



CHAPTER 6

BUYERS BEWARE Uncontrolled Sales and Problem Drugs

POOR PEOPLE make sacrifices to buy drugs. Rarely are these a solution to their problems. The story of one little Bangladeshi girl, struggling for life in a Children's Nutrition Unit in Dacca, is representative of the predicament of many of the world's poor.

She came from a village in Comilla, a district about 30 miles from Dacca. Her mother was poor, a widow, with five other children to feed. The little girl had fallen ill. She got progressively worse, so to get money for medicines and a doctor her mother sold some cooking pots and a few other possessions. She even sold their small piece of land so they could travel to the city. The doctors at the first hospital they tried said she would have to pay for the child to be admitted. So they went to Dacca Medical College. The doctors there examined the little girl and sent them away with a prescription for half a dozen drugs, mostly antibiotics and multivitamin tonics.

Her mother bought some but she could not afford all the drugs. The child was getting weaker so she turned to some relatives for help. But they had nothing to spare. Fortunately, when the mother was getting desperate, some neighbours told her about the Save the Children Fund Nutrition Unit where she would not have to pay. By the time the little girl was admitted, she weighed just over 5 kilos (about 11 pounds). At the age of 6, she was only a little heavier than a newborn baby. The doctor diagnosed severe protein-energy malnutrition and anaemia. The child's life was in immediate danger because the haemoglobin level in her blood had dropped so low that her heart was in danger of stopping. That was not all. She had other complications, including a chest infection, a urinary tract infection and worms.

To stand any chance of surviving, the child needed intensive nutrition treatment. She would have to be fed milk through a nasal tube because she was nearly unconscious, and she also needed several blood transfusions.

But her mother had been sent away to buy expensive drugs. Even if she had found the money to pay for them, they could not have saved the little girl's life. The prescription would have meant money down the drain, because the underlying cause of the child's serious condition was lack of *food*. The tragic irony of this little girl's case is that to get her to the city, to see doctors and buy medicines, her mother had been forced to sell the best guarantee of her children's health. Without that piece of land, it was going to be even harder to stop the other children from getting more seriously undernourished. ⁽¹⁾

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YOU GET SICK, YOU BUY MEDICINE

People everywhere share a need to believe in the healing powers of someone or something. Most of us will readily believe in the power of a drug and in this there is little difference between an educated Westerner and a poor, illiterate man or woman. All medicines, whether traditional herbal remedies or modern factory-produced drugs, have a special mystique.

In the eyes of the poor, modern medicines embody the power and status of the well-fed, Westernised people who are powerful in their societies. This encourages the poor to try to emulate the small minority who consume most of the medicines, in the same way as more and more poor people buy expensive factory goods like tinned foods and fizzy drinks.

Prevention may be better than cure. But prevention takes time. The poor need a quick solution to their health problems. Drugs hold out the promise of an instant cure. They tempt people with the illusion that there is a pill for every ill, provided you can afford to pay for it. In turning to local drug sellers for help, the poor may also be swayed by their status in the community. They may be literate and *seem* very knowledgeable. All these factors leave the poor and sick extremely vulnerable to sales pressures and to dangers from the actual drugs that neither they, nor the medicine sellers suspect.

A doctor working in North Yemen explains how people increasingly depend on buying medicines to solve ill-health problems: "Yemenis have come to want, indeed to feel they need what they perceive as Western medicine. This means for most of them Western *medicines*, simply because drugs, attractively packaged and efficiently marketed, are the only aspect of Western health care they have any experience of. With the emerging demand for medicines from the West, there has been no growing awareness of modern concepts of health and disease. The rudimentary principles of hygiene, nutrition and sanitation are practically unknown. The train of thought for both the patient and the practitioner is simply - you get sick, you see a doctor, nurse or pharmacist, he prescribes a medicine (or more often several medicines, at least one of which should be an injection) and you are made well again." ⁽²⁾

The problem is not just the lack of organised health services. Health planners and doctors are responsible for encouraging dependence on medicines, as David Werner, author of *Where There is no Doctor*, explains: "In Latin America, many of the new programs under the Ministry of Health, Ministry of Education, and other agencies to deliver services and promote community health in rural and marginal areas have been designed by prestigious but poorly informed and out-of-date doctors and nurses. The result is that training and manuals for village health workers still tend to promote bottle feeding rather than breast feeding, restricting food to children with diarrhoea, and overuse and misuse of medication like Entero-Vioform, cough syrups, diarrhoeal plugs, etc." ⁽³⁾

The widespread promotion of modern drugs has had a decidedly negative impact on some poor communities. An anthropologist, analysing the situation in Central

America, concludes: "The growing reliance on modern medicines has not only served to alter local health care traditions and means of coping with illness, but also to drain away resources without providing any long term improvements in health or living standards in the community. Dependence on these products and the agents and institutions which make them available, fosters the notion that the solution to illness resides in the purchase and consumption of medications rather than in improvements in living conditions." (4)

As we have seen, the poor will even put their health at risk by going without food to buy medicines. There has been little detailed research into just how much of their income goes on medicines. But a study in one town in Brazil found that poorer families were spending about 6% of their monthly income on medicines from the *farmacias*. (5) A survey in the Philippines revealed that another poor community spent more - about 10% of their income - on paying for treatment. This, despite the fact that the people defined their main health problems as diarrhoea and low wages which cannot be cured with drugs. (6)

The poor come under direct sales pressure from local traders whose livelihood can depend on selling as many medicines as possible. An anthropologist describes how in South-Cameroon petty traders selling drugs and other commodities are more in evidence at certain times of the year: "Particularly in the cocoa season, when the villagers have money, one meets these traders in large numbers, either on foot or on bicycle. Although the sale of medicines by ordinary traders is against the law, it is practised openly and is socially accepted." (7)

Advertising may also act as a powerful inducement encouraging people to see medicines as the key to health. For example, British doctors working in Nepal make a direct connection between advertising and overspending on drugs. They diagnose that overspending "arises from ignorance and the assumption that the more expensive the medicine the better it will be. This attitude either wholly or partly originates from the copious ... advertising carried out in the towns of Nepal's developed areas by Indian and multi-national drug companies. Likewise, partly in response to this market pressure there is a tendency to use sledge-hammer therapy." (8)

Growing numbers of the Third World poor, particularly migrants to the towns and cities, are now exposed to radio jingles and street hoardings advertising vitamin supplements, painkillers and antidiarrhoeals. Anne Ferguson, the anthropologist who studied attitudes to medicines in El Salvador, concluded that mass media advertising was reinforcing people's dependence on packaged drugs. "Although ... remedies made on the premises of the town pharmacies are still used in the community, reliance on pre-packaged medications is promoted on a national level through mass media commercial advertisements regarding their effectiveness. Prescription products are not advertised on radio or TV, but large companies ... indirectly promote the use of these medications by advertisements suggesting that the quality and efficacy of their products is superior to that of other companies, and that *the solution to illness resides in the purchase and consumption of modern pharmaceutical products.*" (9) (our emphasis)

Direct advertising is of course mainly targeted at the privileged minority in poor countries. But it has exerted a strong influence on the poor, such as in encouraging them to bottle-feed their babies and smoke expensive foreign cigarettes. The direct impact of drug advertising is more difficult to gauge. But advertising aimed exclusively at the educated minority clearly has a strong indirect impact on the poor. It conditions the attitudes and prescribing habits of doctors, who in turn influence the retailers who sell drugs to the poor.

There are few meaningful controls on advertising standards in developing countries. Some advertising appears to increase dependence on medicines by playing on fear and ignorance. The advertisement for Calcium-Sandoz, reproduced opposite, appeared in a magazine in India - a country that operates more controls on drug marketing than many. Its message is unambiguous. If you do not hurry to start your child on a calcium supplement, it may soon be "too late. No amount of calcium given later can repair the damage." By implication, *only* these calcium tablets can provide enough calcium for a growing child. This type of advertisement is clearly aimed at India's better-nourished middle-class. But it is likely to help persuade drug sellers that these calcium supplements must be essential for the under-nourished poor.

Sandoz point out that average calcium-intake is low in India, which it certainly is by comparison with most of Europe and North America.⁽¹⁰⁾ They argue that their product provides a cheaper source of calcium in India than relatively high-priced dairy products: one litre of cow's milk costing Rupees 4-6 provides a similar amount of calcium to two tablets of Calcium-Sandoz, priced at Rupees 0.18.⁽¹¹⁾ But this comparison takes no account of other important nutrients in cow's milk.⁽¹²⁾ Cow's milk is costly, but buffalo milk, with almost twice its calcium value, is readily available in Indian villages, and there are other local foods - particularly pulses and vegetables - which people could be encouraged to eat more of to boost their calcium-intake.⁽¹³⁾

These alternatives to medicines are masked by advertising campaigns. For example, promotion has opened a large market for vitamin and mineral supplements including extra calcium in Mexico, a country where people get plenty of calcium from *tortillas* which are soaked in lime.⁽¹⁴⁾

But to some extent the poor choose to buy expensive drugs, regardless of commercial and advertising pressures. Most people will readily believe that an expensive drug must be better than a cheaper one. If we feel ill - or a close relative does - we want to buy medicines. Whether the medicines are likely to serve any useful purpose is very much a secondary consideration. This dependence has obvious dangers, particularly where there are no controls on drug sales.

THE HAZARDS

All too often, there is a cruel contrast between the advertising claims and the reality of drug use in the Third World. Far from offering a "solution to illness", as an Ethiopian health planner points out, the random and dangerous use of powerful drugs has actually "brought about ill health".⁽¹⁵⁾

Calcium-hungry bones are weak and easily damaged. Calcium-Sandoz strengthens bone structure.

Bones can't be seen. Yet they are critical for the growth and development of your children. Calcium is a vital component of bones and teeth. Calcium deficiency results in weak and brittle bones. Teeth become loose and develop cavities.

For strong teeth and healthy bones give your child 3 to 4 vanilla-flavoured Calcium-Sandoz tablets every day.

In addition to Calcium, each tablet is fortified with Vitamins C, D and B12.

Your child loses calcium every day. This must be replaced. Otherwise his growth will suffer. Ordinary meals may not provide enough calcium.

Start him on Calcium-Sandoz today - before it is too late. No amount of calcium given later can repair the damage.

Remember, not all calcium tablets are the same. Insist on Calcium-Sandoz only. Do not settle for substitutes.

Calcium-Sandoz—the world's best calcium developed by Sandoz in Switzerland.



Calcium-Sandoz®
For strong teeth and healthy bones

(Credit) Mike Wells.



For many of the world's poor, the only medicines readily available come from market salesmen with little or no knowledge of the ineffectiveness or potential dangers of some of their products.

The problem is that drugs are inherently 'unsafe'. According to the *British National Formulary*, "Almost any drug may produce unwanted or unexpected adverse reactions".⁽¹⁶⁾ A professor of clinical pharmacy explains that "a drug's effects are like shot-gun pellets - some land on target, others do not", so "any drug produces some undesired effects along with the desired effects ..."⁽¹⁷⁾ Consequently there are risks to be balanced against possible benefits in the use of any drug. In Britain, where the use of drugs is controlled by strict 'prescription only' regulations, as many as one patient in ten is *reported* to suffer some adverse reaction to a prescription. Furthermore, a Cambridge Regius Professor of Medicine considers that the estimate of 6,000 deaths each year "associated with National Health Service prescriptions" is "unlikely to be an under-estimate".⁽¹⁸⁾

In developing countries where drug use is uncontrolled, the extent of drug-induced illness is impossible to measure. According to Dr. Silverman, "Among Latin American medical authorities - especially haematologists, pathologists and other experts - the damage caused by drugs is believed to be shockingly high".⁽¹⁹⁾ But most people who take drugs in developing countries are not seen by doctors, let alone haematologists. In fact hardly any of the people prescribing and selling medicines in poor countries have any inkling of their possible dangerous side-effects and interactions with other drugs.

A French pharmacist found that 90% of pharmacies she visited in Mexico were staffed by unqualified sales assistants. All they knew about drugs they had learnt from visiting sales representatives.⁽²⁰⁾ They are fairly typical of drug sellers throughout the Third World, such as those observed by an anthropologist in El Salvador. "Pharmacy personnel in small towns have rarely received any formal training in the use of the products they sell. Some are skilful, but it is not uncommon for illiterate or semi-literate clerks or children to prescribe and dispense medications to customers seeking advice."⁽²¹⁾

The hazards are all too obvious. In Mitford market in Dacca, capital of Bangladesh, we bought one of the latest anti-cancer drugs over the counter. This drug which is used to treat lethal brain tumours, can have fatal side-effects.⁽²²⁾ The salesman assured us not only that it was "safe" but that it "cured all cancers".⁽²³⁾

'PROBLEM' DRUGS

Manufacturers that we have approached about cases of misleading drug information and the marketing of harmful and non-essential products in poor countries invariably stress the differences in opinions and regulations that exist from one country to another.⁽²⁴⁾ For example, within Europe drugs considered too hazardous for sale in Britain and Scandinavian countries are still marketed in West Germany, Italy and other countries. Undoubtedly this complicates the issues as there can be as many opinions on the degree of risk of drugs as there are experts.⁽²⁵⁾

But the 'differences' argument is advanced by companies to 'prove' that they are doing all that can reasonably be expected of them and that it is up to Third World governments both to decide which drugs they will allow onto the market, and

to make sure they are used safely. But the argument needs to be turned on its head. Third World regulatory agencies rely on manufacturers for information on which to base their decisions. Inevitably manufacturers are in a position to convince governments that the advantages offered by their products outweigh possible hazards. As a result, drugs with known toxic side-effects are freely available in Third World countries. They are doled out to the unsuspecting often by illiterate sales assistants, quacks, even children, who can have no idea of the dangers, or that there may be 'safer' alternatives.

If anything the 'differences' - poverty and uncontrolled drug sales - put even more onus on manufacturers not to try to market drugs that can do more harm than good in developing countries, especially when they are not vital. Manufacturers are understandably sensitive about any singling out of individual 'problem' drugs - not least because all drugs carry some risk. But some carry more risk than others particularly in poor countries.

ANTIDIARRHOEALS

The dangers can readily be seen if we look at a number of antidiarrhoeal drugs widely sold in poor countries. According to WHO, diarrhoea is *the* major killer of children under three, particularly babies. ⁽²⁶⁾ Two kinds of drugs are used to treat diarrhoea. One attacks the underlying infection causing the diarrhoea, the other stops only the *symptoms* of the infection, in other words, just the diarrhoea.

Any number of symptomatic antidiarrhoeals are marketed in the Third World. Amongst the most widely sold are Lomotil, manufactured by Searle, and the Ciba-Geigy products, Entero-Vioform and Mexaform. All are sold to treat young children of even very poor families. But experts, including Professor King and colleagues who compiled a WHO *Primary Child Care* manual for health workers, are adamant that "most children with diarrhoea don't need drugs". ⁽²⁷⁾ They state that symptomatic drugs including diphenoxylate (the active ingredient of Lomotil) and Entero-Vioform "do not help children and are not necessary" ... "These drugs often *seem* to work with adults, because most adult patients with diarrhoea cure themselves. Many children have diarrhoea and you can waste much money giving them drugs which do not help." ⁽²⁸⁾ (original emphasis)

Tragically, poor mothers are not aware of this. They *do* spend money on Lomotil, Entero-Vioform and Mexaform with the false assurance that these medicines will make the child better. No-one tells the mother that the immediate threat to her baby's life is not diarrhoea, but dehydration, which she can prevent with a home-made solution of water, salt and sugar.

Drug sellers through their ignorance, encourage mothers to believe that antidiarrhoeals will make the babies better. Manufacturers appear to have been doing very little to warn of the dangers. ⁽²⁹⁾ A mother's false sense of security can lead to her baby's death.

LOMOTIL

But poor people are even less likely to be told that, apart from not being particularly helpful to their children, these comforting products also have hidden dangers. In the case of Lomotil (which contains diphenoxylate hydrochloride and atropine sulphate) the manufacturers warn British doctors that “Lomotil should be used with caution in young children”, because “accidental overdosage may produce unconsciousness with respiratory depression, particularly in children, or atropine poisoning, or both”.⁽³⁰⁾ These toxic reactions can be fatal.⁽³¹⁾

One doctor explains that the indiscriminate use of antidiarrhoeals in prolonged attacks of diarrhoea can run the risk of their acting as a “blindly harmful stopcock”.⁽³²⁾ Lomotil stops diarrhoea from coming out, but to do that it also prevents the body from getting rid of the organism causing the infection. So Lomotil can make the infection last longer.⁽³³⁾ Although the child’s body stops expelling fluid and vital electrolytes, these are not necessarily absorbed and may just be accumulating in the paralysed gut. This means that Lomotil can hide the seriousness of a child’s condition, because it “can mask the signs of dehydration”.⁽³⁴⁾ The dangers are potentially so great that experts urge doctors treating children to “avoid the potentially dangerous use of Lomotil for the treatment of diarrhoea”.⁽³⁵⁾

In recent years Third World prescribers have not been given the same warnings as British and American doctors. Since 1973 the US regulatory agency has stopped its use in children under two.⁽³⁶⁾ In Britain Lomotil is sold only on prescription, and Searle advises doctors that it “should not be given to children under one year old”.⁽³⁷⁾ But in Third World countries, where there are no effective prescription controls, the manufacturers have recommended dosages for babies under a year old. The London-based action research unit, Social Audit, carried out an in-depth case-study and found that Lomotil has been recommended in India for babies “aged up to 3 months”, and for Brazilian babies weighing “only 3kg (or some 6½ lbs) - a low-to-average birth weight”.⁽³⁸⁾

Lomotil has also been sold in poor countries without any warnings that it can be harmful to children. For example, in 1980 in North Yemen we bought packs of Lomotil *with neomycin* freely over the counter. Those packs, manufactured in High Wycombe, England, in May 1979, gave no precautions for use in children. This combination product with neomycin is even more expensive than Lomotil alone. Moreover, both WHO and the *British National Formulary* (1981) advise against the use of neomycin in treating diarrhoea.⁽³⁹⁾ Lomotil is also widely sold in Central America. The label of a small bottle purchased by OXFAM staff in the Dominican Republic in 1980 does give a warning in Spanish that the drug should be used “delicately”. It also advises that in the event of an overdose the patient should be admitted to hospital. But there are no recommended *maximum* doses on the label.

