



CHAPTER 10

HELP OR HINDRANCE?

The Rich World's Response

“The ‘haves’ are rarely willing to relinquish their control and their resources and share them with the ‘have-nots’.” (The Brandt Report)

THE BRANDT REPORT has documented the inflexibility of rich world institutions in the face of the problems confronting the Third World poor. ⁽¹⁾ Poverty is condemned but it is also tolerated. Rich world interests oppose changes in the world economy that might offer some hope for the poor, but challenge the dominance of the rich. Poor people are central to any analysis of the problems of the Third World. But when it comes to the solutions, the poor are almost invariably shifted backstage. Their interests tend to be lumped together with those of Third World governments and the powerful people in their societies, who may be as unenthusiastic about change that threatens their position as their counterparts in the rich world.

The solutions to the problems affecting the poor that concern us here - the lack of essential drugs and harmful marketing practices - cannot be separated from these wider political and economic issues. But in this chapter we focus on rich world attitudes in relation to Third World drug policies and the role of rich world governments, manufacturers and international and non-governmental organisations.

INTERNATIONAL ORGANISATIONS

The UN agencies most actively involved in helping to plan and implement drug policies appropriate to the needs of developing countries are WHO, UNCTAD, UNIDO and UNICEF. ⁽²⁾ Apart from the fact that these organisations have their headquarters in Geneva, Vienna and New York, it may seem strange to include them in a chapter on the rich world's response to the Third World's needs. After all, developing countries far outnumber developed nations amongst the 157 member states of WHO. But their inclusion here *is* appropriate.

The UN agencies are in the unenviable position of having to perform a balancing act in response to the conflicting demands and pressures imposed on them by very different governments. Their policies are, however, unlikely to succeed unless they are backed by the economic muscle-power of the rich industrialised countries. WHO officials are acutely aware that where health issues overlap with industrial and trade policies the whole area rapidly becomes a political minefield. They have to bear in mind that major drug producers may be few in number, but they can

control the purse strings. Over half the total annual WHO budget is made up of contributions from just half a dozen leading drug manufacturing countries (the US, West Germany, Japan, France, Britain and Italy). The United States alone contributes almost a quarter of WHO's entire budget. ⁽³⁾

The other obvious weakness inherent in the UN system is that WHO and other agencies can do little more than make recommendations. If governments choose not to act on them, UN agencies can do nothing besides issue polite reminders. For example, Dr. Halfdan Mahler, Director General of WHO, pointed out to member states attending the 1980 World Health Assembly that they were not making good use of the technical assistance available to them to serve their people's most pressing needs. ⁽⁴⁾

Thousands of pages of enlightened analysis of Third World drug problems have been written and filed away in cubic metres of reports. Similarly countless resolutions urging governments to act on WHO recommendations have been adopted by the World Health Assembly, but never translated into action. Not surprisingly all the paperwork and the resolutions have made almost no impact on the lives of the Third World poor. In some developing countries shortages of essential drugs are becoming more acute despite the false impression created by government reports to WHO that everything is under control.

WHO has traditionally concerned itself with the technical and professional aspects of drug use. It has played an important role in disseminating drug information. ⁽⁵⁾ But its focus of attention on drug policies shifted in the mid-seventies, soon after Dr. Mahler became Director General. WHO then grasped the nettle and began to emphasise the underlying social and economic issues. For example, in addressing the World Health Assembly in 1975, Dr. Mahler denounced inconsistent standards in drug marketing practices between developed and developing countries as "unethical and detrimental to health". ⁽⁶⁾

Dr. Mahler went on to point out that WHO had already made "a significant contribution towards assisting countries in improving drug quality, safety and efficacy". But he stressed that "It is now important to assist countries also in formulating and implementing national drug policies. The question is not merely technical, but also political and ethical, involving governmental responsibilities as well as the global social responsibility of the pharmaceutical industry with regard to both the availability of existing essential drugs and the development of better ones." ⁽⁷⁾

These wider social and economic issues have always concerned the relatively newer UN agencies, UNCTAD and UNIDO, which were set up during the 1960s expressly in response to problems generated by the growth of trade and industry. ⁽⁸⁾

UNCTAD has worked closely both with individual governments and at regional level in documenting the problems and drawing up new drug policies to counteract them. UNCTAD officials emphasise the need for poor countries to sever their dependence on monopoly suppliers. They advocate bulk-purchasing on competitive tender; revision (or suspension) of patent restrictions, and less

restrictive terms for the transfer of essential drug technology from rich to poor. In contrast to WHO, UNCTAD stresses that it is unrealistic not to include the private drug market in any rationalisation. The volume of private sales makes this essential to protect the interests of the majority. ⁽⁹⁾

UNIDO has carried out feasibility studies and provided technical assistance to a number of countries in setting up local production of finished drugs. UNIDO is also involved in projects to establish the production of bulk drugs using multi-purpose plants. ⁽¹⁰⁾ UNICEF shares WHO's close involvement in extending primary health care services and has its own drug procurement operation based in Copenhagen. Essential drugs are bought in bulk and re-sold to developing countries well below market prices. ⁽¹¹⁾

UNICEF, UNCTAD, UNIDO and other UN agencies are also all collaborating with WHO on different aspects of the WHO Action Programme on Essential Drugs, which is now the most comprehensive international programme on Third World drug policies. ⁽¹²⁾ The Action Programme emerged under the aegis of Dr. Mahler and the first significant step towards its adoption was taken in 1978 when the World Health Assembly passed a resolution (WHA31.32) urging member states to adopt essential drug lists, generic names and other measures including tougher drug legislation. The resolution also mandated WHO to cooperate with other UN agencies in assisting member states to adopt new drug policies and continue discussions with drug manufacturers on the supply of essential drugs. WHO also received a mandate to evolve strategies for reducing drug prices and to develop a code of drug marketing practice. ⁽¹³⁾

The first major evaluation of progress on the Action Programme took place four years later - at the May 1982 World Health Assembly. ⁽¹⁴⁾ The delegate from Ghana echoed the views of other member states in referring to the Action Programme as "one of the most exciting developments in the international health field". ⁽¹⁵⁾ But many delegates felt there had been rather more talk than action on the programme and some were particularly critical that dialogue with industry had been both so protracted and so unproductive. This view was expressed more forcefully by the Algerian delegate. He was highly sceptical about industry's motivation in switching from opposition to the concept of 'essential' drugs to a desire to participate and referred to the industry as "a new Trojan horse" inside the Action Programme. ⁽¹⁶⁾

The feeling that the industry's involvement needed to be approached with caution grew during the course of the Assembly. Delegates had earlier been promised concrete details of the terms under which manufacturers would be prepared to supply essential drugs to developing countries. ⁽¹⁷⁾ In the event delegates received no written clarification of the industry's well-publicised offer to supply essential drugs for public use in poor countries under "favourable conditions", although the offer had been made through the industry's international representative body three years previously. ⁽¹⁸⁾

A number of West German manufacturers made the first approach to WHO as early as 1977. At the time the pharmaceutical newsletter *SCRIP* quoted a leading German industrialist as saying: “But they [poor countries] must understand that they can’t get everything free, and must not attempt to undermine our patent and trade-mark positions which are essential for the industry’s profitability and existence.”⁽¹⁹⁾ The clear implication was that as *quid pro quo* for special prices for their health services, Third World governments would have to respect patents and brand names (against the recommendations of UN agencies). To date this assumption has not been publicly ruled out by the industry. When Dr. Vischer, President of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), addressed the 1982 World Health Assembly to clarify industry’s position, he left delegates still uncertain about whether the industry’s offer really held out any tangible benefits for the majority of developing countries. Dr. Vischer explained that “the words ‘favourable conditions’ ” meant “quite simply ... a *preparedness* to supply drugs to the countries taking part in the Drug Action Programme at *non-commercial* prices”.⁽²⁰⁾ (our emphasis) Readers who have seen the striking differences in drug prices (documented in Chapter 4 of this book) will share the bemusement of delegates to the World Health Assembly as to what is so “favourable” about a “preparedness” to negotiate on “non-commercial” prices.

Dr. Vischer went on to say that until countries were clearer about their drug requirements (quantities, pack sizes, labelling, time-scale for orders) he suggested “that it would not be helpful to speculate on how the term ‘favourable conditions’ should be interpreted in terms of actual prices”.⁽²¹⁾ So three years on from when the offer was originally made discussions with industry had yet to yield concrete results in the form of drugs for the world’s poor.

The deadlock was a classic chicken-and-egg situation. Industry (understandably) could not quote prices until it had a concrete order to go on. WHO, for its part, rightly had no intention of endorsing a deal for the world’s poorest countries without being sure that it would be to their advantage. However, we understand that in 1981, when industry was asked to quote its prices for the specific needs of one African country, Rwanda, the prices they came up with averaged out at more or less the same as those Rwanda was already paying *without* having to agree to any special terms.⁽²²⁾

Consequently, if lower prices were to be made conditional on their agreeing to recognise patents and brand names, most developing countries would probably do better bargaining for themselves by buying on competitive tender. That was certainly the conclusion of a number of delegates at the 1982 World Health Assembly. Brazil, for example, pointed out that by buying drugs on competitive tender for health service requirements, the Government never paid more than 50% of local commercial prices.⁽²³⁾

A number of the poorest countries expressed their uneasiness at the prospect of any long term agreements they might have to strike with powerful drug producers. These would reinforce their dependence and leave them highly vulnerable to future

market whims. Some thought that a policy whereby individual countries made agreements with manufacturers on a one-to-one basis also ran counter to some of the key aims of the Action Programme, above all the need to build up collective self-reliance through local production and regional cooperation. ⁽²⁴⁾ The consensus reached in discussion on the Action Programme indicated that WHO should give less priority to Geneva-based discussions with industry and concentrate on its role as a ‘catalyst’ for positive new policies in the Third World itself. ⁽²⁵⁾ This was summed up in the strongly-worded resolution passed by the 1982 World Health Assembly which urged that the Action Programme should be enforced ‘in its entirety’ and that WHO’s Regional Offices should see that the programme is ‘vigorously pursued’ in developing countries. ⁽²⁶⁾

The fact that delegates wanted the Action Programme to be implemented ‘in its entirety’ is crucial in ensuring future progress on a WHO code of marketing practice (WHO was mandated to start work on a code in May 1978). A number of delegates wanted to know why no progress had been reported on the code. Countries of very different political complexions pressed for what the Chilean delegate described as ‘dynamic legislation ... as a defence against certain unethical practices of some producers’. ⁽²⁷⁾ Cuba, Burundi, Romania, and Samoa all raised the question of a WHO code. But the most forceful intervention on the need for a WHO-sponsored international code was made by the Dutch delegation. The Netherlands urged that a code was necessary ‘to prevent serious problems in which the good name of our organisation (WHO) might be at stake’, having previously cited problems including ‘misinformation, incorrect advertisements, ineffective products, the introduction of inappropriate technologies and ... a possible move from essential drugs to non-essential drugs in the programme’. ⁽²⁸⁾

Although a number of delegations gave priority to the need for a code, immediate prospects of a code being introduced at the May 1983 World Health Assembly are not good. Senior WHO officials make no secret of the fact that influential member states are firmly opposed to any international regulations on drug marketing. The organisation is still feeling the shock waves after the adoption of the International Code of Marketing of Breast-milk Substitutes in 1981 in the face of strong opposition from the United States. ⁽²⁹⁾ WHO officials feel that a code on drugs would be too much of a political hot potato for the organisation in present circumstances. Some see the ‘threat’ of a WHO code as a useful Sword of Damocles to encourage industry’s cooperation. Their fear is that attempts to push through a code would encourage such fierce opposition that the future of the entire Action Programme might be in jeopardy. It is a gamble they will not take without concerted pressure from more member states than have so far pushed for a code publicly.

