td>
</tr>
<tr>
<td>KSFC (b)</td>
<td>3.00</td>
<td></td>
</tr>
<tr>
<td>KSIIDC (c)</td>
<td>6.00</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>11.57</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>31.57</td>
<td></td>
</tr>
</tbody>
</table>

**NOTES:**
(a) Interest-free loans (later converted to Equity Capital)
(b) Karnataka State Financial Corporation
(c) Karnataka State Industrial Investment Development Corporation.

**SOURCE:** MIT July, 1981.

difficulty. Even so, the company did not know whether the Government's labour laws would allow the company to select the staff for the new factory using such criteria (97).

An extensive training programme was introduced. The components of this were suggested by Astra and the details determined by MIT. Workers were divided into three classes, depending on their ability to understand English and to read and write a local language. Those who appeared best suited to understand the GMP requirements were

(97) Interview with S.V. Raman, July, 1981. Despite the claims that the new factory would provide more employment, initial levels would be lower. Jobs would be lost, at least until the new factory was extended.
trained for production by MIT staff and a lecturer from the Indian Institute of Science, a well-respected academic institution located in Bangalore. Some further details of the training programme are included in Appendix 8.5

During the construction of the new factory, the two companies completed the legal formalities. The company 'Astra-IDL' was incorporated under the Companies Act of 1956 on the 11 July, 1979, and it was given a licence to commence business on 6 November that same year (98).

The formal agreement between the two companies was signed on the 8 May, 1980. This document formally registered the financial and technical aspects of the project which had been previously discussed between the two companies and with the Government. The provisions included:

(i) The initial share capital would be Rs200,000.
(ii) Astra-IDL would have the right to export Astra products to all countries except where Astra already manufactured.
(iii) Astra would communicate new technical information on their products as it became known.
(iv) Astra-IDL would pay Astra a lump sum of Rs500,000 for all technical information. Astra would send "competent personnel" to assist in the implementation of such information and the expenses of these people would be met by Astra-IDL.
(v) The Astra products should be manufactured, as far as possible, with Indian raw material. Astra would assist in the

(98) Both of these matters were handled by the Registrar of Companies for the State of Karnataka.
analysis and assessment of such raw material and in the selection and purchase of equipment.
(vi) Astra had the right to send "duly authorised agents or employees" to inspect the working methods of Astra-IDL. Similarly, Astra-IDL could refer problems to Astra and send samples of the products twice a year. Astra could then "advise the company...and make suggestions."
(vii) Astra would be paid a royalty of 3 per cent on the newly-introduced bulk drugs (99). The rate would be 4 per cent for exported bulk drugs. Royalty payments would be subject to Indian tax.
(viii) Technical information passed between the two companies should be kept secret. However, Astra-IDL might sub-licence the information to: "another Indian Party should it become necessary. The terms of such sub-licence will, however, be such as are mutually agreed upon..."
(ix) "The agreement shall remain in force for a period of eight years, unless terminated prior thereto..." (100).

8.7 MARKETING METHODS OF ASTRA-IDL

Whilst the factory was being designed, the marketing executives of the two companies began to develop their strategy. They soon found that the promotional methods in Sweden and India were

(99) These were Astrafer (which used a new process to make jectofer), terbutaline sulphate and Prilocaine.
(100) A wide range of smaller, local authorities had to be contacted for various reasons. These included the State Industrial Areas Development Board, The Controller of Cement and the authorities of the local aerodrome (the nearest neighbours). Whilst such matters frequently consumed much time and paper, they all proceeded smoothly and did not alter the direction of the project. Further details of these authorities are included in Appendix 8.6.
substantially similar. MIT used Medical Service Representatives (MSRs) to promote their sales in two ways. Medical doctors were approached, as in the West, with literature, free samples and through personal consultations. The MSRs were expected to see each doctor in their territory about once per month. The retail outlets were also monitored to check that they were well stocked with MIT products. Some indigenous practitioners used allopathic drugs and MIT representatives found them to be valuable customers for tonics and multivitamin preparations. They did not, however, regard such contacts as a major part of their activity (101).

At the time of the first contacts with Astra, MIT had not developed a comprehensive distribution network. In particular, they did not employ their own distributors, but relied on outside companies, and they had only one depot, which was located in Bangalore. By 1981, the company had started to establish a more complete system, including four regional depots, in addition to the depot in Bangalore (102). Stocks were transported from the depots to 250 Associated Warehouses (AWs) and thence to the retail outlets. This involved the company in a higher direct cost but was expected to be cheaper and more cost-effective than using independent distributors. Table 8.8 illustrates the two methods of distribution and the costs involved.

The Astra involvement did not introduce any material change to these methods of promotion and distribution and the new joint venture

(101) By 1981, the field staff comprised some 135 MSRs, supported by 25 Area Sales Executives and 8 Area Sales Managers. The Head Office included a staff of 20 marketing personnel. Hence, a total of nearly 190 employees were directly involved in marketing activities. Interview, MIT Marketing Manager, Bangalore, July, 1981.
(102) These were located in Hyderabad, Calcutta, Delhi and Gharibbad (in the State of Uttar Pradesh).
TABLE 8.8
Methods and costs of distributing MIT products; 1976 and 1981

<table>
<thead>
<tr>
<th>Distribution Chain</th>
<th>Cost (b)</th>
<th>Distribution Chain</th>
<th>Cost (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished Product Store</td>
<td></td>
<td>Finished Product Store</td>
<td></td>
</tr>
<tr>
<td>Depot (Bangalore)</td>
<td>3</td>
<td>Regional Depots</td>
<td>5</td>
</tr>
<tr>
<td>Distributors</td>
<td>8</td>
<td>Stockist</td>
<td>5</td>
</tr>
<tr>
<td>Stockist</td>
<td>5</td>
<td>Chemist (a)</td>
<td>12</td>
</tr>
<tr>
<td>Chemist (a)</td>
<td>12</td>
<td>Consumer</td>
<td></td>
</tr>
<tr>
<td>Consumer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost to MIT</td>
<td>28%</td>
<td>Total Cost to Astra-IDL</td>
<td>22%</td>
</tr>
</tbody>
</table>

NOTE: (a) The 12% paid to the chemist is statutory. (b) Cost expressed as a percentage of sales.

SOURCE: MIT 1976 (Reply to Astra Questionnaire)

raised the enthusiasm of the marketing staff. Most of the TNCs in India had stopped the introduction of new products in the late 1970s and, in consequence, their medical representatives found it difficult to gain the attention of doctors. MIT, on the other hand, could point to the new Astra products which would soon be on the market and emphasise the international collaboration, which implied an improved quality in their own drugs (103).

The image of the product was very important to both Astra and to

(103) On the whole, MIT did not advertise in the popular press, as they did not have many OTC products. An exception to this was made in 1979 when the Astra product, terbutaline sulphate, was launched. Advertisements were placed in the leading English-language daily newspapers proclaiming that Astra and IDL were collaborating in India. It stated that a new product to combat Asthma had been introduced. Readers were advised to contact their doctors to find out more details.
the new joint venture. Astra-IDL was relying on export sales to balance their foreign exchange flows and enable them to import bulk drugs. Indian manufacturers frequently found difficulty in establishing the quality of their goods and the new company hoped that it could overcome this difficulty by emphasising the part played by Astra. In return, Astra would need to ensure that the quality of the product met their standards. Should a poor quality product become associated with their name, it might affect Astra sales elsewhere.

When terbutaline sulphate was introduced by MIT, the relevant Astra Product Manager visited India. He discussed the methods by which it was to be promoted, and explained the various promotional leaflets compiled by Astra in Sweden. This type of visit was repeated by the Astra Anaesthetics Product Manager when lignocaine was launched some months later.

Once the products had been launched, Astra continued to give marketing support in the same ways as to their subsidiaries. Literature in English is now sent out regularly and staff in Södertälje also respond to special requests. Special visits, about once every six months, are made by the Astra marketing managers and visits to the Far East are arranged to include Astra-IDL with the Astra subsidiaries in that region (104).

(104) When interviewed in October, 1980, an Astra marketing executive suggested that there were two areas in which Astra's international experience might aid the commercial success of Astra-IDL products. Firstly, the methods of stock ordering and distribution might be improved. Secondly, it might be possible directly to influence clinical usage of their products. For example, medical representatives could suggest new ways of using lignocaine, and seminars and conferences might also be arranged.
8.8 THE FUTURE OF ASTRA-IDL

The above account covers the period up to 1982, when production started at the new factory. It is impossible, therefore, to do more than indicate directions in which the joint venture might move. Interviews held in October, 1980, with Hellström and in July, 1981, with Raman, both indicated that any expansion of Astra-IDL should be self-financing and much will depend on the sales income generated (105).

The first phase of production at the new factory involved chemical synthesis and the formulation of lignocaine parenterals. All other dosage forms were still manufactured on the old refurbished premises and by some local Small-Scale companies under licence. One possible area of expansion is, therefore, the introduction of equipment to make other dosage forms.

Secondly, the company hoped to extend the geographical area in which its products are sold. In India, it was intended to establish a depot and marketing organisation to cover the north-eastern states. Efforts would also be made to develop the export sales of both the MIT and Astra line of drugs.

Thirdly, new products may be introduced, including more Astra products, as well as other new drugs. For example, plans had been made to introduce Astra's combination drug, 'Triglobe', (containing trimethoprim and sulphadiamine) in 1982 and the selective beta-blocker, 'Metoprolol', in 1983 (106).

(105) The very early signs were encouraging. A loss of Rs10 million during the initial period had been sanctioned but the actual deficit was only a quarter of that figure. Interview with Raman and Hellström, Sweden, August, 1980.
(106) By June, 1983, the Indian authorities had not allowed the
Being an 'Indian' company, Astra-IDL is not required by the Government to undertake research. Nevertheless, this possibility has been considered, and may feature in the future activities of the company. Astra-IDL regarded itself as too small to undertake fundamental research and instead it expected to explore new methods of synthesising and formulating existing products. Fundamental research may be performed in existing state institutions with Astra-IDL finance (107).

Whilst all of these possibilities might create employment, either within Astra-IDL or elsewhere, the initial employment levels were lower than they had been in MIT. In July, 1981, MIT employed a total of some 410 people, including the marketing and production departments. The initial employment in Astra-IDL totalled around 300, although plans have been made to increase this to between 400 and 450 within five years, should the volume of business expand as hoped.

8.9 DEVELOPMENTS WITHIN ASTRA, SWEDEN

During the late 1970s and early 1980s, the Astra-IDL scheme was only one of the overseas projects being pursued by Astra. Whilst the large Japanese and USA markets continued to be of primary importance, Astra had become involved in several LDCs. In 1976, it opened a sales office in Lagos, Nigeria, from which seven sales representatives operated (108). By 1979, Astra had begun to negotiate with registration of Triglobe, but Metoprolol had: "been on the market for a few months". Personal communication, Hans Hellström, June, 1983.

(107) Contacts have been made with the Indian Council for Medical Research (ICMR) and the Central Drug Research Institute (CDRI), Lucknow, with which IDL had previously collaborated.

several local companies to establish a joint venture (109).

Work had also been carried out in three Arab countries, Iraq, Kuwait and Saudi Arabia. In the first country, Astra was contacted in 1977 by a delegation from the Arab Company for Drug Industries and Medical Appliances (ACDIMA), which is jointly owned by 13 countries. A Swedish consortium of four companies was established, and it conducted a feasibility study for an antibiotics plant in Iraq (110). A similar group of three companies, again including Astra, subsequently studied the feasibility of establishing pharmaceutical factories in Kuwait and in Saudi Arabia.

Towards the end of the 1970s, Astra founded a new company to cater for this new interest in LDCs. In 1978, it established Astra Development AB, a wholly-owned subsidiary within the Astra organisation with a small staff. Employees are seconded from Astra AB to meet particular needs as they arise.

In addition to the above work in the Middle East, this company undertook a comprehensive project study in Mozambique, after that country's Ministry of Health commissioned Astra Development to advise on local pharmaceutical production. The project study was financed jointly by the authorities in Mozambique and the Swedish International Development Agency (SIDA). The report was published in May, 1980 (111). To date (1982), Astra has not become actively involved

(109) This would commence by building up a distribution system and might later introduce local production. Astra Digest, June, 1979, p5.
in any other LDCs.

The continuing work of Astra Development represents the sustained, albeit cautious, interest of the company in the commercial possibilities in such countries. It illustrates the way in which Astra has elected to meet the commercial challenge of the late 1970s when, as one senior manager had warned in 1979, the company was in danger of excluding itself from selling drugs in LDCs:

"Those who want to participate in these markets must go in now. In five years it may be too late...Astra's ultimate goal is not to sell technical know-how to the developing countries. Expertise will help it to achieve its long-range objective - to sell more of Astra's original products... Astra Development's activities should be regarded as prospecting." (112)

Astra has, at least, opened the way for greater activity in LDCs. IDL now has the potential to expand within India and overseas.

(112) Per-Olof Mårtensson, Executive Vice-President, Astra Pharmaceutical Division. Astra Digest June, 1979.
CHAPTER 9

CONCLUSIONS

The purpose of this final chapter is threefold. In the first few paragraphs there is a broad description of the findings of the study. The bulk of the chapter is then concerned with a summary of these themes, based on the eight preceding chapters, together with the conclusions which can be drawn. Finally, there is a brief section in which some possible developments in the field of pharmaceutical technology transfer are described, as well as some suggestions for future research work.

Questions about Technology Transfer

In the introduction to this study, I posed two questions about technology transfer in the pharmaceutical industry. In summary, they were: "Why does technology transfer take place?" and "What effects does it have?". In fact there are no straightforward answers to these questions. Instead, technology transfer has been found to lie in the midst of a complex system of relationships, as will be shown.

Three connected themes recur continually throughout this study. Firstly, there is a multiplicity of factors which influence the decisions made by private or state companies to establish pharmaceutical factories in less developed countries (LDCs) and which determine the effects of such investments. The investment decision itself, the range of drugs which it is decided to produce, and the techniques of manufacture, are each affected by such matters as host Government regulations, the level of industrial development, the nature of health care, demography, climate, and the experience of other
pharmaceutical companies.

The second theme is that, with the single exception of the climate, these factors are not independent, but are linked to each other, and are themselves affected by the technology transfer process. For example, the decision of a private company to manufacture drugs in a particular LDC may arise from a Government import ban, which is, itself, prompted by a shortage of foreign exchange or by the policy of drugs procurement for the state health services, or by the technical ability of indigenous pharmaceutical companies, or by a host of other possible factors. The response of the various interested parties to such an import ban will determine the potential for further strengthening or relaxing of the import regulations, or for imposing other restrictions on the practices of the private pharmaceutical companies. Thus, the relationship between these various factors is not static, but dynamic. Changes in one area may influence events elsewhere which, in turn, affect other parts of the system. Historical trends are also very important, since the ways in which, for example, industry and the health care services have developed over the years inevitably affects their current orientation and the influence they exert on technology transfer.

The third theme is that, almost without exception, the choices made by the various interested parties are not purely technical, but are based on political priorities. Thus, matters such as the industrial development strategies pursued by host Governments, the nature of the health care services, the support given to foreign and domestic private companies or state industry, and the investment strategies of the private companies, are not neutral matters, but represent political choices. Consequently, the developments arising
from technology transfer in the pharmaceutical industry, and the type of factors which influence it, reflect political relationships, both within the host country and internationally.

As will be clear, there are many matters which could be considered to influence technology transfer. An attempt has been made to illustrate some of them in Figure 9.1, together with some indications of the ways in which pressure can be exerted, both directly and indirectly. This diagram is intended to be illustrative, rather than an exhaustive list of the possibilities; similarly, it gives no indication of the relative strengths of the different influences.

The Potential Benefits of Technology Transfer

When Western pharmaceutical companies establish factories in LDCs, they affect the host country in various ways. According to the supporters of the TNCs, and the companies themselves, various benefits might accrue. The provision of good quality drugs is often stressed, and certainly the manufacturing standards of the foreign companies are usually similar to those in the West. In addition, the introduction of advanced technology, manufacturing knowledge and managerial skills are emphasised, whilst it is claimed that the factories provide employment opportunities and stimulate domestic enterprise. It might seem that the pharmaceutical TNCs would be eager to transfer technology since, historically, they have usually been able to operate overseas factories on profitable terms. However, the volume of sales in most LDCs is not great, when compared to the turnover of the majority of TNCs and there are also various disadvantages involved in overseas manufacture.
A SCHEMATIC REPRESENTATION OF SOME OF THE FACTORS WHICH INFLUENCE TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL INDUSTRY

FIGURE 9.1

SOURCE: Original
It was clear from the case studies made of Ciba-Geigy and Astra, and from the interviews carried out with many other pharmaceutical TNCs that, in the last twenty or so years, the company ideal has been to centralise production in the home country and to export the drugs to LDCs. This is especially true for the chemical production of bulk drugs, but it also applies to the formulation of this material into dosage forms, although companies might prefer to operate three or four such units. Various reasons were given to support this preference. Cost ranked highly, since drugs are high in value, but low in bulk, so that it is cheaper to reap the economies of scale and export the products of a single large production unit. However, control was also important, and not just to monitor the quality of the drugs (although this problem is not negligible). TNCs indicated that it was important to them to exercise control over how their drugs were made, which of the drugs were sold in a particular country, the prices charged and the number of people who had access to the company's secret information on the manufacture of the drugs and their therapeutic performance. The pharmaceutical industry is notably international, in that practically the same drug can be sold throughout the world with minimal adaptations. Companies plan their strategy on a global basis and are anxious lest, for example, the price they are seen to charge in one country affects the price they are allowed to charge in another, or in case the adverse performance of the drug in one place influences sales worldwide. One straightforward illustration of the desire to control technical matters is provided by the Astra-IDL joint venture, where the Swedish company drew up a list of technical matters which it designated 'A', 'B' or 'C'. Those marked 'A' indicated that Astra reserved the right to dictate the design of certain key areas in the new plant (this is
The Role of LDC Governments in Enforcing Technology Transfer

However, this centralised pattern of drug production is not universally adopted. In practice, pharmaceutical plants are built overseas, both in industrially developed countries and in LDCs. Almost all the private companies interviewed indicated that host Government regulations were primarily responsible for this. Import restrictions have been by far the most common way of effecting technology transfer; the Governments of both India and Indonesia prohibit the import of finished pharmaceuticals, and in India it is very difficult to obtain permission to bring bulk drugs into the country. In addition to complete bans, such as these, restrictions merely on the level of imports allowed have also resulted in local manufacture. The Ciba-Geigy plant at Bhandup, Bombay, was built to enable the company to sell a larger volume of its drugs in India (Section 7.3.1).

In some cases, then, technology transfer can be seen as a preemptive move. Companies build factories overseas to prepare for the time when the host Government will impose a ban on the importation of finished products, and when local production will be required if the company is to continue to sell its drugs. On the other hand, not every country has the potential to prohibit imports successfully. The Government may face no formal barriers to this (except amongst economic communities, such as the EEC, ASEAN and the like). However, the size of the pharmaceutical market determines whether an import ban might be feasible. If the potential for sales does not seem particularly high, then a TNC faced with import restrictions might simply withdraw from that country, rather than accept the cost and
inconvenience of local manufacture. In both India and Indonesia, the potential market is sufficiently large for many TNCs to accept the various costs of producing drugs overseas.

Linked to this is the question of Government stability, since a large company might be unwilling to commit resources of time and money to building a factory overseas, unless it is likely to be able to sell its products over the period necessary to recover its outlay. Consequently, Western companies may have an interest in supporting LDC Governments whose policies seem favourable to them, whilst opposing those which impose unfavourable regulations. This is illustrated by the reactions of the various industry sectors to the reforms carried out by the Governments of Sri Lanka and Bangladesh, described in Section 2.2.3.

The broad attitudes held by pharmaceutical TNCs towards technology transfer are described in Chapter 2, whilst Chapters 4 and 5 concentrate on some of the events in India and Indonesia. Chapters 7 and 8 contain more detailed studies of technology transfer by Ciba-Geigy and by Astra, in association with IDL of India. It is clear from these accounts that there are various technical problems for TNCs to overcome and that the unit cost of pharmaceutical production in most LDCs is greater than in the West. The climate is of relatively little significance, although the temperature and humidity can enforce process changes or the installation of more expensive equipment. Much more important is the level of industrial development, which manifests itself in the availability and quality of raw materials, equipment, labour and services, such as public utilities and equipment repair. On the whole, the production methods selected were somewhat more labour-intensive than in the West, but labour costs
remained a relatively low proportion of total production costs.

Linked to this last point is the question of employment created by technology transfer in the pharmaceutical industry. Private companies in India, in particular, have stressed the number of jobs which their new factories are likely to create, but the actual results are not encouraging. It would seem that the number of jobs created per unit of capital expenditure is unusually low, when compared to other industries, and the linkages which the pharmaceutical industry has with other sectors are too weak to stimulate significant employment elsewhere. Indeed, in India, where imports are restricted to a minimum, it is difficult to see why the establishment of new factories, which essentially take business from others, should create any employment. In fact, it is more likely that the labour input per unit of production will decline as production processes become more cost-efficient.