In September 1981 Searle made the encouraging announcement that “in response to concerns expressed by Social Audit, Searle has decided to revise its product labelling to indicate clearly that Lomotil should be used for the adjunctive treatment

of diarrhoea and is not recommended for use in children under two years of age provided these changes are acceptable to local regulatory bodies".⁽⁴⁰⁾

Lomotil is a useful drug of convenience for the rich. But it can cost "up to 25 times more than other widely used symptomatic treatments for diarrhoea".⁽⁴¹⁾ In response to the concern we have expressed that Lomotil is unlikely to represent 'value for money' for the poor, Searle have sent us the results of various clinical trials, but the reliability of some of these has been seriously called into question by Social Audit.⁽⁴²⁾ The hazards remain. How will illiterate drug sellers understand that Lomotil is only an "adjunctive treatment" without pictograms backed by an active health education campaign?⁽⁴³⁾

CLIOQUINOL

Ciba-Geigy's anti-diarrhoeals, Entero-Vioform and Mexaform, both containing clioquinol, are freely available over the counter in many developing countries. In most cases we found them on sale in foil strips, without instructions or warnings. Sales assistants in Bangladesh, India and North Yemen were obviously completely in the dark about the controversy that has surrounded the use of clioquinol since an 'epidemic' of drug-induced illness broke out in Japan in the 1960s. More than 10,000 people in Japan were victims of what came to be known as 'SMON' (sub-acute myelo-optic neuropathy). As a result of using clioquinol, they suffered numbness, weakness in the legs and eye damage. Some of the people who had taken prolonged high doses ended up in wheelchairs, others completely blind.⁽⁴⁴⁾ It has since been established that clioquinol can cause "toxic effects on the central nervous system".⁽⁴⁵⁾ The manufacturers of the most-widely sold clioquinol products, Ciba-Geigy and others, have paid compensation to victims in Japan and Europe.⁽⁴⁶⁾

Entero-Vioform which was once sold over the counter in Britain "for the prevention and treatment of holiday diarrhoea" was effectively removed from the British market when all its licensed indications were withdrawn.⁽⁴⁷⁾ One anti-diarrhoeal containing clioquinol was still listed in 1981 as available on a doctor's prescription, but doctors are warned: "Special precaution: avoid prolonged administration".⁽⁴⁸⁾ It has been withdrawn in other developed countries and the expert committee that decided on the WHO selection of essential drugs excluded clioquinol because they decided that the risks outweighed the benefits.⁽⁴⁹⁾ But some developing countries have included clioquinol specifically for use in amoebic dysentery as a three to four day course can be cheaper than treatment with antibiotics.⁽⁵⁰⁾

Ciba-Geigy's UK-based Head of International Medical Liaison has assured us that the company is "making genuine attempts to ensure adequate literature and warnings are given about taking long courses or too many courses which could give rise to neurological symptoms. The problem is ensuring that this information reaches the patient."⁽⁵¹⁾ From our research we know it clearly does not. Salesmen in North Yemen, India and Bangladesh whom we questioned about the safety of Entero-Vioform and Mexaform assured us that these drugs were "completely

safe”, as they urged us to buy handfuls of foil strips to treat “all” diarrhoea. They gave us vague and contradictory advice about the dosage we should take, and in many cases, no maximum dosage appeared on the packaging we received.

Ciba-Geigy is by no means the only manufacturer of anti-diarrhoeals containing clioquinol which has not succeeded in ensuring that Third World patients and, in some cases, even doctors receive any warnings about prolonged use. In Bangladesh, for example, Fisons’ local subsidiary is marketing *Fistrep*, a product containing 250mg of “iodochlorhydroxyquinoline” (ie clioquinol under its less well-known chemical name) and 100mg of streptomycin sulphate. The dose recommended for adults in the Bangladesh *Prescriber’s Guide* 79 (current in September 1980) was 1.5g daily. This means that even if they resisted the temptation to take more, *within a week* Bengali patients would have taken as much clioquinol as some of the Japanese SMON victims. ⁽⁵²⁾ Fisons are not of course responsible for the entry in the Guide, but *Fistrep* has been selling in foil strips without warnings of the maximum dose.

At the moment there is no evidence to suggest that Bengalis are particularly susceptible to SMON. But nor is there any conclusive evidence to prove that they are any less susceptible than people in Japan, Sweden, or Britain. In the circumstances there is little room for complacency. ⁽⁵³⁾ A remark recently attributed to the Managing Director of Fisons (Bangladesh) - if correctly reported - is particularly disturbing. He is reported to have expressed the view that “We are businessmen first. First of all we want profits... we are oversensitive about reports from WHO. Restrictions on drugs and pesticides imposed in the US and Canada should not be applied in our country because our people are ethnically and biologically different from others.” ⁽⁵⁴⁾

BAD INFORMATION MEANS DANGEROUS DRUG USE

It is inevitable that drug use will be even less safe in the Third World if manufacturers do not make sure that the people dispensing their products understand how they should be used. Getting the key information across to ‘prescribers’ with no medical training obviously presents major problems, particularly when so many are illiterate. A Swiss professor of pharmacology stresses that it is very difficult to balance the conflicting needs of Third World doctors, untrained drug sellers and illiterate patients, with the added complication of very limited space. Too much information can be as dangerous as too little. People may find it all too daunting and ignore all the warnings. ⁽⁵⁵⁾

In some cases, even with the best of intentions, manufacturers can end up detracting from the safe use of their products. In Third World countries it has become increasingly common to sell drugs in foil strips without cardboard packs or package inserts. This has the advantage of keeping down prices whilst still protecting drugs from humidity in tropical climates. But foil strips have the major disadvantage of allowing almost no space for vital information on dosage, and precautions for use.

The marketing manager of Fisons (Bangladesh) explained to us that manufacturers can come up against opposition when they attempt to make drug information more readily available. When Fisons consulted local doctors on whether they would like drug information to be in the local language, many were fiercely against the idea. The doctors' stated objection to the proposal was that it would encourage dangerous self-medication. ⁽⁵⁶⁾ Clearly they take a dim view of any move that might make patients less dependent on them.

Similarly, in Central America some major foreign manufacturers are reported to have "eliminated the package inserts they used to include with their prescription products, purportedly in an effort to reduce the over-the-counter sale of these medications". ⁽⁵⁷⁾ But this suppression of information had little impact on self-medication. If anything it made the situation worse. "The lack of package inserts describing indications for use, contra-indications, warnings and doses of medications led people to misuse products. For example one of the pharmacy owners was hospitalised as a result of an overdose of a product she took to treat a headache. The package contained no information regarding dose, very general indications for use and a label saying 'to be sold only with a physician's prescription'." ⁽⁵⁸⁾

In most developing countries a label that reads "to be dispensed on Doctor's prescription only" can be little more than decorative. Moreover, because drugs are so often prescribed by untrained people, the fact that package inserts are invariably written in technical jargon that is intelligible only to doctors and pharmacists drastically limits their usefulness. Warnings given in simple, direct language, or in picture form, could help encourage the safe use of drugs. At the moment, manufacturers in many cases are failing to put across information essential to the safe use of their products. In some cases the information given to Third World prescribers has been dangerously misleading.

The problems are illustrated by the way in which anabolic steroids have recently been promoted in poor countries. Their use is controversial and limited in developed countries, not least because they can cause serious toxic side-effects.

ANABOLIC STEROIDS

These drugs have not turned out to be as useful as was once hoped. ⁽⁵⁹⁾ Their recommended uses have been shrinking so that in Britain and other developed countries they are now used for relatively few serious conditions including osteoporosis (bone disease), blood diseases such as aplastic anaemia, and chronic kidney failure "with varying degrees of success". ⁽⁶⁰⁾ They are also given to women with breast cancer (though less so with modern surgery), people with chronic debilitating diseases, especially the elderly, and patients after major surgery to help build up body protein. ⁽⁶¹⁾ But a professor of clinical pharmacy stresses that it is "much more important to ensure that the patient takes a nourishing diet (high in protein)" than anabolic steroids. ⁽⁶²⁾

Anabolic steroids became popularly known as body-builders because of the publicity over their use by athletes. But the *British National Formulary* is adamant

that “their use as body-builders or tonics is quite unjustified”, not least because anabolic steroids have very nasty side-effects. ⁽⁶³⁾ They can cause irreversible virilisation (hirsutism, enlargement of the clitoris and deepening of the voice). Most patients on anabolic steroids suffer some adverse effects to the liver, which can include jaundice and liver tumours. Another possible side effect is sodium retention causing oedema and heart failure. But experts stress that they can be particularly harmful to children: “The use of anabolic steroids to promote growth in underdeveloped children may lead to premature fusion of the epiphyses and stunting of growth in adolescence.” ⁽⁶⁴⁾

ORABOLIN DROPS

However, in Bangladesh the Dutch manufacturers Organon have been promoting a number of anabolic steroids specifically “for paediatric use in conditions like marasmus, malnutrition, poor weight gain, retarded growth, kwashiorkor etc.,” listing one advantage after another without a word of warning about the hazards. Doctors are told, for example, that either one of Organon’s two products Durabolin and Deca-Durabolin “stimulates appetite and ensures adequate food intake ... checks protein depletion ... increases resistance against infectious diseases [and] improves the general constitution and restores sense of well being”. ⁽⁶⁵⁾

Dr. Schweiger, a British doctor working in a remote rural area of Bangladesh, drew our attention to the problem in 1980. A visiting Organon sales representative had specifically pointed out their anabolic steroid, Orabolin drops, because he knew the doctor was “working with malnourished children”. ⁽⁶⁶⁾ The insert on Orabolin from the Therapeutic Index of Organon (Bangladesh) is reproduced overleaf together with Organon’s data sheet on Organon tablets for British doctors. (Orabolin Drops are not sold in Britain.)

Doctors in Bangladesh have been told that Orabolin is “a powerful anabolic agent” which is “exceptionally well tolerated, causes no fluid retention and is free from harmful effects on liver ... The raspberry flavoured liquid administered in drops is especially meant for younger children and infants.” No warnings are given. ⁽⁶⁷⁾

Doctors in Britain are advised that Orabolin is “not recommended for children”. Warnings include the fact that “anabolic steroids may cause fluid retention ... tumours of the liver have been reported occasionally”, and that the development of tumours “cannot at present be excluded, and this should be considered when the use of this product is proposed, especially in young people who are not suffering from life-threatening disorders”. ⁽⁶⁸⁾

In December 1981 Organon informed us that “It is our policy that promotion both verbal and written should be confined to indications as approved by the respective health authorities. It is therefore obligatory for local companies to have all material used for doctors’ information approved by headquarters. Unfortunately sometimes the system does not work and something slips through. The printed material you saw, when in Bangladesh [i.e. September 1980] had not yet arrived (and consequently not approved) with Organon International. We

ORABOLIN®
Tablets and Drops



Composition:
Tablets containing 2 mg. Ethylestrenol.
Drops containing 2 mg. Ethylestrenol per ml. aqueous solution.

Clinical Effects:
Ethylestrenol, the active principle of ORABOLIN, is a powerful anabolic agent, which is fully effective when orally administered. Extensive tests have shown that ethylestrenol has an anabolic/androgenic ratio almost 20 times than that of methyltestosterone. In practice the small daily dose required, 0.05 mg. per Kg. body weight, ensures that the only clinical effect is anabolism.

ORABOLIN stimulates the appetite, promotes weight gain and in elderly debilitated patients produces a marked psychological improvement. Metabolic balance studies have shown that both nitrogen and calcium are retained during treatment, and that a negative nitrogen balance during corticosteroid therapy can be reversed. ORABOLIN is exceptionally well tolerated, causes no fluid retention and is free from harmful effects on liver and adrenals.

The raspberry flavoured liquid administered in drops is especially meant for younger children and infants.

Indication:

In adults :- Convalescence, weight loss, debility, osteoporosis, slow - healing fractures, during corticoid therapy, as an adjuvant after acute and chronic diseases.

In Children :- Retarded growth, lack of appetite and insufficient weight, nutritional disorders, failure to thrive and after infectious diseases.

Dosage:

Adults : 2 tablets daily

Children : According to body weight

Weight in Kg.

Less than 10 kg.

10-30 Kg.

more than 30 kg.

Drops per day

5 drops

9 drop/kg.

30 drops.

Packing:

Bottles of 20 tablets.

Dropper-bottles of 5 ml.

ORABOLIN®

Presentation: Ethylestrenol Tablets: Round, flat and concave, coded 583 on one side, with Organon and star on the other side.
Active ingredient: Ethylestrenol BP 2 mg. per tablet.

Uses: Ethylestrenol is an anabolic agent, the nitrogen and calcium retaining effects of which are fully effective when it is administered orally.

Dosage and administration: Adults: 1-2 tablets orally daily (not recommended for children).

Contra-indications, warnings, etc: Contra-indicated in pregnancy, prostatic carcinoma, breast carcinoma in the male and in severe disturbances of liver function.

Treatment should be discontinued if cholestatic jaundice appears or liver function tests become abnormal. **Concomitant therapy** have been reported occasionally in patients subjected to prolonged treatment with C-17-steroid androgenic anabolic steroids. The possible drug interactions may induce or enhance the anabolic effect of ethylestrenol. Such interactions are excluded and this should be considered when the use of this product is proposed, especially in young people who are not suffering from life-threatening diseases.

Precautions: In young people, fluid retention or oedema or anabolic steroids may cause fluid retention. Skeletal maturation should be followed carefully when treating young people, since anabolic steroids in high doses may be observed in young women whose cycles are not yet stabilised.

In diabetics, the need for insulin or other anti-diabetic drugs may be increased. When administered in the recommended dosages and for short periods of time (up to four weeks) side-effects may occur very rarely. Occasionally after high dosages, some liver function tests show abnormal results. However, after discontinuation of completely reversible. In some cases, particularly those treated with high dosages, nausea and some water retention may occur.

The possibility of menstrual disturbances exists, probably resulting from an inhibition of the secretion of gonadotrophins from the pituitary and/or from the occurrence of a progesterational effect. In such cases the treatment should be discontinued or the dosage decreased.

Pharmaceutical precautions: Protect from light.
Legal category: POM.
Package quantities: Bottles of 100 tablets.
Further information: Nil.
Product licence number: 0085/5043.

Conflicting information on prescribing for children. Left, therapeutic information, Bangladesh; right, entry from data sheet for British doctors.

Help the child to grow with

Orabolin



A child's world is full of fun and laughter, love and care of parents. And that is what all children need to grow healthy and sturdy.

But it is not always so. Unbalanced diet, poor appetite and frequent illness often interfere with the normal growth of children.

Orabolin

Ensures
normal
growth

Stimulates
appetite

promotes
optimal
weight

GROWTH IN EVERY DROP



STRENGTH IN EVERY TABLET



ORGANON (BANGLADESH) LIMITED

Advertisement which appeared in a magazine issued at a conference on The Role of Rural Doctors in Child Care, at Dacca Children's Hospital in May 1981. The conference was sponsored by WHO and the Bangladesh Ministry of Health.

have a rather strict product surveillance activity and also as a result of your information we have taken corrective measures with respect to Bangladesh, as well as other countries where this may have occurred.’’⁽⁶⁹⁾

In January 1982 we wrote to Organon asking for a copy of the revised product entry. We did not receive this, but in April we were sent a copy of an Organon ‘Product Safeguard’ for Orabolin which the company advise us they distribute to doctors in Bangladesh. This contains ‘warnings and precautions’, but repeats that “Orabolin drops are especially suitable for use in children” without specifying any limitations on their use.⁽⁷⁰⁾

ANAPOLON

Organon is not the only manufacturer to have been marketing anabolic steroids in Bangladesh as body-builders for children. The Bangladesh subsidiary of ICI produces an anabolic steroid, Anapolon (oxymetholone), under licence from Syntex. The advertisement on page 107 shows that ICI have promoted this to doctors as a “potent, *safe* anabolic agent” with “manifold uses” including to “promote growth in underdeveloped children”. (our emphasis) A number of the claims made are directly contradicted by the Syntex UK data sheet. British doctors are warned that Anapolon in high doses “may lead to virilisation in ... pre-pubertal children” and that it can have “slight” virilising effects even in low doses.⁽⁷¹⁾ The ICI Bangladesh advertisement claims “no effect on liver function”. But the *British National Formulary* entry for Anapolon states that “jaundice and liver disturbances are common”.⁽⁷²⁾

The Chairman of ICI’s Pharmaceutical Division has written with the reassurance that “I believe that your criticism of certain of the claims made does have substantial justification. I accept that the unqualified use of the word ‘safe’ is inappropriate - and more importantly, that the suggestion that the product be used in children who are under-developed as a result of malnourishment is open to criticism. Within the ICI international pharmaceutical operations, great care is taken to ensure that technical claims made for any ICI product are both medically and scientifically justified ... I find that Anapolon, being a product produced under licence and sold in only one country, has not been subject to the full rigours of that system. Steps have immediately been taken to withdraw all copies of that product leaflet...’’⁽⁷³⁾

In April 1982 Ciba-Geigy announced their decision to withdraw their anabolic steroid Dianabol worldwide. Dr. Burley advised us that Ciba had “come to the conclusion that the balance between the use of the drug in certain medical conditions such as osteoporosis and anaemia is outweighed by the unfavourable side-effects when the drug is used either as a vitamin supplement or by athletes and others wishing to improve their performance”.⁽⁷⁴⁾

PAINKILLERS

When a decision is made to withdraw a drug in Europe or the US, the evidence suggests that it by no means follows that manufacturers will always voluntarily

ANAPOLON

OXYMETHOLONE

THE POTENT, SAFE ANABOLIC AGENT

- Restores weight loss
- Promotes utilisation of protein
- Stimulates appetite
- Speeds post-operative recovery and convalescence after illness
- Improves physical condition
- Induces sense of well-being
- Corrects de-calcification and relieves low back pain of osteoporosis especially in post-menopausal and senile women
- Promotes growth in underdeveloped children
- Non-virilising
- No fluid retention
- No effect on liver function
- Well tolerated at all ages

THE MANIFOLD USES OF 'ANAPOLON'

After debilitating diseases, muscle wasting states such as poliomyelitis and in bedridden patients. Malnutrition, carcinoma, arthritic conditions, asthenia, tuberculosis and sprue.

After severe infections.

After surgical operations.

After burns, fractures, injuries, etc.

During and after corticosteroid therapy to counteract excessive protein loss.

For children underdeveloped or debilitated as the result of illness or malnourishment.

DOSE :

Average course : Adults 1-2 tablets (5-10mg.) per day over 30-45 days.

Children $\frac{1}{2}$ -1 tablet per day for 30 days.

PRESENTATION :

Scored Tablets of 5 mg. in packs of 25.



ICI Bangladesh
Manufacturers Limited
9, Motijheel Commercial Area
Dacca - 2

Promotion of anabolic steroid for malnourished children, Bangladesh.

remove their product from the Third World market. The problems are illustrated by two chemically-related painkillers, whose use has recently either been controlled or completely stopped in a number of developed countries. By contrast, they continued to be widely marketed in Third World countries for over-the-counter sale, with no warnings of the dangers.

AMIDOPYRINE

For over 30 years amidopyrine has been known to cause agranulocytosis. This fatal blood disease kills by destroying the body's protective mechanism against infection - the white blood cells. As early as 1938 sales in the US were restricted to a doctor's prescription. In 1963 in response to the consensus of medical opinion, the drug was voluntarily withdrawn in Britain by one of its leading Swiss producers, today's Ciba-Geigy, (Ciba and Geigy merged in 1970).⁽⁷⁵⁾

Amidopyrine is only one of a number of drugs, such as chloramphenicol, that can cause similar fatal toxic reactions.⁽⁷⁶⁾ But whereas chloramphenicol is an inexpensive life-saving drug, invaluable in typhoid epidemics, not only does amidopyrine not save lives, but it offers few advantages over other 'safer' painkillers. When the drug also came under suspicion of causing cancer, the Swiss drug regulatory authorities recommended its complete withdrawal.⁽⁷⁷⁾ In 1977 two Swiss manufacturers, Ciba-Geigy (which marketed four amidopyrine-based products) and Sandoz, with two, announced their intention to remove amidopyrine from all their formulations by the end of the year.⁽⁷⁸⁾ They were to be reformulated with propyphenazone, a chemically-related drug.