For its part, the US Government has left no room for doubt about its views on the matter. During the discussion at the 1982 World Health Assembly the US delegate strongly objected to a draft resolution on the marketing of breast milk substitutes. (This was put forward to improve enforcement of the 1981 code.) The Americans were particularly unhappy with a reference stating that the code ‘was designed to *regulate* these marketing practices’. (our emphasis) The US

delegation was unsuccessful in quashing the 1982 follow-up resolution but they did get the wording changed to read that the Code had been “intended to, *inter alia*, deal with these marketing practices.”⁽³⁰⁾

On the issue of a pharmaceuticals code, the US delegate to the January 1982 meeting of the WHO Executive Board stated that he himself “did not think it would be constructive to give that matter (the question of a WHO Code) any further consideration particularly in view of the fact that the Director-General was shortly to be engaging in consultations with the representatives of the International Federation of Pharmaceuticals Manufacturers Associations. It was important not to take any steps which might jeopardise the outcome of those consultations.”⁽³¹⁾ His words were echoed by the US delegate at the May 1982 Assembly who expressed the hope that the Assembly would “take no action that might damage that cooperative relationship and prove counterproductive regarding the supply of essential drugs to countries where they were most needed.”⁽³²⁾ Other US officials have recently been more explicit in referring to the code as “irrevocably opposed by the US”.⁽³³⁾

RICH WORLD GOVERNMENTS

Most governments of drug-producing nations have a decidedly ambiguous relationship with the local drug industry. This is particularly true of major drug-exporting countries such as Britain.⁽³⁴⁾ An industry-funded publication refers to the “dual and seemingly conflicting functions” of the British Department of Health and Social Security (DHSS) and explains: “On the one hand, its role could be seen as that of a regulatory authority with direct controls over the development, marketing and promotion of drugs...” but “on the other hand, the DHSS is the sponsoring department for the industry and is, therefore, keen to assist the latter’s performance, especially in the field of exports.”⁽³⁵⁾

EXPORT CONTROLS

Before a new drug can be marketed in Britain, manufacturers have to obtain a product licence from the Government. These licences are made conditional on the drug being approved by the Committee on Safety of Medicines, which makes a thorough check on the safety, quality and efficacy of each new drug. But when it comes to drugs produced for export the regulatory functions of Government appear to be overshadowed by a desire to achieve a healthy export balance. Drug exports are specifically exempted from these controls.⁽³⁶⁾ The same is true in other major drug producing nations, such as Switzerland and France, which have also excluded drugs for export from regulatory controls.⁽³⁷⁾

This gives exporters *carte blanche* to export drugs that have been withdrawn at home because they proved unsafe or ineffective. Effectively there is nothing to stop overseas sales of drugs that would never have been licensed for sale on the home market. In the words of a US Congressman, “under current law, companies can pretty much export whatever they can convince ... people abroad to buy”.⁽³⁸⁾

In most developing countries controls are notoriously weak - if not non-existent. As a result patients and consumers in poor countries are left highly vulnerable to questionable practices. The full extent of the problem is impossible to gauge because governments of exporting nations are reluctant to release details of exactly which products get exported where. ⁽³⁹⁾ Trade secrecy is well defended by governments and manufacturers alike.

When questioned about the different standards applied to drug exports, rich world governments advance essentially the same arguments. For example, successive British Governments have all stressed that factors such as disease patterns, climate, diet and the availability of health services vary so much from one country to another that regulatory decisions taken in Britain would have little relevance to the requirements of developing countries. Consequently, as a civil servant explains, "The United Kingdom has long argued that the only effective and appropriate method of controlling the safety and efficacy of medicines is for the less developed countries to develop their own procedures for control". ⁽⁴⁰⁾

Does this mean that if a British manufacturer goes on marketing an unsafe drug after it has been removed from the home market, the British Government feels under no compulsion to do anything? And would this apply even to the marketing of drugs with known toxic side-effects in poor countries where they will inevitably be sold without a doctor's prescription? When these questions were raised in the British Parliament in 1979 Government spokesmen were adamant. "It is for the governments of the Third World to decide whether they will permit that to happen ... there is a limit to what Her Majesty's Government can do." ⁽⁴¹⁾

The response was negative, albeit realistic in view of the difficulties for a national government in attempting to control the activities of transnational companies. But the absence of export controls is also presented in a positive light - in terms of the need for exporters to respect each country's right to choose. In the words of a spokesman for a former British Government, "Is it not reasonable to question whether we have the right to deny a foreign government the right to make their own decision on the basis of their own expertise on the circumstances prevailing in the country?" ⁽⁴²⁾ A corollary to this freedom of choice argument is that policy statements usually imply that developing countries are also opposed to tighter export controls.

The arguments sound persuasive. After all, interference smacks of neo-colonialism. But looking at the argument in the light of the needs of poor countries it is not true that people in the Third World are happy with the existing situation where the onus falls on them to sift out hazardous and ineffective drugs. In fact there is a growing body of Third World opinion urging exporting nations to take an active role in safeguarding the health of people in developing countries. One illustration of this is the joint "Declaration on the Export of Hazardous Substances and Facilities" issued by participants from nine developing countries who attended an international seminar in Malaysia in 1980. The Penang Declaration urges that "there should be no distinction between domestic and foreign consumers; so that

if a hazardous substance or production facility is banned, disapproved or restricted in any country, the presumption will be that it will be treated equivalently for export purposes.”⁽⁴³⁾ The Declaration also stipulates that governments should only allow the export of a banned product to go ahead in exceptional circumstances, after the exporters or the government of the importing country have made a special case that the benefits expected from the hazardous product would outweigh its health risks.⁽⁴⁴⁾

An attempt to introduce export legislation along these lines was made in the United States in 1980 when Congressman Barnes presented a bill to Congress on the Export of Hazardous Products. It sought to shift the burden of proof so that a case would have to be made in favour of rather than against the export of a product banned or restricted in the US.⁽⁴⁵⁾ Not only has Congressman Barnes’ bill been abandoned, but in May 1982 the Reagan administration was considering lifting a 44 year old prohibition on the export of unapproved drugs.⁽⁴⁶⁾ However there is a fundamental weakness in controls that apply only to exports from major drug producing nations. They can do nothing to stop manufacturers from producing banned or obsolete drugs in factories overseas.

INFORMATION POLICIES

The major fallacy in rich world complacency about the Third World’s ‘freedom of choice’ is that this freedom can only be illusory unless regulatory agencies and drug prescribers receive a good flow of accurate and balanced drug information.

When the question of the need for manufacturers to give full information to Third World prescribers was raised in the British Parliament in 1979, the Government expressed a decidedly optimistic view of information provision in developing countries. In the words of one Government spokesman, “It is *likely* that many governments supply information to their doctors reflecting the licensed status of products in the United Kingdom and in turn, the promotional literature used in the United Kingdom, which must conform to that approved status ...”⁽⁴⁷⁾ (our emphasis) Rich world health officials imply that the poor world’s needs are already adequately covered by existing sources of drug information that can be tapped by their regulatory authorities. For example, British health officials point to the British Pharmacopoeia, and other national quality specifications, which can provide a reference framework on formulation and quality.⁽⁴⁸⁾

A number of major drug producing nations, including the US, UK, Japan and Italy, are participating in a WHO Certification Scheme set up to give importing nations some guarantee of the quality and reliability of drugs on the world market.⁽⁴⁹⁾ Governments that join the scheme undertake to monitor the quality of drugs produced locally and importers can ask for a certificate indicating whether a particular drug is licensed for sale on the home market. But the scheme is not as comprehensive as it might be. WHO itself points out it provides no guarantee of the quality of drugs once they reach their destination.⁽⁵⁰⁾ Moreover, it is being under-used. Some key drug exporters such as Switzerland and West Germany

were not among the original signatories, and by May 1982 less than half the WHO member countries had agreed to participate. ⁽⁵¹⁾ Some exporters would not agree to comply with all the terms of the scheme. Britain, for example, undertook to certify only the quality (not safety and efficacy) of drug exports, in accordance with the Medicines Act. ⁽⁵²⁾

Governments of drug-producing nations also stress that WHO is already collecting and disseminating drug information useful to developing countries. They also point out that Third World regulatory agencies can always consult reference books and their better-equipped counterparts in developed countries for assistance in evaluating drugs. ⁽⁵³⁾ But the existing mechanisms are totally inadequate to meet the needs of the regulatory agencies throughout the Third World. Data-collection and dissemination on new products, adverse reactions and drugs withdrawn from the world market is handled by only a couple of scientists at WHO headquarters. WHO also runs a computerised system to collect details of drug adverse reactions in Uppsala in Sweden. But hardly any developing countries are amongst the two dozen nations to whom information is currently being circulated, despite the fact that more developing countries would like to participate if they were allowed to. ⁽⁵⁴⁾

Some recent initiatives to give more support to developing countries in improving their regulatory systems have been coordinated within the European Region of WHO. These proposals have had most active backing from the Nordic countries (Norway, Denmark, Sweden and Iceland). Some have met with opposition from other European Governments, notably those of Switzerland, West Germany, France and Britain. ⁽⁵⁵⁾

One recent initiative was a series of discussions between regulatory authorities from developed and developing countries held in Rome. Referring to one of the aims behind the meetings (“to propose a scheme for cooperation in registration and drug control between developed and developing countries”) a senior WHO official felt the need to describe the intention as “innocent” when he addressed an audience including representatives of the US drug industry. ⁽⁵⁶⁾ A proposal that has been fiercely resisted by governments of a number of influential drug producing nations is to establish a Drug Evaluation Unit in Copenhagen. Amongst other functions, this would assist developing countries by providing reliable and impartial assessments on new drugs. Industry may be keen to see more uniformity in drug registration procedures which would cut their costs, but there is concerted opposition to any suggestion of supra-national evaluations of new drugs. ⁽⁵⁷⁾

In assessing new drugs the question whether they are really *needed* is central to poor countries. But amongst developed countries, the Norwegian Government is exceptional in including a “test of need” for new drugs. ⁽⁵⁸⁾ Most governments in the rich world are unanimous in opposing the concept of “need” becoming a criteria for assessing new drugs. ⁽⁵⁹⁾ Inevitably this limits the relevance and usefulness of their regulatory decisions as a guide to Third World health authorities.

