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Chapter 8

The Industry and the Developing World

8.1. Pharmaceuticals in Developing Countries

At the present day, entire populations in developing countries are still faced from year to year with the fact that effective medicines are hardly available to them, or not at all. The problem has a series of causes, the responsibility for which lies with different parties. In most respects however, the underlying obstacle, extending far beyond the pharmaceutical sector, is one of shortage. Consistently, though to variable degrees, developing countries are short of money and education, of skilled people and wealthy institutions. Many lack adequate communication, the means to exploit what resources they have and the ability to attract the business and investment that might bring them prosperity. In some parts of the world all these difficulties are compounded by weakness of the legal system, an unreliable infrastructure and political instability. And in the meantime, laudable development efforts made in one direction are sometimes outweighed by disasters in another; in the field of health, the HIV/AIDS epidemic has proved a catastrophe that was unforeseeable a generation ago.

Where pharmaceuticals are concerned, the figures speak for themselves. The World Health Organization estimates that one third of the world’s population lacks access to the most basic medicines, while in the poorest parts of Africa and Asia this figure climbs to one half (WHO 2000a, 2000c, ‘t Hoen 2002, WHO 2004). The Organization has also estimated that, in Africa and South-East Asia, prompt diagnosis and treatment with appropriate medicines could save some 4 million lives a year (DFID 2003). To view it from a different angle: 15 per cent of the world’s population consumes 91 per cent of the world’s drugs by value (World Health Report 2003), while every 3 seconds, a child dies of one of the key diseases of poverty, many of which are curable (Amsterdam 1999).

Bearing in mind that medicines are often society’s primary instrument for curing and alleviating disease and that (alongside vaccines) they are a prominent tool for its prevention, it is clear that the developing world
cannot hope to progress greatly in improving health as long as good and appropriate medicines are in such short supply. A high proportion of deaths in the developing world are due to illnesses which are in principle curable with medicines that currently exist; others might be cured or relieved with drugs that currently seem within the reach of research, given a little more effort and investment in the right direction. Finally, one can point to instances where useful and necessary drugs have disappeared because of lack of commercial interest in their production. In the case of African trypanosomiasis, which leads to some 40,000 deaths annually, the supply of all four applicable medicines had by 1999 either ceased (eflorinthine HCl) or become insecure (sodium suramin, melarsoprol, pentamidine isethionate) (Pécoul 1999).

Over a long period, the international pharmaceutical industry played no role of any significance in the development of Africa or various other parts of the third world. While it vigorously sought growth opportunities in other new markets it found little reason to look to the tropics and certainly no moral grounds for doing so. As a former executive in a multinational recalls:

Looking back I see a clear contrast between the way the drug business was reacting to the opening up of the former Soviet republics when they broke free in the nineties and what had happened in Africa in the seventies. In the former USSR we indeed hurried in, perhaps almost too hastily, to take part in the development process. You must not however ascribe that to ethics or idealism; we simply wanted to grow as they grew, because that could create a vast market as we went along. The chances looked good because these were mostly industrialised states with a strong workforce, and they simply needed a repair job; our business trainees understood them; we guessed they would soon be looking for western drugs and finding the money to paid for them at decent prices. In places like most parts of Africa we were much less certain. There was a real chance our money would be going down the drain, not into development. With Europe and America taking virtually all we could buy in the seventies we were not going to take big risks in a part of the world that we didn’t really understand with diseases that we had no comprehension of. So we did what we had been doing for eighty years, sending our medicines on consignment to agents, hoping to get some money back, and beyond that leaving well alone. (Interview 26)

The result of such experiences has been what the United Kingdom Government has called a “mismatch between pharmaceutical needs in developing countries and the current nature of the global pharmaceutical market” (DFID 2004 at p. 14). The failure of world-class firms to provide a dependable supply of affordable medicines except to a small upper crust in the cities led the public authorities and the missions to set up alternative
channels of distribution using alternative suppliers; that in turn rendered
the scene even less inviting for the multinationals.