Three years later, however, Ciba products containing amidopyrine were still being sold under the brand-names Cibalgin and Spasmo-Cibalgin in ten developing countries, and Portugal. In only one case was any warning given about the risk of fatal agranulocytosis.⁽⁷⁹⁾ The drug was still being used for minor pains including "painful conditions of all kinds e.g. headache, toothache, feverish colds, chills and influenza".⁽⁸⁰⁾ In December 1979 all six Ciba and Sandoz formulations were on sale over the counter in Mexico.⁽⁸¹⁾ Ciba explain that they "did not think that the substitution of propyphenazone was urgent or demanded a product recall".⁽⁸²⁾ The reason for withdrawing amidopyrine was ostensibly the cancer risk, not agranulocytosis (which had been known about for so long). Consequently Ciba decided "to give priority to northern or non-tropical countries where nitrites are found in higher concentrations" because of the greater consumption of processed foods "such as sausages and hamburgers, but also beer".⁽⁸³⁾

But it was not just a question of the old stocks that remained on pharmacy shelves in developing countries. As *The Lancet* reported in November 1981, "There is evidence that Ciba-Geigy has continued to manufacture preparations containing amidopyrine and that they have been selling off old stocks of preparations containing amidopyrine even after registering the new formulations".⁽⁸⁴⁾ Mexican trade statistics for 1978 show that Ciba imported 8,500 kilos of amidopyrine into the country, with 80% of the supply coming from Switzerland.⁽⁸⁵⁾

Ciba-Geigy did successfully register the new formulation of Spasmo-Cibalgin without amidopyrine with the Philippines Food and Drugs Administration (FDA) in November 1978. But preparations with amidopyrine continued to be imported up to May 1978. ⁽⁸⁶⁾ The old formulation of injectable Spasmo-Cibalgin was still in stock in a wholesale distributor's warehouse and was being sold to retail pharmacies in November 1980. A team from Dutch television which filmed these stocks interviewed the Managing Director of Ciba-Geigy Philippines who said that they had been told to deplete their existing stocks of the old formulation with the agreement of the Philippines FDA and Ciba headquarters in Basle. In November 1980 Dr. Arsenio Regala, the Philippines Food and Drugs Administrator, said he knew nothing of this arrangement. The Dutch film "Healthy Business" was shown in Europe at the beginning of 1981. Subsequently a 'to whom it may concern' letter dated 7 May 1981 arrived from the Philippines FDA saying that permission to use up old stocks of amidopyrine had in fact been granted, provided the manufacturers gave full information and warnings on the product labels. ⁽⁸⁷⁾

In September 1980 we purchased foil strips of Cibalgin over the counter in Bangalore in India. These contained amidopyrine and gave no dosage instructions or warnings. The manufacturing date appeared on each strip showing that they had been produced in Bombay in *February 1980*.

The delay in registering the new formulation of Cibalgin in India was apparently partly due to reluctance from the Indian Government. ⁽⁸⁸⁾ Whereas amidopyrine was formulated locally, the new active ingredient, propyphenazone, would have to be imported. The Swiss companies were not alone in continuing to market amidopyrine. In 1981 there were reported to be 33 formulations on the Indian market alone. ⁽⁸⁹⁾ The Central Drug Authority issued instructions to manufacturers in 1980 to withdraw amidopyrine "in a phased manner". But according to an Indian newspaper report in 1981 the Government "did not specify a deadline for the withdrawal and this seems to have been taken advantage of by the manufacturers and druggists". ⁽⁹⁰⁾

There is also evidence that at least one of the major manufacturers continued actively to promote sales of amidopyrine in a developing country two years after the drug's withdrawal had been announced in Switzerland. In 1979 a salesman for Ciba-Geigy was reported to be distributing free samples of Cibalgin in Maputo, the capital of Mozambique, dismissing fears over possible toxic side-effects as exaggerated. At that very time, a young British teacher was being rushed out of the country for emergency treatment, one of the few *recognised* victims of drug-induced illness in a Third World country. Carol Gates had been prescribed Cibalgin - for a headache. Without advanced medical treatment she would have died. ⁽⁹¹⁾

Dr. Burley of Ciba-Geigy informs us: "I have never defended the lack of information in our literature about Cibalgin in Mozambique, and this matter was settled between Carol Gates and ourselves. Because of the very great publicity that surrounded the Carol Gates case, I think I was quite right to say that amidopyrine drew far more attention than perhaps it warranted. Anyway the situation is now

unlikely to arise with aminophenazone (amidopyrine) again.”⁽⁹²⁾ Dr. Burley explains that Ciba-Geigy stopped manufacture of all aminophenazone derivatives by December 1981.

DIPYRONE

Some of the most widely sold painkillers in the Third World today contain dipyrone, a drug that is chemically related to amidopyrine and can also cause fatal agranulocytosis in an estimated 0.57% of users.⁽⁹³⁾ Dipyrone has been described as “about as effective as aspirin”.⁽⁹⁴⁾ The drug has been completely withdrawn from the market in Britain and the US on the grounds that “the incidence and risk of potentially fatal agranulocytosis ... far outweigh any benefit that can be derived from its use”.⁽⁹⁵⁾

The balance of risks, however, has been assessed very differently in West Germany, the home market of some of the leading manufacturers of these drugs. These include Hoechst, Boehringer Ingelheim, Asta-Werke and Merck, which all market dipyrone products in the Third World. In West Germany the widespread use of dipyrone and similar drugs for minor pains is highly controversial. At the beginning of 1982 an expert committee recommended that their use should be restricted to prescription only. Hoechst and other manufacturers oppose any new restrictions on the grounds that they are not justified by the risks.⁽⁹⁶⁾ At any rate West German doctors and pharmacists are well aware of the controversy and of the possible toxic side-effects, unlike many of their counterparts in developing countries.

According to UNCTAD at least ten different leading brands of painkillers containing dipyrone are marketed in the Third World.⁽⁹⁷⁾ In Mexico, for example, the eighth best-selling drug on the entire market, Hoechst’s NeoMelubrina, contains it, as does the next most popular analgesic (by sales value and volume), Boehringer’s Buscapina Compositum.⁽⁹⁸⁾ Consequently, thousands of patients in Mexico alone, who know nothing of the possible risks, may be unnecessarily exposed to danger when ‘safer’ alternatives exist.⁽⁹⁹⁾

Health authorities may have difficulties in removing these and other products. In Bangladesh, for example, having assessed the dangers of the uncontrolled use of dipyrone, Drug Administration officials instructed manufacturers to remove products containing dipyrone from the market by 1980. This ban encountered local opposition. Subsequently another government department ruled that the ban need not take effect until the end of December 1982.⁽¹⁰⁰⁾

INJECTIONS

There are some drugs that present a major health hazard in developing countries because they cannot be given safely by untrained drug sellers. One of the most striking examples is injectable drugs. Injections are very much in demand throughout the Third World. Many of the world’s poor believe that tablets and pills are a second-rate substitute for an injection. Drug sellers are also keen on injections because they can charge customers both for the actual drug and for injecting it.

There are contrasting views on why injections are so popular. An OXFAM researcher writes from Upper Volta that injections are widely used. "This is a characteristic feature of Voltaique medical practice and the reasons seem complex. Originally injections were introduced by French doctors and probably became entirely associated with the new Western medicine. Pills, liquid, or ointments were similar to traditional medicine, while the needle was a complete novelty..."⁽¹⁰¹⁾ In Africa as a whole from the 1950s the eradication of yaws by the use of injectable penicillin is reported to have made a deep and lasting impression.⁽¹⁰²⁾

By contrast, Dr. Hassani in North Yemen attributes the popularity of injections to the traditional belief, common to most societies, that anything that makes you better must hurt. In Yemen treatments administered by traditional cuppers and burners can be very painful. Dr. Hassani explains that many of his patients insist on having injections of calcium gluconate. These can, and should, be given slowly and painlessly. But if he gives the injection correctly the patients complain that they have been cheated because they could not feel the 'difference'. So in Yemen doctors and drug sellers inject calcium fast. As another doctor points out - this practice can kill.⁽¹⁰³⁾

The Yemenis' addiction to injections carries other unsuspected dangers, as a doctor working in a remote, mountainous area explains: "Many hormone injections and vitamin injections are given for 'gawi' (strength). These drugs are not known to be effective and in some cases are positively dangerous. Many a time we have seen a hormone preparation given to a woman because of a delayed period. The doctor had not examined her and in fact, often it was a brother, father or husband who had brought it to her. No one could read to see that one of the contra-indications was early pregnancy!"⁽¹⁰⁴⁾

A recent report by the Institute of Development Studies in Britain on health services in rural Ghana showed that some health centres give injections to over 80% of patients. The over-use of chloroquine injections in particular was rampant. They were routinely given to adults who complained of fever but were not in a serious condition. These patients could have been treated with antimalarial tablets for a fraction the cost of the injections. Unnecessary injections can cost more than money. Young children routinely injected with chloroquine were needlessly exposed to the risk of sudden death from absorbing the drug too fast.⁽¹⁰⁵⁾

Because the Ghanaian clinics gave so many injections, they were always short of syringes. So disposable syringes had to be rinsed out and reused. In some health units one needle was used for more than 20 patients.⁽¹⁰⁶⁾ Few untrained injection givers have any notion that if they hit the sciatic nerve, they can paralyse their patient's leg, or that an unsterile needle can cause painful abscesses or serum hepatitis. They are not aware that a dirty syringe can kill.

Manufacturers must be aware of the dangers, for back-room injections are routine and in some Third World countries it is a common sight for ordinary people to be buying syringes and vials for home injections. In Bangladesh Fisons' subsidiary has produced an instruction leaflet in Bengali on how to give an injection safely

and Pfizer showed a documentary there on the subject. ⁽¹⁰⁷⁾ But few injection givers come into contact with helpful advice. In the home of one poor family in North Yemen we witnessed a home injection of procaine-penicillin and streptomycin which one woman gave another for a cut thumb which had already been well daubed and protected from infection with gentian violet. Before giving the injection the woman unwrapped the disposable syringe and left it on the floor. She made no attempt to cleanse her cousin's arm. This injection of two antibiotics to forestall a possible infection carried dangers undreamt of by these Yemenis.

ANTIBIOTICS AND DRUG RESISTANCE

The combined injection was of two key drugs, penicillin and streptomycin. These are relatively inexpensive and therefore used as *first line* drugs for attacking a range of bacterial infections. Streptomycin is particularly useful for TB. But if these antibiotics are over-used the bacteria they attack quickly build up resistance. Bacteria can make themselves resistant to streptomycin very fast, so the drug becomes useless for TB sufferers. They then end up paying for more costly *second-line* antibiotics. Drug resistance presents problems everywhere. But it can make the difference between life and death in poor countries.

An Indian doctor explains that the use of streptomycin "in combination with penicillin [and] chloramphenicol for ordinary infections is creating increasing problems for developing countries like ours. Primary resistance of tuberculosis to streptomycin which is one of the first-line drugs is a calamity. We can't afford expensive second-line drugs. Further infection of individuals with resistant tuberculous mycobacteria helps in making the situation worse." ⁽¹⁰⁸⁾ A doctor in Bangladesh confirms that "patients are very likely to die as a result of this". ⁽¹⁰⁹⁾

Despite the obvious dangers, in many Third World countries manufacturers are marketing products containing streptomycin and other first-line antituberculous drugs for trivial, unnecessary uses. For example, UNCTAD reports that many cough and cold remedies containing streptomycin are sold in Nepal, a country where almost a quarter of child deaths are caused by TB. ⁽¹¹⁰⁾

These antibiotic mixtures are more irrational than they may at first appear. Antibiotics attack *bacteria*. Colds are caused by *viruses*. So it is futile to take an antibiotic for a cold. It is also pointless, and even self-defeating to take antibiotics as a routine treatment for diarrhoea. The *British National Formulary* stresses that "most cases of diarrhoea are not bacterial in origin", but "even when a bacterial cause is suspected, antibiotics ... should be *avoided* ... because they may prolong rather than shorten the time taken to control diarrhoea and carrier states". ⁽¹¹¹⁾ (original emphasis)

Yet antibiotics are commonly taken for diarrhoea and non-bacterial infections all over the Third World. One drug store owner in a large village in Bangladesh told us that he *always* recommends the antibiotic Sumycin (tetracycline syrup) for young children suffering from diarrhoea. Not surprisingly, it is his best selling product and he orders it frequently. He said that the sales representative for the manufacturers, Squibb, has never mentioned on his monthly visits that tetracycline

should not be used indiscriminately for any attack of diarrhoea. Nor had the drug store owner ever heard that he should not sell tetracycline for young children or pregnant women. The Sumycin packs he sold gave none of the warnings that must be given in developed countries. ⁽¹¹²⁾ Squibb Bangladesh assure us they have never promoted Sumycin for the treatment of diarrhoea and have promised to investigate the retailer in question. ⁽¹¹³⁾

In the Bangladesh *Prescriber's Guide* (current in September 1980) doctors are informed that Upjohn's antibiotic Lincocin (licomycin) is particularly useful for treating a number of conditions including "acne vulgaris". ⁽¹¹⁴⁾ The *British National Formulary*, referring to licomycin, stresses that "These antibiotics have a very limited use because of their serious side-effects". ⁽¹¹⁵⁾ Upjohn inform us that they do not recommend Lincocin for "acne vulgaris" in any country. They point out that they have no editorial control over guides like the *Bangladesh Prescriber's Guide*, and that they will attempt to have the indication removed from the Guide. ⁽¹¹⁶⁾ But the scale of the problem of over-use of potentially dangerous antibiotics is enormous. In 1978, Lincocin was the second best selling drug on the *entire* Mexican market. ⁽¹¹⁷⁾

Some rich world manufacturers appear to have actively encouraged the misuse of powerful and potentially dangerous antibiotics for mild infections. For example in North Yemen the Swiss company, Rivopharm, has marketed Rivomycin Strepto (a combination of chloramphenicol and dihydrostreptomycin) indicating that the drug can be given to infants for "common diarrhoea". ⁽¹¹⁸⁾ No mention is made of "the liability of chloramphenicol to produce life-threatening toxic effects, particularly bone-marrow aplasia..." which in the authoritative words of *Martindale* (the pharmacists' 'bible') means that the drug "should never be given for minor infections". ⁽¹¹⁹⁾ It was recommended by a Yemeni pharmacist to the author (along with Entero-Vioform) for a mild attack of diarrhoea.

Rivopharm wrote to us on 11 February 1982 stating: "We strongly object and we are at a loss to understand the basis of your statement that 'Rivopharm appears to be actively encouraging the misuse of two powerful and potentially dangerous antibiotics'. We believe that you overlooked the clear and distinct statement (in English and French) [not Arabic - author's comment] on the Rivomycin Strepto outer carton ... that the product is 'to be dispensed on medical prescription'." ⁽¹²⁰⁾ This statement was confirmed in a further letter of 8 April 1982. But by 17 May there was an apparent change of heart and a more encouraging response from Rivopharm. "We would like to communicate to you that the leaflet insert of Rivomycin Strepto is under examination and revision, as part of our regular revision procedure. This revision will be done with the view to change the leaflet and in particular to delete the words 'common diarrhoea', which may be misleading as you have rightly indicated." ⁽¹²¹⁾

However greater impetus to drug misuse of this sort comes from local manufacturers. For instance, in Bangladesh one of the leading local companies has recommended the use of ampicillin for influenza, coughs, infantile diarrhoea, boils, even hepatitis (for which there is at present no known drug cure). ⁽¹²²⁾

As a result all the key *first-line* antibiotics are used irrationally throughout the Third World. The pattern seems to be, when in doubt, prescribe an antibiotic. A pharmacist in Bangladesh will recommend a penicillin injection for a baby with nappy rash. Hospital doctors in North Yemen will give penicillin injections to a breast-feeding mother with sore nipples. In Bangladesh a young boy knocked down by a motorised rickshaw is prescribed tetracycline (and half a dozen other drugs) for mild concussion. Even in remote areas of the Amazon, poorly trained health workers have been distributing tetracycline capsules with apparent total disregard for the problems of drug resistance. ⁽¹²³⁾

The extent of the over-use of antibiotics is illustrated by the records of drug consumption from just one health station in Ethiopia over a *three month* period. During that time a total of about 100 patients consumed the entire stock of 500 vials of procaine-penicillin, 500 vials of streptomycin, 4,000 capsules of tetracycline and 2,000 capsules of chloramphenicol. The patients' records show that some were given streptomycin for coughs, and others simultaneous course of three antibiotics (chloramphenicol, penicillin and streptomycin) for bronchitis. ⁽¹²⁴⁾

Since both manufacturers and prescribers give too much encouragement to the indiscriminate use of antibiotics, it is hardly surprising that ordinary people have come to see antibiotics as panaceas. When her child falls ill, a poor woman in Bangladesh may well try to save money by going straight to the pharmacy, bypassing the doctor. She remembers that last time the child was ill, the doctor prescribed ampicillin or penicillin syrup, and the baby recovered quickly. This time, no matter what is wrong with the child, she buys the same antibiotic. As soon as the baby seems better, she stops giving it the medicine to save some for next time. ⁽¹²⁵⁾

Most of the Third World poor (and many in the rich world) have no idea that it is dangerous to take just a few capsules of an antibiotic, or break off a course of treatment as soon as you begin to feel better. An incomplete course enables the bacteria to build up resistance and makes outbreaks of drug-resistant disease a virtual certainty.

In developing countries antibiotics are sold loose on market stalls without packs or instructions - often illegally. In the open markets in Upper Volta antibiotic capsules are displayed on huge trays alongside assortments of equally colourful sweets. They cost about 5p for three and people will buy a single capsule to cure a headache or stomach pain. ⁽¹²⁶⁾ Antibiotics are even sold in incomplete courses by the pharmacies. In Nepal, for instance, a health worker reports that it is an everyday occurrence to see people buying two or three capsules of chloramphenicol or tetracycline when a child has diarrhoea or is feverish. ⁽¹²⁷⁾ In a number of African countries, people take the odd penicillin or ampicillin capsule as a blanket protection against illness, particularly venereal disease. ⁽¹²⁸⁾

The inevitable result of this random medication is that reports of drug resistance are coming in thick and fast from all over the Third World. Since 1972 there have been reports of chloramphenicol-resistant strains of typhoid from a growing

(Credit) Leigh Hart.