The Problems faced by pharmaceutical companies which manufacture drugs in LDCs

The main financial concern expressed by the TNCs was that they were being required to invest capital in fixed assets. Once factories have been established, the company has a commitment to attempt to recover the expenditure, and must face the changing environment in the host country. Given the more stringent regulations in many LDCs over the last decade or so, coupled with the conflicts in such countries as Iran and the Lebanon, TNCs now appear less willing to commit funds to overseas factories. At the same time, many, like Ciba-Geigy, have adopted careful planning methods in order to estimate more accurately the potential for overseas investment (Section 7.5).
On the other hand, it is not clear why the Government of any LDC should encourage local manufacture, since the results are difficult to assess. Various commentators have asserted that a whole range of advantages will accrue; Lall, for example, cited the potential benefits to the health care services, a “catalytic” effect on industrial development and “tangible economic benefits” which, he argued, might include savings on foreign exchange or the availability of drugs at lower costs (Section 2.1.5).

However, the motives of the Governments of India and Indonesia, at least, would seem to be rather more complex than those indicated by Lall, and the actual policies to be subject to the influence of interest groups both within and outside the country. The potency of external forces can be illustrated by the foreign exchange crises which affected India in the 1950s and Indonesia a decade later. In both cases, the responses of the more wealthy nations to these events paved the way for Western pharmaceutical companies to transfer technology on particularly favourable terms — something the companies were keen to do to counter existing or expected restrictions on imports. The events in India are described in Sections 1.3.2 and 5.2.1 and the results are illustrated in Table 5.7. However, the timing of investments in Indonesia is less easy to analyse because of Soekarno’s earlier reluctance to admit private enterprise.

The wide range of considerations indicated in these paragraphs demonstrates the validity of those themes mentioned at the beginning of this chapter. Many interest groups are involved, and their political decisions all affect one another.
Other Interested Parties

It is appropriate at this point to mention the various United Nations agencies which have taken an interest in the pharmaceutical industry. They have produced many documents, which have included suggestions for increasing the level of pharmaceutical production in LDCs (see Section 2.2). However, it appears that they have as yet had negligible direct influence on the investment patterns of pharmaceutical TNCs, and only limited effect on the policies of LDC Governments. The most noticeable activity has been in training technical and medical workers from LDCs.

Similarly, the various international aid and development organisations have had only minor successes in affecting the overseas business practices of the pharmaceutical TNCs. These are usually represented by the decision of a company to withdraw a particular drug from the market, or in the adoption of better conditions for LDC workers. There is no evidence that the development organisations have had any more far-reaching influence, although they may have some restricted influence on the health care policies of LDCs, where they have initiated health care schemes with significant demonstration effects.

Social and Political Considerations in LDCs

It is difficult to generalise about the political circumstances within the host country. In India and Indonesia, many of the features which characterise the current socio-economic relationships can be seen to have their origins many years ago, not least in the period of European colonisation, dating from the 17th Century.
Within this study, it has been possible to describe only briefly the effects of colonisation in India and Indonesia. However, two themes clearly emerge as having had an important bearing on the pharmaceutical industry today. Firstly, both India and Indonesia fulfilled a valuable economic role for their European rulers. Their purpose was principally to supply raw materials for European industry, whilst local manufacture was not encouraged unless it served to further this end. There is evidence that the Dutch in Indonesia actively destroyed indigenous industry (Appendix 1.1), whilst the lack of support from the British Raj for Indian enterprise may have been an equally powerful disincentive.

Secondly, it would appear that European colonisation reinforced the pre-existing patterns of inequality in various different ways. The early European settlers relied on the indigenous rulers for protection and support. When the original East Indies companies of both Britain and the Netherlands were taken over by the state, the relationship between coloniser and local elite became translated into one of mutual protection and assistance in the national administration. After political independence, this has persisted in that the distribution of wealth and power in both India and Indonesia is highly skewed.

The Europeans settled primarily in the cities, such as Bombay, Delhi, Calcutta and Madras in India and Jakarta in Indonesia. In the 1980s, regional inequalities can be seen most strongly in the various urban-rural disparities of wealth and resources. The great majority of modern industry is concentrated in the cities, so that a few Indian States, and the Indonesian island of Java, are notably more developed than other regions. In fact, one significant conclusion
from the studies of the pharmaceutical industries in India and Indonesia is that, like most other industries, they have remained concentrated in particular regions. The Indian pharmaceutical industry is centred on Bombay, with a few factories in Gujarat, West Bengal and Karnataka. In Indonesia, the distribution is even more skewed, with the great majority of the TNCs choosing to build factories in Jakarta. On the whole, the same patterns have been followed by large and small domestic companies, whilst it has been found that the linkages generated by the pharmaceutical industry were insufficient to give significant support to other forms of industry, either in these regions or elsewhere (Sections 4.4.2 and 6.3.2).

The cultural effects of inequality are reflected in the ways in which the formal health care services have developed. Allopathy, or Western medicine, was favoured by the Europeans and health care facilities were established to serve the early settlers. However, these services were not generally extended to the mass of the populations of either India or Indonesia. Instead, they were intended primarily for the Europeans, then for the indigenous elite and, eventually, for certain selected, economically important, groups of workers. This pattern can be seen to persist after political independence. For example, only some 20 per cent of the populations of both India and Indonesia are thought to have access to allopathic drugs. The majority rely on a range of indigenous systems of medicine, or try to survive without health care resources. The position in India is described in Section 3.6.2. As that section shows, the practice of allopathy itself is not static, but is subject to a wide range of influences. Amongst the important factors, is the role of the medical doctors and the other health care professionals. The duties
which they are expected to perform, their attachment to Western norms and professional values, and the social classes from which they are drawn, all affect the performance of the health care services. The relationship which the health care services have with the pharmaceutical industry and the extent to which they support or challenge the prevalent socio-economic structures are subject to the same factors. Thus, the political interests of the various groups express themselves in the ways in which the pharmaceutical industry is oriented.

Some Implications of the Links between Health Care Services and the Pharmaceutical Industry

Within a study of this breadth, it has been possible only to hint at some of the features which characterise the relationship between the pharmaceutical industry and the practice of medicine. Nevertheless, it is possible to describe some of the ways in which this relationship is expressed, and to indicate the effect they appear to have. As has been indicated in the first half of Chapter 3, the value of medical statistics is severely limited when considering health. Although freedom from disease can be recorded, the definition of 'disease' is, in itself, problematical. Moreover, statistics do not reflect the full context of health care and can indicate little about the nature of the services available. It is rather the case that health reflects the socio-economic condition of the nation in such areas as racial, regional, cultural, sexual and class inequalities, the rights and resources available to individuals, and the distribution of political power. These relationships extend to the orientation of the pharmaceutical industry and the ways in which it is linked to the various parties with an interest in the
provision of health care services.

The co-existence of allopathy with the various indigenous forms of medicine has been mentioned above. Despite the fact that Western medical services appear to reach less than one-quarter of the population of India or Indonesia, it is allopathy which has been favoured by the Governments, more or less to the exclusion of other systems. It is possible only to speculate why this should be so, but it seems that the apparent successes of Western curative and preventive medicine are not, in themselves, sufficient explanation. International links are also important, both in the past and in the present. Not only have the models of health care services been developed over several centuries of colonial involvement, but Western norms and practices also remain important today. Many doctors and some paramedical personnel working in LDCs have been educated in the West, whilst others are trained in local colleges established along similar lines. The various professional groups value international recognition highly and are willing to plan medical education to achieve this goal. Inevitably, the repercussions are felt in medical practice, especially in the replication of hospital-based services and the development of medical doctors whose professional duties grant them a particular social status.

As far as drugs are concerned, doctors tend to follow the patterns of the West, with respect to the form of drug therapy and, even, the use of identical products. More significantly, medicines are expected to play a similar therapeutic role as in the West, although the standards of living of the populations may be rather different. One possible factor which serves to maintain this state of affairs is that many of the minority who use allopathic drugs are
from the wealthier sections of Indian and Indonesian society and are, themselves, influenced by Western norms. (Significantly, the foreign companies seem to sell proportionately more of their drugs to the wealthiest portions of this minority sub-group; see Section 4.4.4 for the evidence in Indonesia.) Medical doctors frequently claim the right to prescribe the drugs which they see as therapeutically appropriate, and they are largely supported in this by their wealthier and more vocal patients.

In this respect, private sector health care is important for various reasons. It is supported by the wealthier sections of society, and it offers greater remuneration, thereby attracting the more able medical doctors. This sector is particularly influential, and is a prime target for the representatives of the private companies. As one indication of the value of this activity, some 30 per cent of the staff of foreign companies in Indonesia are engaged in marketing and they concentrate on the private sector doctors. As in the West, the main method of marketing is by personal contact between the medical doctor and company representative. The emphasis is on the therapeutic potential of the drugs, rather than on their cost-effectiveness.

All this naturally favours the drug companies, because they can sell their drugs throughout the world without major adaptations. However, it would seem that Governments may also find some benefits in a closely controlled and Western-oriented health service. At one level, health care can be seen as a commodity, as argued by Navarro and others (Section 3.4.1). Thus, the distribution of hospitals, clinics, health care workers and other resources, reflects the distribution of power in the country. This idea has some limited value
in India and Indonesia, where it reveals the existence of various inequalities.

More important, as far as drugs are concerned, is the type of work done by the health services. If the emphasis is placed, either in theory or in practice, on curative services, and if those services rely on drug therapy, then drugs assume a particular importance. By its nature, drug production tends to be limited to certain geographical areas, to be performed in easily identifiable buildings by well-defined and registered organisations and to use specialised inputs of raw materials, equipment and personnel. Drugs are used largely by registered practitioners under controlled conditions and are not widely available to the mass of the population. Therefore, a concentration on drug therapy as the single major function of health care services gives the authorities scope for control over the well-being of the population. It is not simply that the volume of drugs is limited and denied to many (along with the other essentials of food, shelter and clean water) although this may well be important. It is more significant that the population must rely on the major authorities, such as Governments and authorised professionals, whilst more devolved or less organised forms of political power, represented by popular based health care facilities (and, to a limited extent, by informal small-scale drug manufacturing units) become much less important.

It is possible to speculate that this pattern will be extended into the wider political field. Those who have the official sanction of Government or profession are seen to be responsible for political action. In contrast, little is expected from less formal movements.
Limitations of the Existing System of Drug Production and Distribution

Even if the context of centrally-authorised drug production and distribution is accepted, various problems emerge. It can be seen that the regulatory policies of both India and Indonesia have had their limitations. In both countries the Government has recognised the wide range of effects which can result from pharmaceutical technology transfer. Several central Government Ministries are involved in authorising and directing pharmaceutical production, both by TNCs and domestic companies. The Ministry of Health figures largely, but so do the Ministries of Industry, Finance and Law, as well as the various technical service departments. This is shown most succinctly in Figure A6.1, which illustrates the large number of Indian authorities which must be contacted before a company is granted permission to manufacture a specified quantity of any particular drug.

Amongst the criteria which the authorities rank as most important when deciding whether to grant a licence, is the supposed need of the drug, based primarily on the consumption in previous years, rather than the disease pattern in the country. However, there have been shortages of many drugs, even when compared to these artificial target figures, and the various reasons for this state of affairs are discussed in Section 6.3. This section also includes an indication of how these targets for drug production may vary from those indicated by therapeutic needs.

Two features of Indian practice stand out as evidence of the difficulty of planning adequate supplies of drugs by means of comprehensive regulation. First is the Drug Price Control Order of
1979, which introduced a framework for the pricing of all drugs, whereby those considered therapeutically more useful were supposed to be available at lower cost to the consumer. The most conspicuous result has been that private companies have tended to avoid these low price products, because they are also less profitable, and they have faced little pressure to do otherwise. Secondly, there is the almost universal tendency to concentrate on the monetary value of drug production as the prime indication of the success of the pharmaceutical industry. As several commentators have shown, this is grossly inadequate, because it fails to take account of the type of drugs produced, the ways in which they are used, and to whom they are available. It is also arguable that it militates against effective price control, as that would apparently decrease the value of production.

The Indonesian Government has adopted a rather different approach in its attempts to regulate the pharmaceutical industry. As in India, several different Ministries are involved in controlling the establishment of pharmaceutical factories, and the drugs must also be registered. However, there is much less official control over the scale of production. Instead, market forces predominate and the manufacturers concentrate on those drugs which sell well, rather than being officially guided by supposed therapeutic needs. Again, there is apparently a relative shortage of several important drug types whilst, as in India, there seems to be over-production of some of the more popular drugs, especially antibiotics (Section 4.4.4). Thus, market forces can be seen to be an inadequate control for the production of useful drugs. On the other hand, there has also been relatively little success in India, where a host of regulations have been adopted with the intention of making the pharmaceutical industry
fulfil several unconnected goals.

One final aspect of the links between the pharmaceutical industry and the provision of health care is that of drug safety. Much has been made of the very unfortunate side-effects which can result from the use or misuse of certain drugs. Two Ciba-Geigy products, clioquinol and the combination drug, Cibalgin, have been criticised for this reason (Section 7.5). The debate over such drugs has proved a useful focus for debates about the wider purpose of drugs and health care services. However, it is my contention that some of the criticisms have been misplaced. Certainly the effects of 'unsafe' drugs can be tragic for the relatively small number of people who suffer their ill-effects. However, such concerns should not obscure the more serious problems. Reliance on drugs, especially the well-produced but more expensive products of the TNCs, may divert both public attention and financial resources away from the things which contribute to physical health.

The Role of Large Domestic Companies and Their Relationships with TNCs

The final major interest group in this complex structure is the domestic company, of which there are several forms. The traditional image is of unscrupulous and rapacious TNCs in conflict with a local Government and acting contrary to the interests of medical services intent on caring for the mass of the population. At the same time, the foreign companies are said to stifle domestic enterprise, although the latter would operate in a more socially responsible manner. My opinion is that pharmaceutical manufacture by TNCs in LDCs may give some technical support to certain local entrepreneurs,
although this is difficult to quantify. However, there is limited evidence that indigenous manufacturers are more concerned about the well-being of the mass of the population.

There are three main types of domestic company. These are the large private company, small-scale units and the state enterprises, run by central or local Governments. Each has its own problems and aspirations.

In India and Indonesia, the combined sales of the domestic companies are comparable in value to those of the foreign sector. However, there are many more domestic companies than TNCs, and it is difficult to generalise about their activities, ownership, or long-term prospects. Certainly their technical standards have been heavily influenced by the TNCs, even though many of the domestic companies were in operation before the Western companies arrived. This was the case in India.

The quality standards for both product and manufacturing techniques have been directly and indirectly affected in such ways as the formation of Government regulations which reflect Western standards, technology transfer 'on the hoof' when ex-employees of foreign companies join domestic units, and by the apparent preferences of medical doctors for the products of the TNCs, whether for reasons of familiarity or quality. The question of familiarity emerged, for example, in the debate in India over the 1978 New Drug Policy, and the proposed abolition of brand names. The Indian companies argued that the medical doctors preferred the products of the TNCs simply because these companies had: "household names... deeply rooted in the minds of the medical profession and the consumer at large..." (Appendix
6.4). As far as quality is concerned, it was the TNCs which largely benefited from the ill-fated attempts in 1972 to abolish brand names in Pakistan. Doctors selected the drugs of the larger companies on the grounds of quality (Section 2.2.3).

It was clear from the series of interviews carried out in India and in Indonesia that, for many private domestic companies, the TNCs represented a level of technical and commercial excellence at which to aim. Some domestic companies suggested that they had deliberately restricted their range of products in order to specialise in the same way as the TNCs. The high regard in which the Western companies were held was, in part, reflected by the number of qualified workers who sought employment in the TNCs to gain from their working practices, salary levels and the range of social benefits available. Despite this, there was a significant number of workers in Indonesia who were willing to move from foreign to domestic companies. In that country, in particular, wage rates in the two sectors were often similar, and it was said that the breadth of responsibility frequently given to the managers of domestic companies was attractive to many young employees.

In India, there is rather limited contact between the various industry sectors. However, this separation is not so marked in Indonesia, where Government regulations have resulted in many TNCs engaging domestic companies to produce some drugs under licence. This is mainly for dosage forms for which they do not have the necessary equipment themselves. This would seem to be a fruitful area of contact, probably because both companies are essentially in partnership and both are concerned to produce drugs of a suitable quality. Several domestic companies indicated that they had learnt much from
this type of relationship, both about the process they were operating and, informally, on other aspects of drug manufacture.

The case of Astra-IDL should also be mentioned here, as an example of a joint venture between a TNC and indigenous company where the latter played a significant part, both technically and financially. (This is in contrast to most of the joint ventures in Indonesia, where the local partner was usually selected more for its ability to provide capital rather than technical expertise.) In this case, Astra was not solely interested in avoiding the ban on imports but, to some extent, was also keen to develop its experience of techniques suitable for manufacturing drugs in LDCs.

It is more difficult to generalise about the social impact of the larger domestic and foreign companies, even if we leave aside the context of drug production and distribution. The managers of companies in both sectors inevitably tend to form a social elite, as a result of their income levels, which are many times the national averages, and through their contact with Western standards of commercial behaviour. Amongst the domestic companies, in particular, many of the owners and senior employees come from particular racial or regional sub-groups, such as the Parsis, Bengalis, Gujaratis and some Maharashtrians in India (Section 5.2.2) and the Chinese in Indonesia (Section 4.4.3). However, it would be unrealistic to argue that the privileged position of these classes could be attributed to the operation of the pharmaceutical industry; it is rather that the industry reflects wider social realities.

Many of the TNCs operating in India and Indonesia were found to sanction working conditions for their employees which were very dif-
ferent to those in the West, and which would not have been accepted by workers there. This was particularly evident in the case of the construction workers employed on the Astra-IDL project (Section 8.6) but, to some extent, was the case in every factory I visited. The universal response by spokesmen of the foreign and large domestic companies was that they could not be held responsible for the national social conditions. It is also interesting to note that there was apparently little pressure from trades unions in the parent companies of the TNCs for any improvements in the conditions of workers employed in the subsidiaries.

A few large foreign and domestic companies in India now produce drugs at several sites. Partly this is a result of Government regulations, which have blocked expansions to existing plant. This has enabled the companies to exhibit classical 'multinational' behaviour within one country, in that some production requirements can be exchanged between factories to take account of the availability of raw material and Government incentives and to sidestep labour unrest. This can be seen to apply to some extent in the case of Ciba-Geigy (Section 7.3).

Pharmaceutical TNCs are often criticised for the ways in which their products are marketed and tested in LDCs (Section 2.2.2) and, indeed, these criticisms have some validity. However, it should not be assumed that the indigenous companies are always blameless in the standards they adopt. In practice, the combination of liberal concern in their home countries and the desire of the TNCs to avoid adverse publicity which might affect sales worldwide, has led many companies to monitor their standards of behaviour in LDCs with some care. The Code of Practice, voluntarily drawn up by Ciba-Geigy
(Appendix 7.16) is a good example of this trend, although this document goes further than would be accepted by many companies.

**Small-Scale Companies**

Small-scale domestic companies fulfil a different role. Their level of operations is limited by both official regulations and pragmatic fact. They are qualitatively different from either the larger domestic or the foreign companies. Despite this, the majority of the small-scale companies, both in India and Indonesia, tended to operate in a manner similar to the large companies. They sold a wide range of drugs, under brand names, to state and private outlets, and adopted similar marketing techniques, although on a reduced scale. The quality of the products of such companies was frequently questioned, by the larger companies and by Government authorities in both countries. This would seem, in part, to be a result of the confused role which the small-scale companies are expected to play. They mimic the activities of the large companies, yet can rarely afford the quality control equipment or the developmental work which is considered necessary by their larger rivals. If the national Governments are concerned to encourage small-scale industry, as is nominally the case in India at least, and if the small companies are expected to continue in their present role, then assistance could be given in several ways. On a simple level, some small-scale companies in India claimed that they were unable to install an adequate range of quality control equipment whilst remaining within the Government spending limits which define such companies. This could be avoided by placing such expenditure outside these limits, and by enforcing quality control standards more effectively. Alternatively, there was
no evidence that testing facilities were shared by the small-scale companies, although the geographical concentration of the pharmaceutical industries within India and Indonesia should make this feasible. The small companies face further technical problems, in acquiring and developing manufacturing techniques. Again there is scope for Government assistance, both in collecting knowledge and adapting techniques for the particular conditions in that country. In India, such facilities already exist, but the small companies claim that they are inadequate.