The prospects of rich world governments putting the interests of developing countries before their trade balances are not optimistic. However, one encouraging sign is a statement made somewhat surprisingly by the West German delegate to the 1982 World Health Assembly. Dr. Gaudich is reported to have said that “the industrialized countries of the European Region should really direct their efforts to ensuring that no drugs were exported which were not admitted in the country of origin and that patient information was of the same quality in the exporting and in the importing country, particularly in regard to drug safety and such matters as contra-indications, warnings and precautions to be taken ”. ⁽⁶⁰⁾

TECHNICAL ASSISTANCE

Rich world governments are of course contributing valuable technical assistance to developing countries in the field of drug production, management and training. For example, the Italian Government has recently allocated \$15 million (£8.3m) specifically to the WHO Action Programme on Essential Drugs. ⁽⁶¹⁾ According to a recent WHO report, the Norwegian, Dutch, Swedish, Danish, French, West German, Swiss and US Governments are all helping to finance projects to improve the supply of essential drugs in developing countries. ⁽⁶²⁾

Under the British aid programme funds were allocated to finance medical sciences training for over 1,000 students from developing countries in 1980. ⁽⁶³⁾ Special training of official inspectors for medicines control has also been arranged jointly between the British Government medicines inspectorate and the law department of the Pharmaceutical Society of Great Britain. ⁽⁶⁴⁾

In addition to their proportionately large contributions to WHO and other international agencies, governments of rich drug producing nations all allocate considerable official development aid funds to health-related projects. For example, an estimated 8% to 10% of the total British aid programme was allocated to health aid in 1980. This means that developing countries benefited from between £69 and £86 million in health aid. ⁽⁶⁵⁾ In the same year Britain benefited from sales revenue on over £404 million worth of pharmaceutical exports to developing countries (including the relatively rich oil-producing states). ⁽⁶⁶⁾

Some aid funds are allocated to projects directly related to the needs of the poor - such as the training of village health workers. But the vast majority (over two-thirds of total British official development assistance in 1980) was either fully or partially tied to the purchase of British goods and services. ⁽⁶⁷⁾ In some cases poor countries have been encouraged to buy expensive capital equipment and high-technology machinery at the expense of the basic services relevant to the needs of the poor majority. The non-governmental organisations are increasingly putting pressure on rich world governments fundamentally to reappraise the *quality* of official aid and ensure that aid benefits the Third World poor instead of adding to their deprivation. ⁽⁶⁸⁾

Rich world governments have generally been slow to respond to initiatives that would put the interests of poor consumers before those of rich world

manufacturers. But in 1981 governments of all the industrialised countries (with the sole exception of the United States) showed their willingness to take a stand to safeguard the health of the world's poor by voting for the International Code of Marketing of Breast-milk Substitutes. In the build-up to the World Health Assembly vote, the British and other Governments showed their readiness to listen and to be swayed both by the body of professional opinion and pressure from the general public and supporters of aid agencies and other non-governmental organisations.

NON-GOVERNMENTAL ORGANISATIONS

An assortment of very different organisations share an active interest in the supply and marketing of pharmaceuticals in developing countries. The views of the manufacturers are represented both by national and international industry associations whose main function is to bring pressure to bear to defend their members' interests. Similarly, the lobby on behalf of patients and consumers (particularly the Third World poor) is actively pursuing changes in current drug marketing practices. The activities of lobbyists based in the rich world need to be looked at alongside those of Third World pressure groups because they work closely together. We look first at a number of charitable organisations based in developed countries, that are involved in supplying drugs to charities in developing countries.

ECHO

ECHO (the acronym for Equipment to Charity Hospitals Overseas) in Britain, and Action Medeor, in West Germany, are both non-profit-making organisations that supply essential drugs to charity and mission hospitals throughout the Third World. We shall concentrate on ECHO, the larger of these two similar, but unconnected organisations.

ECHO was set up in 1966 on the inspiration of the Burtons, a husband and wife team, after they returned from carrying out medical missionary work in Africa. Whilst in Africa they had experienced the chronic shortages of basic medical equipment. Back in Britain, they launched an imaginative scheme to collect obsolete, but perfectly serviceable, hospital equipment and send it to poor countries where it would be put to good use.

Today the renovation of used hospital equipment is a relatively small part of ECHO's operations. But the supply of new equipment, worth just under £1 million in 1980, has grown to the extent that ECHO now has a Technical Department to provide a back-up service to customers and adapt equipment so that it can use solar energy systems. Standard equipment is either bought at competitive prices, or ECHO commissions small manufacturers to produce specific items, like operating tables, to very simple, highly cost-conscious designs.

In the early 1970s ECHO carried out research into its customers' needs and found that most were facing problems with the escalating cost of basic drugs. Peggy Burton explains the background to ECHO's decision to supply drugs: "In 1974

the worldwide supply of drugs to mission hospitals was still critical. Inflation fanned the flames created by world poverty and need. The questionnaire we circulated threw up enormous demands, especially in the basic generic, life-saving drugs such as antibiotics, anti-leprosy, anti-tubercular and anti-malarial drugs. For example, a mission on the Ivory Coast spent £15,000 on drugs in 1973; for the same amount of drugs in 1974 it spent £26,000. In 1975, the same drugs would cost nearly £40,000. ECHO set itself the task of reducing the expenditure to the 1973 level.’⁽⁶⁹⁾

ECHO soon found itself handling large drug orders, particularly when aid agencies like OXFAM needed emergency supplies for disaster relief work. Demand rose, so that in 1977 a budget of £224,000 was specifically allocated for drug purchases that year. By 1980 ECHO’s annual drugs turnover had leapt to £2 million. The scale of ECHO’s operations is illustrated by the fact that it has held stocks of up to a third of total world production of the vital anti-leprosy drug, dapsone, ready to turn round orders within 7 to 14 days.

ECHO supplies a range of 120 basic generic drugs which it buys both from British generics manufacturers and increasingly from Pharmamed, a non-profit-making factory in Malta. Pharmamed was set up by the International Dispensary Association (IDA), with funds from the Dutch Development Bank. In 1981 its production was 600-700 million tablets a year, which were sold to ECHO, IDA, Action Medeor and other non-profit-making drug suppliers in Europe.⁽⁷⁰⁾

ECHO sells only good quality generics (to British Pharmacopeia standards) and offers its customers considerable savings on the cost of equivalent brand name products. According to Dr. Burton, ECHO’s Medical Director, “The price saving is in the range of the generic drug being anything from one-quarter to one-tenth of the price of the exact equivalent advertised product”. He adds that “the argument the multinationals used to give that their ethical products were superior to the generic, has no real basis in scientific fact ...”⁽⁷¹⁾

A number of research-based manufacturers have shown their readiness to collaborate with ECHO. Some are charging ECHO specially reduced prices for a few of their patented products that are particularly relevant to Third World needs, but normally prohibitively expensive. For example, ECHO has bought rifampicin from Ciba-Geigy (under its brand name Rimactane) at a quarter of the commercial price in Britain. This obviously helps the mission hospitals. For manufacturers, ECHO offers the advantages of regular, sizeable orders.

ECHO has recently produced its own Pharmaceutical Data Sheet Compendium. This booklet gives a simple description of how to use each of the basic generic drugs supplied. It is aimed at nurses and health workers who may not be aware of the existence of simple generic equivalents to brand-name products. Dr. Burton explains, “we have found that this information is rarely available to the users of simple basic generic drugs, whereas the multinational companies flood the world with literature concerning their advertised ethical drugs”.⁽⁷³⁾ At the receiving end, some hospitals are translating the data sheets into local languages so that they will be of use to people working in village dispensaries.

AID AGENCIES

Amongst ECHO's biggest customers are aid agencies such as OXFAM, particularly when emergency drug supplies are provided in disaster situations, but also when drugs are supplied as part of the main core of small-scale development work. Recently, as we have seen, some of the biggest European aid agencies, notably NOVIB, have put up funds to help create self-reliance in drug supplies with the building of Gonoshasthaya Pharmaceuticals factory in Bangladesh. Aid agencies are also campaigning for drug policies to benefit the poor.

But there is also a negative side to aid agencies' involvement in drug supply. Like manufacturers, some have created problems by exporting a mass of drugs that poor countries do not want, or need. The problems have been particularly acute in disaster situations where human and physical resources are stretched to the limit. For example, during the disastrous floods in Bangladesh in 1974, a motley collection of medicines and samples, scrambled together by generous and well-intentioned donors, poured into the country. The physical effort of picking through the drugs to sort out the useful from the useless was a sheer waste of the overworked doctors' time. A former Director of Drug Administration in Bangladesh stresses that this sort of philanthropy which remains blind to real need can be positively harmful. ⁽⁷⁴⁾

OXFAM staff and health teams experienced a similar situation during the height of the Kampuchean emergency in 1979, when random drug donations from all over the world created chaos. ⁽⁷⁵⁾

But it is not only in emergencies that unsolicited gifts of medicines can cause serious problems. According to a Government official in Upper Volta, "The most uncontrolled section of imported medicines are the gifts from governments and aid agencies. These gifts are accepted without quibble or question and of course many of them will be, at the very least, inappropriate. There are also problems for the nurses or dispensers in actually administering these free medicines, since they come from various countries of origin, and of course have differing strengths. There may also be the temptation for the nurses to hand out these free medicines to patients, not because they are suitable treatments, but because they are all that is available." ⁽⁷⁶⁾

HEALTH PROFESSIONALS

Individuals and groups of health workers, nurses, doctors and pharmacists in developed countries are increasingly expressing concern over the scale of the problems faced by their counterparts in poor countries. Many come up against similar dilemmas in their everyday work - particularly the heavy dependence on drugs which is perpetuated by promotion and patient demand.

One example of a group of health professionals which is taking an active interest in the specific problems of drug use in developing countries is the International Pharmaceutical Federation (known as FIP). FIP has set up a special Third World

project, which is co-ordinated by Professor D’Arcy, Head of the Pharmacy Department at Queen’s University, in Northern Ireland. The first objective was to discover the key problems that lend themselves to technical solutions. FIP members would then offer their services to Third World health authorities as consultants on pharmacy training, drug storage and transportation and technical aspects of setting up local production. FIP planned to make specific recommendations to WHO based on the information gathered from the national pharmaceutical associations in various Third World countries. But Professor D’Arcy believes that in addition to the technical problems, “FIP must also tackle the problems *from home* by setting up a more active dialogue with the industry on the special needs of the Third World”.⁽⁷⁷⁾ (our emphasis)

A number of European and American non-governmental medical groups have acted to fill the vacuum created by the lack of objective information on the safety and efficacy of new and existing drugs. In Britain, the *Drug and Therapeutics Bulletin*, edited by Dr. Andrew Herxheimer and written by general practitioners and specialists, discusses appropriate treatments and reviews manufacturers’ claims for their products. The bulletin was started in 1963 and initially sent to doctors on a subscription basis. Since 1980, the Government has paid for it to be distributed to all doctors in Britain. The UK Consumers Association, which publishes the bulletin, also offers free subscriptions to Third World health officials and prescribers.⁽⁷⁸⁾

A number of professional groups and individual doctors both in developed and developing countries have produced reports highlighting abuses in drug marketing and use in the Third World. The intention behind these studies has been to inform professional and public opinion and encourage positive corrective from governments and drug manufacturers.⁽⁷⁹⁾

A recent example of the growing alarm shared by scientists and health professionals at the worldwide misuse of drugs is the “Statement Regarding Worldwide Antibiotic Misuse” issued by participants attending a conference on bacteriology in the Dominican Republic in 1981. The signatories, mainly from the developed but also from developing countries, set up the Alliance for the Prudent Use of Antibiotics (APUA). As a first step they intend to press for national and international committees to issue guidelines on the prudent use of antibiotics and to lobby for “proper standards of advertising and dispensing” of antibiotics to be adhered to worldwide.⁽⁸⁰⁾

TRADE UNIONS

The Geneva-based International Federation of Chemical and General Workers Unions has a longstanding interest in drug marketing practices. In Britain, officials of the General and Municipal Workers Union (GMWU) have been particularly active in exploring new policies to benefit people in the Third World.