Penicillin on sale on a market stall in Upper Volta. Exposure to heat destroys its effectiveness; penicillin should be refrigerated.

number of Indian states. One research institute in India found that 690 out of 822 salmonella strains they were able to identify were resistant to at least one antibiotic and some were resistant to three or more. An outbreak of drug resistant disease led to the closure of the entire paediatric unit of a hospital in Bangalore, and another strain of salmonella, resistant to five antibiotics, lasted 20 months and killed over 80 babies in Delhi hospitals. ⁽¹²⁹⁾

The most serious epidemics of drug-resistant disease to date have been reported from Central America. In 1969 an epidemic of Shiga dysentery killed 12,500 people in Guatemala and 2,000 more in El Salvador. The disease was resistant to chloramphenicol, tetracycline, streptomycin and sulphonamide drugs. Three years later there was an outbreak of typhoid affecting over 6,000 people in Mexico. As with the strain of typhoid reported in India that year, the drug of choice, chloramphenicol, proved useless. At the start of the epidemic there was a high fatality rate with one in seven dying before doctors realised that trying to treat the sick with chloramphenicol was futile. ⁽¹³⁰⁾

The growing scale of antibiotics resistance has alarmed the experts. At a conference in 1979 the Dean of the London School of Hygiene and Tropical Medicine called for action: "The widespread use of antibiotics, even by quite poor people in poor countries must be discouraged by controlling their availability, as individual benefits are likely only by chance and disadvantages to the community are a certainty." ⁽¹³¹⁾

Much of the onus falls on Third World governments to introduce controls, but little can be achieved without the active cooperation of the rich world. This fact was highlighted by US experts in the aftermath of the Mexican typhoid epidemic. They attributed part of the onus for the deaths caused by drug resistance to manufacturers who had been promoting chloramphenicol for trivial uses. In a statement to the US Senate, Professor Lee of the University of California stated his belief that "the problem is related to the promotional practices of the drug companies. It is serious and it can affect not only the residents of the countries involved and all those who visit there as well, but people who have never travelled to Latin America." ⁽¹³²⁾

Drug resistance can provide manufacturers with an incentive to carry out further research to develop new products. ⁽¹³³⁾ But to the consumer - above all the poor Third World consumer - drug resistance is disastrous, because it pushes up the cost of life-saving treatments. The threat of drug-resistant disease emphasises the impossibility of shifting responsibility for responsible drug marketing entirely on to the shoulders of Third World governments.



CHAPTER 8

TRAIL-BLAZERS Small-scale Solutions

POOR PEOPLE suffer most ill health, but benefit least from modern health care and life-saving drugs. The Third World market is flooded with unnecessary and overpriced medicines which poor people make great sacrifices to buy, unaware that their uncontrolled use is wasteful and dangerous. That is our diagnosis of the problems.

Before identifying some of the policy options open to Third World governments in tackling these problems, we shall focus now on what is being achieved nearer the grass-roots. Some of the small-scale projects we shall describe are acting as trail-blazers for programmes now being adopted on a national scale. OXFAM's involvement with these and many other health projects, has taught us about the problems the poor confront. Watching the progress of these projects over some years, and learning from friends and colleagues in the villages, we have seen that improvements can be achieved with persistence. But we also have been forced to the realisation that some of the more intractable problems for the Third World poor cannot be tackled locally. In the case of medicines, action must also be taken in the rich drug-producing nations, where many of the market pressures originate.

GONOSHASTHAYA KENDRA

One of the most exciting projects in which OXFAM participates is Gonoshasthaya Kendra (the People's Health Centre) in Savar, a rural district about twenty miles from the capital of Bangladesh. ⁽¹⁾ The project was set up in 1972 by Dr. Zafrullah Chowdhury and a group of medical colleagues who had worked together treating casualties and refugees during the country's struggle for independence in 1971. Their first objective was to set up community-based health services for the 200,000 people living in the villages of Savar.

From the outset the emphasis was on prevention. The team at Gonoshasthaya Kendra were committed to stopping their centre from becoming nothing more than "community disease centre". ⁽²⁾ They became increasingly aware that health care alone could do little to improve health without an attack on poverty. So the scope of the project was extended to include schemes for agricultural credit, literacy and vocational training. Both the wide range of community development work at Gonoshasthaya Kendra and the project's bold new initiative in establishing a modern drug factory are important because, by themselves, attempts to improve the supply of essential drugs could have little impact on health.

Health promotion is carried out by teams of paramedics who are given a year's training, partly at the base health centre and partly out in the villages. There are now over 60 paramedics who divide their work between the villages, four sub-centres and the main centre. The paramedics are able to handle the majority of common illness including diarrhoea and dysentery, scabies, upper respiratory tract infections, night blindness, worms, anaemia and 'body pain', which is mostly backache.

Difficult cases are referred to the four doctors at the main centre, who supervise the paramedics' work and carry out surgery. But most of the out-patients who come to the centre are seen by the paramedics who also carry out some straightforward operations. For instance, 85% of tubectomies are performed by the paramedics, with a lower complication rate than the doctors. In the villages, the paramedics make house-to-house visits to encourage disease prevention and keep an eye on the health of mothers and young children who are most at risk. Children are vaccinated free of charge and women of child-bearing age are immunised against tetanus. The paramedics carry vaccines in thermos flasks, in addition to a small number of basic drugs.

Drugs are only used when they are essential. Prevention comes first. For example, to help prevent diarrhoeal disease, women are encouraged to use tubewell water for cooking and drinking. They are also shown that instead of buying expensive anti-diarrhoeals, they can make a homemade rehydration solution, *lobon-gur*, from *lobon* (salt) and *gur* (molasses) - ingredients which are easy to get hold of locally. Rather than routinely handing out vitamin A capsules, the paramedics try to convince mothers to include plenty of green vegetables in the family diet. If medicines are necessary, the paramedic will wait while parents give children their medicine, to make sure they understand the correct dose.

As this basic health care is now helping to ensure a better survival rate for children, the paramedics are in a better position to offer advice to mothers on birth control, and monitor the use of contraceptives, particularly the pill. The injectable contraceptive, Depo-Provera (medroxyprogesterone acetate) was used on the project, but although it was popular, its use has been abandoned because of fears over the unknown degree of risk. Close monitoring of the women who received Depo-Provera revealed that over an eight-month period, eleven women suffered such severe bleeding that they had to be admitted as in-patients. The health team at Gonoshasthaya Kendra have contacts in the health field all over the world, so they are at an unusual advantage in keeping themselves informed about the controversy in Europe and the US, over the use of Depo-Provera. However, after stopping use of the drug, the health team openly expressed their uncertainty, as to whether "we have helped our women or not".⁽³⁾

The traditional village midwives, the *dais*, have also been incorporated into the health team as far as possible. They are trained to use more hygienic methods for deliveries, and are also involved in family planning.

The project can claim to have made an impact on health. For example, there has



A health worker in Bangladesh teaches villagers the importance of oral rehydration in the treatment of diarrhoea.

been a definite fall in the incidence of severe dehydration, and of skin diseases such as scabies. The birth rate in the project area is now about a third less than that for the rest of the country, and whereas the infant mortality rate in Savar is now about 120 deaths for every 1,000 babies born, the national rate is 140 deaths, and higher still in some rural areas.

But the Gonoshsthaya Kendra team are the first to acknowledge that their health activities can only be seen as a qualified success. They have had difficulty encouraging active community participation in village health, so outsiders still play a key role as health promoters in the villages. Originally, health volunteers were recruited from the Savar villages, but they showed little commitment and were replaced by the full-time paramedics. Many of the paramedics are young, unmarried women from outside Savar. As unmarried women in a traditional Muslim society, they cannot live alone so they have to be based at the centre, not in the villages. The fact that they are outsiders also means that many move on to live and work in other areas, leading to a fairly high drop-out rate.

Many of the villagers have little time for the paramedics who go round the villages. They prefer to walk all the way to the main centre, or a sub-centre, where they assume the services must be better. Village health committees were set up to encourage people to take an active interest in health and participate in running the sub-centres, but these initiatives were blocked by apathy and political constraints. As a result the better-off, more powerful people in the community have been able to manipulate the health committees to their advantage.

This highlights the major obstacles the poor face in attempting to improve their health. Real progress is held back by the social and economic forces underpinning poverty. The poor are ultimately at the mercy of whoever owns the land they work, and controls water supplies and credit. In the words of the woman in charge of Bhatsala People's Health Centre (which is modelled on the Savar project): "The poor feel that lack of food is the root of their health problems. A change in their ability to produce enough food is necessary for any change in the health status." ⁽⁴⁾

To free the poor from the oppression of the landowners and the money lenders, the team at Gonoshasthaya Kendra set up Gono Krishi Khamar (or the People's Farm). This scheme aims to increase food production by trying out new farming methods, and to make credit available to poor landless farmers through a credit cooperative. Initially, some local landowners used intimidation to try to destroy the credit cooperative. Now it is firmly established, but the intimidation continues. The landowners have been taking advantage of the fact that the landless poor can obtain credit from the cooperative. So they have increased their charges for supplying water from the tubewells, which were installed under a joint Government and UNICEF programme. These tubewells were of course intended to benefit the whole community, but the powerful managed to wangle things so that the wells were dug on *their* land.

If people are to be able to get access to water, land and credit to grow enough food to be healthy, it is vital that they should be in a position to defend their rights in the face of harrassment from the powerful, usually educated people in the community. To this end the People's School has been set up at Savar to educate the children, who in turn help with adult literacy classes for their parents.

A further serious obstacle to better health is the fact that the women are held back from playing an active role in improving hygiene and nutrition both by their lack of education and their low status in the community. Their oppression is being actively challenged at Gonoshasthaya Kendra. Most of the paramedics are women, who are visibly seen to be challenging convention as they set off for work in the villages on their bicycles. But village women are also participating in literacy classes, and acquiring radically new vocational skills to enable them to gain some independence and more equality. They are learning shoe-making, bakery, sewing, carpentry, welding and other skilled manual jobs that have been strictly male preserves.

GONOSHASTHAYA PHARMACEUTICALS LIMITED

One of the tasks recently accomplished by the women in the project workshop is the construction of all the metal window-frames for the project's brand new pharmaceutical factory. ⁽⁵⁾ The factory started production in May 1981 with the formulation of the first batches of ampicillin and paracetamol.

It is an ambitious step for Gonoshasthaya Kendra, a charitable trust, to have set up a sizeable commercial operation to manufacture drugs in rural Bangladesh. But the team at Gonoshasthaya Kendra had strong motivation, having experienced the difficulties of obtaining inexpensive, good quality generics, with the local market dominated by the subsidiaries of big research-based manufacturers. As the team at Gonoshasthaya Kendra explain: "The project experience, and especially the problem of getting good and cheap medicines to the people ... led to thinking about a pharmaceutical factory based on four principles: low prices, quality, manufacture of essential drugs only and responsible marketing." ⁽⁶⁾

Gonoshasthaya Pharmaceuticals Limited (GPL) is unique in Bangladesh and probably in the Third World in being a private company with its production entirely geared to meeting the needs of the people. All the shares in the company are owned by the charitable trust and under its charter profits are limited to 10-15% (after payment of duties and bank charges). Half of the profits will be ploughed back into the company to expand production, reduce prices further and fund research. The remainder will be used to fund health and development projects.

Over the first three years of production, the factory will build up to formulating a range of about 30 drugs all included in the WHO Selection of Essential Drugs. Every effort will be made to keep prices down by purchasing raw materials by competitive tender on the world market. Despite its initial high overheads, the retail prices of GPL's drugs are considerably lower than those of equivalent products on the local market. Comparative prices are illustrated in the table below, which also shows GPL's deliberate policy of setting different profit margins - lowest on the drugs considered most useful.

(Credit) Dr. J. Yudkin.



Women workers at Gonoshasthaya Pharmaceuticals Ltd. have been trained in technical skills. Here components are prepared for the factory.

(Credit) Dr. J. Yudkin.



GPL's factory has been built in a rural setting. Some of the profits are to be ploughed back into rural development work.

**COMPARATIVE RETAIL PRICES BETWEEN GONOSHASTHAYA
PHARMACEUTICALS LIMITED (GPL)
AND OTHER MANUFACTURERS IN BANGLADESH, APRIL 1982**

**Maximum retail prices per
capsule/tablet in paisa
(100 paise = 1 taka)**

| <i>Drugs</i> | <i>Unit cost to GPL</i> | <i>GPL Profit</i> | <i>GPL</i> | <i>OTHERS</i> |
|--------------------------|---------------------------------|-----------------------|------------|---|
| ampicillin (250mg) | 76.2 | 6.57% | 100 | Hoechst 186 Square 175 Beecham 169 |
| tetracycline (250mg) | 38.4 | 5.26% | 50 | Squibb 110 Pfizer 106 Albert David 77 |
| metronidazole (250mg) | 25.6 | 22.7% | 40 | BPI 79 (200 mg tab) Square 65 |
| paracetamol (500mg) | 11.7 | 3.41% | 15 | Fisons 24 Square 25 |
| diazepam (5mg) | 7.1 | 36.6% | 12.5 | Roche 55 Square 30 |
| frusemide | 26 | 85.6% | 60 | Hoechst 125 |

Source: Chowdhury & Chowdhury, "Essential Drugs for the Poor" (see ref. 5)

Prices will not be kept low at the expense of quality. GPL is a modern factory, with quality control facilities comparable to the local big name producers. GPL aims to be competitive by going for large-scale production, taking advantage of modern machinery, production and management techniques. The factory has 42,000 sq ft of floor space, making it one of the largest in Bangladesh. It was built with capital provided mainly by the Dutch charity NOVIB, a loan from the Bangladesh Shilpa (Industrial) Bank and further contributions from OXFAM and Christian Aid. ⁽⁷⁾ Although GPL has had to rely on foreign donor agencies to provide the initial capital and the International Dispensary Association in Holland for technical assistance, the underlying objective of the project is self-reliance. Designs for the factory building, air-conditioning and machinery layout were all planned and executed by Bangladeshis. Similarly, the production, quality control and marketing managers are all Bangladeshis who have gained valuable experience in the past working for big foreign manufacturers.

There are plans to carry out research into using locally available raw materials as excipients (the non-medicinal ingredients like starch that are mixed with the

active ingredient to make up a medicine). Attempts are also planned to develop better dosage forms to suit local conditions - for instance, to take account of the nutritional status of the poor, and humidity during the long months of the monsoon. This sort of research tailored to meet local needs is largely neglected by the bigger foreign-owned companies. Patents on both processes and products are protected by law in Bangladesh. But Dr. Chowdhury stresses that GPL would not want to patent any new process discovered because they do not believe in "the monopoly of knowledge".⁽⁸⁾

To achieve greater self-reliance and leave their operations less vulnerable to external pressures, the team at GPL are keen to expand into the more complex production of raw materials. These would have to be produced on a large scale to make the operation cost-effective. But the main difficulty to be confronted would be in obtaining the necessary technology. This is seen as an important wider objective behind setting up the factory.

In January 1982, GPL marked its official opening by hosting a conference on Technology Transfer to the Third World, with participants from many different countries. Previously, the team had explained: "Gonoshasthaya Kendra is not only interested in proving its ability to set up this particular pharmaceutical factory, but sees this effort as a learning situation for a genuine transfer of technology to the Third World. This is not achieved by multinationals bringing in complete blueprints which give no opportunity for training and experience of local manpower ... We hope that our work will demonstrate possibilities for such self-reliance ... Most important of all, transfer of technology does not itself mean improvement for the poor. To find ways which guarantee that industrialisation can be controlled by the poor masses of Bangladesh rather than becoming an instrument of oppression, is one of the main goals of GPL".⁽⁹⁾

The unskilled labour force is drawn from the villages of Savar and skilled labour from the capital. Most of the unskilled and semi-skilled production work is being carried out by local women who received a year's special training before the factory started production.

In its first year of operation GPL has faced technical difficulties particularly with production interrupted by power cuts and damage to equipment caused by fluctuations in the electrical current. They have also experienced management problems. The original production manager broke his two year contract after five months to go and work with WHO in Jordan, after GPL had funded a three months' training period for him in Europe. The factory was late in starting production because of bureaucratic delays in obtaining its initial raw materials import licence. But now that it is producing good quality, low cost drugs the major problem GPL faces is in ensuring that these drugs actually reach the poor for whom they were intended.

GPL expects to sell about 60-70% of its production to the government health services and the voluntary health sector. This distribution through organised health services is seen as "the safest and quickest way to channel the benefits

of cheap drugs to the people most in need”.⁽¹⁰⁾ The remainder will be sold on the open market. This raises a major problem for GPL in trying to prevent middlemen from stealing the advantages intended for the poor by jacking up the prices. According to Dr. Chowdhury cases of retailers charging more than the maximum retail price for GPL products have already been reported. He comments: “A lack of confidence in anything that comes from Bangladesh itself is part of our sad colonial heritage, and pharmacists, having heard something of Dutch financing, charge excessive prices claiming that this is a new ‘Bilati’ (European) medicine.”⁽¹¹⁾

The team at GPL are well aware that past attempts to promote the use of cheap generics have failed because doubts about their quality are easily whipped up in the minds of doctors and patients. GPL has its own sales representatives to promote its products to doctors and pharmacists, but priority is also given to the need to popularise wider health issues. This is done through the health project’s monthly magazine, “Mashik Gonoshasthaya”, printed on its own presses. The magazine is written in simple Bengali and aims to be lively and informative. It covers many health issues including appropriate non-drug treatments and warns against the socially damaging effects of existing drug sales and over-medication. 15,000 copies of the magazine are distributed each month.

A drug company’s success depends to a great extent on its reputation with doctors. So there are plans to invite doctors and pharmacists to visit Savar to see for themselves that GPL drugs are produced in a modern, efficient factory. This will be an extension of visits arranged in the past for groups of medical students with the aim of exposing them to village reality and the radical approach to health care adopted at the People’s Health Centre. This is all tantamount to a visit to Mars for most middle class medical students after the secluded anatomy sessions at medical school, but it is crucial in influencing the attitudes of the country’s future doctors to accept a new direction in health services to benefit the mass of the people.

The drug factory is an exciting new venture. Local drug company managers that we interviewed in 1980 told us that they did not see GPL as a threat to their market because the potential demand for drugs is so great, with the planned expansion of primary health care facilities. Certainly, if it is to succeed and offer a model for voluntary agencies in other countries to follow, GPL will need to count on the active goodwill of the rich world manufacturers who are in a position to threaten its future viability.

GPL has already experienced the problems of trying to challenge existing market power. In 1981 the Government invited manufacturers to quote their prices to supply ampicillin. In the previous year, a local state-owned manufacturer supplied the drug at 99 paisa a capsule. In 1981 GPL tendered to supply ampicillin at 93 paisa, based on raw material prices quoted to them by a local trading company. The day after GPL had submitted its bid, the trading company revised its quotation for the raw material which would have allowed GPL to supply the finished drug at 5 to 17 paisa less.

Dr. Chowdhury takes up the sequence of events: “We did not win the tender. It went to a national company which had bid at 80 paisa per capsule. The retail price of the same company’s ampicillin is 159 paisa. For the Government this was the cheapest ampicillin they had ever purchased and giving credit where credit is due, some officials thanked us, requesting us to keep up the good work.”⁽¹²⁾

VOLUNTARY HEALTH ORGANISATIONS

The voluntary health organisations in both India and Bangladesh have set up associations to look after their members’ interests and act as forums for discussion and information sharing on a broad range of health issues. Both use their own monthly newsletters, seminars and training workshops to exchange ideas and information. For instance, women health workers attending a workshop in Bangladesh were able to pool ideas on how to handle the problem of uneducated villagers who take a whole course of tablets at once because they do not understand the instructions.⁽¹³⁾

The voluntary health sector in India is very big, providing a third of organised health services in the country. Although the public health service infrastructure covers most of the population, in the rural areas there is a desperate shortage both of personnel and resources. Funds allocated to medicines for primary health care were increased by tenfold in 1975, but still account for only 6p a head.⁽¹⁴⁾ The Voluntary Health Association of India (VHAI) collects and disseminates information and advice to both health personnel and patients. As VHAI explains: “Education and awareness as to how to avoid disease and then how to handle it appropriately at the lowest possible cost is the crux of our approach in low-cost appropriate health care.”⁽¹⁵⁾

To help reduce costs, VHAI is encouraging its members to standardise prescribing for specific health problems and prescribe only single-ingredient drugs by generic name. For example tetracycline formulated with vitamin C is widely sold in India, but costs twice as much as straight tetracycline. One member, the Deenabandu Medical Mission in Tamil Nadu in the south, has found that by rationalising prescribing along these lines, and using herbal medicines as the first line of treatment, overall health care costs can be reduced by almost a third.⁽¹⁶⁾

VHAI is also keen to influence the attitudes of the general public to discourage the over-use of medicines. So they stress to patients the dangers of misusing injections, tonics and steroids and try to encourage people to adopt a positive attitude of “self-responsibility” towards their health.⁽¹⁷⁾

The difficulties of obtaining regular supplies of reliable drugs at competitive prices is shared by members of both associations. In Bangladesh The Voluntary Health Services Society (VHSS) has been collecting information on comparative prices of drugs on the local market. The intention is to issue price guides to help members and avoid duplicated effort on market intelligence work. VHSS has also succeeded in reducing drug costs by organising pooled procurement for its members. For example, it was able to bulk-buy mebendazole (deworming tablets) from a local manufacturer and pay only half the standard wholesale price.⁽¹⁸⁾ In future, its members’ needs will increasingly be met by Gonoshasthaya Pharmaceuticals Limited.