However, it may be unrealistic to expect small companies to operate effectively in this way, since the technical and commercial strengths of the larger units tend to precipitate the dubious practices of the small companies in desperate attempts to compete. In contrast, it may be socially more useful if small companies were each to concentrate on the production of a very limited range of drugs which could be sold under generic names to state health services or private dispensers. This would have several advantages. The companies could develop manufacturing and testing expertise in a limited range of products, which could be made in somewhat larger quantities at lower unit costs. Less capital equipment would be needed which, together with the limited range of techniques, might encourage greater dispersion of the industry, or the establishment of village-based operations to supply local needs. On the other hand, it is not clear how such a scheme might be promoted, given the nature of the Indian and Indonesian economies, where little effort is made to influence the activities which private companies elect to take up.
State-Owned Pharmaceutical Companies

Finally, there are the large state companies, HAL and IDPL in India and P.T.Kimia Farma and Manggarai in Indonesia. As has already been mentioned in the text (Sections 5.2.4 and 4.2.3) these companies face various difficulties, not least because they are expected to compete with the larger private companies, yet are subject to extensive bureaucratic controls. These restrictions are supposed to guide the companies towards fulfilling several social and economic roles. However, in my opinion, it is unrealistic to require such companies to operate at a profit, or to assess them solely by their financial performances. Instead, their manufacturing capacity might be used to support the health care services, or other pharmaceutical manufacturers, with financial losses being accepted as a necessary part of Government expenditure in the health care sector. Thus, HAL, IDPL, and Kimia Farma, in particular, might concentrate on the production of bulk drugs for supply to other formulators in the private or public sector. This would be a particularly useful service if the small companies were encouraged to develop in the ways outlined above.

Given the structure of pharmaceutical distribution in Indonesia, with the reliance on private dispensers, it is likely that Kimia Farma and Manggarai are providing a useful function in supplying formulations to the various state outlets. However, the continued use of brand names by Kimia Farma is puzzling, whilst the depth of Government control over the activities at Manggarai seems excessively restrictive. In both countries, there would seem to be no easy answer to the problem that the more able staff are lured into the private sector by the better conditions of employment.
Prognosis

The preparation of any formal thesis is a lengthy process. By the time the study is ready for submission there is often new material available. This has been the case here, and it has proved impossible to consider in depth anything published after the end of 1982, although there are a few references to material released in 1983. However, it appears that the broad conclusions which can be drawn from the evidence in the bulk of this study continue to hold. In particular, the concerns and ambitions expressed by the various interest groups continue to be applicable. There has been no significant change.

The purpose of this final section is not to try to predict the details of any regulations which may be enacted in the near future: rather it is to discuss, in broad terms, some of the ways in which the relationships between the different interest groups might express themselves, and the possible consequences.

From time to time, it is suggested that the Indian pharmaceutical industry be nationalised. Could this be done? If so, what would be the likely effects? Although the statistics presented in Chapter 5 indicate that the production by the various indigenous sectors, of both bulk drugs and formulations, is at least comparable to that of the Foreign Sector, there are significant qualitative differences. In particular, many of the TNCs specialise in certain classes of product. If they were to withdraw from India, there might be shortages of these drugs or, at least, a decline in the flow of new product and process information from the parent company. In itself, this might not be too serious. Few of these areas of speciality represent par-
particularly important therapeutic classes, whilst the knowledge of the production techniques would be retained by the employees of the TNCs. In any case, few new products have been introduced into India during the last decade.

The technical problems might be overcome then, but there are other reasons why the Indian pharmaceutical industry is unlikely to be nationalised. First is the question of foreign aid and technical assistance, which affects many sectors of the Indian economy. Inevitably, action in the pharmaceutical industry would have repercussions elsewhere. Similarly, the power which foreign companies exert in other sectors could be used to influence events in the pharmaceutical industry. Second, it is unlikely that attempts at nationalisation would receive widespread support within India itself. Many of the more powerful sections of society have a vested interest in the industry continuing to operate in its present form. Such groups include employees of the TNCs, medical doctors, suppliers of raw materials and equipment and drug distributors. Even if the ownership of the industry were to change, it is unlikely that there would be significant qualitative change in its activities, since the indigenous companies show little incentive to do other than copy the TNCs. Moves in India and Indonesia to limit the foreign shareholdings of local companies have done little more than re-distribute wealth amongst those who are already wealthy.

In this context, it is interesting to note the emergence of TNCs owned by Indians. Sarabhai is the best-known in the pharmaceutical industry, and Astra-IDL may yet fulfil a similar role. As yet, such companies have begun to manufacture drugs in only a few other countries, but they may be able to expand this activity to other LDCs,
given that the technology they can offer may be better suited to take account of the factor endowments in such countries. This is not to imply that their products will, necessarily, be used in a more beneficial way.

It would appear that the publication of the various essential drugs lists has had little effect in India and Indonesia, although the recent Indonesian laws on registration (Section 4.3) may yet provide a suitable mechanism for rationalisation. The medical profession and private industry alike have opposed any restrictions to lists of essential drugs. As far as the authorities are concerned, with the emphasis remaining on the therapeutic value of the selected drugs, there may be only limited financial savings, even if such lists are used. An alternative approach, which may be of more benefit to Indonesia or other countries with smaller pharmaceutical industries, would be to take greater account of local manufacturing capacity. Drugs could be selected for local manufacture because of the ability of local companies to produce them, as well as for their medical utility. There may be greater incentive to pursue such a strategy because of the financial savings which might accrue. In the Indian context, private companies might be granted licences for other products if they agreed to manufacture some of the selected drugs. Little work has yet been done to assess the potential for rationalising drug production in this way.

Amongst the various technical difficulties which restrict drug manufacture in LDCs, is the limited size of the market. This makes various processes uneconomic for indigenous companies and discourages TNCs from transferring more production to their subsidiaries. For this reason, it will be interesting to see the ways in which
cooperation develops amongst groups of countries, such as the ASEAN nations. However, I have been unable to find any significant recent studies of the efficacy of such cooperation amongst inter-national groups.

Given suitable terms of trade, combined with import restrictions, such groupings might be able to establish economically viable plants to produce bulk drugs by conventional synthesis or by fermentation. Jointly financed plants would have the potential to supply drugs to national health services, whilst enabling LDC nationals to acquire a range of technical and managerial skills. Cooperative ventures might also be able to perform useful research. The need is not so much for new drugs, even in the unlikely event that sufficient funds were available, but more for establishing drug 'needs', given existing patterns of morbidity and health care. Whether all this would be arranged so that it benefits the mass of the population is another matter.
APPENDIX 1.1

EARLY EUROPEAN INVOLVEMENT IN INDONESIA

The first Europeans in the region were Portuguese and Spaniards. Portugal captured Malacca in 1511 and, in 1522, gained direct access to the valuable Moluccas (The Spice Islands). The Spanish had established a settlement, in nearby Tidore, in 1521 and Caldwell and Utrecht assert that they would have found the scientific and technical skills of the indigenous peoples to be similar to their own (1). They cite evidence that the Javanese cast their own cannon and used gunpowder as early as the 15th Century. The Javanese were skilled in the working of steel and precious metals and they were also renowned for their capacity to build ships. One authority claimed that: "Navigational techniques and general nautical technology were of a very high order, for local seamen and traders made their way to China in one direction, and to India, Ceylon, the Middle East and Madagascar in the other." (2)

However, this indigenous development was sharply arrested by the European incursions. Spain and Portugal were followed by two other European powers, the Netherlands and Britain. The effects of the latter two were both extensive and long-lasting, transforming Indonesia into a producer of agricultural goods for the European market. Whereas the efforts of the Spanish and the Portuguese had been haphazard and largely uncoordinated with developments in Europe, in contrast, the British and the Dutch both founded powerful East

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(1) Caldwell and Utrecht (1979) p6f.
(2) Oliver and Fage (1962). The culture of the archipelago had already developed several distinctive art-forms which were known outside the area. These included the 'wayang' (shadow puppets), 'batik' (wax-resist dyed cloth) and the 'gamelan' orchestra.
India Companies'. Each saw in Indonesia a substantial means of supporting the home economy and were prepared both to acquire and to defend this territory militarily.

Both countries surveyed the area in the late 16th Century. Drake passed through the archipelago in 1579 and Cavendish in 1586 (3). In 1602, the English East India Company set up a 'factory' at Banten in north-west Java (4). The Dutch, however, were unwilling to admit any competition. They seized Jakarta in 1611(5) and established their capital, Batavia. Gradually, a series of forts was developed and the Dutch rule became increasingly entrenched by the extension of territorial control. Treaties were made and broken with the indigenous rulers and mercenaries were used to preserve Dutch domination. By the middle of the 18th Century, most Javanese were governed directly by Batavia or by Javanese rulers heavily influenced by Dutch 'advisers' (6). The Dutch influence was also strong in Celebes and The Moluccas whilst the other European countries were still powerful elsewhere; for example, the British were dominant in Borneo.

Caldwell and Utrecht (7), in their analysis of this period of control by the Dutch East Indies Company, suggest that the agricultural potential of the region was vigorously exploited by means of 'coerced cash crop labour'. The peasants were compelled to cultivate coffee, sugar and spices and deliver it to the company for export. At the same time, the company suppressed enterprises which did not

(3) Fryer and Jackson (1979) p38.
(5) Grant (1964) p11.
(6) Fryer and Jackson (1979) p37-62.
(7) Caldwell and Utrecht (1979) p14f.
further its own profit. For example, servants of the company uprooted spice trees which had been surreptitiously planted by Moluc-
cans attempting to meet the requirements of other traders active in the archipelago.

Towards the end of the 18th Century, however, both the Dutch East Indies Company and the Netherlands itself were in considerable financial difficulty. The Company had suffered through the inefficiency and corruption of minor officials and counter-productive methods of enforcing production (8). The Netherlands assumed the debts of the company and was then also involved in a series of costly wars and unsuccessful economic adventures.

The British occupied the East Indies themselves between 1811 and 1816 but the Dutch returned in 1825. They fought a long and debili-
tating war before regaining control of the island in 1830. With their finances in a parlous state, they introduced drastic measures to gain economic benefit from their colony. This system, called the Cultuurstelsel (Cultivation- or Culture-System), has been described thus:

"In essence, this was a much more systematic, methodical and widespread application of the old system of forced deliveries...The great secret of the system was to utilise an existing coercive apparatus to convert the labour of the Javanese masses into readily saleable crops...coffee and sugar were the most important, others included pepper, cloves, nutmeg, indigo, silk, tea, cinnamon, cochineal and tobacco."(9)

Caldwell and Utrecht describe three factors of the system which,

(8) For example, Javanese land was 'leased' to the Chinese for cash. However, their methods both impoverished the people and fostered civil strife. Caldwell and Utrecht (1979) p15.
(9) Caldwell and Utrecht (1979) p18.
they argue, benefited the Dutch to the detriment of the Indonesians and which had long-term effects on the economy. Firstly, the traditional Javanese aristocracy was both reinforced and absorbed by the Dutch administrative hierarchy. Secondly, indigenous enterprise was, as before, stifled. Thirdly, the wealth produced by this system was both substantial and largely exported: "Such facts as we have strongly suggest stagnation, at best, or even deterioration in the material condition of the Javanese peasantry."(10) At the same time, the Dutch exchequer benefited greatly from their colony. Java was run for profit, and exports from the East Indies contributed roughly a third of the Dutch annual budget of 60 million guilders (11).

The Cultuurstelsel was largely demolished in the 1860s and 1870s. Fluctuations in commodity prices were coupled with improved methods of agriculture and with various liberal sentiments fostered in Europe during the 1840s. In its place, Indonesia was opened up for private capital, from both the Netherlands and elsewhere, to exploit its agricultural and mineral wealth. The islands were united under Dutch rule and the necessary infrastructure of railways, roads, telegraphic installations and docks were developed in the state, using revenue realised by the colony.

Private investment grew in the latter part of the 19th and during the early 20th Centuries. The disruption of communications between Europe and Asia during the First World War stimulated the development of Indonesian production. However, the great majority of such enterprises remained in agricultural and extractive industries and the financial and commercial services for them (12). By 1930,

(12) Fryer and Jackson (1979) p54f.
Western investment in Indonesia totalled some $2,000 million. About 65 per cent of this was from Dutch sources, with the British, Chinese, French and Japanese also having substantial shares (13).

(13) Callis (1941) p36.
APPENDIX 1.2

THE EARLY HISTORY OF INDIA

Up until the 12th Century, a succession of Hindu potentates had ruled over their own regions. This pattern was broken by the invasion of Muslim Turks who conquered the northernmost part of the country. By the mid-15th Century, they had been displaced by the Afghans, but the Turks re-invaded in 1517; they established the Mughal empire, which lasted until the 18th Century, and united a large amount of land under a single ruler, removing powers from the indigenous rulers.

Contemporary reports describe both the luxurious splendour enjoyed by the nobility and the abject poverty of the mass of the population. The cost of fine buildings and gardens left little money for productive works; only a few trunk roads and small canals were built during the two centuries of Muslim control (1).

European activity in India dates from the 15th Century. The Portuguese arrived in 1497 to seek both "Christians and spices" (2). The Christians were the subjects of the mythical Prester John but the spices were commercially more interesting and the Portuguese established themselves in the west of India to further this purpose. Well-defended ports were built on the Malabar Coast to secure the route for the spices from the East Indies.

The lure of spices also attracted the Dutch, the French and, later, the British. The Dutch had gained the ascendancy in the East

(1) Spear (1973) p40-47.
(2) Spear (1973) p62.
Indies and like Portugal, they sought to bring the goods safely back to Europe and built ports in Ceylon, at Cape Town and in India. India was relatively unimportant to them, being merely a link in the chain, a place where they could obtain textiles to exchange for spices in the East Indies.

In contrast, India came to be the most important of all Britain's colonies, the 'jewel in the crown'. Spear suggests that this happened only because the Dutch ascendancy in the East Indies excluded Britain there. Both countries were eager to find a reliable source of spices and, thus, India was only of secondary interest. The main Indian products were textiles, saltpetre and sugar but they were bulky and more expensive to produce. Spices were cultivated only in the southernmost part of the Indian subcontinent (3).

The British East India Company was founded in 1600 and established its first Indian 'factory' at Surat in Gujarat a decade or so later. By 1690, it had set up further godowns in Bengal and at Madras:

"In the west the main articles were cotton piece-goods, cotton yarn and indigo from Gujarat; from the Malabar coast pepper and such other spices as could be bought second hand from Ceylon and the East Indies; from Madras and the south-east coast again piece-goods, and yarn and sugar; from Bengal specially silks and saltpetre. The opium trade was to come later. In return India bought metals such as tin, lead and quicksilver, novelties, specially mechanical ones, tapestries and ivories. But these purchases never equalled the Company's payments."(4)

During the 18th Century, the Mughal empire began to crumble

(4) Spear (1973) p67-68. Spear indicates that the value of trade in this period was more than 10 per cent of the public revenue of Great Britain. Spear (1973) p77.
under the weight of Afghan attack and internal weaknesses. The British East India Company took the opportunity to extend its interests, both commercially and territorially. In 1757, for example, the professional soldier Clive led military operations against the French and against the Mughal ruler in Bengal who had occupied Calcutta. Calcutta was retaken and the Mughal leader replaced by a puppet in the power of the Company. By 1773, the British Presidencies in Madras and Bombay were brought under the control of Calcutta and the unified Company continued to expand. Cornwallis became Governor-General of the Company's territory in 1786. He introduced measures to reinforce the power of the British in India; in particular, all high Indian officials of the Company were dismissed and their posts reserved for Europeans (5).

Indigenous private enterprise was also developing strongly and, by the 17th and 18th Centuries, Indian entrepreneurs had developed a considerable capacity for manufacture and trade. Raychaudri suggests that India was a major manufacturing country, and it was certainly a major supplier of textiles to the whole of South East Asia, Persia, the Arab countries and East Africa. The other major items of export were silk, sugar, saltpetre and indigo, which all involved a certain amount of processing. At the same time, there was a very rich merchant class, trading in its own ships, and some of the merchants formed 'limited liability companies' to supply the staples of export to the European factories (6).

However, the structure of the society, in which the goods were manufactured and sold, worked against the possibility of any

(5) Spear (1973) p95-96.
(6) Raychaudri (1968) p84-87.
effective commercial opposition to British expansion. The Indian economy was principally subsistence, with the manufacture of cotton and silk textiles being essentially fringe activities. Marx has described the pervasive village system of common land ownership and cultivation which supported the local craftsmen, barber and the like (7). Artisans who produced goods for wider internal trade and for export had not coalesced into a homogeneous class, necessary for the development of large industries. At the same time, the wealthy, with sufficient capital to promote indigenous industry, instead supported the feudal structures and then collaborated with the British (8).

Indian society was divided, in terms of class, culturally and geographically:

"[Division] was not so much a chronic malady...as a periodic malaise caused by the nature of Indian polity and the tensions produced by over-lapping races and rival cultures in a sub-continent which provides few convenient physical compartments for the growth of integrated nationalities...[there] was the absence of the phenomenon of nationalism...In India the horizontal division of caste and the vertical divisions of religion were more important than those of race."(9)

In contrast, the British in India were united. The company was relatively well-organised and it was supported by the state. Cornwallis, at the end of the 18th Century, and Lord Wellesley, in the early years of the 19th, were only two of the more prominent Governors-General of the British East India Company under whose leadership it was reformed and its territory extended by military means. Expansion continued throughout the first half of the 19th

(8) Gupta (1980).
Century so that, by 1850, the majority of India was controlled by the British. The exceptions were the relatively small coastal enclaves controlled by the French and Portuguese, and independent 'native states' in the interior of the country.

In 1857, the relative tranquillity which the company had enjoyed was shattered by the 'Indian Mutiny'. After this was eventually put down, with what was euphemistically called 'vigour', the charter was removed from the British East India Company and India came under the direct rule of Britain. The legislature was reformed under a Governor-General, who retained this title, with the addition of the honorific 'Viceroy'. British rule was reinforced and extended to all levels of society. This lasted until 1947, when India was granted full political independence.

The imposition of British rule, both through the Company and then directly by the state, exerted a profound influence on the Indian economy in general and the nature of its industry in particular. The Industrial Revolution in Britain meant that India assumed a new relevance to the British economy. British industries relied on overseas raw materials, such as cotton, whilst seeking foreign markets in which to sell their goods; India could provide both. The textile industry is the most obvious and widely cited indicator of the industrial relationship between Britain and India. It demonstrates the differences in industrial development between the two countries and the effects which British rule had on the indigenous industry in India.

The influence of British manufactured goods was felt most strongly in the early 19th Century. The mills of Lancashire were
able to manufacture goods more cheaply than was possible by unmechanised means. In contrast, the manufacturing of textiles in India was relatively sophisticated but, despite catering for an international market, it was not mechanised. It suffered from direct competition as first the export market was removed and then British goods began to invade the home market itself. Apart from the impact on the Indian economy, this resulted in much poverty amongst the Indian weavers (10).

During the 19th Century, the home cotton industry was extremely important to Britain and, in 1850, about 12 per cent of the population was employed in the manufacture of cotton textiles whilst the industry contributed about 8 per cent of the whole national revenue. The Indian market was particularly lucrative, absorbing about a quarter of the total exports (11).

The transition of the Indian textile industry from handicrafts to mechanical production eventually began in 1854, when a Parsi cotton merchant established a mill in Bombay (12). In a short time, the production of cotton textiles had become the main industry in which Indian entrepreneurs invested. Bhagwati and Desai suggest several reasons for this, including the nature of the home market, and the availability of the technology which could be purchased abroad with comparative ease and did not require large numbers of skilled workers.

(10) Spear (1973) p118-119.
(11) "...between 1814 and 1835, British cotton manufactures exported to India rose from less than 1 million yards to over 51 million yards. In the same period, Indian cotton piece goods imported into Britain fell from 1.25 million pieces to 306,000 pieces, and by 1844 to 63,000 pieces. By 1850 India, which had for centuries exported cotton goods to the whole world, was importing one fourth of all Britain's cotton exports." Dutt (1955) p48.
However, the indigenous cotton industry suffered from what it regarded as unfair competition from the Lancashire mills. Spear has expressed the position thus:

"The ground for this opinion was the abolition of all tariff duties in 1879, a measure which indirectly benefited Lancashire, and the imposition in 1895 of an excise of 5 per cent on Indian cotton goods to countervail a similar tariff on Lancashire goods imposed in the interest of revenue. This was generally regarded as naked discrimination in favour of foreign goods." (14)

One of the specific tactics used by rioters in Bengal in 1904 was to boycott British goods and ceremonially to burn Lancashire cotton (15).

(13) In particular, the Indian market was (a) itself large enough to enable a non-exporting industry to prosper, and (b) consisted of private Indian consumers, so that the purchasing policy of the British Government could not be used to discriminate against them. Bhagwati and Desai (1970) p25-26.

(14) Spear (1973) p173. See also Dutt, who writes: "[I]t was not only the technical superiority of machine industry but also with the direct state assistance of one-way free trade...that the predominance of British manufactures was built up in the Indian market." Dutt (1955) p48.

(15) Spear (1973) p176.
APPENDIX 2.1

THE MANUFACTURE OF TABLETS (1).