HEALTH ACTION INTERNATIONAL (HAI)

Health Action International was launched in Geneva in May 1981, at the end of an international seminar on Pharmaceuticals, attended by participants from 27 developing and developed countries. ⁽⁸¹⁾ HAI is a network of over 50 development action, consumer and other public interest groups and organisations. Its founder members include development agencies such as OXFAM, the International Organisation of Consumer Unions and organisations of health professionals such as the Voluntary Health Association of India. Each member has different priorities and specific areas of interest, but all share both a common interest in health and medicine in developing countries, and a commitment to achieving positive changes.

Amongst the North American and European groups, one of the most active HAI members is the London-based action-research unit Social Audit, which has produced a number of publications documenting discrepancies in drug marketing practices. ⁽⁸²⁾ In 1981 Social Audit released the first of a planned series of 'anti-advertisements' aimed at encouraging Third World prescribers in particular to be sceptical in approaching manufacturers' claims for their products. The first of these anti-advertisements, *WHO says Lomotil has no value?* is reproduced opposite. By focussing on a specific product, Social Audit were instrumental in getting the manufacturers to agree to change their labelling worldwide. ⁽⁸³⁾ But Social Audit stress that this specific case-study into one drug raises far-reaching issues of corporate responsibility and the impact of uncontrolled practices in developing countries. ⁽⁸⁴⁾

Consumer organisations in a variety of developing countries form a key part of HAI's international membership. The Regional Office for Asia and the Pacific of the International Organisation of Consumer Unions (IOCU) acts as HAI's clearing house and the editorial office of *HAINews*. IOCU and its associated organisations in a large number of developing countries do not confine themselves to the 'narrow' issues popularly associated with 'consumerism' in developed countries. As Anwar Fazal, President of IOCU emphasises, "The consumer movement is an integral part of the development process and is therefore even more important for developing countries. The consumer movement concerns economic justice ... it concerns human rights ... it concerns action and change." ⁽⁸⁵⁾

These HAI members are thus concerned with medicines in the broad context of poverty and health. For example, the Consumers' Association of Penang (CAP) has been actively campaigning on the pharmaceuticals issue for some years. CAP has focussed on inconsistent standards in drug marketing - as one aspect of how the rich world takes advantage of the poor. CAP has lobbied against double standards in marketing by creating public awareness and pushing for the withdrawal of hazardous drugs. But the problems are also tackled in the villages through health education to make poor people aware of alternatives to unnecessary and potentially dangerous drugs. ⁽⁸⁶⁾

The World Health Organization says:
“A number of medicines, which are of no value and are even dangerous, are often given to treat diarrhoea. Money and time are wasted in their use.” So . . .

WHO says LOMOTIL has NO VALUE?

LOMOTIL (diphenoxylate/atropine) is made by the US multinational drug company, G.D. Searle; and promoted to physicians all over the world in terms such as “established success”, “good tolerance”, “excellent value” and “ideal for every situation”. This leaflet — prepared and published by Social Audit Ltd., and friends* — calls into question these claims.

LOMOTIL may be of value in giving *symptomatic* relief for non-specific “travellers’ diarrhoea” in adults. But experts say Lomotil — and other products like it¹ — have little or no place in the treatment of young children — especially in developing countries, where infective diarrhoeas are the major cause of death in children aged under three.¹ Lomotil’s limitations include:



POTENTIAL DANGERS

“Lomotil, which is widely used in the treatment of diarrhoea in the paediatric age group, is dangerous and unwarranted . . . we urge that all physicians treating infants and children avoid the potentially dangerous use of Lomotil for the treatment of diarrhoea.”

(Clinical Notes [1974])²

“Lomotil can relieve the symptoms of acute gastroenteritis in children, but it can also mask the signs of dehydration and cause fatal toxic reactions . . . use of this combination for treatment of diarrhoea in children is hazardous.”

(The Medical Letter [1980])³

“Lomotil is a dangerous combination of drugs contra-indicated for children under 2 years of age and probably never indicated in childhood diarrhoea.”

(Pediatrics [1980])³

QUESTIONABLE USEFULNESS

“The use of Lomotil as an antidiarrhoeal agent in children is difficult to justify . . . we doubt if it has any place in the treatment of diarrhoea in children.”

(Arch. of Dis. in Child. [1979])⁴

“A diarrhoea that needs 4 such tablets to be cured would probably have been cured without it too. A more prolonged diarrhoea needs proper investigation and specific therapy rather than a blindly harmful stopcock.”

(Leb. Med. J. [1974])⁵

ECONOMIC WASTE

Lomotil costs up to 25 times more than other widely-used symptomatic treatments for diarrhoea.

(AMREF [1980])⁶

“Lomotil (no value).” (WHO [1976])⁷

IOCU's Regional Office, which is also based in Penang, has drawn up a Consumer Action/Research Kit identifying 44 "problem" drugs to act as a guide for groups in other developing countries that want to carry out their own action-research to stop sales of unnecessary and harmful drugs. ⁽⁸⁷⁾ IOCU is also setting up a *Consumer Interpol*, grouping together about 120 organisations in 50 countries covering every continent. Members and various documentation centres in developed countries will feed information into a central data bank on regulatory decisions taken to withdraw or restrict the use of potentially harmful products. News of these decisions will then be disseminated to local groups in developing countries. Armed with this information, they will lobby their own governments to adopt similar restrictions. When plans for a *Consumer Interpol* were first drawn up, its purpose was described as fighting "deceptive and unfair trade practices" that have a "particularly severe impact on the most disadvantaged consumers". ⁽⁸⁸⁾ The project has received financial backing from the Dutch Government.

For the majority of HAI members the immediate objective is to campaign against double standards in marketing practices. HAI's longer term aims are to press for health-centred drug policies to benefit the world's poor. Central to this strategy are attempts to publicise and encourage public support for bold Third World initiatives for better drug use. HAI is also lobbying for meaningful international controls on drug marketing practices.

During its first year HAI produced a critique of the International Federation of Pharmaceutical Manufacturers' Associations' International Code of Marketing Practices. HAI sees the industry voluntary code as a conspicuously unconvincing attempt to put its own house in order and forestall WHO controls. ⁽⁸⁹⁾ In May 1982 HAI played an active role in lobbying at the World Health Assembly and prepared a special briefing pack focussing on the key issues confronting delegates to the Assembly. HAI's views were extensively reported in the press and the resolution on the Action Programme on Essential Drugs which the Assembly adopted gives HAI an added incentive to increase its worldwide membership and build up its campaigning strength on the international scene. ⁽⁹⁰⁾

INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA)

The IFPMA represents pharmaceutical manufacturers associations in 47 countries, over half of them in developing countries. Its Secretariat is based in Zurich. IFPMA was founded in 1968 to improve contact between national and industry associations, and participate in discussion in areas such as health legislation. One of IFPMA's declared objectives is "to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntarily agreed on". ⁽⁹¹⁾

IFPMA's public pronouncements on Third World policy issues have shown industry's ability to move with the consensus of medical and world opinion. For example, in 1977 IFPMA's initial reaction to the WHO Selection of Essential Drugs

16 Samples

16.1 Except when provided for identification or demonstration purposes, samples should only be supplied in response to a signed request from a doctor; such requests, except in respect of products controlled under the Misuse of Drugs Act, may not be accepted on a pre-printed card or form which incorporates more than the company name and address. The form must be handed by a representative to the doctor who should then add all other details.

Wherever practicable, an individual sample should not represent more than four days treatment for a single patient. When samples are provided to assist doctors in the recognition or identification of a product, or to demonstrate the use of a particular apparatus or equipment, only the minimum quantity necessary for this purpose should be supplied.

16.2 Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed direct to the doctor or given to a person authorised to receive the sample on his behalf. A similar practice must be adopted for products which it would be unsafe to use except under medical supervision.

16.3 Samples of products restricted by law to supply on prescription, which are made available to representatives for distribution, should be strictly limited in quantity and an adequate system of accountability should be established.

16.4 Samples sent by post must be packed so as to be reasonably secure against the package being open by young children.

16.5 Distribution of samples in hospitals should comply with individual hospital regulations, if any.

V. Samples

Samples may be supplied to the medical and allied professions to familiarize them with the products, to enable them to gain experience with the product in their practice, or upon request.

Codes of Practice on samples. Left, the voluntary code of the Association of British Pharmaceutical Industries; right, from the Code of the IFPMA.

was decidedly hostile. An industry statement described the WHO initiative as “ill-advised and counter-productive”. IFPMA did not mince its words in declaring that industry was “strongly opposed to the concept of a generally applied and restrictive essential list”. According to IFPMA, if essential drug lists were taken up by governments they would “result in substandard rather than improved medical care and might well reduce health standards already attained”.⁽⁹²⁾ But in 1979 IFPMA gave its qualified approval to the concept of limited lists for developing countries. This retraction of its earlier position followed after IFPMA received assurances from WHO that there had never been any suggestion that a single list should be universally applied, or that the WHO model list would not be updated to include useful new drugs as they came on to the market.⁽⁹³⁾

Despite its initial opposition IFPMA has since taken an active interest in the WHO Action Programme on Essential Drugs and negotiated with WHO on behalf of its members. IFPMA continues to stress that “to focus attention on prices without giving proper attention to quality is a disservice to developing countries”.⁽⁹⁴⁾ It has offered 3-6 months’ training courses in drug quality control to trainees from developing countries on behalf of its members. To date only six candidates have been trained, one more is being trained and nine more traineeships are under discussion.⁽⁹⁵⁾ These places have not been taken up with the alacrity that industry expected, which may reflect reluctance on the part of some developing countries to have their officials develop a predilection for the products of the brand-name producers.

THE IFPMA CODE

The IFPMA International Code of Pharmaceutical Manufacturing Practice includes some very positive statements on the “Obligations of Industry” in the preamble, which is almost as long as the code itself.⁽⁹⁶⁾ But the code is so loosely worded that there is a real danger it may only serve to legitimise existing unacceptable standards of promotion in developing countries. For example, this is the case even with such reasonable-sounding statements as: “Particular care should be taken that essential information as to pharmaceutical products’ safety, contra-indications and side effects or toxic hazards is appropriately and consistently communicated *subject to the legal, regulatory and medical practices of each nation*”. (our emphasis)⁽⁹⁷⁾ This loads responsibility onto Third World governments, rather than manufacturers, to take measures to ensure that there is always a full disclosure of information.