VHAI is also taking practical steps to help its members obtain the drugs they need, by negotiating a ten year contract with a small manufacturer in the State of Maharashtra. The manufacturer is being asked to formulate 50 essential drugs, gearing production and distribution to the specific needs of VHAI's members. Costs will be kept down by ensuring that raw materials are purchased at competitive prices, and because the scheme will cut out additional promotional costs. ⁽¹⁹⁾

NEPAL HILL DRUG SCHEME

The problems of drug distribution are acute in Nepal, one of the world's poorest countries, where the rugged, mountainous terrain makes transport extremely difficult. Only half of the country's health posts are accessible by road, so drugs and other supplies have to be carried on foot. These distribution problems and the very small drug budget allocated to the health posts means that drug supplies, which are delivered only once a year, will usually last no more than about 3 to 4 months. ⁽²⁰⁾

This means that for most of the year patients are forced to buy the drugs prescribed for them in the health posts out in the private drug stores, which often charge exorbitant prices and stock a mass of unnecessary drugs. With only 25 trained pharmacists in the whole country in 1979, most pharmacies are staffed by totally untrained sales assistants, who may have little understanding or interest in drugs, beyond their sales potential. ⁽²¹⁾

The Hill Drug Scheme was set up in eastern Nepal in 1969 with two objectives. Primarily it aimed to improve the supply of low-priced essential drugs to the areas covered, and to encourage safer drug use by giving retailers some basic training. The success of the scheme hinged on its attempts to persuade selected retailers to sell drugs more as a service to the community than as a means of making as much profit as possible.

The project is coordinated by the Britain Nepal Medical Trust which bulk-buys drugs both from the Nepalese manufacturers, Royal Drugs Limited, and from companies in India. The drugs are then supplied to villages where there are government health workers trained to prescribe them and distributed through retailers specially selected with the help of local officials on the *panchayats* (village or town councils). The retailers receive some basic training and undertake to dispense only the essential drugs supplied to them. They also agree to sell the medicines at fixed prices, with a set 10% mark-up. The scheme was intended to provide a back-up to health workers, allowing them to refer patients to these retailers in the knowledge that they would not be overcharged or sold unnecessary medicines. ⁽²²⁾ In fact health workers have not shown a great deal of interest.

Over a dozen retailers have participated in the scheme at any one time and sold medicines at much lower prices than the bazaars. But the scheme has had only limited success. Its major problem is that retailers stand to make far less money selling the limited range of basic drugs at fixed prices, than they would from stocking the mass of over-the-counter remedies on sale in the bazaars. So it has

been very hard to find retailers with both the necessary capital and the motivation to participate in the scheme. A recent project report explains: "Ideally the retailer is someone with an interest in medicine, an interest in community service and the ability to manage finances (ie pay in advance for drugs on the shelf). However, this community-minded capital *wallah* is an endangered species." (23) Almost invariably the retailers have to be given their stock on credit. Recovering money from them has proved a time-consuming and expensive process.

On balance the Hill Drug Scheme strategy of trying to improve drug availability through the private sector has not been as successful as hoped. In the words of Dr. Cassels, Medical Director of the Britain Nepal Medical Trust, "... all too often the retailers' need to make a profit has been incompatible with the patients' need to obtain medicines cheaply." (24)

BHOJPUR DRUG SCHEME

In 1980 a new model was tried, this time to increase drug supply within the health services. Dr. Cassels stresses that the Nepalese Government is in no position to provide more free medicines. "With costs rising and more and more new health posts being opened every year the effective medicine budget per health post is in fact going down." (25) The new scheme pioneered in the Bhojpur district of eastern Nepal is modelled on the fixed prescription charge that patients in Britain are asked to pay for National Health Service prescriptions. Hospital and health post patients in Bhojpur who had previously received medicines free must now pay a prescription fee of Rupees 2 (8p).

Exemptions were made for TB, leprosy and antimalarial drugs, and for patients suffering from "chronic diseases" who would not be expected to pay more than once every three months. The Health Post Committees were made responsible for collecting the prescription fees which go into a central fund to buy more medicines from an agreed list. The advantage for patients is that, whereas before they were forced to pay high prices in the bazaars when stocks of free government drugs ran out, now there should be regular drug supplies at the health posts.

The scheme is intended to be self-financing. In its first year, income from prescription fees only covered about one third of the cost of drugs bought by the Britain Nepal Medical Trust which had to make up the deficit. But subsequent analysis of why the scheme ran at a loss has been valuable in highlighting specific problems in drug use in the health service. Amongst these, over-prescribing was a major problem, with health post patients receiving an average of 3.7 items on the one prescription fee. Some expensive items, particularly antibiotics, were over-used, as were costly proprietary preparations like cough mixtures. About 20% of patients complaining of the same symptom as on their last visit were given prescriptions without a charge, because the "chronic illness" exemption had not been clearly defined. The standard fee was also unrealistically low to cover the cost of drugs for in-patients, averaging Rupees 27.68. (26)

Solutions have been proposed to make the scheme pay for itself and these now await approval by the Nepalese health authorities. The major change proposed is that the prescription fee should be replaced by a charge for each item prescribed. A drug manual has been prepared to help prevent over-prescribing and misuse of antibiotics. Items on the list considered disproportionately expensive will in future be available only at cost price. Measures are proposed to stop repeat prescriptions being given free to patients who are not chronically sick and a daily charge for in-patients is proposed.

If the Bhojpur Drug Scheme can be made economically viable and remain acceptable to patients and health workers, it could be more widely adopted throughout Nepal. But the major concern of all involved is to ensure that the scheme continues to make treatment accessible the whole population - especially the poorest. ⁽²⁷⁾

VILLAGE THEATRE IN MEXICO

Nothing can be done to stop poor people wasting money on medicines that are arguably useless or potentially harmful, unless *they* can be convinced that 'wonder drugs' are not all they may seem. It is all the more necessary to make the poor aware of the problems in countries where medicines are widely promoted over the radio, as happens in Mexico.

In the mountainous state of Sinaloa, Project Piaxtla aims to involve the *campesinos* (farmworkers) and their families in helping set up their own health care network. As part of the project's educational work, the village health team in Ajoya found an imaginative and entertaining way of using health festivals to get their message across. They helped to organise improvised theatre skits to draw local people into identifying with 'real life' situations at the same time as stimulating their awareness of the issues. David Werner, author of *Where There is no Doctor* and director of Project Piaxtla, explains: "We have come to believe strongly that education and awareness-raising is essential to the process of demystification and sensible use of medications." ⁽²⁸⁾

The health workers in Ajoya performed one sketch aimed at opening people's eyes to the overuse and misuse of medicines. The following is David Werner's translation of the health workers' play, which conveys something of the universal experience of the Third World poor: ⁽²⁹⁾

It is nearly dawn. The rooster crows: "Cock-a-doodle-doo." (The rooster is actually a health worker in costume). The old man and his wife stir in bed, as they usually wake up early in the morning. Beside the bed is an enormous 'radio' with a sign that reads 'Radio Deception'. Hidden inside the radio is an actor.

Old Dona Luisa turns on the radio. There are the sounds of country music. Then the voice from the radio says: "Good morning to you all. The last song was dedicated to Juanita Torres in Ajoya, Sinaloa. And now before we play more country

favourites, a word from the Drug Company: 'Are you feeling weak and tired? Do you find it hard to wake up in the morning? You may be suffering from *tired blood*. What you need are the new *Vita-Meyerhov* vitamin pills. You'll wake up every morning feeling like dancing. Remember, *Vita-Meyerhov*.'

As Dona Luisa gets up and begins to make maize tortillas for breakfast, the music and advertisements continue. But look. Her husband, Don Lino, is still in bed. He feels too weak to get up.

Finally Dona Luisa coaxes him out of bed and gives him a cup of coffee. He asks what there is for breakfast. She answers: "Just tortillas. You know that's all we have."

Just then, they hear a knock on the door. (Bang, bang, bang.) It is their neighbour who makes his living by selling medicines that he buys in the city.

Today he is selling *Vita-Meyerhov*. Old Luisa is excited because she just heard about *Vita-Meyerhov* on the radio. She is sure that it will make her husband wake up strong and eager to work, like before. The salesman tells them the bottle is worth 300 pesos [over £6]. But since they are such good friends, he will let them have it for only 150 pesos.

But the old couple only have 50 pesos. So they have to sell their 2 chickens at 50 pesos each in order to pay for the vitamins.

As their neighbour, the salesman, walks away with the chickens, the couple eagerly talk about how wonderful things will be when old Lino's health is restored.

The next scene takes place a few weeks later. Again it is dawn, the rooster crows: "Cock-a-doodle-doo", and Dona Luisa turns on the radio. The beat of *ranchero* music drifts out into the silent dawn. The radio announcer wishes a good morning to all, and goes on with more praise for the products from the Drug Company. While the radio announcer is praising the miraculous *Vita-Meyerhov*, we see that old Lino is too weak to get out of bed by himself. His wife tries to pull him out.

Lino, tries to get up, but falls to the ground. Dona Luisa cannot lift him up herself.

Frightened, she runs out to get help from the village health worker. The health worker comes running.

Between them, Dona Luisa and the health worker lift old Lino back onto the bed. The health worker figures out that his weakness comes from not eating well. The family has barely enough maize to make tortillas, and none to trade for beans.



They sold their last two chickens to buy the Vita-Meyerhov vitamins.

The health worker explains that the eggs from those chickens would have helped Lino much more than the vitamin pills. But Dona Luisa is not easily convinced. She thinks that her husband should be given 'artificial life' (Intra-Venous (IV) solution). The health worker tells her that this is just sugar water; it would be safer and cheaper for Lino simply to mix sugar and water, and drink it. But what the old man really needs is more and better food. Maybe their neighbours can get together and help them out with the food problem. He will speak with them.

After the village health worker leaves, the old man and his wife talk things over. They are not sure they trust the young health worker. "What does he know? He is just a villager like us. We saw him when he was born. An ugly baby at that." They decide to get Miss Ivy, the nurse, to give Lino some IV solution.

So that afternoon, Miss Ivy comes to the house. (To make the play more entertaining, the role of Miss Ivy is played by the same young man who plays the health worker. He has to change costumes quickly.) Nurse Ivy gives Lino an intravenous solution. He says he feels a little stronger already.

Because they do not have much money, the old couple give the nurse their prize rooster in partial pay for her services. But they will still owe her money.

The next morning when old Luisa wakes up, she notices that old Lino has a fever and seems very ill. She cannot wake him.

She runs to get the village health worker. He comes right away. He asks what could have happened to cause this sudden turn for the worse. Dona Luisa admits that they did not follow his advice and instead gave Lino IV solution.

The health worker examines Lino and finds that he is in critical condition, probably because of a blood infection introduced with the IV solution. He runs back to the health post to get antibiotics to fight the infection.

But before the health worker can return with the medicine, Lino dies. The lesson is painfully clear:

Food, not medicine, is the key to good health - especially for people who are weak and hungry. Do not waste your money on vitamins advertised on the radio.

Buy food - not vitamins.

And do not use IV solutions to gain strength.





CHAPTER 9

HEALTHY SOLUTIONS Third World National and Regional Policies

IN EARLIER chapters we focused on policies and practices that harm the poor and inevitably facilitate the misuse of drugs. Of course, the picture is not uniformly bleak. Third World policy-makers are acutely aware of the problems. Some, notably in Sri Lanka, Mozambique and a variety of other countries, have pioneered constructive solutions. In this chapter, we look at some of them.

This means that there are workable blue-prints to revolutionise drug policies to benefit the poor. Health planners in other developing countries can adapt them to suit local needs. They can also call on technical assistance from UN agencies like WHO, UNCTAD and UNIDO, that have helped devise many of the new strategies. Already these policies have led to major improvements. For example, the use of generic names, restricted drug lists and buying by competitive tender have succeeded in cutting costs massively and increasing supplies of vital drugs. On the face of it, it may seem incomprehensible that such obviously advantageous policies have not been universally adopted.

Yet there are powerful obstacles to change. The crucial one is lack of political will. In the words of a senior WHO official: "Some authorities consider drugs simply as consumer products which are subject to the laws of supply and demand."⁽¹⁾ Consequently, their drug policies relate more closely to the needs of industrial and trade development than health development.⁽²⁾ In many developing countries health ministries are notoriously weak, compared with the more influential ministries of commerce. But, if health-centred drug policies are to stand any chance of being adopted, WHO and industry commentators stress that health ministries must have bargaining power.⁽³⁾

Most governments are under pressure not to rationalise their drug policies. As the senior WHO official observed, "Pressure groups have arisen - particularly among certain pharmaceutical industries and in sections of the medical professions - which would prefer to see the status quo maintained".⁽⁴⁾ Local and foreign business interests lobby hard for any rationalisation to be confined to the public sector, leaving the vast private market largely uncontrolled.⁽⁵⁾

In some cases policy-makers may themselves oppose changes. An anthropologist's observations on one African country could apply more widely: "It seems probable that the delay in the adoption of the WHO directives concerning cheap essential

medicines is also due to the fact that influential people will lose attractive privileges when foreign pharmaceutical firms are forced to deliver medicines in a way which is commercially unattractive.”⁽⁶⁾

Despite the obstacles, many developing countries have introduced some controls on both the public and private sectors. These range from ‘paper tigers’ - that look good but change nothing - to measures that are actively enforced. We shall focus here on some of the key policy options open to developing countries. But WHO stresses that individual measures have only a limited chance of success. The countries that have most successfully tackled problems of drug supply, use and distribution are those that have adopted comprehensive national drug policies, giving clear priority to essential drugs for primary health care.⁽⁷⁾

MAJORITY HEALTH SERVICES

Among the countries that have made the most impressive achievements in reaching virtually the entire population with health services are China, Cuba and Vietnam, and the less well-publicised success stories of Sri Lanka and Papua New Guinea. Their approach has varied a great deal. For instance, whereas Cuba opted for what one observer has described as a “super-professionalised and centralised approach to health care”,⁽⁸⁾ China, Vietnam and Sri Lanka, with proportionately far fewer doctors, have set up decentralised services run by community-based paramedics.

On the communes in China, for example, where about 850 million of the population live, health care is provided by ‘barefoot doctors’ (or village health workers) chosen by the commune, which pays for their training. Workers have been paying about one-twentieth of their average monthly income for free medical treatment, and a small prescription charge for medicines.⁽⁹⁾ This puts the richer production brigades in a position to afford better services. But it does not rule out the possibility of a poor brigade getting help from a richer one, if for example one worker has rheumatoid arthritis and needs constant and costly injections.⁽¹⁰⁾

Papua New Guinea has also succeeded in setting up decentralised health services with a referral system. In contrast to China, it has a population of under 3 million. But it has major communication problems with its people divided into different ethnic and language groups, living in scattered and isolated settlements separated by rugged mountains and jungle. These difficulties mean that about 10% of the people still have no easy access to health care facilities, as they live some 2-3 hours’ walk from the nearest aid post.⁽¹¹⁾ The health services are organised into various tiers starting with the aid post, which serves a community of about 2,000 people. The orderlies who run the aid posts receive 1-3 years’ training and can handle 95% of the problems brought to them. More complicated cases are referred to the nearest health centre, which acts as a referral point for a population of 10,000 to 50,000. They are staffed by orderlies and nurses who work under the supervision of a health extension officer. Any patient needing an operation or complicated in-patient treatment can be admitted to the provincial hospital. Treatment is given free at the aid posts and most of the health centres. There are hospital charges, but these are waived for children, the old and the poor.⁽¹²⁾

Up until independence in 1975, health spending in Mozambique had been allocated almost exclusively to expensive curative services for the urban elite. Since then there has been a radical reallocation of priorities and health resources. For example, whereas 47% of the national drug budget was once consumed by the central teaching hospital, it now receives only 10%. Priority is given to preventing disease. But because of the need for essential drugs, spending on drugs rose five times, in real terms, in the five years after independence. ⁽¹³⁾

Mozambique stands out as having developed and implemented a comprehensive drugs policy to support its overall health strategy. Within months of independence all drug policy-making was centralised under the Technical Committee for Therapeutics and Pharmacy which immediately started work rooting out wasteful and unnecessary drugs. ⁽¹⁴⁾

ESSENTIAL DRUG LISTS

Countless WHO reports have concluded that the single most important measure needed to cut costs and ensure that drugs are used effectively is to limit the number available to those “most necessary for the health care of the majority of the population”. ⁽¹⁵⁾

As early as 1959 Sri Lanka acted to rationalise prescribing in the public sector. Under the impetus of serious economic problems and resulting drug shortages, the Government restricted all health service prescriptions to the 500 drugs on the Ceylon Hospital Formulary. ⁽¹⁶⁾ Mozambique introduced similar legislation and its more restrictive National Formulary in 1977 - the same year that WHO produced its first model list of essential drugs. Since then a growing number of countries have made their own selections of essential drugs based on local needs. At the last count, in April 1982, 70 countries had restricted drug lists. ⁽¹⁷⁾

Many of these lists, however, represent little more than policy goals because they have yet to be strictly enforced. Virtually all are intended to apply only to the public sector. Moreover, even in the public sector only a minority of countries have rationalised drug use to the same extent as Mozambique where doctors need special permission to prescribe a non-formulary drug. ⁽¹⁸⁾ In many cases controls on government purchases can be circumvented. Just one example is the situation in Mexico, where company sales representatives can still promote their products and distribute free samples in the hospitals. As a result doctors put pressure on hospital administrators to buy drugs not included in the country's ‘*Cuadro basico*’ - its list of 426 essential drugs. ⁽¹⁹⁾

Limited lists can only reduce drug costs if they are backed by an efficient purchasing system. In Brazil the central procurement agency, CEME, bases its purchases on a restricted list and has succeeded in buying drugs at under 50% of local commercial prices. ⁽²⁰⁾ A report of the United Nations Centre for Transnational Corporations (UNCTC) describes this system as a trade-off in which the government agency “applies its list to a restricted market, and the private sector collaborates by providing it with drugs at preferential prices ... as long as the richer markets are left unaffected”. ⁽²¹⁾ The obvious advantage of the system is that essential drugs

are secured cheaply for some of the poorest. But only a minority benefit from these free drugs - an estimated 9% of Brazil's population in 1973. Meanwhile the majority of the poor are still vulnerable to high prices and non-essential products in the private market. ⁽²²⁾

These shortcomings, common to many countries, are no argument against the importance of limited drug lists. They underline the need for curbs on promotional pressures and for controls to apply also to the private market.