Tablets are produced by the mechanical compression of powders or, more usually, granules, in metal dies. Granules are favoured, because they give a free-flowing mixture, which facilitates the filling of the die and the production of a product of uniform composition. The granules are made from the active ingredient, mixed with other 'excipients', each of which has a specific function. The excipients must be therapeutically-inert, of the highest purity, and also enhance the performance of the active ingredient. The common types of excipient include:

(i) Diluents: potent drugs may have a dose of only a few micrograms, so a diluent or filler is added to produce a tablet of suitable size. Much used for this purpose are: sucrose, dextrose, lactose, sorbitol and kaolin.

(ii) Absorbents: are used when liquids or oily substances are tabletted. These include magnesium oxide and magnesium carbonate, whilst lactose and starch can be used both as diluent and absorbent.

(iii) Adhesives and binders: assist in preparing a suitable solids mixture for sieving, and in holding together the granules. Common adhesives include gum acacia, syrups, starch, gelatine and glucose.

(iv) Disintegrants: are used because many of the synthetic

(1) This description is taken, primarily, from Burlison (1968), with additional material from Rawlins (1977) and Kirk-Othmer, Encyclopaedia of Chemical Technology, 3rd Edition, Volume 17, p277-285.
drugs, in particular, are only sparingly soluble in water. The purpose of the disintegrant is to aid the solution process in the stomach, by increasing the available surface area. Various starches, colloidal silicas and micro-crystalline cellulose have all been used for this purpose.

(v) Wetting Agents: are used with active ingredients which are normally water-repellent. Sodium lauryl sulphate is a common, non-toxic, wetting agent.

(vi) Lubricants: assist in the tabletting process. The granules are compressed against the walls of the die, and would stick to them without lubrication to ease tablet ejection. Magnesium stearate and calcium stearate are both effective lubricants.

(vii) Flavours: are often added to make the tablet more palatable. Lemon and lime oil are commonly used.

Formulation 'recipes' describe the exact quantities of active ingredient and excipient to be used for each batch and the ways in which they are to be mixed.

The mixture is granulated and 'pre-compressed', dry or, most commonly, moist. Some, or all, of the dry ingredients are mixed with a 'binding' or 'granulating' liquid to form a damp mass. The binding liquid may consist of starch or gum acacia suspensions, or glucose solutions; when these ingredients are also used as drug excipients, it may be sufficient to add only water at this stage. The moist mixture is then sieved to give coarse granules, dried, and the granules reduced to the desired size for compression. Different drugs require the various excipients to be added at particular stages throughout these operations (2).

(2) A few, simple, tablet formulae are given in Burlison (1968)
The granules are then compressed into tablets. Commercial production uses single punch machines, with an output of 60 to 90 tablets per minute or, usually, multiple punch machines with 16 to 51 sets of punches and dies, which can produce up to 5,000 tablets per minute. In order to produce a suitable tablet, the products must be prepared correctly, and the clean tablet punch set to give the correct pressure, exactly aligned and so on. Finally, tablets may be coated with coloured syrup mixtures to make them more attractive and palatable, and to protect the active ingredient. There may be several layers, such as an undercoat of gum acacia or gelatine solution; subcoats, which are mainly sucrose; and a final wax polish to enhance the appearance. The coats are added in discrete operations.

p35-38. In the past two decades, a process of spray granulation has been introduced, whereby the granulation process can be carried out in one operation. A bed of dry ingredients can be mixed with the granulation liquid and fluidised in warm or cold air. See Burlison (1968) p43.
APPENDIX 4.1

BRIEF CASE-STUDIES OF FOREIGN COMPANIES IN INDONESIA

<table>
<thead>
<tr>
<th>Company</th>
<th>Country of Origin</th>
<th>Approx. rank in world Drug Market</th>
<th>Approx. rank in Indonesian Drug Market</th>
<th>Date of first Investment in Indonesia</th>
<th>Number of Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>USA</td>
<td>15-20</td>
<td>15-20</td>
<td>1950s</td>
<td>c200</td>
</tr>
<tr>
<td>B</td>
<td>Europe</td>
<td>20-30</td>
<td>30-40</td>
<td>1970</td>
<td>c150</td>
</tr>
<tr>
<td>C</td>
<td>Europe</td>
<td>15-20</td>
<td>?</td>
<td>1979</td>
<td>c150</td>
</tr>
<tr>
<td>D</td>
<td>Europe</td>
<td>?</td>
<td>5-10</td>
<td>1950s</td>
<td>c300</td>
</tr>
</tbody>
</table>

NOTES: Company A: Early investor. Unusually low level of shares held by Indonesians. Also allowed to manufacture drugs under licence.

Company B: Rather late investor. Factory in East Java, but Head Office in Jakarta.

Company C: Late investor. Allowed various concessions by the Government because of important product. Active local partner.

Company D: Early investor, before introduction of the Foreign Investment Law. Subsequent expansion registered under that Law.


COMPANY A: is an American TNC with sales which place it in the lower reaches of the world's top twenty pharmaceutical companies, a position similar to the one it holds in Indonesia. It has been active in Indonesia since the 1950s, first through the importation of its finished pharmaceuticals and then by engaging an Australian manufacturer to produce under licence. This practice was subsequently prohibited and the company took advantage of the 1967 Foreign Investment Law to
become one of the first foreign pharmaceutical companies to invest in Indonesia. It proved impossible to find a suitable local partner and the Government permitted this company to make a 100 per cent investment, although they were required to divest 30 per cent of their shares after 10 years of operation.

A Dutch national, with experience of Indonesia, was employed to establish the factory on the outskirts of Jakarta, and to negotiate with the local architects and contractors. The volume of business increased, requiring an expansion of production facilities in 1976, and local managers foresee the need for a further expansion in the mid 1980s. No difficulty had been experienced in obtaining permission for the first expansion and the company now produces a wide range of dosage forms, including film coated, and sterile liquids. They introduced the latter successfully after experience in other industrially less-developed countries. The company also formulates products for a smaller European company with which it has a global agreement; this practice is not normally permitted by the Indonesian authorities.

The final manufacturing stages for the production of a well-known diuretic are carried out in a separate chemical manufacturing area. Although the process is not particularly difficult or dangerous, the product is easily oxidisable and has to be carefully blanketed in nitrogen to prevent degradation.

Several key Indonesian staff left during the 1970s to join other foreign and local companies but improved conditions and intra-company relationships have greatly decreased the turnover more recently.

The company has cooperated with the Ministry of Health in its
hygiene education and family planning programmes. It believes that this has contributed to the leniency shown to its unusual position of shareholdings and manufacture under licence for another foreign company and in the granting of permission to expand production. After 10 years' operation in Indonesia, plans were being made to divest shares to Indonesian investors and approaches had been made to the stock market (opened in 1977) to investigate the possibility of public quotation.

COMPANY B is a large European TNC with activity in a wide range of chemical manufacturing industries, and sales in pharmaceuticals which place it in the top thirty pharmaceutical companies in the world. It has been active in Indonesia since the early 1960s and originally imported its products directly to a trading subsidiary. The position was reconsidered in 1968-69, after the introduction of the Foreign Investment Law, but financial analysis which recommended investment was over-ruled by the parent company for reasons of general company strategy. (This illustrates the difficulty of obtaining information without a strong base in the country; companies with greater representation in Indonesia were aware of the impending moves to restrict and later to ban imports of finished pharmaceuticals.)

The position was reconsidered in late 1970 and the decision made to invest, with a local distributor taking 10 per cent of the shares. Unlike most of the foreign companies, which located themselves as close to Jakarta as possible, this company, acting on the advice of a local consultant, built the factory in East Java, several miles outside the major port of Surabaya.

The company spokesmen said that he now regretted this decision
for several reasons it is difficult to communicate with the Indonesian head office, located in Jakarta, and there is a relatively limited pool of qualified staff in the area. He considered that the advantages of that location, such as easier clearance of imported goods through Surabaya and the lower wages which can be paid, did not outweigh the disadvantages. Staff turnover has been very low and, paradoxically, this presented a problem, since the work force had aged together, and young personnel could not be introduced to responsible positions. It might also have been difficult to find expatriate managers willing to live in this comparatively rural area but, in fact, suitable personnel have been found.

The company manufactures a rather small number of ethical and OTC products which, nevertheless, includes a wide range of dosage forms, and its sales figures place it in the top forty companies operating in Indonesia. A proportion of the output is exported to the company subsidiary in Malaysia and no products are made under licence. In addition, a cardiovascular product is synthesised, and it is only in Indonesia and its home country that this company manufactures bulk material.

Financial losses were made in the first years of operation, and disinvestment was seriously considered, before strict cost-cutting measures restored profitability. However, it was only after eight years of investment in Indonesia that a cumulative profit was realised.

COMPANY C is another European transnational, specialising in pharmaceuticals and consumer products; current sales place it just within the world's top twenty pharmaceutical companies. Although this
company has been operating in Indonesia since the mid 1960s, it had not made any investment until the end of the 1970s. Until that time, two local companies had manufactured the company's products under licence. One concentrated on oral products, such as tablets and capsules, and the other on sterile liquids for injections. As required by law, another Indonesian company was engaged to distribute the products and the distributor also employed a sales force on behalf of the foreign company, which was directed by a small representative office headed by a resident expatriate manager.

With sales increasing, but with the evidence of declining market shares held by other non-investors, the decision was recently taken to invest in Indonesia. A local partner was found in one of the companies which had previously manufactured under licence. This company holds 30 per cent of the shares in the new joint venture, in accordance with the revised equity regulations of 1974, which require that initial holdings by indigenous investors be not less than 20 per cent of the total.

The new factory, which is being built on land adjoining the Indonesian partner's existing factory in Jakarta, includes a full range of pharmaceutical production machinery and, also, a chemical plant to carry out the later stages of the manufacture of a very widely-used antibiotic. It is unusual for a company investing in this period to be given permission to construct a factory in Jakarta, and this was seen by the company spokesman as the direct result of the plans to produce an important range of antibiotics.

This company reported a somewhat different experience to that related by the first foreign companies to invest in Indonesia. In
technical matters, the route was somewhat easier in that there was now a larger pool of experienced labour, wholesalers were better prepared to supply raw materials, Government utilities had been developed, and a greater number of equipment suppliers could offer an after-sales service. On the other hand, Government regulations had become more strict and investment procedures apparently less straightforward. They had relied on their Indonesian partner for guidance with Government officials and for advice on the recruitment of staff and selection of equipment and material suppliers.

This company operates a large factory in Singapore which serves as a regional centre and where several Indonesian employees, intended for key managerial posts have been sent temporarily to gain experience.

COMPANY D is also a European-based company and has sales in Indonesia which place it in the top ten companies there. However, its position in world sales is obscured because of mergers which took place during the 1970s.

In contrast to Company C, Company D has been active in manufacturing pharmaceuticals in Indonesia, with a significant indigenous shareholding, since the 1950s, but it is similar in that it has, only recently, decided to invest under the Foreign Investment Law. Pharmaceutical manufacture began in 1958 and the company was the first non-Dutch company to manufacture in Indonesia. It is located in Bandung which, at that time, was being promoted by Soekarno as the likely future capital of Indonesia, in contrast to the colonial headquarters of Jakarta. This situation offers the advantage of a pool of labour which is both cheap and also relatively experienced because
of the food-processing industry in that region. Road travel to the commercial centre of Jakarta takes only 3 hours. However, the company reported that it would still prefer to be centred in Jakarta, and it has its head office in that city.

The company escaped nationalisation during the 1950s and 1960s and emerged into the 1970s operating, essentially, as a manufacturing concern which happened to have substantial foreign ownership. Unlike the great majority of foreign companies it did not register under the Foreign Investment Law, having no need of the facilities which that regulation offered. Meanwhile, the parent company was the subject of takeovers and mergers in the home country and restructuring of the Indonesian subsidiary was suspended.

The company suggested that this position was acceptable to the Government authorities but that it could not continue to expect special treatment indefinitely and it had sought to 'regularise' its position by investing under the Foreign Investment Law to extend its facilities in Bandung. This application was approved in the late 1970s, with the familiar requirement that chemical manufacture should be undertaken, an area which the subsidiary had not, hitherto, entered. The expansion of the plant was scheduled to be commissioned in 1982 and the company has experienced no particular difficulties which could be attributed to the timing of this investment.
APPENDIX 4.2

BRIEF CASE-STUDIES OF DOMESTIC COMPANIES IN INDONESIA.

TABLE A4.2

Some Domestic Pharmaceutical Manufacturers in Indonesia: 1981

<table>
<thead>
<tr>
<th>Company/Organisation</th>
<th>Approx. rank in Indonesian pharmaceutical Industry</th>
<th>Date Founded</th>
<th>Approx. number of employees</th>
<th>Approx. number of firms with licensing agreement made</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>20-30</td>
<td>1966</td>
<td>800</td>
<td>6</td>
</tr>
<tr>
<td>F</td>
<td>10-15</td>
<td>1974</td>
<td>250</td>
<td>10</td>
</tr>
<tr>
<td>G</td>
<td>-</td>
<td>1950</td>
<td>200</td>
<td>10</td>
</tr>
<tr>
<td>H</td>
<td>10-20?</td>
<td>1971</td>
<td>150</td>
<td>-</td>
</tr>
<tr>
<td>J</td>
<td>-</td>
<td>1967</td>
<td>27</td>
<td>-</td>
</tr>
</tbody>
</table>

NOTES: Company E: Large number of employees.

Company F: Produces soft capsules. Active R&D programme.

Company G: Majority of production carried out under licence for other companies. Recently started two joint ventures with foreign companies. Owned by pribumis

Organisation J: Non-profit making foundation, supplying drugs to the voluntary health sector.

SOURCE: Interviews by the author, Indonesia, 1981.

COMPANY E is a very large, domestic company in terms of both its sales and personnel: about 800 people are employed, with 200 engaged in marketing and most of the remainder in production. The company started in 1966 as a family concern with a medical practitioner as managing director. It was amongst the first to invest under the Domestic Investment Law and, in 1972, established a new factory on the outskirts of Jakarta, with substantial additions in 1976 and 1980. Corporate activity includes cosmetics and veterinary products.
but pharmaceutical production accounts for about 90 per cent of the total turnover.

The company is able to manufacture all common dosage forms, with the exception of soft capsules but including sterile liquids. Some 90 different bulk substances are formulated into a total of 110 different pack sizes as the company's own products, which it distributes itself through a network which reaches every major city in Indonesia. In addition to its own products, the company also manufactures, under licence, all the products of a relatively small West German company, and of a Japanese company, neither of which has made an investment in Indonesia, and it carries out all the marketing and distribution of these products. The licensing agreement prohibits the export of these products but a company spokesman suggested that would be difficult because of the high costs of formulation in Indonesia using imported material. Several large, foreign companies with investments in Indonesia, but without the facilities to make certain dosage forms, have contracted manufacture to this company, which also acts as sole distributor for all the products of these companies.

Unlike many in the domestic sector, this company bought most of the equipment from the same sources as the foreign sector, especially West German suppliers who operate an active after-sales service. It also buys raw material from a range of countries in Western Europe, and this had led to the apparently anomalous situation whereby one large West German concern sells raw material to this domestic company and also transfers supplies of the same material to its subsidiary in Indonesia. This material is formulated by each company to give essentially the same product and the domestic company sells more of it than does the subsidiary. However, the European parent company
continues to supply raw material to the Indonesian domestic company, as it considers that the markets reached by the two products in Indonesia are different; the high priced product of the subsidiary is bought by a different range of consumers.

The company has a Research and Development section which employs 60 people engaged in microbiological tests and formulation research. One common technique for establishing a suitable formulation is by buying a sample of the product already marketed in Indonesia or overseas and analysing the composition. This gives the ingredients of the product, and serves as a basis for developing the formulation process to be used by the company.

COMPANY F is the most recent large domestic company to emerge and it now has sales which place it just outside the ten largest pharmaceutical companies in Indonesia. It has a single owner and, as with many companies, he is a member of the ethnic Chinese minority in Indonesia. This owner had studied extensively in the Netherlands, married a Dutch woman and established manufacturing facilities for cosmetics, chemicals and pharmaceuticals in that country. Products of the company were imported to Indonesia until this was prohibited by the Indonesian Government in 1974. As a result, a manufacturing facility was set up in Indonesia in partnership with another Indonesian who subsequently took it over, and a second facility was built in 1977. The company did not require any financial incentives from the Government and its main investment is, therefore, not registered under the Domestic Investment Law.

This latest factory includes a wide range of pharmaceutical facilities, including equipment for sterilising gauze by gamma
radiation and the production of soft capsules. It is one of only two companies in Indonesia, domestic or foreign, to produce the latter. The information for this technique was bought from the American developer of the process, and introduction into Indonesia proved difficult because of the high level of humidity. This problem has now been overcome, and the company manufactures products in soft capsules for three foreign and two domestic companies, including the Government-owned operation, Kimia Farma; however, the Government did not assist the company in acquiring the manufacturing technique.

Various types of formulation are made under licence for four foreign companies which have not invested in Indonesia, and these products are distributed by an associated distributor which also handles the company's own products. Raw materials are purchased mainly from Europe, and agreement is made with the associated companies in the Netherlands to facilitate bulk purchase.

As well as the advances in formulation techniques, the company has also established an aggressive policy in R&D and in raw material synthesis. R&D work includes the familiar operations of formulation development but more fundamental work is also being carried out to isolate and identify the active ingredients in jamu products and to extract compounds with therapeutic value from natural products; this work includes the isolation of steroidal material from sisal. The research and development work is coordinated by a pharmacy teacher from the Institute of Technology at Bandung, who spends part of the week at each organisation.

The company has also made a significant investment in a raw materials synthesis plant to produce three of the drugs with the big-
gest sales in Indonesia. The plant was designed by a Japanese com-
pany which has trained Indonesian staff at their parent company in
Japan, and an American architect based in Jakarta, designed the
building. Despite the relatively large volumes that the plant is
designed to produce, the company estimates that imported material
will still be cheaper; they rely on the Government to control imports
and on the subsequent development of the basic chemical industry to
stimulate the success of this venture. Production started in late
1981 with the commissioning programme assisted by Japanese techni-
cians.

COMPANY G is a very well-known domestic company situated in Jakarta.
It employs 200 people, the great majority of whom are directly
engaged in manufacturing, but its financial ranking is unclear,
because almost all of its work is contract manufacture for other com-
panies. The company was founded in 1950 as a dispensing business and
is one of the few large companies in pharmaceutical manufacture or
distribution to be owned by an indigenous Indonesian, rather than by
ethnic Chinese. In 1954 it began to import the products of a large
West German company, and then negotiated an arrangement with this
company to introduce manufacturing know-how and staff training. In
the course of this programme, German pharmacists worked in Indonesia
and, by 1958, all the antibiotics of the German company were being
formulated by Company G in Indonesia. By 1970, equipment to manufac-
ture sterile liquids had been introduced and the decision was made to
concentrate on manufacture under licence for large foreign companies.
Ten years later, the company had manufacturing contracts with ten
foreign companies and pharmaceutical production represented some 60–
70 per cent of the total group turnover, with the remainder compris-
ing household goods, antiseptics and chemical raw materials.

The licensing arrangements of Company G vary from customer to customer in terms of the types of products to be manufactured, the method of payment and the scope of the agreement. Some TNCs, particularly the smaller companies, engage company G to produce all their products under licence whilst others, with significant investments in Indonesia, licence only the manufacture of sterile liquids for which they have no facilities themselves. Payment is made by royalties, which vary from zero from one company which sells raw material to company G and buys back the finished goods at an agreed price, to 7 per cent by another company which engages company G to arrange the distribution of the products. Capital expansions are financed by bank loans, guaranteed by the foreign collaborators. More recently the company has negotiated two joint ventures with large European TNCs and factories for chemical production, as well as for pharmaceutical formulation, have been built on adjacent sites.

Manufacturing know-how is developed by the company itself with the aid of technical advice from its foreign collaborators. When a licensing agreement is negotiated, technicians from the foreign company visit Indonesia and up to three Indonesian staff visit the parent company of the TNC for several months to observe the facilities and manufacturing processes.

COMPANY H, like Company F, is of relatively recent foundation. It evolved from an import business after 1971 when the plans of the Government to ban the importation of finished goods became widely known. Construction of the factory began early in 1974 and production a year later.
The company spokesman said that he had set himself the objective of: "developing a technically advanced factory to match the best in Indonesia", and its progress in this respect was recognised when a recent evaluation of quality, made on behalf of the Armed Forces in Indonesia, placed the company very highly. This rating is also reflected by the fact that the company supplies large quantities of drugs to the civil servants' health insurance scheme.

The company considers that this development has been achieved through a vigorous policy of developing its own R&D and production facilities, and through informal contact with the several foreign licensors placing contracts with this company. The company spokesman further described his company's strategy as follows: "We elevated ourselves to gain respect so that we could communicate on a two-way basis."