A further illustration of the weakness of the IFPMA code is the short paragraph on samples, reproduced on p.179 alongside the corresponding section from the Association of British Pharmaceutical Industries (ABPI) Voluntary Code. Reservations about the IFPMA code were expressed even by some IFPMA members. The Swedish manufacturers association, LIF stated: “The code is unclear, unstructured and does not go far enough”.⁽⁹⁸⁾ It is weakest in the area of monitoring and enforcement which is limited to industry personnel acting as “judges in their own cause”.⁽⁹⁹⁾

One commentator writing in the US industry newsletter *Pharmaceutical Executive* describes the IFPMA code as having been introduced to forestall “a coming WHO effort to impose unacceptable controls over all pharmaceutical commerce in the Third World”.⁽¹⁰⁰⁾ He comments, “The code pledges industry to provide high quality products, to base its claims on valid scientific evidence regarding indications and conditions for use, to provide full scientific information with scrupulous regard for truth in all matters (including contra-indications and toxicity), and to use complete candour in dealing with government health officials, physicians, nurses, other health providers and the public. To some, this may sound like a pledge in favour of motherhood and against cancer. But the real political question is whether the code will be adequate to defeat the forces against private enterprise within WHO.”⁽¹⁰¹⁾

According to Catherine Stenzl, coordinator of the International Research Group for Drug Legislation and Programs, drug industry lobbyists are in a good position to block unwelcome moves towards controls on marketing within the United Nations system. She quotes a private communication from a Member of the European Parliament stating that “the pharmaceutical industry have a committee of six operating in Geneva whose sole job is to infiltrate every international institution to prevent mandatory legislation against the ... activities of multinationals”.⁽¹⁰²⁾

Unlike the Health Action International lobby on behalf of poor consumers, industry’s views are directly represented in WHO proceedings. The IFPMA was officially accredited with NGO-status within WHO in 1971. According to Catherine Stenzl, this decision was “taken against the recommendations of the competent commission”.⁽¹⁰³⁾

DRUG MANUFACTURERS

The fact that the IFPMA Code was drafted at all is indicative that the drug industry is sensitive to its reputation. Manufacturers are acutely aware that reports of unethical marketing practices in the Third World have attracted criticism worldwide. They realise that sales performance in the more lucrative rich world markets may be conditioned by how they are seen to discharge their social responsibilities in the poor world.⁽¹⁰⁴⁾

Manufacturers are increasingly conscious of the need to improve their Third World “image”. For example, in May 1981 Ciba-Geigy held a special 3-day seminar on Third World policies attended by senior staff from their Basle headquarters and worldwide subsidiaries, and several UN officials. On the first day of the seminar participants were assigned the task of analysing “the problems and criticisms faced by the pharmaceutical industry and Ciba-Geigy in the Third World”.⁽¹⁰⁵⁾ Executives taking part in Working Group One were asked to hold a brainstorming session to identify “whatever criticisms, attacks, or reproaches against the pharmaceutical industry and Ciba-Geigy” came to mind. Their next task was to discuss “who is mainly voicing them” and the “additional arguments these critics are using”, the purpose of the session being to “try to develop ideas and strategies for dealing with arguments of this kind”.⁽¹⁰⁶⁾

NEW STRATEGIES

Ciba-Geigy certainly adopts a more open style than many manufacturers in acknowledging the need for a special Third World policy and in making clear what this is. A recent article in *Business International* refers to Ciba as “The first known major drug company to establish a specific corporate policy acknowledging an ethical responsibility to meet the ‘special needs’ of developing countries”.⁽¹⁰⁷⁾ Ciba set up a new subsidiary company, Servipharm Limited, in 1977 - the very year that the first WHO selection of essential *generic* drugs was produced. Servipharm markets a range of its own brands of generic drugs (‘branded generics’) - many of them included in the WHO selection.⁽¹⁰⁸⁾

Ciba-Geigy and other manufacturers that have diversified into producing branded generics have clearly not been motivated solely by a sense of corporate responsibility to the world’s poor. As the Director of the British Office of Health Economics explains, “Many western research-based companies have seen the *economic* logic of supplying certain basic medicines to the less developed countries at lower prices than would be economic in relation to the more affluent nations”.⁽¹⁰⁹⁾ (our emphasis)

Moreover, Ciba-Geigy has not been slow to make contingency plans to protect its profitable research base. Its Third World policy document states: “In cases where, for reasons of economy, it is impossible to include original Ciba-Geigy preparations (ie brand-name products) in these national lists, Ciba-Geigy Pharma will try to secure the necessary financing (eg via the World Bank, developmental aid organisations, etc) by taking the initiative itself.”⁽¹¹⁰⁾

The issue of how to respond to the perceived threat to their market power from large-scale, low-priced generic production concerns all the research-based technology-intensive manufacturers. A book published in 1982 identifies over a dozen “defensive”, “offensive” and “anticipatory” strategies open to the market leaders to safeguard their speciality medicines still under patent.⁽¹¹¹⁾

The strength and weakness of the WHO model list of essential drugs - the fact that it is open to interpretation - makes it possible for the research-based manufacturers to try to persuade Third World regulatory authorities to include some of their latest patented products. As many as 63 of the drugs included in the WHO list are given as “examples of this therapeutic category” and health authorities are advised to “choose [the] cheapest effective drug product acceptable”.⁽¹¹²⁾ This leaves the door wide open for manufacturers of antibacterials, antidiarrhoeals, psychotherapeutic and other drugs to argue the special case for purchasing their more expensive but ‘better’ patented products which may offer few significant advantages over far cheaper, older drugs.

Some commentators see the strategy of diversification into branded generics pursued by some of the leading manufacturers as a very mixed blessing for the world’s poor. They fear that the biggest companies, with the advantages of large economies of scale in production and advertising will undercut any smaller

producers. If competition in the generics market were eliminated in this way, industry could revert to its highly concentrated structure and prices might rise. In the words of UNCTAD, “an agreed price floor could emerge even for generics”.⁽¹¹³⁾ Furthermore, future rapid obsolescence in production technology could reinforce the Third World’s dependence as a captive market.

The leading companies cannot be expected to relinquish their market power voluntarily. Consequently it would be unfair to dismiss any policy move to supply the Third World market with branded generics solely on the grounds that this might enable leading companies to undercut local industry. Manufacturers that move into generics production are at least offering Third World buyers an alternative to expensive brand-name products. It is then vital for Third World buyers to ensure that they do not become over-dependent on monopoly suppliers of branded generics.

POSITIVE RESPONSES TO THIRD WORLD NEEDS

We have already seen that through the IFPMA, industry has offered to supply essential drugs for public health service use in poor countries under ‘special’ conditions - although the precise advantages are not entirely clear. By May 1982, 42 manufacturers had contacted IFPMA expressing interest in supplying developing countries with a total of 230 drugs - 130 of them included in the WHO Selection of Essential Drugs.⁽¹¹⁴⁾

Just one illustration of industry’s public expression of concern for the needs of developing countries is the statement that IFPMA made to the 1979 World Health Assembly that they wished “to put firmly on record that the pharmaceuticals industry entirely shares the WHO’s concern in its objective of improving health care and in particular improving the access of drugs, vaccines and sera of the poorer developing countries”. IFPMA also advised delegates that “As a particular illustration of this concern ... a number of companies in our industry have volunteered to place certain drugs used in communicable disease control at the disposal of the WHO under special conditions”.⁽¹¹⁵⁾

The Belgian company, Janssen, echoes other manufacturers in demonstrating its awareness of the problems of drug supply in developing countries: “Unfortunately, we ascertain far too often that the drugs we found and developed after years of research, do not always reach the people who are most in need of them. It is often very difficult to reach the rural populations in developing countries. But the biggest problem for people who have to do with a strict minimum of existence remains ... the *price* of the drug. Therefore Janssen Pharmaceutica has contacted the WHO and proposed to supply mebendazole at a very low price for the use of worm eradication programmes.”⁽¹¹⁶⁾

Some leading manufacturers have also been actively involved in providing consultancy services to advise on improvements in national drug policies and the logistics of supply. A recent example is the *Burundi Pilot Project* which is the result of collaboration between the Ministry of Health of Burundi, WHO, and Roche, Ciba-Geigy and Sandoz.⁽¹¹⁷⁾

We have already discussed industry's contribution to research into developing new drugs to treat tropical diseases. Some of this research is being carried out in developing countries, as in the case of four laboratories set up by the Wellcome Trust with profits made by Wellcome's manufacturing companies. ⁽¹¹⁸⁾

Manufacturers have shown that they are open to persuasion and have cooperated with Third World governments in voluntarily agreeing to withdraw potentially harmful products. For example, Glaxo's subsidiary in Bangladesh agreed to withdraw its combined penicillin and streptomycin products, sold under the brand name Seclomycin. ⁽¹¹⁹⁾ Meanwhile, some years ago Fisons (Bangladesh) Ltd was asked by the health authorities to produce fewer tonics and more life-saving drugs. In response, local managers claim that the company has been exploring the possibility of producing more speciality drugs to treat TB, cancer, hypertension and diabetes under licence from other manufacturers. ⁽¹²⁰⁾ In India, Glaxo is responding positively to the Government's desire for foreign companies to produce more bulk drugs as opposed to formulations. Already, 15 drugs and intermediates are manufactured locally from the basic stages and Glaxo plans to expand basic drug production to include a further nine drugs to treat intestinal worms, diarrhoea and dysentery, heart disease, allergies and arthritis. ⁽¹²¹⁾

Many industry spokesmen readily acknowledge that it makes sense for Third World governments to have limited drug selections for the public health services. But they resist the idea of a limited selection being applied to the private market. In response to our suggestion that manufacturers should only market essential drugs in poor countries, a senior executive of Ciba-Geigy expressed the view that "This is a difficult question because of the needs of the prosperous minority in contrast to the bulk who are often very poor. I think the local health departments have to determine basic needs and draw up their version of the WHO 200 drugs list. I don't think one can suspend the normal basis of commerce except by government decree in a Communist type society, and many Third World countries do not want this." ⁽¹²²⁾

ADDRESSING THE CRITICS, NOT THE CRITICISMS

In listing six "lessons" to be learnt from the Anti Infant Formula Campaign (which led to the adoption of a code of marketing practice) a recent article in *Business International* urges manufacturers to "address the issue, not the critics". ⁽¹²³⁾ Nonetheless, industry representatives have shown a marked tendency to devote their energies to accusing their critics of political extremism rather than focussing on the criticisms they make.

For example, according to Lewis Engman, President of the US Pharmaceutical Manufacturers Association, "The ultimate concern of at least some of the people behind the campaign for a WHO pharmaceutical marketing code is not the health of the Third World consumers. The ultimate concern is economic change in the direction of state control, and ultimately state ownership of private concerns. As such the code movement is part and parcel of the movement toward a new

economic order, a movement which touches health care only incidentally, a movement which has as its real goal the redistribution of wealth worldwide and the seizure - by political force if necessary - of economic power by those with no respect for the profit incentive and the rights of private property on which our society is based.” ⁽¹²⁴⁾

Similarly a few manufacturers have responded to OXFAM’s enquiries about their Third World policies and marketing practices by suggesting that these issues are not of legitimate concern to a charity. For example, the Group Public Relations Manager of Glaxo writes that “there must be considerable concern that your activities as reflected in your letter to us, seem totally out of keeping with the charitable objectives of OXFAM and more in keeping with those of a politically oriented pressure group”. ⁽¹²⁵⁾

WE’VE PRODUCED THE GOODS...