Sri Lanka, Mozambique and Afghanistan are exceptional in having taken measures to restrict both the health services and the private market to a selection of essential drugs. ⁽²³⁾ In Sri Lanka the National Formulary Committee reviewed 4,000 drugs imported for use in the private sector in 1962 and recommended that they should be reduced to 2,100. After a major policy review in 1971 import licences were withdrawn from all but 600 approved drugs. This rationalisation of the private market was achieved by removing all irrational combination drugs, products of doubtful efficacy and unacceptable safety hazards and brands of almost identical drugs. ⁽²⁴⁾

Private medical practice was banned in Mozambique immediately after independence, and the number of drugs granted import licences was cut from 13,000 to 2,600. This selection was further reduced with the removal of drugs considered either non-essential or unnecessarily expensive. Now only the 355 drugs included in the 1980 National Formulary are routinely supplied and prescribed. ⁽²⁵⁾

SAFER, MORE EFFECTIVE DRUG USE

Limited drug selections have major advantages in encouraging the safe and effective use of medicines. Many health authorities draw up much shorter lists of drugs that can be safely and effectively used by paramedics. For example, Bangladesh has selected 31 drugs for primary health care use and in Sri Lanka no more than 60 drugs are dispensed at rural clinics. In Mozambique the *agentes polyvalentes*, paramedics with only primary school education and 6 months' training, are restricted to using about 50 drugs. ⁽²⁶⁾

With fewer medicines in use it becomes a more manageable task for governments to ensure that health workers and doctors receive vital drug information. For example, the 1981 *Proposed Essential Drug List for Zimbabwe* includes details of cost-effective treatments for common diseases and specific guidance on the use of some categories of drugs like antibiotics. ⁽²⁷⁾ Peru has compiled information sheets on each basic drug and a number of countries have developed standard treatment schedules. Mozambique's *Therapeutic Guide* sets out the first-line treatment for TB as a combination of streptomycin, isoniazid and thiacetazone. Only if this fails should the second-line treatment of rifampicin and ethambutol be given, as it costs 8 times more. Health workers are also urged to avoid expensive syrups and drops unless they are strictly necessary as these preparations can cost 20 times more than tablets. ⁽²⁸⁾

GENERIC NAMES

Many governments have seen the advantages of buying drugs by generic name. Very few have attempted to make generic prescribing or labelling compulsory. The Hathi Committee, which reported to the Indian Government in 1975, recommended phased abolition of brand names as one element of comprehensive new drug policies. The Committee suggested that initially generic names should be made compulsory for 13 drugs.⁽²⁹⁾ In the event, it was not until 1980 that the Indian Government moved to ban brand names for 5 drugs.⁽³⁰⁾

After the setting up of the State Pharmaceuticals Corporation in Sri Lanka in 1971, the use of generic names, already enforced in the public sector, was extended to the private sector. Manufacturers were obliged to label their products with generic names in bold type. Brand names could appear in lettering only half the size. Exceptions were made for some patented products imported in small quantities. However, after a change of Government in 1977, the enforcement of generic names was relaxed and some major manufacturers reverted to their old style of labelling, as illustrated opposite.⁽³¹⁾

In Afghanistan legislation introduced in 1979 compelled private wholesalers to import only generic drugs listed in the national formulary. Brand name products could only be imported if no generic equivalents were available and in these cases the state buying agency carried out the transactions.⁽³²⁾

In 1972 the Government of Pakistan made generic names compulsory. But the policy was reversed four years later after a mass of substandard drugs flooded onto the market. A subsequent investigation by the Pakistan Monopoly Control Authority disproved claims that there had been anything wrong with the generics policy itself, only with its implementation. The policy failed because quality control checks were totally inadequate and little was done to convince doctors of the advantages of generic prescribing.⁽³³⁾

These advantages are clear to prescribers in countries where quality control works efficiently. In Papua New Guinea, for example, generics are bought on competitive tender and undergo strict quality control testing in laboratories in Australia, before being imported into the country. One doctor in Papua New Guinea comments: "Perhaps the major advantage is that we are not canvassed or otherwise bothered by reps and drug advertising. It leads to clear thinking and better prescribing to use only generic names."⁽³⁴⁾ There are similar reports from Mozambique.⁽³⁵⁾

CENTRALISED PROCUREMENT

A 1979 report summarising the results of a survey of drug policies in Asia, Africa and Latin America, instigated by the Non-Aligned Movement and other developing countries, concluded that, "In spite of the availability of good quality drugs at much cheaper prices, many developing countries are tied to traditional sources of supply - namely, the transnational corporations. This is mainly due to the fear that these companies may retaliate. There is inadequate appreciation that it is within their power to formulate new policies, which when implemented would enable them to reduce their imports bill by as much as 50% or more."⁽³⁶⁾



Sri Lanka insisted on packaging emphasising generic names until a change of government in 1977. Left, post-1977 packaging; right, pre-1977 packaging.

Sri Lanka was the first country to prove that the drug import bill could be cut dramatically when it pioneered its system of bulk purchasing through a centralised government agency. Initially the Sri Lankan system was limited to drugs imported for the health services. But a major drug policy review in 1971/72 identified the need to stop the massive wastage of valuable foreign exchange caused by private importers paying high prices to monopoly suppliers. Wide disparities were discovered between the private importers' prices and those that the Government was paying for the same drugs by buying by generic name on worldwide, competitive tender - in other words, by 'shopping around' for the best price, after inviting a range of manufacturers to compete for an order. ⁽³⁷⁾

During 1972/73 the State Pharmaceutical Corporation (SPC) began a phased takeover of drug imports that had previously been carried out by 134 private importers. The prices paid by the private importers in the first half of 1972 were later compared with those paid by the SPC for the same drugs in the second half of the year. This showed that centralised purchasing achieved a 40% overall saving on the cost of importing just 52 drugs. For example, chloroquine had previously been imported from six different suppliers. After choosing from a variety of quotes, the SPC bought chloroquine from Sterling UK at *less than half* the price paid earlier to another manufacturer by the private importers. ⁽³⁸⁾

The SPC only accepted the cheapest offer for 11 of the 52 drugs. It lacked the quality control facilities to test drugs offered at exceptionally low prices by unknown suppliers. So Sri Lanka continued to buy from the research-based manufacturers, but at far lower prices. The experience proved that it was possible to challenge the market power of leading manufacturers. In the words of SPC Chairman, Dr. Bibile, "The results demonstrate the kind of foreign-exchange savings that accrue to a developing country when it establishes a state buying agency and adopts an open-tender procedure for purchasing. It places the agency in a strong bargaining position and compels competition even among the transnational corporations which had previously monopolised the market." ⁽³⁹⁾

Encouraged by Sri Lanka's success, a number of countries have since set up national procurement agencies to bulk buy drugs on the world market. In most cases these public tenders are used to buy drugs only for the health services, not for the private market as happened in Sri Lanka. ⁽⁴⁰⁾ Centralised procurement has been particularly successful in Costa Rica, where the Social Security Agency is estimated to have saved the country £17.6 million in 1978 alone. The policy has contributed to the Social Security Agency's success in increasing its ability to meet the people's drug needs from 46.8% in 1970 to 81.5% in 1976. ⁽⁴¹⁾

Previously the Costa Rican Government's ability to buy the cheapest reliable generics was seriously hampered by laws protecting patents. But its bargaining power has increased with reforms in patent laws enacted after a dispute over the result of a 1978 tender. At the time a foreign manufacturer filed a case against the Costa Rican agency for deciding to buy from a generics producer instead of paying the much higher price for its own patented product. ⁽⁴²⁾

The 1979 report on the results of a survey of 14 Third World countries found that many are still paying very high prices, even though they buy drugs by competitive tender. The survey revealed that “At present a large part of drug purchases of developing countries follow relatively primitive tendering procedures, if at all, with little available information concerning alternative suppliers, quality and costs of the product”.⁽⁴³⁾

A senior scientist working on the WHO Drug Action Programme confirms that, whereas it appears very logical and straightforward to suggest that poor countries should buy drugs on international tender, at least for the public sector, it is hard to “imagine how they can buy through international tender without a proper means of communication outside their own country”.⁽⁴⁴⁾ Very few developing countries share Cuba’s advantages in having both sophisticated quality control facilities and a market intelligence network operating in major drug producing countries.⁽⁴⁵⁾

Mozambique’s centralised procurement agency, Medimoc, for example, has worked under the limitation of poor quality control facilities. These are being improved, but it has also experienced difficulties in keeping up with demand, partly as a result of transport delays and partly because manufacturers often require an advance payment in dollars. Tenders are made annually and it can be a year before the drugs actually arrive. In the meantime international currency fluctuations can contribute to dramatic price rises which may make it necessary to reorder.⁽⁴⁶⁾ But despite the problems, Medimoc has achieved excellent results. Prices paid in 1979 were similar to, or up to 20% less than 1975 prices, without any adjustment for inflation. In some cases prices have dropped substantially. For example the 1979 prices for methyldopa, cotrimoxazole and frusemide were respectively 72%, 44% and 7% of 1975 prices.⁽⁴⁷⁾

LOCAL PRODUCTION

Developing countries at very different stages of industrial development have taken active steps to reduce their dependence on imported drugs. Their strategies range from attempts to obtain the drugs they need by influencing what subsidiaries of foreign companies produce locally, to building up local production under public ownership.

In India the Hathi Committee advocated in 1975 that foreign subsidiaries should be stopped from merely carrying out formulation and packing, particularly of over-the-counter remedies like vitamin tonics and cough mixtures. The Committee urged that they should be actively encouraged to set up bulk drug production and bring valuable technology into the country.⁽⁴⁸⁾ Since then a succession of carrot and stick measures have aimed to implement this policy. The 1978/79 New Drugs Policy stipulates that manufacturers which only produce finished drugs will have to reduce their foreign ownership, but those prepared to produce bulk drugs can keep up to 74% foreign equity, depending on how many they produce and the sophistication of the technology they import.⁽⁴⁹⁾

To date this policy has not led to the expected rise in bulk drug production, and the new policies have been heavily criticised by the industry which blames over-regulation for holding back growth in this area.⁽⁵⁰⁾ Nevertheless, in contrast to most developing countries, India has a sizeable state owned drug industry which produces predominantly bulk drugs. Both public and private Indian companies now export drugs and production technology.⁽⁵¹⁾

Very few developing countries have as much bargaining power as India in dealing with subsidiaries of the transnationals. Bangladesh, for example, has up till now had little success in persuading foreign manufacturers to produce more bulk drugs locally. Foreign companies that set up local production whilst the country was part of Pakistan were allowed to do so on condition that they produced some raw materials as well as finished drugs. However, because the terms of their undertaking were left extremely vague, some manufacturers have been able to dodge the issue, justifying their reluctance to set up bulk drugs production on the grounds that it would be uneconomical.⁽⁵²⁾

This apparent impasse has encouraged a number of countries, including Bangladesh, to look to government-controlled production as the best solution to guaranteeing supplies of essential drugs for public health needs. In Bangladesh the Government's existing formulation plant at Tejgaon is being expanded and there are plans to set up new production units to produce raw materials.⁽⁵³⁾

In the small African state of Lesotho the Government has established local production with technical support from the International Dispensary Association, a non-profit making organization. The Lesotho Dispensary Association, set up in 1977, satisfies Lesotho's needs for basic drugs and is now expanding its production to supply neighbouring countries.⁽⁵⁴⁾

Some countries have already succeeded in setting up large-scale state-controlled production. China, which is now reported to be virtually self-sufficient in drugs and a sizeable exporter, is an obvious example.⁽⁵⁵⁾ In Cuba the situation before the 1959 revolution closely resembled that of many developing countries today. Cuba was dependent on imports from foreign manufacturers for 80% of its drug requirements. A recent UNCTAD study shows that now the Cuban state-owned industry supplies over 80% of the country's needs. Like India, Cuba has also developed its own technology to produce some bulk drugs.⁽⁵⁶⁾

Less well-known is what the UNCTC has recently described as the Egyptian Government's "remarkable achievement in moving the country from being dependent on imports for 80% of its drug needs (in 1963) to producing 83% of total demand locally" (in 1980).⁽⁵⁷⁾ The public sector alone can now meet nearly 70% of total requirement.

Egypt's achievement can be directly attributed to the comprehensive drugs policy pursued by successive Governments since all but two drug companies were nationalised in 1962/63. The first step taken was to centralise policy-making on imports, production and distribution under one state agency. A drug research and control centre was set up to carry out quality control and production research.

Priority was given to training scientists and engineers, estimated to number about 22,000 in 1978. Production in the public sector is now closely integrated with seven factories engaged in formulation, one producing basic chemicals and other packaging materials. Any raw materials that cannot be produced locally are imported by the state trading corporation. ⁽⁵⁸⁾

The Egyptian drug industry is still dependent on foreign manufacturers for production equipment and chemical intermediates. Foreign expertise is needed to produce some speciality drugs which are produced under licensing agreements or joint ventures with some major research-based companies. But because of the size and market power of the nationalised industry, Egypt is in a better bargaining position than most developing countries to obtain technology on favourable terms. ⁽⁵⁹⁾

DISTRIBUTION

Many developing countries are attempting to improve *public* drug distribution through extending the primary health care infrastructure. But the logistics of transport, storage and administrative back-up remain problematic in most.

Some countries have set up efficient distribution systems ensuring that public dispensaries receive the drugs they require. In Papua New Guinea, for example, detailed procedures have been established to avoid wastage. The aid posts and health centres supply information to one of six regional stores on their requirements and current stocks. The pharmacist in charge of the regional store then sends in a printed order form for the region's requirements to the central medical store, giving a stock-in-hand figure for every item on the list. This allows the central store to make an accurate assessment of the country's overall needs and prepare tenders. ⁽⁶⁰⁾

The extent to which governments control *private* drug distribution is heavily influenced both by political considerations and the availability of drugs through the public sector. For example, after the expulsion of the French in 1954, North Vietnam imposed strict controls on private retailers. Despite the controls, overcharging by drug sellers was widespread because of the serious shortage of drugs. Decentralised health services had already been established during the nine year struggle for independence, so the state system could provide people with an alternative to buying drugs over the counter. Consequently the Government decided to ban all private drug sales and incorporate existing pharmacies into the state system. A Vietnamese doctor explains: "The pharmacists' interests were taken into consideration, but the people's interests were to be the first consideration." ⁽⁶¹⁾

The difficulties of controlling private drug distribution in non-socialist countries can be considerable. Many countries have laws banning over-the-counter sales of drugs that should be sold on prescription. In practice, these are virtually impossible to enforce. Attempts have been made to control private sales by issuing licences only to qualified pharmacists. This is the case in El Salvador where licences to sell drugs are restricted to pharmacists or *idoneos* (salesmen with a formal

qualification in drug use). In practice these controls are easily by-passed, as an anthropologist observed: “Licensed pharmacists or *idoneos* often appear at the store only to sign the appropriate documents for the renewal of the pharmacy licence, in early January, and thereafter simply to pick up their pay checks on a monthly basis. Their time is spent pursuing other business interests.”⁽⁶²⁾

Another policy option considered by some governments is to limit the range of drugs that untrained retailers can sell, in much the same way as restricting paramedics to an agreed list. This system has been adopted in Mozambique.⁽⁶³⁾ But regulatory authorities in most developing countries have little more than a handful of drug inspectors. It would be an impossible task for them to monitor the vast number of scattered retailers, not to mention illegal traders. So most have concentrated any efforts made on trying to control the drugs that come onto the local market.

DRUG REGISTRATION

In the rich world stringent controls are applied to new drugs before they can be marketed. In Britain, for example, the main objective of licensing procedures is to ensure that the usefulness of drugs outweighs their possible hazards and that they are effective for each use recommended by the manufacturer. Criteria of cost-effectiveness, vital to poor countries, are not taken into consideration in allowing a new drug onto the market.

Most developing countries operate some, often minimal, registration procedures. Few regulatory authorities in the Third World are in a position to evaluate the evidence produced by manufacturers to support their claims. Few have access to unbiased scientific evaluations, much less facilities to make their own clinical trials. They have to rely on regulatory decisions taken in Europe and the US. These are often contradictory, but should keep dangerous or ineffective drugs off the market. However, they offer poor countries no guarantee that a new drug represents value for money in meeting their specific needs.

The registration system operated in Cuba before the 1959 revolution illustrates the problems faced by other developing countries today. This is described in a recent UNCTAD report as “merely a bureaucratic formality with a firm presenting a large volume of information, which no one read, and then making the required payment of excise taxes as well as other irregular payments.”⁽⁶⁴⁾

Today the Cuban National Formulary Commission makes a detailed evaluation before any new drug is approved for use in the country. Controlled clinical trials are carried out to assess whether the new drug has clear medical advantages over cheaper drugs already on the market. According to the UNCTAD report, the experience of the Cuban regulatory authorities has shown that disregarding “the subjective factors introduced by commercial propaganda, ... when economic studies are made, it is found that in the majority of cases, the cost per treatment with the new drug is four to ten times higher than with the one in current usage, with more or less the same effectiveness”.⁽⁶⁵⁾

New drugs are not the only problem. Most regulatory authorities are confronted with the existence of a mass of similar and non-essential products that have already been licensed for sale. In April 1982, the Mexican Government announced new regulations designed to make it easier to cancel existing licences. Whereas product registrations used to be valid indefinitely, they will now be subject to review every three years. If the manufacturer does not apply for a product to be re-registered, its existing licence will automatically lapse. In future the Mexican regulatory authorities will also have new criteria on which they may decide to cancel registration. These include evidence that the manufacturer's original registration documents were misleading, and any cases where combination products have no clear advantages over single-ingredient drugs. ⁽⁶⁶⁾

The major constraint on effective registration systems is often that the regulatory authorities lack the powers to enforce their decisions. For example, according to the 1979 Annual Report of the Supreme Board of Drug Control in North Yemen, on occasions their procedures have been completely by-passed. Manufacturers have approached other apparently more sympathetic departments to get permission to market their drugs. ⁽⁶⁷⁾

IMPORT AND PRICE CONTROLS

A considerable number of Third World governments apply some form of controls on the prices of finished drugs. Some try to prevent retailers from overcharging by compelling manufacturers to print the maximum retail prices on the packs. This measure is enforced in North Yemen and Pakistan. ⁽⁶⁸⁾ Some governments have been particularly successful in keeping down prices. Egypt, for example, applies strict controls to all drug prices. ⁽⁶⁹⁾

Over the last ten years successive Indian Governments have introduced a variety of measures in attempts to peg the prices of finished drugs. With about 15,000 formulations on the market, the Government has been forced to implement selective controls. One scheme was based on regulating the prices of some of the market leaders' products. But the drug price index continued to rise. According to a recent case study by the UNCTC these controls proved ineffective because they covered only about one-third of the manufacturers' products. "Apparently, pharmaceutical firms took advantage of the loopholes in the (Drug Price Control) Order and increased the prices of unregulated drugs to compensate for the controls. Also, the price of imported raw materials and intermediates remained largely outside the purview of the new controls." ⁽⁷⁰⁾

The main difficulty faced by governments attempting to control prices of finished drugs manufactured locally is that they are seldom in a position to evaluate manufacturers' figures on their production costs. Drug control agencies throughout the world have problems in assessing transfer prices for chemical intermediates and bulk drugs.