Equipment for a wide range of dosage forms has been installed, but the company does not manufacture sterile liquids or soft capsules. The spokesman suggested that this was because he could appreciate the technical problems involved in such operations and did not consider his own company ready to undertake such steps. Manufacture under licence is carried out for four foreign companies which have not invested in Indonesia, and the contracts include marketing their products.

The company manufactures its own range of products, which are introduced on the basis of market surveys. Raw material is bought principally from Italy, though this pattern may have to be revised with recent moves in that country to introduce patent protection. Technical ability is developed through the company's own facilities
(which include an extensive information service to gain access to well-known medical and technical journals) and through contact with the foreign principals. Indonesian staff visit the TNC for training, and technical staff of the foreign company visit Indonesia to inspect the facilities and advise. The company reported that they were frequently able to obtain informal advice on their own processes in this way, even though the legal agreement did not cover such an eventuality. It was considered that the manufacturing ability of the company was developing still further but that technical staff were frequently attracted away by rival domestic companies who valued their experience and paid higher wages.

ORGANISATION J was founded in 1967 in Solo in Central Java and moved in early 1981 to new premises on the outskirts of that city. The operation was financed initially by locally-raised funds, with some foreign aid, but the expansion was facilitated by a grant from a Protestant missionary organisation in West Germany. The organisation employs 27 people in the full range of activities from manufacturing to administration, packaging and dispatch. The organisation concentrates on the production of standard preparations for the treatment of the more common diseases in Indonesia (which include TB, malaria, diarrheoa and worms) and these are formulated into the more familiar dosage forms, such as tablets, syrups, ointments and hard capsules. They are distributed under their generic names.

Raw material is bought from Indonesian wholesalers, who obtain it from Western Europe, Taiwan, The Peoples' Republic of China and Japan. The factory was established with the aim of providing medicines at low prices for all sections of the community and, thus, concentrates on supplying Protestant Health Units throughout Indonesia,
which give priority to buying such products. More recently the service has been extended to supply the Association of Voluntary Health Services of Indonesia, which coordinates the Catholic Health Units. Organisation J also handles the orders of Health Units for the products which it cannot manufacture and buys the drugs in bulk quantities from commercial companies, thereby obtaining better terms. Unlike the practice of most private companies, drugs are supplied to Units outside Java at the same prices as they are sold inside Java and such Units do not have to pay the extra costs of dispatch.

Although the enterprise is non-commercial, it is required to be registered under the Ministry of Health and is subject to the legislation which regulates all pharmaceutical companies.
APPENDIX 5.1

THE RAW MATERIALS FOR BULK DRUG PRODUCTION IN INDIA

Bulk drugs may be considered under three broad areas: (i) those derived from the higher plants, (ii) those derived from lower plants, micro-organisms and animal sources, and (iii) synthetic drugs, derived from organic chemicals. India is particularly rich in raw materials for the first two categories. The Hathi Committee identified some fourteen plants which are "of medicinal value" and grown in India; eight of the plants yielded drugs which, the Committee decided, were "essential" (1). Such plants are cultivated by the state, and on privately-owned plantations (2).

A variety of drugs is produced from materials in the second category; they include insulin, from animal pancreas, and four, widely-used antibiotics, penicillin, the tetracyclines, chloramphenicol and streptomycin. Although slaughterhouses exist throughout India, the pancreas they produce is not suitable for the current methods of insulin production. In 1975, all insulin was produced from imported pancreas, although Government laboratories were attempting to scale-up a process using indigenous material (3).

Finally, synthetic drugs represent the most important category in the modern pharmaceutical industry, as described in Chapter 2.

(1) Hathi (1975) p56-57. Mehta (1968) p2 gives further details of India's naturally-occurring medicinal plants. He concludes that: "although the progress in this field has been satisfactory, it must be added that a large potential is still awaiting development."

(2) The Hathi Committee Report gives further details of plant cultivation and endorses the recommendations of the National Council for Science and Technology, which advised the extension of such cultivation. Hathi (1975) p57-58 and 72.

(3) Hathi (1975) p59.
This is also the case in India, where organic chemicals can be derived from (ethyl) alcohol, petroleum or coal. A relatively small amount of chemicals is made from ethyl alcohol, derived from the fermentation of molasses; "unfortunately, several of these units have not been able to produce to capacity because of diversion of alcohol... for potable use." (4) A wide range of chemicals are produced from coal, converted into methane and methyl alcohol. Again, companies experience some difficulties in obtaining a reliable supply of such chemicals, as there is only one source of methyl alcohol, the Fertiliser Corporation of India, at Trombay (5). Petroleum has been discovered in the Arabian Sea, and is refined and processed in India, together with imported crude oil. In the mid-1970s, the amount of imported material was about twice that extracted locally (6).

(4) Hathi (1975) p147.
(5) Hathi (1975) p147.
APPENDIX 6.1

LAWS WHICH HAVE AFFECTED THE PHARMACEUTICAL INDUSTRY IN INDIA

The pharmaceutical Industry, along with all others in India, has been controlled by the Industrial Policy Resolutions of 1948 and 1956. In 1948, Development Councils were set up for different industries, including Drugs and Pharmaceuticals, to lay down targets for domestic manufacture and to encourage liaison between the Public and Private Sectors. This was further developed in the 1956 IPR, when 'Antibiotics and Essential Drugs' were included in Schedule B, which listed industries open to both public and private enterprise.

The Patent Law has been mentioned in the main text. Patent legislation was introduced by the British in the middle of the 19th Century and, eventually, codified as the Indian Patents and Designs Act, 1911. After Independence, the Indian Government set up the Chad Committee to review the situation: "with a view to ensuring that the patents system was more conducive to national interests." (1) The Interim Report of this Committee recorded the opinion that the:

"Indian Patent System has failed in its main purpose, namely to stimulate innovation among the Indians and to encourage the development and exploitation of new innovations in India, so as to secure benefit thereof to the largest section of the public." (2)

A few sections of the Act were amended in 1950, but a new Bill, introduced in 1953, did not proceed through Parliament and the original Act was left largely untouched (3). Further pressure built up

(1) From the preamble of the Committee's Report, quoted by Divecha (1968) p14.
(2) Quoted by Badami (1968) p13.
(3) Divecha (1968) p16. Divecha also records the opinion of Justice Rajagopala Ayyangar, who suggested, in 1959, that the conservation of foreign exchange was the most important factor; the existing Patent Law should continue if the inventions were worked in
during the 1960s from Indian manufacturers. In the pharmaceutical industry, Rangarao suggests that "more than 90 per cent of the patents" were held by foreign companies (4). The patent legislation was reconsidered in 1965 and a new law finally passed in 1970. Product patents were removed, whilst the period for process patents was reduced from 16 to 7 years. Provision was made to enforce the licensing of the processes after 3 years (5).

Despite these changes, indigenous manufacturers still reported problems with patents as late as 1975 (6). Patent applications had been 'frozen' in the 1960s, and the back-log was being considered only slowly. Manufacturers were hesitant to develop new processes as they did not know whether a competitor might have a patent application already pending. By 1981, this difficulty seemed to have disappeared (7).

The 1973 Foreign Exchange Regulation Act (FERA) has been described in Chapter 1. This Act limits the proportion of foreign shareholding allowed in any company; higher levels, of up to 74 per cent, are allowed in certain 'Core Sector' industries. It was thought, initially, that the pharmaceutical companies would suffer most from this Act (8), yet two American companies in other sectors, Coca-Cola and IBM, have been the only foreign undertakings to

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(7) Patent legislation was mentioned in interviews only by employees of the foreign companies, who asserted that patents were now worthless'.
(8) Balasubramanian (1978).
withdraw.

The whole of the pharmaceutical industry was, initially, considered to be in the Core Sector and foreign pharmaceutical companies accepted the requirements (9). However, the Core Sector was redefined under the 1978 New Drug Policy, which led to the Government seeking more data and requiring further equity dilution (10). Even this development does not seem to be a matter of great concern to foreign investors. They have been able to sell their 'excess' shares to many different small investors, thereby retaining effective control, even with minority holdings.

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(9) "The foreign investor is not afraid of FERA. FERA has, as a matter of fact, been no problem...", Orville Freeman, Chairman of the Indo-US Joint Business Council, quoted in "Freeman Sees No Future for Alien Drug Companies in India", Economic Times, 15 September, 1978.
APPENDIX 6.2

REGULATIONS WHICH NECESSITATE CONTINUING COMMUNICATION BETWEEN THE INDIAN GOVERNMENT AND THE PHARMACEUTICAL INDUSTRY

The laws considered in Appendix 6.1 enforced certain actions, but did not entail prolonged contact between the Government and individual manufacturers. In contrast, six areas of legislation which are subject to regular revision and which bring together the regulatory authorities and the industry, are described in this Appendix.

The import of all goods into India is strictly controlled. Each year, the Government issues a report, listing three categories of items; those which cannot be imported because there is sufficient indigenous capacity, those which can be imported in controlled quantities, with specific Government permission, and those which can be imported in unlimited quantities (1). The composition of these categories varies annually; for example, in the late 1970s, a relative abundance of foreign exchange had led to a liberal import policy. Any 'New Drug' (2), can be imported only when the Drugs Controller (India) is convinced that it is safe and efficient (3).

All production by large pharmaceutical units must be licensed by

(1) Interview, S.S. Gothoskar, Drugs Controller (India), New Delhi, May, 1981.
(2) That is, a drug which does not appear in the latest edition of the Indian Pharmacopeia.
(3) "New Drugs are not permitted to be imported unless they have been approved in the country of origin and marketed in a number of countries." Lok Sabha, Statement by B. Shankaranand, Minister for Health and Family Welfare, 3 July, 1980, reported in OPPI Bulletin No.5/80, September/October, 1980, p.12. S. Borkar, ex-Drugs Controller (India) reported that this strict policy had prevented the import of thalidomide. The authorities had no data that indicated that it offered any therapeutic advantage over products already available. Interview, S. Borkar, Bombay, February, 1981.
the central Government, following the Industry (Development and Regulation) Act of 1951 (4). The route taken by a licence application is illustrated in Figure A6.1. Firstly, the different departments within the company estimate the economics of producing the drug in question. Secondly, the request is coordinated and an application made to central Government; many companies retain a permanent representative in New Delhi to handle such applications. Thirdly, the request is considered by the many different Government departments, who may decide to issue a 'Letter of Intent' (5), or reject the application. The reasons for rejection may include the following; prevention of monopolies, location policy, 'ratio parameters' (6), the proposal is not for synthesis from a sufficiently early stage, sufficient capacity is already licenced, or excessive imports would be required (7).

The practice of licensing in the pharmaceutical industry has been the subject of much criticism. Jayaraman claims that: "the concept of industrial licensing... [drove] a wedge... between the two arms of the industry, the Indigenous and Foreign Sectors which were hitherto functioning in unison and mutual benefit." (8) Some companies have been granted licences, thereby effectively denying other

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(5) Signifying the intention of the Government to grant a licence, if the company agrees to certain conditions. Bhai Mohan Singh implies that the different Government departments may be in conflict when considering licence applications. Singh (1978) p46.

(6) That is, the value of a company's formulation production, compared to bulk drugs.

(7) Lok Sabha, Answer to Unstarred Question No.6813, 5 August, 1980. As described above, the Government has also decided the order of preference between the different private Sectors, when considering such applications.

(8) Jayaraman (1980a) p67. However it is difficult to support his claims, that the Sectors lived in harmony before the advent of licensing. As the Small-Scale and Public Sector companies do not need licences, a four-way division has now been created.
FIGURE 46.1  THE STEPS TAKEN IN APPLYING FOR AN INDUSTRIAL LICENCE, INDIA: 1981  
SOURCE: Original, based on Interviews in India, 1981
companies, but have failed to take them up. The penalties for this are considered, by some, to be rather low (9). The Government is said to take a long time to deal with licence applications (10). The situation is exacerbated since, for various reasons, many companies produce more than they are licenced for. The way in which this excess capacity should be 'regularised' is a continuing source of debate (11).

All drugs must be registered with the Ministry of Health before they can be sold in India. The basic legislation was established in the 1940 Drugs and Cosmetics Act, and has required little subsequent change. Although drugs should be registered in their country of origin, clinical trials must also be performed in India. The results are scrutinised, not only for evidence of toxicity but, also, to determine whether the product has any advantages over drugs already registered. Unlike the licensing procedure, no account is taken of the ownership of the company submitting an application for drug registration (12).

Under the 1940 Drugs and Cosmetics Act, the state has the responsibility to investigate the quality of drug production (13);

(9) Interview, I.A. Alva, Secretary, IDMA, Bombay, February, 1981.
(10) On 5 August, 1980, the Government still had to decide on 60 licence applications from foreign drug companies. Over one-third of these had been pending for more than two years, and one application had been made as long ago as 1975. Lok Sabha, Answer to Unstarred Question No. 6886, 5 August, 1980.
(12) There are around 400 different active ingredients registered in India, compared to four to five times this figure in most European countries. Unlike the West, India does not have any method of monitoring adverse drug reactions. Interview, S.S. Kattishetlar, Drugs Controller (Karnataka), Bangalore, June, 1981. The information for this paragraph was obtained from Gothoskar (1980) and Interview with S.S. Gothoskar, Drugs Controller (India), New Delhi, May, 1981.
this is organised by each State, and standards are variable. Firstly, some States combine the Inspectorates of Food and Drug production, whilst, in others, they are kept separate. With the exception of five States, the Director of Medical, or Health, Services and Family Planning, is also in charge of drug control (14). Secondly, the relative strength of the drugs control teams varies greatly from State to State: "... it is known for a fact that only 4 out of 22 States in India are implementing, with some degree of effectiveness, Drugs and Cosmetics Act of 1940... Even these States do not have adequate staff and testing laboratories." (15) This situation is reflected in Table A6.1, which gives the number of Drugs Control personnel in each State, in 1975; it will be seen that the number of Inspectors, relative to the number of manufacturing and sales premises, varies greatly between States (16).

Rangarao has suggested that it would be impossible markedly to improve this situation, merely by increasing the numbers of Inspectors (17). Instead, as the Hathi Committee recognised, the onus should be on the companies to manufacture drugs of good quality (18).

The performance of the pharmaceutical industry is reviewed and

(14) Rangarao (1975) p23. The Hathi Committee suggested that the Drugs Controller for each State should be independent of the health care services. Hathi (1975) p191.
(16) Furthermore, each State is allowed considerable autonomy in arranging its methods of drug control. Interview, S.S.Kattishettar, Drugs Controller (Karnataka), Bangalore, June, 1981.
(17) "Any attempt to enforce the quality with the existing pattern of production and sales by employing adequate numbers of inspectors, analysts and laboratories is an economical and technological imbecility." Rangarao (1975) p23.
(18) The penalties for producing drugs of poor quality are relatively light. The Committee suggested that these should be made more stringent; some members mentioned even capital punishment, or deprivation of civil rights and flogging. Hathi (1975) p195-6.
### TABLE A6.1
The Numbers of Drug Control Personnel, Drug Manufacturing Units and Drug Sales Premises in Indian States: 1975

<table>
<thead>
<tr>
<th>State</th>
<th>Number of Inspectors (1)</th>
<th>Number of Manuf. Units (2)</th>
<th>Number of Sales Premises (3)</th>
<th>Column (2) div. by Column (1)</th>
<th>Column (3) div. by Column (1)</th>
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<td>Andhra Pradesh</td>
<td>16</td>
<td>210</td>
<td>12325</td>
<td>13.1</td>
<td>770.3</td>
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<tr>
<td>Assam</td>
<td>40</td>
<td>19</td>
<td>1987</td>
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<td>4</td>
<td>84</td>
<td>6100</td>
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<td>3691</td>
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<td>531</td>
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<td>2378</td>
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<td>205</td>
<td>4582</td>
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<td>/</td>
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<td>Dad.&amp; Nag.</td>
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<td>#</td>
<td>/</td>
<td>/</td>
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<td>227.1</td>
</tr>
</tbody>
</table>

**NOTE:** # - data not given in source.

**SOURCE:** Rangarao (1975) p22-23. (See also Gothoskar (1983) p224.)

A forecast in each Five-Year Plan. In preparation for each Plan, the Ministry of Petroleum, Chemicals and Fertilisers establishes a Working Group to prepare estimates of the requirements of each drug, in the light of market trends, and to estimate the necessary investments and the way in which these should be distributed between the Sectors (19). When released, these forecasts are the subject of discussion.

documents produced by interested parties, especially the manufacturers' trade bodies (20). Eventually, the figures are revised and widely published (21). The 6th Five-Year Plan envisaged a particularly large increase in pharmaceutical production (22). This has enabled manufacturers to warn that, unless some of the 'restrictions' of the New Drug Policy (23), are modified: "the Plan targets will not be achieved." (24)

The final area of legislation is **Price Control** by means of which:

"Products which are selected for price control [in India] are of key importance to the economy... the price policy must be such as would help maintain an adequate flow of investment for a steady expansion in their output to keep pace with rising demand." (25)

Control over the prices of bulk drugs and formulations has been exerted since 1962 (26). In that year, the border conflict with the People's Republic of China prompted the Government to control the prices of essential commodities. This was reinforced, in the following year, by an order freezing prices at their April, 1963 level, (27)

(20) For example, see OPPI (1981b) p5.
(22) "The growth that has been envisaged for the industry in the current plan is equal to what it has achieved cumulatively during the last 25 years." "Shortage of Drugs", Economic Times, 5 February, 1981.
(23) Considered in Chapter 6.
(24) OPPI (1981b) p5.
(26) Although Jayaraman (1980b) records that intermittent price control was exerted over essential items during the Second World War.
However, the Government made little provision for subsequent price rises; companies had to submit multiple applications for price revision and were, frequently, made to wait several years (28). The basis for Government decisions was often said to be unclear and inconsistent. Jayaraman refers to it as 'adhocism' (29).

A formal method of calculating drug prices was introduced by the Drug Price Control Order (DPCO) of 1970, based on a 1966 Tariff Commission Report (30). Under this Order, the retail price of a formulation was to be based on the raw materials and manufacturing costs, together with a fractional 'mark-up', which varied with the type of product (31). The Government also established a method for calculating the maximum price of 17 'essential' bulk drugs, which were subject to periodic revision (32).

However, the bureaucratic machinery was unable to cope with the vast number of applications which the companies now had to submit. The Hathi Committee found that drug prices had been fixed in an "inequitable" manner (33), whilst Khorakiwala claims that companies with-

(29) Jayaraman (1980b) p146.
(31) Further details are given in Agarwal et al (1972) p2289 and Hathi (1975) p175-177. The mark-up depended on the technology used in production, rather than whether the drug was considered therapeutically important.
(33) Hathi (1975) p181. In addition, the DPCO (1970) provided for an alternative scheme of pricing, under which the manufacturers could elect to price products within the restraint that their overall profit was below a certain level. "Most of the manufacturers availed themselves of this alternative scheme. The actual mark-ups varied from 4% to 800%." CMIE (1980) p6.
drew drugs with 'uneconomic' prices, and that this had led to shortages (34). The Government responded by introducing a new system of 'Leader Prices' and identifying around 150 important drugs, which represented the majority of the drugs sales, and established prices based on the returns of the more competent producers. These were introduced in 1975, and became levels which no producer could exceed. Other drugs were exempt from price restriction, and subject only to market forces (35). This system was retained until the late 1970s, when it was replaced by the DPCO (1979) (36).

(36) This is considered in Appendix 6.3.
THE DRUG PRICE CONTROL ORDER [DPCO] (1979)

The DPCO (1979) uses the concept of 'mark-ups', introduced in the DPCO (1970). The maximum price of a formulation is calculated on the basis of the costs of the raw materials and company manufacturing costs, together with a percentage increase. Drugs are placed in one of four categories according to their supposed therapeutic value, with Category I being the most important. The following mark-ups are allowed: Category I (40 per cent), Category II (55 per cent), Category III (up to 100%), whilst the remainder are exempt from price control. A leader price is also established for each formulation, based on the returns of those major manufacturers considered to be cost-efficient and other companies cannot sell at higher prices. Norms are set for acceptable levels of overall company profits and they depend on the size and type of activity of the individual company. In addition, prices of bulk drugs are to be determined by reference to these standards, with certain other provisos (1).

(1) DPCO (1979) and Press Release by C.V.S. Mani, Development Commissioner (Drugs), Department of Chemicals and Fertilisers, New Delhi, 3 April, 1979.