Industry representatives often stress that manufacturers are doing all that can reasonably be expected of them for the Third World and that the onus must fall on governments to introduce new drug policies to ensure that the poor get the drugs they need. The Director of the British industry-funded Office of Health Economics has stated that “... the pharmaceutical firms have produced the goods. It is up to the developing countries to introduce the primary health care schemes which can make proper use of them - as China alone, so far, seems to have done.” ⁽¹²⁶⁾

There is a great deal of truth in this statement as far as it goes. China, Mozambique, Sri Lanka and other developing countries that have succeeded in making the best use of limited resources to cater to the needs of the majority have done so because they have had the political resolve to introduce effective primary health care cover and comprehensive drug policies. But many developing countries have faced concerted opposition to their attempts to introduce new drug policies, not least from the drug industry itself. In the major drug-producing nations the degree of control on prices, promotion and production varies considerably. Manufacturers often complain that controls are too strict, but they rarely challenge the right of rich world governments to protect their citizens through some measure of control.

INDUSTRY OPPOSITION IN SRI LANKA

In an article entitled “National drug policies - more state intervention or less?”, a senior executive of the US-based transnational Pfizer argues forcefully against state intervention and cites the “unfavourable results of introducing centralised drug procurement” in Sri Lanka. He makes no mention of the substantial savings that were achieved, but he does draw attention to the “acute shortages of certain important drugs” that followed the introduction of the new policies. ⁽¹²⁷⁾

It would however appear that some of the more critical drug shortages experienced in Sri Lanka may have been aggravated by concerted opposition to the new policies from foreign manufacturers, and from Pfizer in particular. An account of the

problems that arose has been provided by Dr. Sanjaya Lall of the Oxford Institute of Economics and Statistics and the late Professor Bibile of the University of Sri Lanka and former Chairman of the State Pharmaceutical Corporation. ⁽¹²⁸⁾

In 1973 the Government of Mrs Bandaranaike announced its new “34 Drug Programme” under which the State Pharmaceuticals Corporation (SPC) would centralise procurement of the chemical intermediates needed for local formulation of 34 drugs. A central aim of the new policy was to cut down on the high transfer prices manufacturers were paying for imported raw materials. ⁽¹²⁹⁾

From the outset the US Pharmaceutical Manufacturers Association were resolute in their opposition to the new policy. On 10 May 1973 their President, Joseph Stetler, wrote a six-page letter to Mrs Bandaranaike raising detailed objections to the new policy. Mr Stetler stated: “These actions, if implemented, would effectively destroy operations of the modern research-based pharmaceutical industry in Sri Lanka by removing all business incentives and internationally respected property rights. By so doing, the plan would call into question the Government’s attitude toward *any future private investment in the country.*” ⁽¹³⁰⁾ (our emphasis)

Lall and Bibile claim that: “A widespread ... campaign of denigrating low-cost supplies was launched. And a second source of opposition, the private practitioners, were drawn into the campaign. Reports were made of drugs being ineffective, substandard or toxic, but little hard evidence was produced.” ⁽¹³¹⁾

According to Lall and Bibile seven small local producers responded favourably to the new programme but all five foreign subsidiaries initially showed resistance. Glaxo was the first to accept the programme in principle; Pfizer the last. In Pfizer’s case at least this agreement was a different matter from practical cooperation in implementing the policy. Lall and Bibile quote the then Managing Director of the SPC: “... the SPC made an urgent appeal to Pfizer to make tetracycline capsules required in the cholera epidemic (in 1974) and offered quality tested raw materials and capsules.” ⁽¹³²⁾ Pfizer was asked to use raw materials purchased by SPC from a reputable supplier - the leading West German manufacturer, Hoechst. Lall and Bibile attribute Pfizer’s reluctance to agree to this arrangement to the fact that they had been importing tetracycline from their parent company at almost five times more than Hoechst’s price. ⁽¹³³⁾ According to the Managing Director of the SPC, the outcome of the resulting delay during the cholera epidemic was “that the Hoechst tetracycline lay unused in SPC stores and Pfizer equipment lay idle, while capsules had to be airlifted to the country at enormous expense”. ⁽¹³⁴⁾

Subsequently, the SPC and the Ministry of Industries recommended that Pfizer should be nationalised to ensure its compliance with the new policy. But powerful bargaining counters were brought into play. According to Lall and Bibile, “The reaction of the US was swift, and as it turns out, decisive in preventing such a measure. The US Ambassador personally intervened with the Prime Minister in the matter, and ... we can only speculate as to the nature of his intervention ... The Chairman of the SPC was ordered to ‘continue negotiating’ with Pfizer; no further disciplinary action was taken.” ⁽¹³⁵⁾

When we asked Pfizer to comment on Lall and Bibile's article, they strongly defended their actions and stressed that "the facts of the case to which you refer are substantially different from what we have recorded". Their reply, from Dr. Hodin, Pfizer's Director of Public Affairs, concentrates on their role during the cholera epidemic when tetracycline was urgently needed. Dr. Hodin's account accepts that there was a delay. (Pfizer Sri Lanka was notified of the cholera emergency on 7 November 1974. On 23 December they made a firm quote to supply tetracycline. Discussion between Pfizer and the SPC continued into January 1975 - some months after the outbreak of the epidemic.) But Pfizer maintain that the SPC was to blame for the delay because they failed to clarify whether the tetracycline should be "supplied in capsules or tablets, sugar coated or not" and to stipulate the size and packaging. ⁽¹³⁶⁾ Pfizer also say that they offered the SPC a specially reduced price because of the emergency, and subsequently reduced it further as SPC had received a lower quote. Pfizer conclude that the incident "indicates the inability of that state agency [the SPC] to cope adequately with the health needs of the Sri Lankan people," and emphasise that "we acted quickly, persisted in our efforts to help, and were responsible, with reference to price and other matters of detail that developed in this situation." ⁽¹³⁷⁾

The Sri Lankan experience also demonstrates the wholly negative way in which bold new policies are often portrayed. Pfizer sent us a heavily critical study of UNCTAD's 1977 report evaluating the SPC policies. ⁽¹³⁸⁾ This "critical study" gives the impression that the whole purpose of setting up the SPC was to expand trade with Eastern Europe and China. It concludes: "Though the objectives were good, the practical implementation of changing sources from traditional to non-traditional suppliers did not bring any significant financial saving or provide the consumer with drugs of acceptable quality at a reasonable price." ⁽¹³⁹⁾ In fact the study misrepresents both the UNCTAD report and the original purpose behind the setting up of the SPC which was to obtain drugs from the *cheapest* source not to buy more drugs from Eastern Europe. ⁽¹⁴⁰⁾ We have already seen that the savings achieved by the SPC policies have led to Sri Lanka's being singled out by WHO as an example for other countries to follow. ⁽¹⁴¹⁾ In the words of one analyst there were "dark spots" in the "success story" but instances of substandard imports were in fact few and far between. ⁽¹⁴²⁾

THE BANGLADESH LOBBY

Throughout this study we have focused a great deal on problems with the use and marketing of drugs in Bangladesh, which up until May 1982 the Bangladesh health authorities had failed to resolve. Thus, it is only fair that we should conclude by looking at the obstacles that health officials have encountered in recent years in attempting to implement policy changes.

In the early 1970s, attempts were made to improve the supply of essential drugs available to the health services by buying generics on worldwide competitive tender. These imports were centralised through bulk purchasing by the Trading

Corporation of Bangladesh (TCB). Increasingly orders were placed with Eastern European manufacturers - particularly in Hungary - because they quoted good prices. But the new policy ran into difficulties when doubts were raised about the quality of the Eastern European drugs, despite the fact that the drug control authorities were satisfied that they had undergone adequate quality control. ⁽¹⁴³⁾

Pressure was brought to bear for an official investigation into the increasing volume of imports from Eastern Europe to establish whether any political motive was involved. At the time the TCB was handling 40% of the national requirement for finished drugs and there were plans to expand its centralised procurement operations. In the event the commission of inquiry failed to establish any political motivation behind the imports from Hungary. Nonetheless, the TCB's share of imports was scaled down to 10%. ⁽¹⁴⁴⁾

Existing drug legislation in Bangladesh is based on the Drugs Act of 1940, which was described in a recent Expert Committee Report as "grossly inadequate". ⁽¹⁴⁵⁾ Consequently, according to the Expert Committee: "Much of the unethical practices in manufacture and trade is possible because of the weakness of existing legislation ... There is no provision in the Drugs Act for the control of prices of pharmaceutical raw materials or finished products." ⁽¹⁴⁶⁾

Drug Administration officials have lacked the necessary legal powers to bring quick prosecutions and impose meaningful penalties even in cases of serious malpractice. Thus they have been seriously hampered in dealing with some of the worst abuses such as the case of a local company found to have been filling vials with tap water and selling them as distilled water for injections - a practice that can kill. Similarly, they could do little to control the black market in stolen drugs which we witnessed in operation in September 1980. A stallholder in Mitford market in the capital was selling tetracycline powder from a huge barrel stolen somewhere in transit. The yellow powder was tipped into paper sacks and whatever fell to the ground in the process was simply scooped back off the dirty floor.

The maximum penalty for offences of this nature has been a £14 fine and three years' imprisonment. There could be a delay of up to three years in bringing prosecutions through the courts. Drug Administration officials have long been critically aware of the need to tighten up legislation to safeguard health. They have put a great deal of effort into studying drug legislation in Britain, the United States, India and the WHO Model Drug Law, as a basis for new Bangladeshi drug laws. But when they tried to put their plans into action, they were obstructed. In 1978, a powerful lobby proved successful in blocking tougher legislation. Within months a new Health Minister replaced the man who had sanctioned the proposed new legislation. A committee was subsequently appointed to set about the task of redrafting the new drug laws. More attention was to be paid to local manufacturers' distaste for government controls. ⁽¹⁴⁷⁾

Local manufacturers have brought pressure to bear to block further controls proposed by the Health Ministry by lobbying the Ministries of Industries and Commerce. One recent example of this lobbying activity is a petition sent by the

Bangladesh Aushad Shilpa Samity (the Association of Pharmaceutical Industries) to the Deputy Prime Minister in charge of the Ministry of Industries in June 1981. The petition was sent in the name of individual member companies, including 25 of the largest nationally-owned manufacturers and all the foreign-controlled producers. ⁽¹⁴⁸⁾ The covering letter dated 22 June 1981 stressed that the issues raised in the petition (on drug registration, production and price controls) were all inter-linked and the Association stated that “none of the issues is separable for solution in isolation, nor for any compromise solution”. ⁽¹⁴⁹⁾

Despite the fact that 80% of the population has no ready access even to life-saving drugs, the manufacturers stress the export potential that would be blighted “unless our stand on the important matters is accepted in totality and policies are accordingly formulated for immediate implementation”. ⁽¹⁵⁰⁾ The manufacturers stated their opposition to tougher registration controls, including any attempt to regulate which drugs are marketed or produced locally on criteria of relevance to public health needs. The industry’s ‘stand’ opposed any interference from the health authorities. “What manufacturers will produce and sell should best be left to the investors or their authorised representatives. Attempts should not be made to disrupt the laws of demand and supply through government dictum.” ⁽¹⁵¹⁾

The manufacturers stated that “price control should be abolished” and that they did “not feel that there is any *economic* justification in such control”. ⁽¹⁵²⁾ (our emphasis) An accompanying copy of a petition sent to the Minister of Commerce on 26 August 1980 repeated five times that not only did price control not benefit consumers, but that it was positively harmful to them. ⁽¹⁵³⁾ No mention was made of any possible social and humanitarian criteria behind price controls. Government attempts to monitor and control transfer prices of raw materials were also resisted: “Drugs Administration should not assume the role of import regulatory body concerned with the approval of source, price and quality.” ⁽¹⁵⁴⁾

Some of the manufacturers’ arguments to support their ‘stand’ on registration policies would certainly cut no ice with regulatory agencies on their home markets. For example, they opposed any attempt by the Drugs Administration to withdraw licenses for drugs considered non-essential arguing that “Vitamins, enzymes, tonics etc. are manufactured because doctors prescribe them; these are essential because patients need them.” Furthermore “All products which are prescribed by doctors are essential. Arbitrary criteria of essentiality should not be imposed. When the government is the buyer then it is free to choose the products needed; the doctors should have the same freedom to choose products...” ⁽¹⁵⁵⁾ But governments in developed countries have been in no doubt for some decades that they need to control doctors’ prescribing ‘freedom’ in the interests of the public as a whole.