Amongst developing countries, the Colombian Government made what the UNCTC described as "pioneering efforts to monitor transfer pricing and detect abuses." ⁽⁷¹⁾ The process began some years ago when a Colombian economist

compared the import prices that parent companies charged their Colombian subsidiaries with prices at which the same intermediates could be bought on the world market. He found that, on average, transnationals were overcharging by 155%. In some cases their transfer prices were up to 50 times higher than the cost of the same intermediate from other sources. ⁽⁷²⁾

Fines were imposed on the companies found to be overcharging and a Government agency was set the task of systematically collecting price information from world market sources to check against the transnational companies' invoices. According to UNCTC this monitoring by the Colombian Government led to "a significant reduction of over-invoicing practices and a corresponding decline in the price of finished drugs". ⁽⁷³⁾

Sri Lanka tried a different strategy to tackle high transfer prices. Policymakers decided that the most effective way to keep down prices of imported raw materials would be to centralise procurement under Government control. In the face of strong industry opposition, the State Pharmaceutical Corporation (SPC) took over raw materials imports in 1973. It achieved major savings over the cost of raw materials imported in the previous year. For example, the SPC bought chlorpheniramine from Halewood UK for only 13% of the price Glaxo had charged its Sri Lankan subsidiary for the same drug the previous year. Some manufacturers dropped their *own* prices massively from one year to the next. For instance Beecham reduced the price to its subsidiary for cloxacillin and ampicillin to respectively only 22% and 17% of their previous transfer prices. ⁽⁷⁴⁾

The Sri Lankan State Pharmaceutical Corporation monopoly over raw materials imports was reversed with the change of Government in 1977. But according to Professor Lionel, Head of the Colombo University Pharmacology Department, private imports continue to be closely monitored by the Government and the SPC's low prices provide an incentive to local manufacturers to keep their prices down. Moreover, Professor Lionel explained that there are now fewer shortages than when the SPC was the sole importer and private sector prices are much lower than in countries where controls are weak or non-existent. ⁽⁷⁵⁾

In attempting to control transfer pricing, the Indian Government has fixed the prices of eight critical chemical intermediates which it keeps under review. The state-owned Chemical Pharmaceutical Corporation (CPC) also has a monopoly on importing some of the most important bulk drugs. These are then distributed for formulation to both private and state-owned companies. In its 1981 report the UNCTC states that the Indian CPC has made significant savings by buying bulk drugs on competitive tender. Moreover, "By supplying foreign subsidiaries, it has prevented them from importing bulk drugs from their parent companies at prices fixed by these companies. It has also ensured the regular supply of important drugs to indigenous companies." ⁽⁷⁶⁾

CONTROLS ON MARKETING PRACTICES

A government that introduces comprehensive drug policies, bans private medicine and restricts doctors to prescribing from the national formulary may find there

is little need to introduce controls on marketing practices. In these circumstances manufacturers may abandon promotional activities as they stand little chance of influencing doctors' prescribing habits. This has been the experience of Mozambique, where only a few manufacturers still have local sales representatives. Most Mozambican doctors are committed to the new direction of health policy and have little time for visiting sales reps. ⁽⁷⁷⁾

But where the private market still flourishes and doctors are free to prescribe any drug they choose, controls on marketing practices are essential. However, despite the need, only a minority of Third World governments have adopted measures comparable to those enforced in Europe and the US. The UNCTC singles out Egypt as a country that has adopted "effective regulations on marketing practices". Some controls are stricter than in developed countries. "Although brand name products ... are allowed on the Egyptian market, advertisements are confined to professional journals and samples to professional bodies. No advertisements are allowed for over-the-counter products. Information on each drug is checked for accuracy by a government agency." ⁽⁷⁸⁾

The Costa Rican Government has also introduced strict controls on the promotion of both prescription-only and over-the-counter medicines. Sanctions against companies that break the rules have been written into the legislation, so that a company violating advertising standards can either be fined or have the registration of its products revoked. ⁽⁷⁹⁾

A number of countries have tried to ensure a balanced flow of information to prescribers. In Sri Lanka, government doctors are sent a quarterly publication, *The Prescriber*, started in 1966 by the National Formulary Committee. *The Prescriber* aims to combat the effects of manufacturers' promotion, for instance by providing comparative assessments of new products as against much cheaper, well-established drugs. ⁽⁸⁰⁾

HEALTH EDUCATION

Currently one of the most neglected areas of policy appears to be government attempts to impress on people that there are *alternatives* to medicines. Most governments carry out some limited health education work. In Costa Rica, for example, the Ministry of Health has prepared special leaflets for the public warning against self-medication. ⁽⁸¹⁾ But few governments take advantage of the potential of mass-media advertising campaigns on popular mobilisation to promote preventive health. One of the exceptions is the Sandinista Government in Nicaragua which has organised '*Jornadas Populares de Salud*' - 'days of mass mobilisation' - as part of its strategy for getting people to take more responsibility for their own health. ⁽⁸²⁾

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Mozambique and Sri Lanka are amongst the countries that have adopted the most comprehensive policy changes. The political climate in Mozambique, a socialist country, has been crucial to the Government's success in challenging doctors'

prescribing freedom. In most other countries this is vigorously defended. Members of the country's Portuguese medical establishment who might have opposed the new drug policy left Mozambique after independence. Professor Mazargao of the Technical Committee for Therapeutics and Pharmacy stresses that the limited drug list can only be implemented "through political understanding. It cannot be compulsory, it must be understood."⁽⁸³⁾

By contrast, in Sri Lanka the programme of rationalisation was carried out "in the face of much opposition from the pharmaceutical industry and their agents in Sri Lanka. Some of this opposition was channeled through doctors even up to the Formulary Committee", according to Dr. Bibile, who was Chairman of the State Pharmaceuticals Corporation.⁽⁸⁴⁾ But the positive results of the policies adopted in Sri Lanka are clear. Whereas other Asian countries such as Bangladesh and Nepal were spending 44% of their health budgets on drugs in 1976, but only covering a minority of their population, Sri Lanka was able to meet about 80% of its people's needs. Moreover, according to a 1979 WHO report, "In Sri Lanka the expenditure on drugs constitutes about 7.5% of the total health expenditure, probably reflecting the strict control exercised by the state on drugs allowed to be used in state medical institutions and in the private sector".⁽⁸⁵⁾

But the majority of developing countries have yet to implement significant controls in the drugs field. The difficulties, not least their unequal relationship with the big foreign manufacturers, have led a growing number of developing countries to look for strength in numbers. Neighbouring countries have joined forces to analyse common problems and mobilise their pooled resources in achieving solutions. In the words of Dr. Mahler, Director General of WHO, "Nothing will work more in this area than the joint effort of countries to exchange technologies, information and experiences and jointly boost their bargaining positions".⁽⁸⁶⁾

REGIONAL COOPERATION

Developing countries are actively cooperating over joint drug policies within a number of political, economic and regional groupings. Many of these regional initiatives are backed with financial and technical support from the UN agencies. Under the broad umbrella of the Non-Aligned Movement a succession of resolutions has been passed calling for comprehensive policy changes to be implemented. At their meeting in Colombo in 1976, the Non-Aligned countries agreed to start work on setting up new regional cooperative pharmaceutical production and technology centres, known by their acronym, COPPTECs. Each region would have its own COPPTEC to coordinate regional policy, exchange of information, pooled procurement and the setting up of local production.⁽⁸⁷⁾

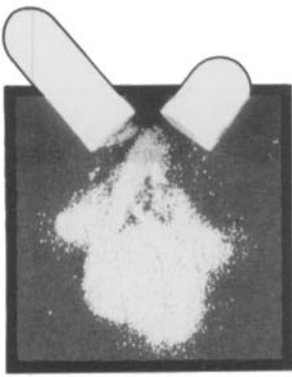
To date many of the proposed regional initiatives, including the COPPTECs, are still in their planning stages. It is obviously unrealistic to expect countries in the same region which may have major political differences to implement joint policies without considerable difficulties. But countries of every political complexion are increasingly stressing the need for positive action within regions and sub-regions, a mood underlined by delegates to the May 1982 World Health Assembly.⁽⁸⁸⁾

Some common market groupings have already achieved consensus on regional priorities, notably the Caribbean countries in CARICOM, the Andean Pact countries and the member states of the West African Economic Community. There is considerable overlap between these initiatives and work coordinated within the WHO regions. Just one example of the positive results is that the Caribbean countries have now set up pooled procurement procedures and have a new regional drug testing laboratory in Jamaica. Similarly, both the Andean Pact countries and 33 African member states of WHO have drawn up a regional list of essential drugs as a concrete basis for joint purchasing and production. ⁽⁸⁹⁾

Besides providing a forum for exchanging information and agreeing joint strategies, regional meetings give individual countries a more forceful and unified voice in making demands on the UN system. For example, at a workshop in Abidjan in October 1981, 17 francophone African states called for the setting up of a revolving fund to help countries acquire drugs. They also urged WHO and UNCTAD to work together in drawing up an international code of pharmaceutical marketing practices, covering promotion, prices, distribution, research and development and transfer of technology. ⁽⁹⁰⁾

Developing countries see regional cooperation as an important means to strengthen their hand in obtaining the drugs they need. But they are acutely aware that even mutual support cannot entirely remove their dependence on the major manufacturers. It is the rich world that controls the key area of drug technology. At a meeting in Harare in April 1982 the Zimbabwean Minister of Health expressed the fears of some Third World policy makers in forceful terms: "Self-sufficiency in Africa can only be achieved by concerted group action in rationalising and coordinating the extension of our own manufacturing capacity, avoiding unnecessary competition and complementing each other in the variety of our products. Of course, this is not going to be allowed to succeed by the giants of the pharmaceutical industry in the developed world. Technology will be denied, royalties will rise and some of us will be made dumping grounds for cheap preparations which will throttle our nascent pharmaceutical manufacturing industry. Our awareness of these problems will make it that much easier for us to avoid the pitfalls of the 'divide and rule' philosophy of the multinationals." ⁽⁹¹⁾

Are these fears justified by the attitudes and policies of rich world governments and manufactures? In the next chapter we examine the developed countries' response to the Third World's desire for change.



CHAPTER 7

TRADITIONAL MEDICINE

IF HUMAN history were telescoped into a day, modern medicines would put in an appearance only in the last few seconds. Over thousands of years different societies have evolved ways of coping with illness and people have relied on plants and other substances believed to have medicinal powers. These traditional health care systems have survived even the rapid incursions of modernisation.

In the Third World today, about three-quarters of the population still rely on traditional medicine - precisely the proportion of people denied access to modern medical care. ⁽¹⁾Indigenous medicine is the major source of health care for many of the rural poor. It is estimated that the village population of India spends ten times more consulting local healers than the Government spends on health services. ⁽²⁾In one area of the State of Uttar Pradesh served by a primary health care centre, there were known to be 110 folk healers. They made up 86% of all health practitioners in the area. ⁽³⁾

Even in the towns, where health centres are more accessible, the poor often consult a traditional healer first. A survey of mothers taking their children to a clinic in the capital of Bangladesh revealed that over half went to a traditional healer before attempting to get help from a doctor or health centre. ⁽⁴⁾This seems to be partly out of habit, and partly because of the prohibitive cost of modern medicine. An OXFAM researcher in Upper Volta points out that the minimum daily wage in the capital in 1980 was about 90p, but many workers were in fact earning much less. "This group treads between traditional and western medicines. For some ailments: headaches, skin conditions, certain fevers, or hepatitis, where the indigenous medicines are recognised as effective, the traditional healer will be visited first. A consultation and the medicine usually made from leaves or roots, can cost between 9 pence and 36 pence; whereas seeing a nurse, even at a free clinic, will often entail buying medicines at a much higher cost. Seeing a nurse privately costs between 90p and £1.80, and visiting a doctor by appointment costs between £1.80 and £3.60." ⁽⁵⁾

There has been a recent surge of interest in traditional medicine. In Europe and North America homeopathy, acupuncture and other alternative health systems have increasingly won acceptance, to the point where acupuncture is now part of the curriculum in some US medical schools. ⁽⁶⁾Since committing themselves to the target behind the WHO slogan "Health for all by the year 2000" (which really means health services for all) Third World governments have also begun

to reappraise the potential of traditional medicine. Dr. Hye, whilst Director of Drug Administration in Bangladesh, explained their thinking: "In recent years, there has been a world-wide search for new approaches to health and health care to close the gap between the 'haves' and 'have-nots' ... and attain a minimum level of health for all citizens within the limitation of a country's own resources. In this context, the utilisation of traditional systems of medicine, which have a long history of practice, utility and know-how ... is obviously a useful approach in attaining the goal of primary health care for all."⁽⁷⁾

WHO has lent its stamp of respectability to indigenous medicine, urging Third World governments not to "rely exclusively on western-type medicine or western-trained physicians in attempting to provide health care for all their people", but aim for a "synthesis ... between the best of modern with the best of traditional medicine".⁽⁸⁾

GOOD AND BAD PRACTICES

Attitudes to traditional medicine are often polarised between contemptuous dismissal and idealised overstatement of its advantages. As with *allopathic* (or conventional modern) medicine, there are of course both negative and positive sides to traditional systems. Some local remedies are simple and effective and enable people to be self-reliant. For example, in Bangladesh people make the most of wood apples (*aegle mermalos*) that grow wild throughout the country. When diarrhoeal disease is at its height in the monsoon season, the raw green fruit can be boiled with sugar and used to treat diarrhoea. In the dry season, the ripe fruit has the opposite effect, acting as a laxative.⁽⁹⁾

Dr. Klouda, OXFAM Medical Adviser, reports from Tanzania that the usefulness of traditional healers is as varied as their healing methods. "The healers' role in society has been greatly romanticised. There is a broad spectrum of such people - from idiots, to charlatans, to people just starting, to the very-experienced, to members of a family who happen to have dealt with some illness before. Some are generalists and some specialise in herbs, or bone-setting, or psychiatry, or social medicine, or magic or witchcraft, or poisoning. Some are a very great benefit - especially because of their personal knowledge of families, the background causes of poor health and their individual attention to their patients."⁽¹⁰⁾

Amongst the most helpful local practitioners are the traditional midwives. WHO estimates that these women help with as many as two-thirds of all births in some countries.⁽¹¹⁾ They are experienced and they give invaluable psychological reassurance. But some of their practices are very harmful, particularly the widespread tradition of applying cow-dung after cutting the umbilical cord. This is responsible for many cases of neo-natal tetanus.

Other local healers' practices are at best dubious and sometimes positively dangerous. Dr. Klouda cites the example of a colleague in Tanzania who "was nearly killed by a drug that partly destroyed his kidneys's tubules". He had been prescribed this remedy by a traditional healer for "weakness" after a bout of malaria.⁽¹²⁾ From Bangladesh, a *kobiraj* (one type of local healer) is reported to

have slit open the swollen legs of a malnourished child, to reduce the swelling. The child ended up with septicaemia, in addition to malnutrition. This was also the fate of another child with kwashiorkor, after a *kobiraj* had made slits in the skin across her stomach. ⁽¹³⁾

REASSURING RITUALS

Traditional healers often wield a great deal of power in their community. Like the white-coated doctor, they are treated with reverence, even fear. In fact there are as many parallels as differences between the role performed by the traditional healer and the doctor. Doctors and healers everywhere tend to build up a mystique around their healing abilities and limit their role to treating patients. Few attempt to stimulate patients' awareness or encourage them to take more responsibility for their own health. Referring to health practitioners in India, one doctor writes that the "obscurantism of indigenous systems and the elitist mysticism of western medicine serve one common interest, that is to prevent people's participation in them in order to further their commercial interests". ⁽¹⁴⁾

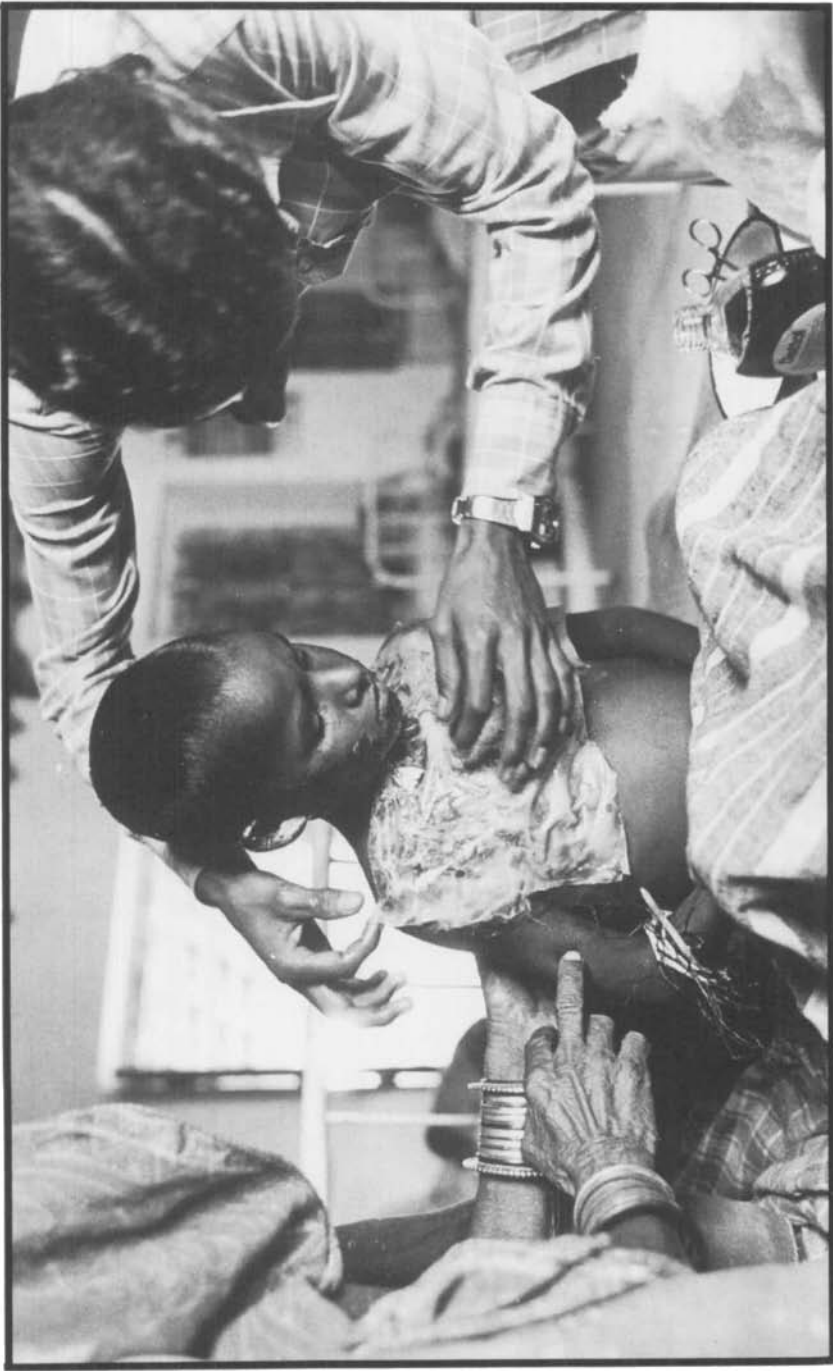
Most illness is self-limiting, so the majority of sick people will eventually recover, whether they are treated or not. But medical intervention can speed up the process, through the physical and psychological effects of healers and the drugs they prescribe. A doctor in the Philippines points out that "basically there is no difference between the doctor and the [local] *herbolario* in terms of the psychological effects of the rituals they perform". He juxtaposes their different but essentially similar rituals:

Patient A "regularly goes to the *herbolario* for his treatment. Every time he goes to the *herbolario*, the *herbolario* will blow on his head, place saliva on his shoulders, recite prayers in front of him and surround the place with incense while the patient sips a herbal decoction ..."