OPPI argued strongly against any moves to 'downgrade' brand names (1). They claimed that the introduction of generic names would confuse the patients and pharmacists, strengthen the position of the less-reputable producers (2), introduce problems of bio-availability, and halt the introduction of new drugs to India (3). IDMA was also to give its name to such assertions, but its original submission on the New Drug Policy had argued, primarily, from the perspective of inter-sectoral competition:

"... the abolition of the brand names... will go against the interest of the Indian sector. The products of Indian companies are known to the medical profession and the consumer by their brand names only. The name of the manufacturers is generally not so well known; whereas the house name of the multinational companies are... household names and are deeply rooted in the minds of the medical profession and the consumer at large. Hence, the abolition of brand names will help the multinational companies more than the Indian companies." (4)

Despite these differences of approach, OPPI and IDMA joined with other trade bodies in a campaign against the abolition of brand names. A joint protest, submitted to the Government in May, 1980 (5), was reinforced by further documents and visits (6). By 1981,

2. Because the superior quality products of the large companies would not, necessarily, be chosen if generic names were used: "... the present drug control infrastructure is inadequate... even in the present situation. It is not difficult to predict what the situation will be once the generic monster is let loose." Bhattacharya (1981) p7.
3. "This will not only discourage research efforts in India but no new drugs successfully marketed abroad will be brought to India." "Brand Name Abolition - Industry's Protest", OPPI Bulletin No.1/81, January/February, 1981, p6-7.
the campaign had been reinforced by a series of advertisements in the lay press. These emphasised the fact that the pharmacist, rather than the medical doctor, would decide which brand of active ingredient to supply. They warned that "Doctor Knows Best", and drew attention to Pakistan's unfortunate experiment with generic names (7). Such arguments led to rifts between the different branches of the medical profession. The doctors bemoaned the fact that they would lose their power to prescribe a particular brand, and impugned the motives of the pharmacists:

"... it will make the patient a pawn in the hands of the chemists and dispensers who will have the opportunity to ignore our prescriptions and sell their drugs of choice, whichever will benefit them with better commission." (8)

Eventually, the companies began to argue that the move to abolish brand names was illegal (9). Hoechst, which sold analgin, one of the five drugs selected for early abolition of brand names, under the name 'Novalgin', took the matter to the Indian High Court and they won a temporary reprieve (10). However, the Government eventually decided to abolish brand names for the five drugs named in the New Drug Policy, and ruled that other drugs must display the generic names more conspicuously than the trade name (11).

(6) "Brand Name Abolition - Drug Producers' Basic Objections", Financial Express, 21 November, 1980.
(7) "Would you rather have your Doctor choose a medicine for you — or somebody else?", reproduced in OPPI Bulletin No.1/81, January/February, 1981, p18.
(8) Dr. Tarun Banerjee, President of the Federation of Obstetrical and Gynaecological Societies of India, quoted in OPPI Bulletin No.3/80, May/June, 1980, p5. See, also, Datey (1975) for an early response to the recommendations of the Hathi Committee.
Similarly, OPPI and IDMA were united in their opposition to the DPCO (1979). On this issue, even more than on generic names, they shared the same objections, and they instigated an equally wide-ranging campaign. The companies had three objections to the regulations:

(i) The sizes of the mark-ups were said to be insufficient. The companies argued that an average mark-up of about 70 to 80 per cent was necessary for them to break even (12). The DPCO had been drawn up in the expectation that companies would sell a range of products in the different categories, thereby realising a satisfactory figure; the companies claimed that many failed to achieve this mix. More fundamentally, all companies do not manufacture the range of products envisaged by the Government (13). Other companies, with a wider range of products, were: "not interested in manufacturing drugs in categories I and II... and are shifting emphasis to other products in which a higher mark-up... is allowed." (14) As part of the 'National Debate on Cost-Benefit Analysis of Price Control Systems', sample calculations were made on the returns of 11 companies. The 1979 pre-tax profit, as a percentage of sales, was estimated to fall from the actual level of 8.2, to 0.3, had the DPCO (1979) been in operation (15).

(12) Aiyar (1978a) and Interview, Marketing Manager, European Company, Bombay, April, 1981.
(13) IDMA drew attention to the plight of one of its members. This company concentrated on the manufacture of sera and vaccines, which are drugs placed in categories I and II, with low mark-ups. The company had little business in the drugs with larger mark-ups to compensate, and it feared that: "our economies are going to be extremely shaky." IDMA (1978) p337-338.
(14) Mehta (1980).
(15) Anon (1981). See, also, similar calculations reproduced in "Implementation of Indian Pricing Proposals will be Disastrous, says OPPI", SCRIP, 3 March, 1979.
(ii) The method of implementation was said to be faulty, as it was based on historical cost returns. The companies argued that the prices of their raw materials rose too sharply to be accommodated by the bureaucratic machinery (16), and they claimed that such price rises could halve the effective mark-ups (17).

(iii) It was argued that the ways in which the drugs were divided into the various categories was unrealistic. Some drugs were said to be misplaced, because they had similar therapeutic functions to drugs placed in a different category (18).

During 1981, some foreign and Indian companies resorted to legal proceedings against price control. In April of that year, two Indian and two foreign companies filed Writ Petitions against the DPCO (1979), claiming it to have: "arbitrary and unworkable provisions... inflexible... harsh... unworkable... we have been driven to the wall." (19) By March, 1982, nine foreign and five Indian companies had filed similar petitions; the Government was awaiting the decision of the courts (20).

The final major issue to arise out of the New Drug Policy was that of licensing. This has received somewhat less publicity, partly because the foreign companies, in particular, have not sought to expand their production greatly in India and, therefore, have not

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(17) Interview, Marketing Manager, European Company, Bombay, April, 1981.
(19) "Price Control - Drug Firms Go To Court", Financial Express, 22 April, 1982.
(20) Rajya Sabha, Statement by Dalbir Singh, Minister of State for Petroleum, Chemicals and Fertilisers, 1 March, 1982.
needed new licences.

The Hathi Committee confirmed that the Foreign Sector was producing drugs in excess of licenced capacities. In some cases, this had arisen quite legitimately, because equipment had been installed before the introduction of the 1951 IDRA. In other cases, companies had produced more to meet the apparent market demand. The Hathi Committee was reluctant to advise the 'regularisation' of these 'excess capacities', in case it was taken as encouragement for companies to exceed their licences on other occasions (21). However, the Government also recognised that any requirement for production to be confined to the licenced levels would result in a decrease in production and likely immediate shortages. The New Drug Policy stated that:

"The criteria for regularisation of production in excess of licenced capacity... will be the highest production actually achieved in any year during the three year period ending March 31, 1977... In the case of foreign drug companies, regularisation of excess production on the above criterion [sic] will be done (a) subject in their making over to non-associated formulators 50% of their total bulk production of any bulk drugs... and (b) subject further to their restricting the value of their total bulk production." (22)

OPPI produced statistics which, they asserted, supported their claim that tying production to these levels would lead to drug shortages (23). They suggested that the capacities should be regularised on the basis of output in the 5-year period up to March, 1979 (24).

Since then, the foreign companies have applied for few new licences, arguing that the other controls, especially those on names

(23) "Drugs: Are We Planning for Shortages?", OPPI Bulletin No.1/80, January/February, 1980, p11.
and prices, are unacceptable. The Indian companies, whilst also being against such legislation, have increased their share of drug manufacture (25).

(25) Some recent reports suggest that this activity by Indian companies has stimulated foreign companies to increase their production. One example concerns the Glaxo drug, salbutamol, and its manufacture by CIPLA, an Indian company. A CIPLA representative told this author, in 1981, that they were able to produce enough salbutamol to meet Indian requirements, but that Glaxo had responded by renewing a licence application for salbutamol, originally made in 1974. CIPLA suggested that, if the Government sanctioned the production by Glaxo, it would adversely affect CIPLA and be contrary to the spirit of the New Drug Policy. “Glaxo’s Salbutamol Production Generates Concern Among Indian Industry”, SCRIP, 8 June, 1981, p15; “Glaxo India Issue Statement on Salbutamol”, SCRIP, 13 July, 1981, p14; and, Interview, Y.K. Hamied, Managing Director, CIPLA, Bombay, May, 1981.
APPENDIX 7.1


DYESTUFFS: Similar stage of development. Geigy had concentrated on wool dyes, CIBA on cotton dyes.

TEXTILES: Similar position to each other.

AGROCHEMS: Geigy were generally more advanced, although CIBA had developed some speciality products, which Geigy did not have.

PLASTICS: Only CIBA had these products, not Geigy.

ADDITIVES: Only Geigy.

DRUGS: CIBA was bigger in terms both of sales and number of products, but there were gaps in the range eg. they had no antirheumatic drugs.

PIGMENTS: Similar position to each other. Not particularly important.

OTHERS: Each company had developed relatively minor side-lines. Geigy sold gardening tools and CIBA photochemicals and some electronic equipment.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1925</td>
<td>CIBA's pharmaceutical products become available in India.</td>
</tr>
<tr>
<td>1941</td>
<td>CIBA (India) Ltd. forms pharmaceutical division.</td>
</tr>
<tr>
<td>1957</td>
<td>Sole distributor, ACDC, selling to Suhrig-Geigy Trading.</td>
</tr>
<tr>
<td>1960</td>
<td>Joint venture with Atul to form CIBATUL to manufacture sulphonamides in bulk.</td>
</tr>
<tr>
<td>1963</td>
<td>CIBA Research Centre opened by Prime Minister of India.</td>
</tr>
<tr>
<td>1967</td>
<td>Suhrig-Geigy Trading no longer sole distributor, but continues to handle marketing for Suhrig-Geigy.</td>
</tr>
<tr>
<td>1972</td>
<td>Suhrig-Geigy starts own pharmaceutical manufacture at Ranoli.</td>
</tr>
<tr>
<td>1974</td>
<td>CIBA and Geigy merger leads to the establishment of CIBA-GEIGY of India Ltd.</td>
</tr>
<tr>
<td>1975</td>
<td>Expiry of contract between Basel and Suhrig-Geigy. 'Loss' of Geigy line of drugs.</td>
</tr>
<tr>
<td>1979</td>
<td>Pharmaceutical plant at Kandla. Primarily for export to USSR.</td>
</tr>
</tbody>
</table>

**APPENDIX 7.2**

**THE CHRONOLOGY OF CIBA AND GEIGY ACTIVITIES IN INDIA**

**SOURCE:** Ciba-Geigy, Basel, January, 1981.
## The Production of Bulk Drugs by CIBA-GEIGY in India: 1979

<table>
<thead>
<tr>
<th>Bulk Drug</th>
<th>Amount (kg)</th>
<th>% Change Planned (for 1980)</th>
</tr>
</thead>
<tbody>
<tr>
<td>calcium coramine</td>
<td>289</td>
<td>+22.5</td>
</tr>
<tr>
<td>cyclophenthiazide</td>
<td>0.9</td>
<td>+9.6</td>
</tr>
<tr>
<td>dexamethazone TMA</td>
<td>9.5</td>
<td>+1.2</td>
</tr>
<tr>
<td>dihydrallazine sulphate</td>
<td>4,174</td>
<td>+11.8</td>
</tr>
<tr>
<td>ethister</td>
<td>3.9</td>
<td>(reduce to 0)</td>
</tr>
<tr>
<td>guanethidene sulphate</td>
<td>50.5</td>
<td>+12.1</td>
</tr>
<tr>
<td>hydrochlorothiazide</td>
<td>783.6</td>
<td>+60.0</td>
</tr>
<tr>
<td>lynestrol</td>
<td>105.0</td>
<td>+6.5</td>
</tr>
<tr>
<td>mestranol</td>
<td>3.1</td>
<td>+6.7</td>
</tr>
<tr>
<td>methandienone</td>
<td>156.2</td>
<td>+4.3</td>
</tr>
<tr>
<td>methyl testosterone</td>
<td>0 (increase to 12.0)</td>
<td></td>
</tr>
<tr>
<td>oestradiol</td>
<td>0.7</td>
<td>-70.0</td>
</tr>
<tr>
<td>oestradiol dipropionate</td>
<td>0.5</td>
<td>+4.7</td>
</tr>
<tr>
<td>oxyphenonium bromide</td>
<td>1027.7</td>
<td>+2.8</td>
</tr>
<tr>
<td>phanquone</td>
<td>5689.9</td>
<td>+12.1</td>
</tr>
<tr>
<td>progesterone</td>
<td>5.1</td>
<td>+28.7</td>
</tr>
<tr>
<td>testosterone</td>
<td>0.9</td>
<td>-33.5</td>
</tr>
<tr>
<td>testosterone propionate</td>
<td>17.8</td>
<td>-13.0</td>
</tr>
<tr>
<td>testosterone un ecyclenate</td>
<td>3.3</td>
<td>+15.8</td>
</tr>
<tr>
<td>testosterone valerionate</td>
<td>2.4</td>
<td>+5.7</td>
</tr>
<tr>
<td>nitrozezepine HCl</td>
<td>0 (increase to 15.8)</td>
<td></td>
</tr>
<tr>
<td>norethisterone acetate</td>
<td>1.7</td>
<td>(decrease to 0)</td>
</tr>
</tbody>
</table>

## The Production of Sulpha Drugs

<table>
<thead>
<tr>
<th>Product</th>
<th>Tonnes</th>
<th>% Change Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>sulphaphenazole</td>
<td>116.1</td>
<td>+2.8</td>
</tr>
<tr>
<td>sulphasomidine</td>
<td>234.4</td>
<td>+1.6</td>
</tr>
<tr>
<td>sulphasomidine micro</td>
<td>1.1</td>
<td>+13.0</td>
</tr>
<tr>
<td>sodium elkosin</td>
<td>0.3</td>
<td>(decrease to 0)</td>
</tr>
<tr>
<td>vesulong</td>
<td>0</td>
<td>(increase to 15.0)</td>
</tr>
</tbody>
</table>

SOURCE: Ciba-Geigy, Bombay, April, 1981.
APPENDIX 7.4

SOME DETAILS OF THE CIBA-GEIGY PLANT AT BANDUP, BOMBAY.

Pharmaceutical Products manufactured:

1. Therapeutic Groups: Respiratory insufficiency
   - Anti-allergics
   - Anabolic (Protein deficiency)
   - Anti-hypertension
   - Mucosal decongestant
   - Sulphonamides
   - Hormones
   - Antimycotic agents
   - Diuretics
   - Amoebicide
   - Analgesic, Antipyretic
   - Local antiseptic
   - Intestinal antiseptic.

2. Dosage Forms (as of 1979)
   - Ampoules (injectables) 9 products 1 to 5 ml
   - Liquids (oral/external) 7 products 10 to 100 ml
   - Creams and ointments 6 products 5 to 20 g
   - Powders (dusting) 2 products 10 to 100 g
   - Coated tablets 5 products † Presentation strip
   - Other tablets 25 products † & foil & bottles

3. Bulk Output (1979)
   - Ampoules 7.3 million
   - Liquids 4.2 million bottles
   - Creams, ointments 5 million packs (tubes)
   - Powders 0.5 million bottles
   - Tablets 1400 million tablets
   - Coated Tablets 75 million coated tabs.

4. Packs Produced (1979)
   - Ampoules 0.7 million
   - Liquids 4.2 million
   - Creams, ointments 5.0 million
   - Powders 0.5 million
   - Tablets 7.3 million
   - Coated Tablets 2.5 million
   
   TOTAL 20.2 million
Consumer Goods

1. Products: Toothpaste
   Cosmetic Powders
   Cosmetic Creams

2. Packs Produced (1979)
   Toothpaste 27.2 million
   Powders 0.5 million
   Creams 0.3 million

Total Number of Packs Produced (millions)

<table>
<thead>
<tr>
<th>Year</th>
<th>1976</th>
<th>1977</th>
<th>1978</th>
<th>1979</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36.5</td>
<td>38.8</td>
<td>32.9</td>
<td>48.2</td>
</tr>
</tbody>
</table>

increase 1976 to 1979 = 32%

Personnel

Total 1,254 of which 63% are in production operations.
There are no female workers, even in packing

Pharmaceutical packing 353 people
Consumer goods packing 157 people

Chemical Production

1. Products:
   Hormones
   Drugs
   End Products 13
   Intermediates 26
   Active Substances 11
   Intermediates 7

2. Production Total - about 95 tonnes per year (1979)

3. Means of Production:
   Manufacturing Units
   Total Reactor Volume about 30,000 litres
   130 Personnel in production.

SOURCE: Ciba-Geigy, Bombay, April, 1981.
APPENDIX 7.5.

FURTHER DETAILS OF THE CIBATUL PROJECT.

(i) Chronology

1958: First contacts Atul and CIBA. Decision to erect sulpha plant in India.
1959: Beginning of planning phase
1960: First contacts with contractor
1961: Selection of processes and orders for development
1962: Recruitment of personnel (Basel and India)
1963: Review of the project. Land selection
1964: Orders for equipment. Selection of sub-contractors
1965: Start of civil work
1966: Start of installations
1967: Mechanical commissioning. Chemical commissioning.
1968: Start of routine production (ASC & drug 1) Second phase of chemical commissioning (drugs 2 and 3)
1969: Review of the chemical processes
1972: Introduction of drugs 4 and 5

(ii) Cost Estimation

Approximate costs in millions of Swiss Francs

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost in Millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Project</td>
<td>18</td>
</tr>
<tr>
<td>Including Engineering in Basel</td>
<td>2</td>
</tr>
<tr>
<td>Development of processes</td>
<td>1.8</td>
</tr>
<tr>
<td>Planning (chemical part)</td>
<td>0.4</td>
</tr>
<tr>
<td>Administration/coordination</td>
<td>0.4</td>
</tr>
<tr>
<td>Commissioning (chemical)</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Total costs for CIBA in Basel</strong></td>
<td><strong>5.0</strong></td>
</tr>
</tbody>
</table>

(iii) Recruitment of Technical Staff in India

<table>
<thead>
<tr>
<th>Department</th>
<th>Positions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulpha Plant Manager</td>
<td>1</td>
</tr>
<tr>
<td>Assistant</td>
<td>1</td>
</tr>
<tr>
<td>Secretaries</td>
<td>4</td>
</tr>
<tr>
<td>Engineering Dept. Engineers</td>
<td>2</td>
</tr>
<tr>
<td>Fitters</td>
<td>10</td>
</tr>
<tr>
<td>Production dept. Senior Chemists</td>
<td>2</td>
</tr>
<tr>
<td>Shift chemists</td>
<td>6</td>
</tr>
<tr>
<td>Operators</td>
<td>60</td>
</tr>
<tr>
<td>Analytical dept. Chief Chemist</td>
<td>1</td>
</tr>
<tr>
<td>Chemists</td>
<td>4</td>
</tr>
<tr>
<td>Assistants</td>
<td>4</td>
</tr>
<tr>
<td>Process Control Lab. Chief Chemist</td>
<td>1</td>
</tr>
<tr>
<td>Shift Chemist</td>
<td>4</td>
</tr>
<tr>
<td>Assistants</td>
<td>4</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

(iv) Training of Indian Personnel in Basel and UK.

<table>
<thead>
<tr>
<th>Year</th>
<th>Position</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1964</td>
<td>Chief Engineer</td>
<td>3 Months</td>
</tr>
<tr>
<td>1965-66</td>
<td>Production Manager</td>
<td>10 Months</td>
</tr>
<tr>
<td>1970-71</td>
<td>&quot; &quot; &quot;</td>
<td>4 Months</td>
</tr>
<tr>
<td>1965-66</td>
<td>Head Quality Control</td>
<td>10 Months</td>
</tr>
<tr>
<td>1971</td>
<td>Project Engineer</td>
<td>2 Months</td>
</tr>
<tr>
<td>1965-66</td>
<td>First Works Manager(a)</td>
<td>6 Months</td>
</tr>
<tr>
<td>1963,70,79</td>
<td>Second Works Manager</td>
<td>3 Months (total)</td>
</tr>
<tr>
<td>1976</td>
<td>Manager sulpha plant</td>
<td>2 Weeks</td>
</tr>
<tr>
<td>1975</td>
<td>Manager Prod. development</td>
<td>5 Months</td>
</tr>
</tbody>
</table>

NOTE: (a) This individual left the company in 1967.

(v) Activity in India by Basel Personnel

<table>
<thead>
<tr>
<th>Time spent in Man weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical Dept.</strong></td>
</tr>
<tr>
<td>Project Leader</td>
</tr>
<tr>
<td>Plant Chemist 1</td>
</tr>
<tr>
<td>Plant Chemist 2</td>
</tr>
<tr>
<td>Plant Chemist 3</td>
</tr>
<tr>
<td>Laboratory Chemist</td>
</tr>
<tr>
<td><strong>Sub Total</strong></td>
</tr>
<tr>
<td><strong>Engineering Dept</strong></td>
</tr>
<tr>
<td>Chief Engineer</td>
</tr>
<tr>
<td>Mechanical Engineer 1</td>
</tr>
<tr>
<td>Mechanical Engineer 2</td>
</tr>
<tr>
<td>Instrument Engineer</td>
</tr>
<tr>
<td>Project Engineer</td>
</tr>
<tr>
<td>Commissioning Engineer</td>
</tr>
<tr>
<td><strong>Sub Total</strong></td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
</tr>
</tbody>
</table>

Total cost of personnel: about 0.6 million Swiss Francs

(vi) Priorities in the introduction of services

<table>
<thead>
<tr>
<th>1. Electricity</th>
<th>For Mechanical commissioning (testing of pipes and reactors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressed Air</td>
<td></td>
</tr>
<tr>
<td>Raw Water</td>
<td></td>
</tr>
<tr>
<td>2. Steam</td>
<td>For Mechanical commissioning (testing of heating systems)</td>
</tr>
<tr>
<td>Instrument Air</td>
<td></td>
</tr>
<tr>
<td>3. Cooling Water</td>
<td>For Mechanical commissioning (testing of cooling systems)</td>
</tr>
<tr>
<td>Chilled Water</td>
<td></td>
</tr>
<tr>
<td>Brine</td>
<td></td>
</tr>
<tr>
<td>4. Treated Water</td>
<td>For Chemical commissioning (plant trials)</td>
</tr>
<tr>
<td>High Pressure steam</td>
<td></td>
</tr>
<tr>
<td>Nitrogen</td>
<td></td>
</tr>
</tbody>
</table>

(vii) Training Programme for Indian Technical Staff

To introduce the new chemists, the following programme was followed. Lectures were given by Swiss and Indian staff.