The Bangladesh manufacturers also stated that any product registered for sale in developed countries “with stringent registration procedures” should automatically be licensed for sale provided it passes the necessary quality tests. This argument would carry little weight in Britain, as would the Association’s insistence the registration of products should only be cancelled on the grounds

that they are found to be harmful or carry an “unacceptable level of risk”.⁽¹⁵⁶⁾ In developed countries governments retain the right to withdraw registration from drugs on other criteria such as lack of proof of efficiency. In Britain drugs must also be licensed for each indication - a far cry from the blanket approval advocated in the Bangladesh manufacturers’ stand.

The substance of this lobby directly contradicts many of the key policy measures that the UN agencies have urged developing countries to adopt to serve the interests of the majority of their people. However European and US parent companies that we have consulted fully endorse the stand taken by their Bangladesh subsidiaries. For example, the chairman of ICI Pharmaceuticals Division comments, “I cannot accept your assertion that the stand taken by the (Bangladesh) Association ‘shows disregard for the social implications and the health needs of the mass of the poor in Bangladesh’. The substance of the Association’s complaint is that retail prices are fixed by the government in an apparently arbitrary manner rather than according to a displayed and rational formula. As a consequence, of this manufacturers are not able to earn a return on their investment which will permit an adequate surplus for reinvestment and expansion of their business.”⁽¹⁵⁷⁾ Other parent companies also criticise “arbitrary price fixing” in Bangladesh. None that we approached has responded to the critical issue of the social implications of their opposition to Government attempts to cut down on wasteful and unnecessary drugs.

* * * * *

BRAVE NEW POLICIES

This report might have ended here. The situation up to June 1982 gave little cause for optimism for the poor in Bangladesh and many other developing countries. Given the political and economic constraints, health authorities seemed unlikely to press ahead with the comprehensive new drug policies urgently needed to improve the supply of essential drugs.

However, recent events in Bangladesh mean that we can end with a positive and encouraging postscript. On 12 June 1982 the Chief Martial Law Administrator passed a Drugs (Control) Ordinance - the first step in implementing a radically new national drug policy designed to give priority to the production of 150 essential drugs. Under this ordinance the registration of over 1,700 unnecessary, harmful and otherwise undesirable drugs has been suspended.⁽¹⁵⁸⁾

The Bangladesh Government acted on the recommendations of its specially appointed an eight-person Expert Committee which drafted the new national drug policy and carried out a major review of over 4,000 products licensed for sale in the country. Bearing in mind the country’s priority needs, the Expert Committee identified 16 categories of non-essential or otherwise problematic drugs to provide

a guideline for assessing which formulations should be withdrawn or modified. ⁽¹⁵⁹⁾ These criteria have been described as “admirable” and as combining “sound therapeutics with an attitude of commonsense economics” by other experts outside Bangladesh. ⁽¹⁶⁰⁾

The different categories recommended for withdrawal include tonics and enzyme mixtures; liquid multivitamin preparations (with the exception of a few for paediatric use); cough medicines, throat lozenges and gripe water; and combinations of antibiotics, corticosteroids and other drugs. Most combination drugs are to be withdrawn when single-ingredient drugs offer acceptable (often cheaper and safer) alternatives. ⁽¹⁶¹⁾ Drugs that can carry unacceptable risks particularly to children - such as liquid tetracyclines and anabolic steroids - have also been banned. In future no prescription drugs will be licensed unless they are formulations listed in the British Pharmaceutical Codex. ⁽¹⁶²⁾

The Expert Committee recommended that a National Formulary should be drawn up not later than 1983 to include only drugs considered essential to health needs. In the meantime national firms will be permitted to continue production of some non-essential drugs but subsidiaries of foreign companies must stop manufacture of simple over-the-counter products such as multivitamins, tonics and antacids. Instead, they will be offered incentives to import the necessary technology and know-how to formulate sophisticated essential drugs and produce bulk drugs. Foreign companies with no factory of their own will no longer be allowed to license other manufacturers to produce their brands locally if equivalent or similar products are already being manufactured in local factories. ⁽¹⁶³⁾

Other important aspects of the new policies include plans to strengthen the Drugs Administration department and the announcement of heavy penalties to control both unlicensed drug sales and the manufacture of spurious and sub-standard drugs. These controls will also apply to Unani, Ayurvedic and homeopathic drugs. The Expert Committee has recommended that generic names should be introduced and the Government has announced controls on prices of finished drugs and selected raw materials imported to produce essential drugs. ⁽¹⁶⁴⁾

These new policies have generated a great deal of controversy both inside and outside Bangladesh. Local manufacturers whose current production will be disrupted by the new measures are concerned about the short-term negative impact on sales turnover. One foreign-controlled producer estimates that about half their sales turnover may be affected. ⁽¹⁶⁵⁾ Some foreign and national companies that are critical of the new policies have called for them to be “reviewed by a broader multi-disciplined forum”. ⁽¹⁶⁶⁾

Under the Martial Law Ordinance 240 products were to have been withdrawn immediately and the remainder by the end of 1982. Local manufacturers expressed concern at the short timescale for products to be removed from the market because raw materials had already been ordered and paid for. Leading foreign and national producers that signed an “Appeal to the Martial Law Authority”, stressed that previously they had been given a minimum notice period of two years to withdraw

a drug “when it was found to be harmful by well-established drug monitoring systems”.⁽¹⁶⁷⁾ Already, the original ruling on the timescale has been modified. There is now to be a phased withdrawal of different categories of drugs over a period of 3, 6 and 9 months.⁽¹⁶⁸⁾

Opposition to the new policies in the local press recalls past experience in implying that there is a political bias behind the new policies. For example, the Expert Committee has been attacked for failing to consult industry and meeting “behind iron curtains”.⁽¹⁶⁹⁾ The association representing leading manufacturers is reported to have warned that “if” the new policies are implemented local production will fall by “up to 80%”; there will be drug shortages and drug factories will be forced to close, “making thousands jobless”.⁽¹⁷⁰⁾ According to one press report: “The treatment prescribed by the Expert Committee reminds one of the classic phrase, ‘the operation was a success but the patient died’. In this case, unfortunately the patient is not the Pharmaceutical industry alone, but the whole economic structure of the country...”⁽¹⁷¹⁾

The opposition aroused suggests that the health authorities are unlikely to be successful in implementing the new policies unless they can count on the cooperation of the country’s doctors and leading manufacturers. It is thus critical that short-term considerations should not be allowed to cloud the long-term goals behind the new policies. Manufacturers now have the option of expanding production to cater for the increasing demand for essential drugs.

HEALTHY PROFITS?

Can industry afford to adjust its priorities to suit the pressing needs of developing countries like Bangladesh? How significant is the Third World market to them?

One company’s assessment of prospects in Bangladesh certainly indicates that there is room for concessions. “The market for pharmaceutical products is growing very fast in Bangladesh. Turnover in 1979 increased by more than 100% and business prospects shall be good for 1980 ... Most of the local as well as foreign firms having factories, are increasing their production capacity, modernising factories and introducing new products. Government is providing them with all sorts of assistance.”⁽¹⁷²⁾

The Third World as a whole is already a significant market for major drug producers. In 1980 just over a third of Britain’s total exports went to developing countries - though mainly to oil-rich countries like Nigeria and the Middle East.⁽¹⁷³⁾ But the potential is even greater. In the opinion of one company executive, “It is obvious that during the next 20 years drug therapy is going to be needed and will become available to a much greater extent in the Third World. Any pharmaceutical company should appreciate that perhaps 40% of its business will be in those areas by the year 2000.”⁽¹⁷⁴⁾

Balance sheets showing profits for single years and individual developing countries are misleading because the position of transnational companies can only be assessed on the basis of their worldwide operations. On these there is little doubt

that the industry as a whole is doing well by comparison with other sectors of industry. In the words of a June 1982 *Financial Times Survey*, "The pharmaceutical industry has passed through the recession almost unscathed". Moreover, "the companies that originate and produce the world's key medicines have every reason to be confident about their current performance and prospects".⁽¹⁷⁵⁾

The healthy financial state of drug manufacturers is further confirmed by a senior executive with 30 years working experience in the industry itself. "In pharmaceuticals there has been a tendency to resist all new regulations and to assume, yet again, that somehow, if only we could get through the next year then things will be 'back to normal'. The public stance of the industry has been to state categorically that if the regulations are not relaxed, then no new medicines will appear - or at least, so few as to force the industry to stop research and deny the public access to the new medicines to which it has a right. The financial results of the industry continue to be an embarrassing counter argument ..."⁽¹⁷⁶⁾

The poor are not going to get the drugs they need unless Third World governments can count on widespread support in implementing what may be seen as unpopular controls on the free market. Governments of the major drug-producing nations have all voted in favour of WHO resolutions urging Third World governments to adopt the sort of policies that the Bangladesh Government has now resolved to introduce. The support of WHO, of rich world governments, and of professional and public opinion worldwide is now essential for the successful implementation of new health-centred drug policies throughout the Third World. This cooperation and understanding is vital to protect the health interests of millions of the world's poor.



CHAPTER 11

HEALTH NOW

Action for Change

OXFAM has no intention of leaving this report to add to the cubic metres of analysis of the problems. It was written to highlight the distortions in drug marketing as they affect the world's poor and to show that there are positive solutions. But above all its purpose is to press for urgent action, and to demonstrate that meaningful changes are conditional on attitudes and actions in developed and developing countries.