Patient B "regularly sees his doctor and during his visits, the doctor will take his pulse first, put a thermometer in his mouth, get his blood pressure and make him lie down while listening to his heart beat through a stethoscope. Then he is given a prescription to buy the necessary medicines ..."⁽¹⁵⁾

There are also strong similarities in the psychological effects of the drugs they prescribe. The oldest herbal remedy can have a placebo effect equal to the latest patented drug. The most obvious difference between traditional and modern drugs is that whereas the latter are tested for safety and efficacy, very few traditional remedies have ever been scientifically screened. Of course this does not mean that all modern drugs are particularly safe or effective, or intrinsically "better" than herbal medicines, especially in the treatment of minor ailments. But there is no doubt that herbal medicines cannot compete with modern drugs in the treatment of most communicable diseases, TB for example, or of serious conditions like diabetes. ⁽¹⁶⁾

(Credit) Mike Wells.



Burns victim receives modern medical treatment. His grandmother has also applied traditional treatment – the peacock feather around the boy's arm.

HERBAL MEDICINES

There is a rich variety of herbal medicines worldwide. The written records of Ayurveda, just one of the ancient systems, contain more than 8,000 herbal recipes. Some date back some 5,000 years, but according to WHO the same recipes are used in India today by about half a million healers. ⁽¹⁷⁾ A single local shrub can be put to very versatile uses. Neem, for instance, is a tree that grows all over the Indian sub-continent. The juice of fresh neem leaves with a little salt is used to treat thread worms and ascaris, and the ripe fruit can be decocted and used for urinary troubles. Neem is thought to have antiseptic properties and broken bones are bandaged with camphorated lint soaked in a neem decoction. Neem oil can be applied to skin to treat scabies. The sap is used for stomach troubles, the bark for sores, and tender Neem leaves for dysentery. ⁽¹⁸⁾

In a world increasingly dominated by Western cultural values, it is easy to forget just how much modern medicine owes to traditional medicine. The wealth of knowledge of medicinal plants built up over centuries in Asia, Africa and Latin America has been tapped by the modern drug industry as the basis for a number of key drugs. Digitalis (from foxglove) has been used for centuries to treat heart failure and still provides the raw materials for a number of modern heart drugs. The snake-root, *rauwolfia serpentina*, was sold in bazaars in India 3,000 years ago for snakebites and as a calmate. From the 1940s, reserpine was extracted from *rauwolfia serpentina* and is still used to treat high blood pressure. Curare, from wourali root, was first used by South American indians as a paralysing arrow poison. One of its active alkaloids is now an important muscle relaxant in modern surgery. The Incas used cinchona bark to reduce fever. This is rich in quinine, one of the first modern antimalarials. Quinine remains important, particularly with the emergence of malaria strains resistant to more recent drugs, such as chloroquine. Quinine is also used for muscle cramp. In China the medicinal value of the ephedra plant has been known for over 5,000 years. Today the alkaloid ephedrine is used to treat asthma. ⁽¹⁹⁾

As modern drug production got underway in Europe and America, some poorer nations were used as an important source of raw materials. An UNCTAD study describes the pattern of pharmaceutical trade established. "In conformity with colonial economic relationships of the time, British pharmaceutical manufacturers opened trading branches and agencies in India and kept India as a preserve for their finished products until the 1940s. British manufacturers and traders shipped out from India chemical raw materials (such as cinchona bark, *nux vomica* seeds, poppy pods etc) and shipped back to India extracts and other medical preparations for general prescriptions." ⁽²⁰⁾

PLANT-BASED DRUG INDUSTRY

Even today with advanced technology, it can still be cheaper to manufacture drugs from a plant extract, rather than synthesising them entirely from chemicals. The Third World continues to provide drug manufacturers with valuable raw materials. A number of hormonal contraceptives are made from diosgenin, an active

ingredient extracted from dioscorea, a plant that grows wild in many parts of Asia. Two major American manufacturers, Searle and Wyeth, now have factories in Southern India and Kashmir to produce the chemical intermediates from dioscorea. These are then exported to the US and Europe to be processed into the actual contraceptive pills, some of which will end up back on the Indian market. ⁽²¹⁾

Other examples of plants growing in developing countries that are processed into modern drugs include *vinca rosea* (rose periwinkle) the source of the modern drug vincristine, used to treat acute leukaemia. *Portulaca oleracea* another traditional medicinal plant that grows wild in the Philippines, where it is known as gualisman, contains the active ingredients of the modern drugs noradrenaline (for low blood pressure) and dopamine (for treating heart failure). ⁽²²⁾ The continuing importance of plant sources to the modern drug industry is stressed by an Indian analyst who comments: "Today more than half the prescriptions written by American physicians are estimated to contain a plant-derived drug - a drug that has either been extracted from a plant, or one that has been synthesised to duplicate (or improve on) a plant substance." ⁽²³⁾

FACTORY-PRODUCED HERBAL MEDICINES

A growing number of developing countries are now keen to exploit the potential of natural plant resources. Amongst them, Tanzania, Nigeria and Burma all have national programmes to build up plant-based drug production, already successfully established in China and Vietnam.

In some countries private manufacturers have launched into the commercial production of herbal medicines, free from the controls imposed on manufacturers of allopathic drugs. In Bangladesh, for example, traditional Ayurvedic, Unani and homeopathic drugs are all exempt from any controls under existing drug legislation. ⁽²⁴⁾ The lack of controls can seriously endanger health, as the President of the British Pharmaceutical Society has recently warned. He cited the fact that "tests on medicines imported into Singapore ... showed that 38 out of 140 samples were contaminated with dangerous amounts of toxic metals - one sample contained 20,000 times the permissible level of mercury and several had 1,000 times that of arsenic". ⁽²⁵⁾ Some officials responsible for drug control have recognised that, in the words of the then Bangladesh Director of Drug Administration, "the precautions observed in the manufacture and distribution of traditional medicinal products should be, as far as possible, similar to those followed for modern allopathic drugs". ⁽²⁶⁾

Because the potential hazards are great, it has been argued that traditional medicines should be put through the same elaborate clinical pharmacological trials and processing as modern drugs. ⁽²⁷⁾ Partly in response, new research institutes are planned for a number of Third World capitals, including Dacca, where the Bangladesh Government has allocated over £4 million for a such an institute. Research scientists are keen to establish the efficacy of local medicinal plants by extracting their 'active principle' or 'pure compound'. Technical back-up has been

provided to a number of countries by agencies such as UNIDO, as for example in the form of a mobile demonstration and training unit equipped to extract the active ingredients from plants.⁽²⁸⁾

The process of vetting and refining herbal medicines by modern scientific methods can be every bit as expensive, however, as developing new drugs. The cost of extracting the active ingredient and formulation into modern dosage forms can destroy the advantages of herbal medicines by pricing them out of the reach of the poor. As Dr. Hye, then Director of Drug Administration in Bangladesh, explained: "Mechanisation of production and commercialisation of distribution have been observed to increase prices of traditional medicines at times far beyond that of comparable modern drugs."⁽²⁹⁾ This has been the experience in China where communes have found themselves paying as much for factory-produced herbal medicines as they do for modern drugs. Consequently, many communes choose to keep the costs down by mixing their own traditional remedies from medicinal plants grown on the communes.⁽³⁰⁾

Many Third World governments are fully aware of the pitfalls. Representatives of the Asian governments attending a WHO meeting in Delhi in 1980, agreed on the importance of seeing that "the supposedly low cost of traditional drugs and remedies, which is one of the major advantages of their use, is not lost in commercialisation and in the enthusiasm to put them in modern pharmaceutical dosage forms".⁽³¹⁾ Furthermore at the first UN meeting on the production of herbal drugs, held in Lucknow, India, in 1978, participants from a range of Third World countries agreed that it is not always necessary to go through the expensive process of extracting the active principle from a medicinal plant, because there is no real *medical* need to do so. In most cases, the patient can make do with a standardised extract, which can be produced cheaply by simple extraction and purification.⁽³²⁾

LOCAL SELF-RELIANCE

In fact, the best way to ensure that traditional medicines are used to the best advantage of the Third World poor is very similar to the approach that WHO urges poor countries to adopt in using modern drugs. At the 1980 Delhi meeting it was agreed that the Third World's policy on traditional remedies should be "to make a proper selection of traditional drugs of established efficacy and safety for use in primary health care".⁽³³⁾

The process of cataloguing and evaluating traditional medicines has to be carried out, not in research laboratories, but in the rural areas where their use has been observed over centuries. This empirical knowledge has been passed by word of mouth from one generation to another but is now increasingly threatened by the pressures of the modern world. In India, for example, concerted efforts are now being made to catalogue the medicinal plants known to the tribal people, who make up nearly a tenth of the population. But it is feared that already much of their knowledge has been lost.⁽³⁴⁾

The same dangers are apparent throughout the Third World as tribal people are forced to change their lifestyles. Under the pressures of social and economic change, more people are being forced from their lands or changing their style of cultivation. A former health minister of North Vietnam has warned of a threat common to many Third World countries. "We are exploiting our forests and reforesting on a very big scale. Within a few dozen years many so-called wild species will have disappeared and our pharmacopeia will be greatly impoverished."⁽³⁵⁾

The need to make a proper evaluation of traditional medicine is seen by many in the Third World as one element in a much wider cultural and social process of achieving self-reliance. Dr. Galvez-Tan in the Philippines explains: "Medicinal plants can be one of the alternatives for our people to use. But many people will still ask the question - 'Do medicinal plants really have a basis enough to warrant their widespread use again?' The answer is yes. It is from the ancient herbs that our modern pharmacopeias have developed... The scepticism regarding herbal medicines can be traced to our cultural 'miseducation'. We have always been taught that the practices of our *herbolarios* and *hilots* are quackery and unscientific. We were led to believe that anything that comes from the 'West is best'. We have failed to recognise the beauty of our own indigenous science and culture."⁽³⁶⁾

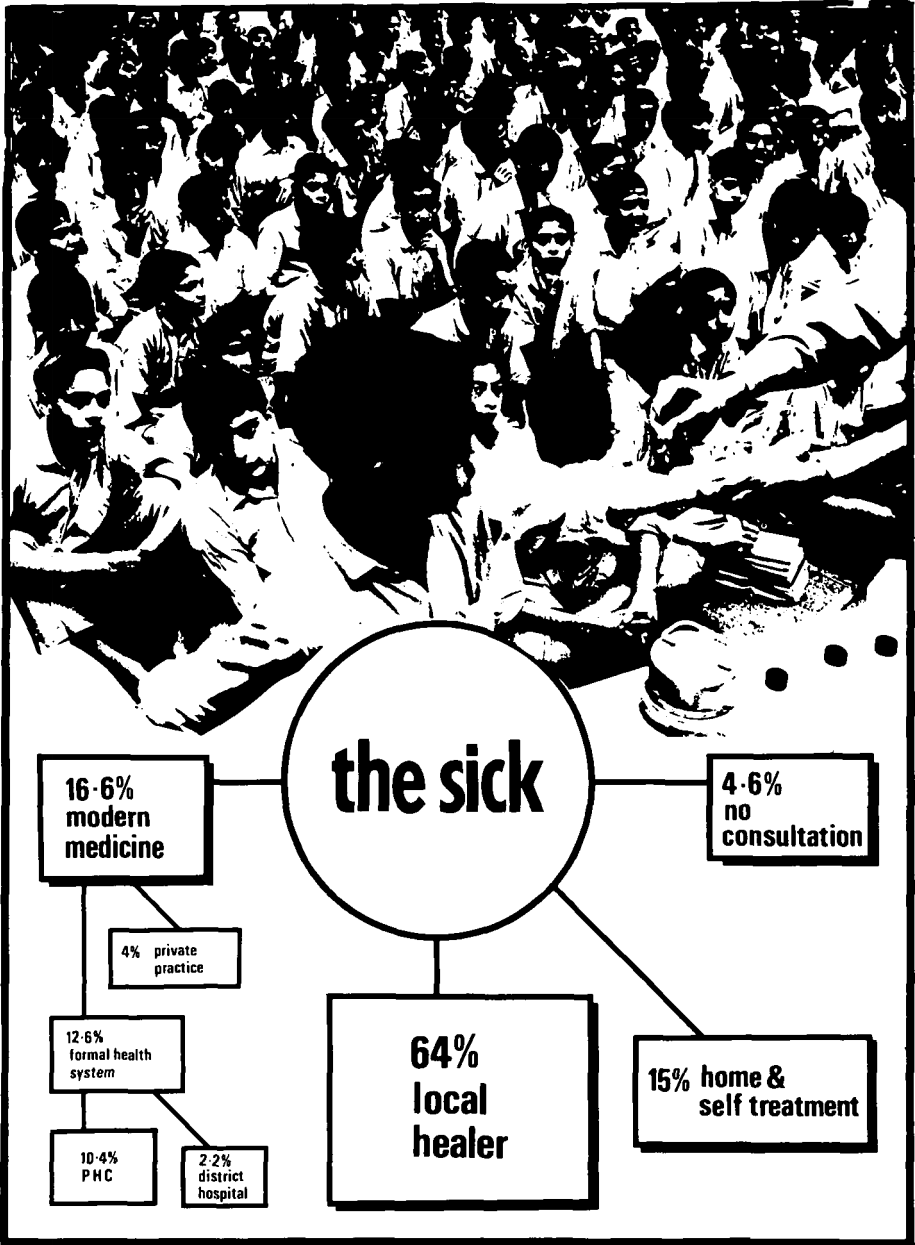
GRASS ROOTS INTEGRATION

To serve the needs of the poor, there has to be a concerted attempt to capitalise on the best of both traditional and modern medicine by integrating the two systems at the primary health care level.

This integration is already taking place. For example in India allopathic doctors and health workers have incorporated Ayurvedic principles on diet, meditation and exercise into their practice. Moreover, research in one Indian community reveals the extent to which indigenous healers look to modern drugs, with these prescribed to 80% of their patients.⁽³⁷⁾ Integration between these two systems has of course been consciously and successfully achieved in China.

But in contrast to China, the problem remains that a model integration of the best of traditional and modern primary health care systems may still do little to improve health if merely grafted onto political and economic structures that perpetuate poverty. There is even some evidence that indigenous healers working in joint clinics with modern health workers in India may effectively be catering mainly for a more educated minority, and treating conditions that are not primary health care priorities.⁽³⁸⁾

Nonetheless, three clear advantages can be seen in attempting to create grass roots integration. The first is stressed by WHO: "A sudden change from traditional to modern medicine causes negative attitudes in the population towards the organised health services. This leads to under-utilization of these services and to competition between them and traditional medicine." Traditional medicine has the advantage of "high consumer approval", so if traditional practitioners are seen working alongside modern health workers, patients will be encouraged to make use of the new primary health care facilities.⁽³⁹⁾



Where the sick turn for treatment in India.

A survey in Sri Lanka reveals that a quarter of traditional healers and 40% of college-trained Ayurvedic healers already refer patients to modern health practitioners.⁽⁴⁰⁾ It is hoped that with joint Ayurvedic/allopathic clinics patients will benefit from choice in whom they consult, and can be referred to the more suitable source of treatment - for example modern drug therapy for TB, but the Ayurvedic healer for stress and other psychological problems. A pilot joint-clinic was set up in Kandy, Sri Lanka in 1980 and similar clinics already operate in parts of India.

The second advantage is that modern practitioners can benefit from the knowledge and experience of indigenous healers, particularly in the use of herbal medicines that can provide simple and readily available treatments.

The Director of the Centre for Scientific Research into Plant Medicine in Ghana has attributed the past failure of many plant-screening programmes to the fact that no attempt was made to learn from local healers.⁽⁴¹⁾ A growing number of people trained in modern medicine have recognised the wisdom of this approach. One doctor in India recently set up a 'self-reliant alternatives to western medicines' project to tap existing knowledge about herbal medicines and put it to good use. Working from a base at a people's health project, in the State of Maharashtra, Dr. Dhruv Mankad is making contact with individuals and groups that have a special knowledge of local medicine and homeopathy. His aim is to compile a list of herbal remedies and establish which are the most successful by testing them out in clinical practice. The results, claiming or disproving the usefulness of local remedies, will then be spread as far afield as possible to benefit the poor.⁽⁴²⁾

Another project in India, run by the Apeksha Homeopathic Society, aims to make homeopathic medicines widely available to poor villagers. Homeopathy has limitations in tackling the diseases of poverty, because the system does not focus attention on the social causes of ill health. But homeopathic medicines do offer some clear advantages over modern drugs in the treatment of the mass of self-limiting illnesses. They provide similar psychological reassurance at much less cost and are potentially far less dangerous than modern medicines.⁽⁴³⁾

Thirdly, integration of modern and traditional practices has the advantage of maximising available skills and improving traditional practices to safeguard health. For example, a study of the comparative performance of trained and untrained traditional midwives in India revealed that: "Deliveries performed by trained traditional birth assistants resulted in a considerably lower percentage of complications due to neonatal tetanus (2.8% versus 8.9%) and other infections (20% versus 73.2%)."⁽⁴⁴⁾

A project in Raymah, an isolated and mountainous region of North Yemen, is specifically designed to try to make the best of the health care already provided to local people. Volunteers from the British Organisation for Community Development are attempting to change the emphasis of the health care provided by both the *saheen* (local "health" men) and the *jidaat* (traditional midwives). Training sessions aim to increase the local practitioners' awareness of the social



A traditional Jiddah in the Yemen provides antenatal care, following training in the basics of modern midwifery.

causes of ill health, and the dangers of over-medication with potentially harmful and expensive drugs. Both the *saheen* and the *jidaat* are encouraged to see their role as being one of service to the community and to act as health promoters by giving advice on hygiene and better nutrition. They are also taught how to use a limited range of basic drugs and prepare other appropriate treatments such as simple oral rehydration fluid. ⁽⁴⁵⁾

In some ways, it would be a simpler task to import new health workers whose attitudes have been entirely formed by the principles of modern primary health care. After visiting the project, Dr. Lusty, OXFAM's Medical Adviser, commented: "A case can be made for ignoring the *saheen* and concentrating on training a new cadre but to do this is to ignore the situation as it stands. The *saheen* are carrying the main burden of health care in the rural areas: anything that can be done to raise the standard of their work will have immediate results."⁽⁴⁶⁾ This is as true of the traditional healers in one mountain area of North Yemen, as it is of local healers responding to the needs of communities throughout the Third World.

In the next chapter we look at other positive and imaginative schemes to improve the health of local communities, and provide them with basic modern drugs.