(a) Lectures

<table>
<thead>
<tr>
<th>Topic</th>
<th>Hrs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry of Sulphonamides</td>
<td>2</td>
</tr>
<tr>
<td>Manufacturing processes</td>
<td>1</td>
</tr>
<tr>
<td>The Sulpha Plant</td>
<td>2</td>
</tr>
<tr>
<td>Quality control</td>
<td>1</td>
</tr>
<tr>
<td>Process Control</td>
<td>1</td>
</tr>
<tr>
<td>Laboratory Equipment</td>
<td>1</td>
</tr>
<tr>
<td>Duties of a plant chemist</td>
<td>2</td>
</tr>
<tr>
<td>Duties of a proc. control chemist</td>
<td>1</td>
</tr>
<tr>
<td>Organisation of the Sulpha staff</td>
<td>1</td>
</tr>
<tr>
<td>Pre entive Maintenance</td>
<td>1</td>
</tr>
</tbody>
</table>

Sub Total: 13

(b) Laboratory Course

<table>
<thead>
<tr>
<th>Topic</th>
<th>Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>How to use the Laboratory Equipment</td>
<td>1</td>
</tr>
<tr>
<td>Production of intermediates</td>
<td>2-3</td>
</tr>
<tr>
<td>Production of drug 1</td>
<td>1</td>
</tr>
<tr>
<td>Production of drug 2</td>
<td>1</td>
</tr>
<tr>
<td>Production of drug 3</td>
<td>1</td>
</tr>
</tbody>
</table>

Total: 6-7

APPENDIX 7.6
QUALITY CONTROL TESTS TO BE PERFORMED ON A CIBA-GEIGY SULPHA DRUG

(a) Statutory Tests (Based on British Pharmacopeia 1963)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Appearance</td>
</tr>
<tr>
<td>2.</td>
<td>Solubility</td>
</tr>
<tr>
<td>3.</td>
<td>Identification</td>
</tr>
<tr>
<td>4.</td>
<td>酸度</td>
</tr>
<tr>
<td>5.</td>
<td>領含</td>
</tr>
<tr>
<td>6.</td>
<td>脱水失重</td>
</tr>
<tr>
<td>7.</td>
<td>硫酸浸出物</td>
</tr>
<tr>
<td>8.</td>
<td>細胞</td>
</tr>
</tbody>
</table>

(b) Additional Tests stipulated by Ciba-Geigy

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>水溶性（NaOH）&amp; 軟透明度</td>
</tr>
<tr>
<td>10.</td>
<td>水溶性（HCl）&amp; 軟透明度</td>
</tr>
<tr>
<td>11.</td>
<td>批密度</td>
</tr>
<tr>
<td>12.</td>
<td>鎛含</td>
</tr>
<tr>
<td>13.</td>
<td>鐵含</td>
</tr>
<tr>
<td>14.</td>
<td>氯化物含量</td>
</tr>
<tr>
<td>15.</td>
<td>硫酸浸出物</td>
</tr>
<tr>
<td>16.</td>
<td>遺留不溶物</td>
</tr>
<tr>
<td>17.</td>
<td>TLC，包括次級斑點</td>
</tr>
<tr>
<td>18.</td>
<td>氣味</td>
</tr>
</tbody>
</table>

APPENDIX 7.7

SOME COSTS IN MANUFACTURING AT THE CIBA-GEIGY PLANT, BHANDUP: APRIL 1981.

(1) Wage rates

<table>
<thead>
<tr>
<th>Typical wages in Rs/month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator</td>
</tr>
<tr>
<td>Graduate Engineer (2 years experience)</td>
</tr>
<tr>
<td>Graduate Engineer (10 years experience)</td>
</tr>
<tr>
<td>Stenographer (basic grade)</td>
</tr>
<tr>
<td>Stenographer (higher grade)</td>
</tr>
<tr>
<td>Assistant Chemist</td>
</tr>
<tr>
<td>Senior Chemist (7,8 years experience)</td>
</tr>
<tr>
<td>Marketing Representative (field staff)</td>
</tr>
</tbody>
</table>

NOTE: All wages include Basic + Cost of living allowance + Housing allowance. All will be plus transport allowance, medical allowance, contributions to pension fund and Gratuity (250 - 300 Rs/month)

(ii) Raw Materials Costs.

<table>
<thead>
<tr>
<th>Costs in Rs/Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid (IP)</td>
</tr>
<tr>
<td>Caustic Soda (100%)</td>
</tr>
<tr>
<td>Benzene</td>
</tr>
<tr>
<td>Pyridine</td>
</tr>
<tr>
<td>Magnesium Metal (a)</td>
</tr>
<tr>
<td>Calcium Chloride (anhydrous)</td>
</tr>
<tr>
<td>Acetic Acid (glacial)</td>
</tr>
<tr>
<td>Activated Charcoal</td>
</tr>
<tr>
<td>Lactose (IP)</td>
</tr>
<tr>
<td>Starch maize (IP)</td>
</tr>
<tr>
<td>Talc Purified (IP)</td>
</tr>
</tbody>
</table>

NOTE: (a) Imported
Cost of Utilities

<table>
<thead>
<tr>
<th>Costs in rupees per unit shown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Towns Water</td>
</tr>
<tr>
<td>Electricity</td>
</tr>
<tr>
<td>Steam (self-generated)</td>
</tr>
<tr>
<td>Nitrogen</td>
</tr>
</tbody>
</table>

Costs in Rupees of some Selected Items of Equipment

1. Bottle Filling Machine, 400x51 containers per hour 89,600
2. Fully automatic strip-packing machine, 1500 tabs/min 54,800
3. Platform Weighing Scale, 0-300Kg 2,730
4. Cast Iron water pump, 100 cub ms/hour, 30m head 6,050
5. Centrifugal pump, StSt 316, FP motor 9,750
6. Cast steel piping, 15mm E.R.W., per metre 14.60
7. Air Circulator, 24" wall mounted FP motor 2,500
8. Drum Mixer, 1HP std.200litres 12,000
9. Eyewash fountain 698
10. Vacuum Pump 51cub ms/hour, 28" Hg vac 13,500
11. St.St reactor 4 cubic metres (Avesta Steel) 445,000
12. Glass-lined reactor, 2 cubic metres 254,000
13. Glass-lined reactor, 4 cubic metre (dbl.mech.seal) 385,932

SOURCE for all Tables in Appendix 7.7: Ciba-Geigy of India, April, 1981
APPENDIX 7.8

CONTENTS OF THE DOCUMENTS COMPILED BY CIBA-GEIGY TO APPRAISE POTENTIAL INVESTMENTS.

1. INVESTMENT PROPOSAL (IP)

(i) Justification of need
   - Analysis of the market
   - Present Capacity
   - Description of the intentions within the plan.

(ii) Technical Solution Proposed
   - Justification of location, alternative proposals
   - New capacity and reserves
   - Provision for future expansion, possible use of redundant capacity
   - Process to be applied
   - Alternatives
   - Rationalisation
   - Ecology
   - Local Laws and Regulations

(iii) Raw Material, Utilities, Personnel
   - Raw material and intermediate requirements and availability
   - Energy requirements
   - Personnel requirements and recruiting possibilities

(iv) Economic Justification and Profitability
   - Estimate of investment costs (within 30%) and size of subsequent investments
   - Principle considerations of economics and profitability
   - Assessment of financial risk.

(v) Organisational Aspects
   - Urgency, time-table for Pre-Project and Final Project
   - Potential losses in case of delay
   - Project organisation
   - Probable expenditure for each decision stage
   - Justification of advance credit requests.

(vi) Proposals
   - Elaboration of Pre-Project and suggestion
   - Appropriation of advanced credits.

2. PRE-PROJECT

(i) Brief description of changes since the previous decision stage
(ii) Description of the solutions developed from the terms of reference
(iii) Assessment and comparison of prospective solutions
(iv) Probable expenditure for the preparation of the Final Project
(v) Justification of any advance credit requests
(vi) Proposals.
3. FINAL PROJECT

(i) Brief description of changes since the last decision stage
(ii) Location within site plan
(iii) Capacity and reserves
(iv) Possibilities of expansion
(v) Description of buildings and installations, flow sheet etc.
(vi) Any interdependency with existing or planned installation
(vii) Safety
(viii) Ecology
(ix) Personnel expansion or reduction
(x) Time-table of implementation
(xi) Listing of expenditure, taking account of inflation (+ or - 10%)
(xii) Justification and cost of subsequent projects
(xiii) Economics and profitability
(xiv) Proposals

4. FINAL REPORT (FR)

(i) Actual capital expenditure compared to budget
(ii) Actual versus estimated profitability
(iii) Achievement of original objectives and justification of any changes
(iv) Conclusions to be considered in future projects.

(The Final Report is submitted within two years of the commissioning)

APPENDIX 7.9

SUMMARISED HISTORY OF THE CONSTRUCTION OF THE CIBA-GEIGY PHARMACEUTICAL FACTORY, INDONESIA.

27.12.68 Approval of the project by President Soeharto
19.03.69 Investment Proposal
21.04.70 First Pre-Project, estimated cost 8.9 million Swiss Francs
13.08.70 Second Pre-Project, estimated cost 9.2 million Swiss Francs
March 71 Access bridge finished
21.07.71 Final Project submitted
23.08.71 Final Project approved by Ciba-Geigy Executive Committee
Jan. 72 Foundation finished
Sept. 72 Start of Installation
30.04.73 First commercial production batch made
11.07.73 Official inauguration, in the presence of:
  - President Soeharto
  - President Director of Ciba-Geigy
  - Head Pharma Division of Ciba-Geigy.

APPENDIX 7.10

SUMMARISED CONTENTS OF A CHECKLIST USED BY ZID, CIBA-GEIGY, TO EVALUATE POTENTIAL SITES.

1. Location
2. Topography
3. Soil characteristics
4. Ownership
5. Conditions of site purchase
6. Date of availability
7. Restrictions - eg planning permissions, rights of way, building regulations
8. Description of locality
9. Any existing buildings and installations
10. Transport infrastructure
11. Water supply - public supply and opportunity for development of own facilities
12. Electricity - considerations as for 11
13. Gas
14. Effluent
15. Post, telephone and telegraph network
16. Climate
17. Regional infrastructure - eg housing, hotels, hospitals, schools mechanical workshops, carpenters and fire brigade
18. 'Peculiarities' - eg strikes, political agitation, religion, earthquakes etc.

APPENDIX 7.11

PHARMACEUTICAL PRODUCTION AT THE CIBA-GEIGY FACTORY, INDONESIA.

1. Dosage Forms Produced

<table>
<thead>
<tr>
<th></th>
<th>1979</th>
<th>1980</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquids, drops and syrups</td>
<td>5,120 l</td>
<td>7,930 l</td>
</tr>
<tr>
<td>Creams and ointments</td>
<td>1,500 kg</td>
<td>1,850 kg</td>
</tr>
<tr>
<td>Tablets</td>
<td>192 mill</td>
<td>181 mill</td>
</tr>
<tr>
<td>Coated Tablets</td>
<td>44 mill</td>
<td>28 mill</td>
</tr>
<tr>
<td>Capsules (hard gelatine)</td>
<td>9.1 mill</td>
<td>8.0 mill</td>
</tr>
<tr>
<td>Ampoules (Made by an Indonesian company under licence)</td>
<td>0.15 mill</td>
<td>0.08 mill</td>
</tr>
</tbody>
</table>

2. Number of packages produced.

In 1979, there were 2.96 million packages made. This includes tubes, bottles, strips and blister packs.

The trend in the number of packs produced, 1976-79 (number of packs in millions):

<table>
<thead>
<tr>
<th>Year</th>
<th>1976</th>
<th>1977</th>
<th>1978</th>
<th>1979</th>
<th>% change, ’76 to ’79</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.7</td>
<td>1.9</td>
<td>2.9</td>
<td>3.0</td>
<td>+74</td>
</tr>
</tbody>
</table>

APPENDIX 7.12

SOME COSTS OF MANUFACTURE AT THE CIBA-GEIGY FACTORY, INDONESIA:
August 1981.

<table>
<thead>
<tr>
<th>1. Wages</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Thousands of Rupiah per month)</td>
<td></td>
</tr>
<tr>
<td>Machine Operator</td>
<td>75 - 100</td>
</tr>
<tr>
<td>Graduate Engineer (2 years experience)</td>
<td>400 - 550</td>
</tr>
<tr>
<td>Graduate Engineer (10 years experience)</td>
<td>600 - 750</td>
</tr>
<tr>
<td>Typist/Secretary</td>
<td>160 - 275</td>
</tr>
<tr>
<td>Asst. Chemist/Pharmacist</td>
<td>125 - 250</td>
</tr>
<tr>
<td>Senior Chemist</td>
<td>350 - 500</td>
</tr>
<tr>
<td>Marketing Rep.</td>
<td>75 - 135 (a)</td>
</tr>
</tbody>
</table>

NOTE: (a) Plus up to 75% of that figure by commission on sales.

<table>
<thead>
<tr>
<th>2. Cost of Raw Materials in Rp/kg</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Caustic Soda (100%)</td>
<td>8,500</td>
</tr>
<tr>
<td>Absolute Ethanol</td>
<td>7,041</td>
</tr>
<tr>
<td>Calcium Chloride</td>
<td>2,048</td>
</tr>
<tr>
<td>Lactose</td>
<td>1,500</td>
</tr>
<tr>
<td>Starch Maize</td>
<td>2,020</td>
</tr>
<tr>
<td>Purified Talc</td>
<td>700</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Costs of Utilities in Rupiah per unit shown</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricity</td>
<td>75 kwh (a)</td>
</tr>
<tr>
<td>Raw Water</td>
<td>300 cubic metre</td>
</tr>
<tr>
<td>Filtered Water</td>
<td>850 cubic metre</td>
</tr>
<tr>
<td>Deionised Water</td>
<td>20,000 cubic metre</td>
</tr>
<tr>
<td>Steam</td>
<td>77,000 tonne</td>
</tr>
</tbody>
</table>

NOTE: (a) Plus depreciation on capital equipment [not specified]

APPENDIX 7.13

SOME FURTHER DETAILS OF THE CIBA-GEIGY CHEMICAL PLANT, INDONESIA.

(i) Chronology of the Project.

5.2.74 Investment Proposal - cost SwFr 1.26 million +/- 20%
22.3.74 Final Project. Prepared by Ciba-Geigy Pharma Indonesia
    cost SwFr 1.56 Million +/- 20%
21.8.74 Approval of the Project by Pharmaceutical Division, Basel, allowing
    a total cost of SwFr 1.511 Million
3.12.74 Application to the Department of Health, Republic of Indonesia
    for the project and master list of equipment.
12.2.75 Approval from the Investment Board of Indonesia for share capital
    increase of 0.6 Million to US $ 3.0 Million and loan structure.
24.2.75 Approval by Department of Health for project and duty-free import
    of master list.
May 75 Start of Construction.
Dec. 75 Start of Installation
March76 Head of Chemical Manufacturing Department appointed.
31.3.76 First batch produced.
5.4.76 Official inauguration by the Indonesian Minister of Health, the
    Swiss Ambassador and the Head of Pharma Production, Basel.
17.6.76 Preliminary Report on the project sent to Switzerland.
July to
Dec. 76 Technical problems with bulk density and filtration encountered.
Jan. 77 Routine production commenced.
### (ii) The Magnitude of Investment - Budget Costs (a)

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost (SwFr)</th>
<th>Nature of procurement</th>
<th>Duty %</th>
<th>Duty SwFr</th>
<th>Inflation %</th>
<th>Inflation SwFr</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant Building</td>
<td>200,000</td>
<td>local</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
<td>60,000</td>
</tr>
<tr>
<td>Solvent Store</td>
<td>40,000</td>
<td>local</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
<td>12,000</td>
</tr>
<tr>
<td>Landscaping Pipetrack</td>
<td>40,000</td>
<td>local</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
<td>12,000</td>
</tr>
<tr>
<td>Eqpt. for prod.</td>
<td>260,000</td>
<td>C.I.F.</td>
<td>20</td>
<td>52,000</td>
<td>0</td>
<td>0</td>
<td>52,000</td>
</tr>
<tr>
<td>&quot;         packaging</td>
<td>37,000</td>
<td>C.I.F.</td>
<td>20</td>
<td>7,400</td>
<td>10</td>
<td>3,700</td>
<td></td>
</tr>
<tr>
<td>&quot;         storage</td>
<td>13,000</td>
<td>C.I.F.</td>
<td>20</td>
<td>2,600</td>
<td>10</td>
<td>1,300</td>
<td>377,000</td>
</tr>
<tr>
<td>Installation</td>
<td>250,000</td>
<td>CIF/local</td>
<td>25</td>
<td>62,500</td>
<td>25</td>
<td>62,500</td>
<td>375,000</td>
</tr>
<tr>
<td>Safety Installation</td>
<td>10,000</td>
<td>CIF/local</td>
<td>25</td>
<td>2,500</td>
<td>25</td>
<td>2,500</td>
<td>15,000</td>
</tr>
<tr>
<td>Spare Parts</td>
<td>15,000</td>
<td>C.I.F.'</td>
<td>20</td>
<td>3,000</td>
<td>0</td>
<td>0</td>
<td>18,000</td>
</tr>
<tr>
<td>Generator</td>
<td>150,000</td>
<td>C.I.F.</td>
<td>30</td>
<td>45,000</td>
<td>10</td>
<td>15,000</td>
<td>210,000</td>
</tr>
<tr>
<td>Eng. Fees</td>
<td>40,000</td>
<td>local</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
<td>12,000</td>
</tr>
<tr>
<td>unforeseen</td>
<td>100,000</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>1,155,000</td>
<td></td>
<td>175,000</td>
<td>181,000</td>
<td>1,511,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** (a) The actual costs were marginally less than this

**SOURCE:** Ciba-Geigy, Basel, January, 1981.
APPENDIX 7.14

CONTENTS OF A CIBA-GEIGY PHARMACEUTICAL MANUFACTURING PROCEDURE

1. Composition - per tablet or ampoule etc.
2. Description of the dosage form - eg colour, form, weight, diameter thickness.
3. Special Measures - safety, "major tips" for manufacture.
4. Amounts of raw material for a "standard batch" (as practiced in Switzerland)
5. Manufacturing steps - required times, temperatures, pressures, filtrations, mixing etc.
6. Suitable machines and equipment.
8. Checks and assays - mainly physical for in-process controls.
10. Storage instructions.
11. Final comments.

APPENDIX 7.15

THE CONTENTS OF A CIBA-GEIGY CHEMICAL MANUFACTURING PROCEDURE

1. GENERAL
   - Reaction formulae
   - Operating principle (summary of the reaction without quantity and equipment details)
   - Use of product.

2. EQUIPMENT
   List of the required apparatus with the following indications:
   - size, materials of construction, position in plant, important details, such as agitator, condenser, regulator, safety devices.
   - special maintenance and control procedures.

3. STARTING MATERIALS
   List of all required raw materials, solvents, regenerates with the following indications:
   - Identification number
   - Name according to Ciba-Geigy nomenclature and commercial name
   - Quantity in kg per batch and mols
   - Assay
   - Quality requirements

4. YIELD
   - Standard yield of the product
   - Yield of solvent recovery

5. CAPACITY
   Quantity obtained, given in
   - batch per week
   - kg per week
   - organisational terms (eg per shift)

6. PROCESS SAFETY
   - Starting Materials, by-products, end product fire and explosion hazard, toxicity, physical data safety precautions, procedure in event of an accident, first aid
   - Chemical sources of danger
   - Technical sources of danger
   - Operational sources of danger
7. OPERATING PROCEDURE
   Detailed description of the operations and indication of:
   - quantities
   - identification of products
   - required times, temperatures, pressures, etc.
   - checks to be performed
   - volumes
   - action in case of deviations

8. WASTES
   (Solid, Liquid and Gaseous)
   - quantities
   - analysis
   - treatment

9. ANALYSIS
   Analytical procedures for:
   - raw materials
   - end product
   - in-process controls

10. REMARKS
    General remarks concerning:
    - Apparatus; improvisations, problems, alternatives
    - Reaction; known problems, side reactions, other procedures

11. APPENDIX
    - Material flow per batch
    - Flow Sheet/Apparatus diagram
    - Drying and Milling procedures
    - Risk analysis
    - Special reports

APPENDIX 7.16

EXTRACTS FROM THE CIBA-GEIGY "CORPORATE POLICY FOR THIRD WORLD COUNTRIES": 1980 revised version.