An executive of one leading manufacturer gives his diagnosis of how changes can be made to happen: "Health care has to be a partnership between drug suppliers, governments and the medical profession, all acting in concert for the patients' benefit. It is difficult to achieve this because of problems with each side of the triangle. Provided dialogue takes place and there is understanding, tolerance and a general desire to be helpful on all sides, a great deal can be achieved, but it will nearly always be slow - too slow for many people."⁽¹⁾ Particularly, it must be added, for the Third World poor. But the triangle has also to be opened up to involve the *patients* - ordinary people as groups and individuals all have a crucial role to play in pressing for action.

What follows is a prescription for some of the more feasible changes that need to be made by governments, international and non-governmental organisations and manufacturers.

THIRD WORLD GOVERNMENTS

Political will is the key determinant of success. It is obviously unrealistic to expect manufacturers voluntarily to make either major changes in their current marketing practices or special concessions to the needs of the poor, in situations where governments are giving business interests priority over the health needs of their people.

The exact measures that governments need to implement will vary a great deal from one country to another depending, among other things, on what has already been achieved. But the crucial policy options identified by many governments and adopted by a few need to be acted on by all.

1. PREVENTION AND PRIMARY HEALTH CARE

Governments need to give preventive and primary health care services clear priority over costly hospital building projects and conventional cure-orientated medical training. A reallocation of health resources to benefit the poor majority has to be put into deeds as well as words.

2. COMPREHENSIVE NATIONAL DRUG POLICY

No country can solve the problems without a comprehensive national drug policy tailored to its specific needs. Key elements and important stages in implementing the policy include the following:

- Identification of priority health problems affecting the poor majority.
- Setting up a permanent multi-disciplinary team with the task of identifying which drugs are essential to the country's needs and to draw up a national formulary.
- Identification of the most vital drugs (to be given priority, for instance, in foreign exchange allocations and in setting up local production). More limited selections of drugs to be used by different categories of health workers also need to be drawn up.
- Rationalisation of the private market by withdrawing registration from non-essential, wasteful and 'problem' drugs not included in the national formulary.
- Making the use of generic names compulsory in prescribing, training, labelling etc.
- Ensuring that paramedics, doctors, nurses and other health workers all receive balanced drug information to suit their requirements, together with guidance on cost-effective treatments for different conditions. There should be a standard data sheet for each drug giving important information for both prescribers and patients.
- Establishment of an efficient public sector drug distribution system. This should have good communications from all units back to the centre on their requirements and any problems encountered with the quality of drugs or adverse reactions.
- Enforcement of controls on private drug distribution to prevent sales of prescription drugs by untrained and unlicensed drug sellers.
- Rationalisation of drug purchases for the public health services through bulk procurement on worldwide competitive tender, and progressive extension of this rationalisation to private sector imports.
- Setting up local (or where feasible regional) quality control laboratories.
- Regulating the type of drugs produced locally by private manufacturers so that they conform to national priorities. Self-reliance in local production of essential drugs needs to be encouraged with incentives to local manufacturers (both national and foreign) and export controls.
- Establishing public-sector production of essential drugs.
- Adoption of comprehensive drug legislation covering areas such as price control, fair conditions on the transfer of drug technology, restricted patent protection and controls on marketing practices.
- Strict curbs on promotion should include banning sales representatives from visiting public health service doctors, and controlling the distribution of free samples, gifts and sales inducements to prescribers. Manufacturers' promotional leaflets and package inserts should be checked against information in data-sheets issued to doctors on the home market. Health authorities could levy a tax from companies on each sales representative they employ and this

revenue could be used to pay for the provision of independent drug information. - Government departments responsible for administering and enforcing drug policies should be adequately staffed and financed and their rulings should be upheld by other ministries.

3. TRAINING

Governments will inevitably face opposition in implementing these drug policies unless they concentrate on winning over the country's doctors as firm allies. This can only be done if doctors and health workers understand what is at stake and what governments hope to achieve. The best approach is to influence the attitudes of health workers during training. Training should be refocused and firmly rooted in social and economic realities so that, instead of being taught curative approaches to rich world diseases, Third World medical students learn their country's needs. During training doctors and paramedics should be encouraged to concentrate on prevention and appropriate non-drug treatments. All prescribers should also receive a firm grounding in the economics of drug prescribing and the critical need always to try the least expensive first-line treatment first. All health workers should be sent manuals with advice on standard treatments for common health problems. Efforts can also be made to influence the prescribing habits of practising doctors by encouraging them to take part in refresher courses, and sending them regular circulars on cost-effective prescribing.

4. HEALTH EDUCATION

Health authorities can use schools, the health services, community organisations and the mass media to put over basic health education and challenge people's dependence on drugs. For example, the message needs to be put across that it makes more sense to spend money on a diet of nutritious local foods than to buy imported vitamins. Health educators could usefully learn from commercial advertisers to put their message across in a lively and compelling way.

RICH WORLD GOVERNMENTS

Governments of developing countries are far more likely to succeed in implementing new drug policies if they can count on the goodwill and active support of rich world governments, particularly those of the major drug producing nations.

1. Rich world governments should increase their financial support to UN programmes that are designed to cater for the needs of developing countries, especially important initiatives such as the WHO Action Programme on Essential Drugs.

2. Having voted unanimously in support of the May 1982 resolution urging that the WHO Action Programme on Essential Drugs be implemented "in its entirety", rich world governments should make sure that it is. In particular they should not try to obstruct WHO from acting on mandates *they* have already given it such as the need to start work on the development of an international code of drug marketing practices.

3. The British and other major drug producers should actively support European initiatives to improve cooperation between the regulatory agencies of developed and developing countries. They should, for example, back the proposals of

the Nordic countries to assist developing countries with drug evaluations and improving their access to useful drug information.

4. The British and other Governments should set up their own investigation of drug policies and the Third World to identify which measures that they could take would be most helpful to health authorities in developing countries. A Government study could usefully focus on a possible tightening up of export controls and a contrasting opening up of access to information on drug exports. For example, as a first step to make it possible to evaluate the impact of existing export policies on developing countries, the Government could set up a register giving details of individual drug exports. This register should be open to public scrutiny, and could be compiled from information readily available to manufacturers, and other exporters.

Another important question for a Government investigation would be how best to assist Third World regulatory authorities by improving their access to expert evaluations of drugs. For instance, it would be particularly helpful for the British Government to make available copies of Licence Applications submitted for the Committee on Safety Medicines; to review the recommendations of the DHSS Medicines Division Professional Secretariat, and in some cases the deliberations of the Committee on Safety of Medicines itself.

5. Britain and other major drug producing countries should take a lead in getting new initiatives on drug exports and information policies more widely adopted such as by all member states of the European Economic Community, OECD etc.

6. As part of a fundamental reappraisal of their development assistance, governments should review the *quality* of official health aid to ensure that it directly benefits the world's poor. Third World governments should not be tied to purchases of expensive pharmaceutical products or high-technology medical services. Instead, priority should be given to funding local projects that benefit poor communities - such as the training of paramedics.

7. Medical training paid for with official aid funds should include more priority for the training of medical and pharmaceutical civil servants from developing countries. For example more British aid funds could be allocated to DHSS courses to improve civil servants' skills in assessing drug submissions and clinical trials.

8. More needs to be done by governments of drug producing nations to promote the transfer of essential drug technology on terms favourable to the least developed countries.

INTERNATIONAL ORGANISATIONS

1. UN agencies should press ahead with their work programmes to assist developing countries in implementing comprehensive drug policies. But they should put more emphasis on 'marketing' policies such as the Selection of Essential Drugs and do more to ensure that their recommendations are translated into action.

2. The UN agencies should resolutely resist pressures to favour narrow rich-world interests and shift the balance so that 'international' policies really cater

for the needs of the majority of their members - the world's poorer nations.

3. WHO in particular should resist pressure to abandon its clear mandate to develop a UN-sponsored international code of drug marketing practices.
4. WHO should look for more allies in attempting to implement difficult programmes, both within the United Nations system and amongst non-governmental organisations. In the interests of balance, it would make sense to give official NGO-status to bodies such as Health Action International so that the needs of the world's poor are represented alongside those of industry.

NON-GOVERNMENTAL ORGANISATIONS

Non-governmental organisations are in a unique position to help set up a productive debate on solutions to the problems of drugs in developing countries.

1. NGOs should make use of their special access to information to publicise examples of constructive policy initiatives being undertaken in both developing and developed countries to provide an incentive to others to follow suit. They also have a duty to make the public aware of obstacles to changes that could benefit the poor.
2. They should take every opportunity to cooperate with other NGOs, international agencies, professional groups, trade unions, industry and governments in pursuing constructive solutions.
3. Aid agencies and other charities should stop giving 'aid' that is not wanted and only supply Third World countries and projects with drugs that they specifically request.
4. Aid agencies, including OXFAM, should continue to fund community health projects that encourage self-reliance, avoiding high-technology medical options wherever possible. More should be done to support grass-roots research into problems related to the use of drugs in poor communities and into creating awareness of positive alternatives to medicines. OXFAM and other agencies should continue to allocate funds to improving the supply of essential drugs.

MANUFACTURERS

We focus on the contribution that can be made by drug producers based in the rich world. Action is of course just as urgently needed on the part of smaller national producers in developing countries whose marketing practices are often far less scrupulous than the major transnational drug companies.

1. Manufacturers should do nothing to obstruct attempts by Third World governments to introduce new drug policies designed to safeguard and promote better health, even when these conflict with industry's immediate interests.
2. Manufacturers should be consistent in the standards they apply worldwide - irrespective of loose controls in developing countries. Marketing practices that would be unacceptable in Europe and North America should be seen as equally unacceptable in developing countries. Companies should abandon the tired old arguments that inconsistent standards are not 'illegal' because a Third World country's laws make them permissible. Instead, rich world manufacturers should take a lead in encouraging higher ethical standards in

promotional practices such as in disclosing full information and employing only suitably qualified sales representatives.

3. Companies should keep to their declared obligation of making sure that drugs “have full regard to the needs of public health” and demonstrate special social responsibility in poor countries by not encouraging demand for non-essential multivitamin tonics, cough and cold preparations and expensive and irrational combination drugs.

4. They should respect the purpose behind the WHO Selection of Essential Drugs and not pressurise public health officials into selecting unnecessarily expensive patented products when cheaper alternatives exist - sometimes in their own product range.

5. Parent companies should take a firm line in reminding their Third World subsidiaries of their social responsibilities, the need to maintain high standards and to comply with the wishes of government regulatory agencies.

6. Companies should cooperate wherever possible with the desire of developing countries to build up self-sufficiency through local production of essential drugs from basic stages.

7. As an immediate step, parent companies could review the product range of their subsidiaries and investigate the possibility of switching production to include more items on local essential drug lists (or on the WHO selection in the absence of a national list).

8. Companies could try to do more to ensure the safe and effective use of their products. They cannot afford to be complacent about labels that read prescription only in countries where drugs are sold in open air markets. A useful exercise would be for manufacturers (or their associations) to commission local research into how their products are actually used in developing countries to try to identify specific measures that *they* could take to counteract misuse.

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These are OXFAM’s suggestions for making more of the benefits of modern medicines available to the world’s poor and counteracting harmful marketing practices. They are only a starting point. Others involved in the process of pushing for change will want to add to and improve on these proposals.

The changes we have suggested need different timescales, but they have one thing in common - the need to start work on them now. The longer action is delayed, the more the poor will suffer.