In order to contribute to the economic development of the Third World we shape our activities there as follows:

1. In the interests of both parties we participate as partners in the development of the economic potential of the DC's. We observe fully the rights and duties growing out of such a partnership.

2. In making business decisions on the Third World, eg. on products, services, technologies, investments, besides economic criteria we take into account the impact of the development of the host country. If a project shows a particularly strong impact, we are - considering the specific situation of the country - prepared to extend our short-range profit objectives.

3. If a DC adopts measures to protect its economy, such as import restrictions, conditions for ownership etc., we keep up the cooperation as long as partnership and adequate returns are not jeopardised in the long term.

4. We consider it our duty to advise our partner against undertakings if we are not convinced of their benefit for the partner (eg. prestige projects) even if such a move proves detrimental to our economic interests.

5. In the DC's we answer for progressive social and personnel policies adapted to the local conditions. In particular we (i) offer employees and workers training in many fields, if necessary abroad, (ii) make it possible for capable staff members to acquire international experience within our group, (iii) consider nationals in filling executive positions.

6. Convinced that in the long run the pursuit of the above principles is a necessity, we shall not be discouraged by unavoidable short-term set-backs and disappointments.

APPENDIX 8.1

COMMERCIAL ACTIVITIES OVERSEAS BY ASTRA: 1926-1980

1926: First export attempts - Finland and Colombia.
1934: Subsidiary founded in Latvia - closed during the Second World War.
1934: Subsidiary in Finland
1938: Investigated potential for subsidiaries in India and Egypt.
1939: Subsidiary founded in Brazil - "activated in 1956"
1940: Subsidiary in Norway.
1941: Subsidiary in Argentina.
1948: Subsidiary in Denmark.
1950: Subsidiary in Colombia (now not 100% owned).
1953: Subsidiary in United Kingdom - Production in St. Albans.
1953: Short-lived subsidiary founded in Spain.
1954: Subsidiaries founded in Canada, West Germany and Italy. The latter is now closed and sales are made through an agent.
1955: Subsidiary in Mexico.
1957: Subsidiary in Australia.
1959: Subsidiary in Netherlands.
1967: Subsidiary in France.
1973: Subsidiary in Belgium.
1975: Joint Venture in Japan.
1978: Subsidiary in Austria.
1979: Joint Ventures in India and Nigeria.

APPENDIX 8.2

A SUMMARY OF THE QUESTIONNAIRE SENT BY ASTRA TO IDL IN JUNE, 1976

General Questions
1. India (Government, demography and economy)
2. The Medical Environment (health problems and facilities)
3. The Pharmaceutical Environment (Government regulations)
4. The Pharmaceutical Industry and Market

Areas of Cooperation/ Business Ideas
5. Bulk Production (expected demand for Astra products, implications of Hathi Committee's list of Essential Drugs)
6. Formulation (as for question 5, possibility of licencing other products)
7. Marketing (areas in which Astra could assist, costs in India)
8. R&D (what might be done by the joint venture)
9. Further ideas on the formation of a joint venture

Detailed Questions
10. Equity allowed
11. Sector to which the proposed company would belong
12. Method of company registration
13. Laws regarding the agreement between Astra and IDL
14. Rules covering the production of pharmaceuticals
15. Other relevant legislation
16. Government's attitude towards foreign participation
17. Regulations for expatriates working in India
18. Availability of skilled labour
19. Export obligations for proposed new company

20. Latest information on the abolition of brand names

21. Likelihood that the National Drug Authority described in the report of the Hathi Committee would be introduced

APPENDIX 8.3

PARTICIPANTS AT THE SCREENING COMMITTEE MEETING DEALING WITH ASTRA-IDL: 14 JUNE, 1978

The Meeting was chaired by Mr. M. Varadarajan, Joint Secretary (Drugs), Ministry of Chemicals and Fertilisers.

Other participants were:

Dr. P. R. Gupta, Drugs Adviser, Ministry of Chemicals and Fertilisers
Mr. Sandhu, Deputy Secretary, Ministry of Chemicals and Fertilisers
Dr. Ghosh, Development Officer, Ministry of Chemicals and Fertilisers
Dr. S. S. Gothoskar, Drugs Controller (India)

together with eleven other representatives from the Small-Scale Industry Directorate, Secretariat for Industrial Approvals, Economic Affairs, Foreign Investment Board, Department of Science and Technology, and Directorate General of Technical Development.

Astra-IDL was represented by Mr. Hellström and five employees of IDL.

APPENDIX 8.4

FURTHER DETAILS OF THE CHEMICAL SYNTHESSES FOR LIGNOCAINE AND TERBUTALINE SULPHATE

Precise details of the manufacturing procedures are unavailable. The manufacture of lignocaine uses a range of reagents and solvents, including: meta-xylidine, acetone, activated charcoal, chloracetyl chloride, di-ethylamine, ligroine, sodium carbonate, sodium chloride, sodium hydroxide, sodium sulphate, sulphuric acid and toluene. Several unit operations are involved, including: distillation, acid extraction, filtration, refluxing, pH adjustment, precipitation, centrifuging and washing. The solvents are recovered in various ways.

The manufacture of terbutaline sulphate uses a similarly wide range of materials. The unit operations include bromination, vacuum distillation, extraction, crystallisation, hydrogenation, filtration and washing.
### APPENDIX 8.5

**SUGGESTED TRAINING PROGRAMME FOR WORKERS AT THE NEW ASTRA-IDL SITE**

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>DEPARTMENTS</th>
<th>DURATION</th>
<th>PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to plans at MIT and ASTRA-IDL</td>
<td>All Departments</td>
<td>(a)</td>
<td></td>
</tr>
<tr>
<td>GMP Concepts/Hygiene</td>
<td>All Departments</td>
<td>2x1 hour</td>
<td>March, 1979</td>
</tr>
<tr>
<td>Materials handling for pharmaceuticals.</td>
<td>QC and Stores</td>
<td>2x1 hour</td>
<td>(b)</td>
</tr>
<tr>
<td>Materials handling</td>
<td>Production Chemists</td>
<td>2x1 hour</td>
<td>(b)</td>
</tr>
<tr>
<td>Warehousing</td>
<td>Stores Personnel</td>
<td>1 hour</td>
<td>(b)</td>
</tr>
<tr>
<td>GMP practices</td>
<td>Production Supervisors</td>
<td>1 hour</td>
<td>April, 1979</td>
</tr>
<tr>
<td>Dry Products</td>
<td>Production Departments</td>
<td>1 hour</td>
<td>April, 1979</td>
</tr>
<tr>
<td>Wet Products</td>
<td>&quot;</td>
<td>1 hour</td>
<td>April, 1979</td>
</tr>
<tr>
<td>Parenterals</td>
<td>&quot;</td>
<td>2x1 hour</td>
<td>April, 1979</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>QC, Production Supervisors and Chemists</td>
<td>1 hour</td>
<td>May 1979</td>
</tr>
<tr>
<td>Specific QC topics</td>
<td>QC, Chemists</td>
<td>2x1 hour</td>
<td>May 1979</td>
</tr>
</tbody>
</table>

**NOTES:**
- (a) Intermittent
- (b) When convenient

**SOURCE:** Drafted by ASTRA, January, 1979, supplied to author October, 1980.
APPENDIX 8.6

THE AUTHORITIES WHICH HAD TO BE CONTACTED BY ASTRA-IDL IN CONNECTION WITH THE NEW FACTORY AT BANGALORE

1. Karnataka Industrial Areas Development Board
2. Central Public Works Department (awarding line of demarcation bordering National Highway)
3. City Improvement Trust Board (also awarding line of demarcation)
4. Inspector of Factories (approval of design details)
5. Boiler Inspectorate (design and installation of boiler)
6. Controller of Cement
7. Joint Plant Committee (Steel Authority of India)
8. Karnataka Electricity Board
9. Aerodrome Authorities (nearest neighbour)
10. Pollution Control Board
11. Bangalore Water Supply and Sewage Board
12. Drugs Controller (Karnataka)
13. Director of Industries

APPENDIX 8.7

ORIGINAL ASTRA COMPOUNDS TRANSFERRED TO ASTRA-IDL

Three of the drugs sold by Astra-IDL were original discoveries by the Swedish company. They are listed below.

1. XYLOCAINE (Lignocaine or lidocaine) This drug is a local anaesthetic and a drug of first choice for many applications. It is on the WHO list of selected drugs (WHO (1977b)). The technology for local manufacture had earlier been transferred to another Indian licensee, but the Astra-IDL agreement meant a substantial upgrading of the inflow of medical information from Astra on the usage of lignocaine in surgery and other fields.

2. BRICANYL (terbutaline sulphate) This is a well-known and widely used drug. Its primary use is as a bronchodilator and it can also be used in combination as a selective adrenergic beta(2)-stimulator.

3. BETALOC, SELOKEN (metoprolol) This drug can be used as a single ingredient and in combination as a selective beta(1)-blocker. It is suitable for the treatment of hypertension and angina pectoris and may also be given to patients with asthma.

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Ciba-Geigy sells a wide range of drugs in India and Indonesia. The majority of these are listed below, together with brief notes on their therapeutic value, based on Parish (1979), the British National Formulary, MIMS, Ciba-Geigy product literature and discussions with a British medical doctor with some years experience in India. This doctor emphasised that, in most cases, it is not possible to make a definitive judgement on the value of these drugs. Instead, the value of the drug should be assessed in the context of local health care facilities. A few of the drugs are included in the WHO "Essential Drugs" List (WHO (1977b)) and these are indicated ("WHO"). Some drugs are combination products (marked "comb") and are thus largely considered to be inappropriate formulations.

**CARDIOVASCULAR SYSTEM**

ADELPHANE (reserpine and dihydrallazine (WHO) (comb.) - can cause depression and nasal congestion. India and Indonesia.

ADELPHANE-ESIDREX ('ADELPHANE' & hydrochlorothiazide (WHO)) (comb.) again an (unnecessary) combination drug. India and Indonesia.

ISMELIN (guanethidine sulphate) - rather strong acting drug, could be dangerous if available to untrained personnel. India

NEPRESOL (dihydralazine sulphate) - vasodilator; useful together with other drugs. India.

SERPASIL (reserpine) - a popular drug, particularly in India. India and Indonesia.

Together, the above drugs make a useful contribution to therapeutic practice, because they represent different methods of action.

TRASITENSIN (oxprenolol and chlortalidone) (comb.) India.

ANTURAN (sulphinpyrazone) - very specialised use in coronary care. Medical opinion is divided over its value.

ESIDREX (hydrochlorothiazide (WHO)) possibly bendrofluazide is better and cheaper, but still a very useful drug. India.

NAVIDREX (cyclopenthiazide) - widely used, effective. India.

HYGROTON (chlortalidone (WHO)) - a very useful, reputable drug in wide general use. Indonesia.

TRASICOR and SLOW-TRASICOR (oxprenolol hydrochloride) - useful beta-blockers; thus drugs against 'diseases of civilisation'. Indonesia.

LOPRESOR (metoprolol tartrate) - as above. Indonesia.
GLYVENOL (tribenoside) - a specialist's drug with specific uses; could be dangerous in the wrong hands. Indonesia.

NITRODERM TTS (nitroglycerin) - a useful (rather sophisticated) form of application. Indonesia.

CENTRAL NERVOUS SYSTEM

TEGRETOL (carbamazepine) - has certain specific uses; valuable to all GPs. To be used under careful medical supervision. Indonesia.

SINTAMIL (nitroxazepine hydrochloride) - something of a 'me-too' drug, but discovered in India and therefore important symbolic value. India.

TOFRANIL (imipramine hydrochloride) - a popular anti-depressant, but there are several important conta-indications. Indonesia.

CIBALGIN (India) and SPASMO-CIBALGIN (Indonesia) (propyphenazon and allobarbitone) (comb.) - this drug has been withdrawn in many countries (see p475.) and is not recommended.

ANTRENYL (oxyphenonium bromide) - other products are more useful, and probably cheaper. India and Indonesia.

RESPIRATORY SYSTEM

CORAMINE-EPHIDRINE (nikethamide and ephedrine hydrochloride (WHO)) (comb.) - a drug of limited usefulness (not in British National Formulary). India.

ANTISTINE PRIVINE (antazoline sulphate and naphazoline nitrate) - there is a division of medical opinion over the value of this combination. India and Indonesia.

OTRIVIN (xylometazoline hydrochloride) - a useful, although not vital drug - especially in child care. India and Indonesia.

VIBROCIL (dimethindene maleate and neomycin sulphate and phenylephrine)(comb.) Indonesia.

FORISTAL (India) and FENISTIL (Indonesia) (dimethindene maleate) - not really a drug of first choice in this sub-group, but a reasonably useful addition.

CORAMINE (nikethamide) - this has some uses, such as in aiding the resuscitation of new-born babies. It should only be used by trained anaesthetists. India.
INFECTIONS

RIMACTANE (rifampicin) (WHO) - a very useful, but costly drug with some dangerous side-effects. It is valuable against TB and, in combination with clofazimine, against leprosy.

AUBRIL (sulphadiazine and trimethoprim) - not a 'combination' drug in the usual sense. Very useful against certain specific infections. India.

ELKOSIN (sulphasomidine) India and Indonesia.

ORISUL (sulphaphenazole) India. Both these drugs are useful, but are also sold by other companies.

ANAESTHESIA

NUPERCAINAL (cinchocaine hydrochloride) - a useful but dangerous drug if used incorrectly.

GASTRO-INTESTINAL SYSTEM

ENTERO-VIOFORM (quiniodochlor). India and Indonesia.

MEXAFORM (quiniodochlor and phanquone oxyphenonium bromide). India and Indonesia.

Both these drugs are now considered inappropriate and are being withdrawn in a phased manner; see p475-478.

ENDOCRINE SYSTEM, OBSTETRICS etc.

REGESTERONE (norethindrone acetate). India.

NORACYCLIN (lynestrenol and ethinyloestradiol) (WHO) - contraceptive pill. India

LUTOCYCLIN (progesterone) - contraceptive pill. India.

OVOCYCLIN (oestradiol dipropionate) - some important uses. India.

PERANDREN (methyltestosterone) - male sex hormone, useful in specialist hands. Definitely should not be available outside medical supervision. India.

TRIOLANDREN (testosterone esters)(WHO) India.

ORIMETENE (aminoglutethimide). Indonesia.

These products are part of a wide field - all need to be used under close supervision.
SKIN TREATMENT

CIBAZOL (sulphathiazole ointment) - very useful, with caution. India.
MILLICORTENOL (dexamethasone trimethyl acetate) - medical opinions vary on the value of this drug. India.
MILLICORTENOL-VIOFORM ('MILLICORTENOL' and quiniodochlor cream) - comb. India.
VIOFORM (quiniodochlor). India.
LOCACORTEN (flumethasone pivalate). Indonesia.

All drugs in this category should be used under close medical supervision.

MUSCULOSKELETAL AND JOINT DISEASES

TANDERIL (oxyphenbutazone). Indonesia.
VOLTAREN (sodium diclofenac). Indonesia.

There are many drugs available in this field. These products are not notably better than the other alternatives.

MISCELLANEOUS

DESFERAL (desferrioxamine mesylate) (WHO) - an iron-chelating agent used for iron removal. Rarely used, but an important treatment in rare blood disorders.

SOURCE: The list of products was supplied by Ciba-Geigy in India and Indonesia, September, 1984.
INTERVIEWS

In addition to the many employees of Ciba-Geigy and Astra and IDL whom I interviewed, I am grateful to the following individuals for allowing me to interview them:

I.A.ALVA (IDMA) Bombay, March, April, May, 1981.
H.ANNETT (Medical Doctor, Kiribati Government Health Service) Kiribati, October, 1981.
R.M.ATKINSON (Johnson and Johnson, Indonesia) Jakarta, July, August, 1981.
Raj BAMMI (CIPLA, Bangalore) Bangalore, June, July, 1981.
D.BANERJI (Centre of Social Medicine and Community Health) New Delhi, May, 1981.
S.BATLIWALA (Foundation for Research in Community Health) Bombay, February, March, April, May, 1981.
R.B.BERRA (and others at Hoffman LaRoche, Indonesia) Jakarta, August, 1981.
S.K.BORKAR (ex-Drugs Controller (India)), Bombay, February, March, 1981.
BIRIBO (Pharmacist, Kiribati Government Health Service) Kiribati, October, 1981.
M.BURSTALL (University of Surrey), Guildford, March, 1980.
D.CALDER (USAID) Jakarta, August, 1981.
J.CASTLE (PT Touche Ross) Jakarta, September, 1981.
K.CHANDRA (Chief of Public Relations, IDPL, and others) Rishikesh, May, 1981.
S.CHANDRA (Indian Institute of Science) Bangalore, June, 1981.
I.COLTART (Medical Doctor, N.M.Wadia Hospital) Pune, April, 1981.
W.A. CUTTING (Dept.of Child Health, University of Edinburgh) Edinburgh, September, October, 1982.
N.DAS (Application of Science and Technology in Rural Areas, Indian Institute of Science) Bangalore, July, 1981.
H.DASSANAYE (WHO) Jakarta, August, 1981.
D.C. Davies (ICI Indonesia) Jakarta, August, 1981.

B.S. Deshpande (Deputy Director, Karnataka State Government Medical Store) Bangalore, June, 1981.


C. Gastel (Carlo Erba, Indonesia) Jakarta, October, 1981.


R. J. Godfrey (Beecham, Indonesia) Jakarta, July, August, 1981.

S. S. Gothoskar (Drugs Controller (India)) New Delhi, May, 1981.


G. Hein (Asia Foundation) Jakarta, August, 1981.

K. Hermele (Swedish Factory Workers' Union) Stockholm, October, 1980.

T. Israelson (Editor, Fabriksarbetaren) Stockholm, October, 1980.


P. B. Kalff (Heinrich Mach, Indonesia) July, August, September, October, 1981.

K. Kalyan (and others, Boots, India) Bombay, March, 1981 and Maharashtra, April, 1981.

S. S. Kattishettar (Drugs Controller (Karnataka State)) Bangalore, June, 1981.

S. A. B. Kipping (Boots) Nottingham, December, 1980.

K. Kirana (Kimia Farma) Jakarta, September, 1981.

H. Kummar (Editor, Deccan Herald) Bangalore, June, 1981.


E. Lembong (P. T. Pharos) Jakarta, August, 1981.


J. B. Moddy (Unique Labs.) Bombay, March, 1981.
P.T. MAHMUD (and others, Manggarai) Jakarta, August, 1981.
D.R. MAITIMOE (Protestant Church of Indonesia) Jakarta, August, 1981.
A.V. MASURKAR (Government Central Pharmacy (Ayurvedic and Unani))
Bangalore, July, 1981.
G. MENEZES (and others, Hoechst, India) Bombay, June, 1981.
B.P. MISTRY (and others, CIBATUL) Gujurat, April, 1981.
A. NAIR (OPPI) Bombay, April, 1981.
R. NARAYAN (St. John's Medical College) Bangalore, July, 1981.
S.S. PANDYA (Acworth Leprosy Hospital) Bombay, March, 1981.
A. PATANI (German Remedies) Bombay, February, 1981.
M.K. PRADHAN (Glaxo, India) Bombay, April, 1981.
S. PRAWIROSUJANTO (Pancasila University) Jakarta, July, August, September, 1981.
B.V. RANGARAO (Centre for Studies in Science Policy, J.N.University)
New Delhi, May, 1981.
A. RAO (Medivenk Laboratories) Bangalore, July, 1981.
B.R.S. RAO (Smith Kline and French, India) Bangalore, July, 1981.
B. V. RAO (Eros Pharma) Bangalore, June, 1981.
K. RAJ (Editor, Economic and Political Weekly) Bombay, March, 1981.
D. RICKARDS (Fisons) Loughborough, June, 1980.
H.A. RIVAI (Darya Varia) Jakarta, September, 1981.
C.L. SARRIS (Pfizer, Indonesia) Jakarta, August, 1981.
M.SIRAIT (Government Food and Drug Administration) Jakarta, August, September, 1981.

K.SUBRAMANYAN (Ministry of Finance) New Delhi, May, 1981.

B.SUHARTO (Kalbe Farma) Jakarta, September, 1981.

M.SUKARYO (Kimia Farma) Jakarta, September, 1981.

I.SUNDARESH (Export Promotion Council, Government of India) Bombay, April, 1981.

G.SURYADI (BKPM) Jakarta, October, 1981.

TAN ENG LIANG (Soho Industri) Jakarta, August, 1981.


S.F.TIWOW (BKPM) Jakarta, October, 1981.