8.2. The Basis of Duty for Industry

From the 1970’s onwards, a series of writers and travellers unleashed
a barrage of fury against the multinational industry for its attitude to the
developing world. In part it was castigated for its indifference, in part for
activities ranging from the sale of anabolic steroids to stimulate the
appetite of starving children to the hawking of costly and unnecessary
vitamins. The writings were inspired by tragic memories. Diana Melrose
in 1982 introduced her *Bitter Pills* with one such story:

“As the boat drew into the shore we heard a strange sound from the bank. A
woman was crying. We found her with a dead baby in her arms and a collection
of medicine bottles beside her. She had spent all her money on these expensive
drugs….This Bangladeshi woman had never been told what was obvious to the doc-
tor who found her. The baby had become severely dehydrated from diarrhoea. Her
death could have been prevented with a simple home-made solution of water, salt
and sugar. No amount of medicine could have kept her alive.”

The indignation was often met with a denial of responsibility or with
counter-accusations of irresponsible criticism. Only gradually, as the cen-
tury drew to a close, did a debate become possible and a consensus on
action slowly begin to emerge.

Although there has been much criticism of the international pharma-
ceutical industry in connection with the drugs situation in the Third World,
any discussion of its performance must be based on a clear view of what-
ever duties it may reasonably be said to have. In a purely legal sense, a
commercial company can only be said to have a duty towards a community
in which it has a presence. If Thomas Beecham, making his Pills in
Lancashire in the nineteenth century, had chosen to continue his business
in the same manner and market in which it began, he would have acquired
no duty towards the people of Kenya. Only when a company actively
begins to pursue its business within a particular country (whether by man-
ufacturing goods, establishing a distribution system, advertising products
to its population or in some analogous way) will it become subject to the
laws of that country. The fact that it has sold some of its products to an
independent trading house that has proceeded to resell them at its own ini-
tiative to a range of countries does not of itself create obligations for the
primary manufacturer under the legal systems of those countries. At most
he might incur indirect liability if the product were in such a country to prove dangerously defective or falsely labelled; in that case local proceedings might be brought against the intermediary who could then in turn attempt to pursue a claim across national borders against the primary supplier. Such things do happen but not significantly, since the legal route is complex and slow. The manufacturer will only become directly subject to the legal requirements which pertain in the market where his goods are ultimately sold if he has in some way established a presence in that market.

Current discussion of the pharmaceutical industry’s performance in (and towards) the Third World concentrates in fact on much broader issues. The realities of the present day comprise a global market in pharmaceuticals in which no more than 500 medicinal substances are of real importance in treatment and in which a much smaller number of international and transnational firms are generally in a position to control their supply and their pricing as well as the development of new and better products. In that situation, the view has emerged that the pharmaceutical industry, having acquired a position of global power and wealth, has thereby also assumed worldwide the moral duties that go with that station. If one accepts that view, then it follows that, to put it briefly, the industry should adhere worldwide to the legal and ethical standards that have now been so widely defined across the world of pharmaceuticals; and it should respect those standards even in those parts of the world where governments and courts are not in a position to proclaim or enforce them.

It was thinking such as this that inspired Oxfam in 2001, shortly after the merger that led to the formation of GSK, to call on the new corporation to set a moral example to the entire industry:

Oxfam believes that pharmaceutical companies face a major reputation risk if they do not do more to promote access to life-saving drugs in the developing world. This is particularly important at a time of unprecedented scrutiny of the industry’s record in this field. The withdrawal of public support could lead the industry to suffer the same problems of staff recruitment and retention suffered by companies charged with complicity in human rights abuses or environmental damage. Perhaps more significantly it carries with it the threat of more stringent government regulation.

GSK could assume a critical leadership role by adopting a more supportive approach to public health in its policy towards developing countries, even within the current TRIPS regime. It is both ethically correct and in the company’s self interest to ensure that those who own and control medical knowledge use all means at their disposal to stop preventable diseases from killing millions of people every year, particularly if they are using their exclusive marketing position to prevent others from developing the same knowledge. (Oxfam 2001)
A year later, Oxfam joined with two other development agencies – Save the Children and VSO – to examine the activities in the Third World of 11 major pharmaceutical companies; on the basis of their analysis, they developed a standard for assessing the “corporate social responsibility” of drug companies in responding to health problems in developing countries. Their report “Beyond Philanthropy” (Oxfam 2002) offers a series of benchmarks intended to assist investors in assessing the attitude of companies in this field; the benchmarks may also be valuable to companies themselves in designing and reforming their policies and the principles that should guide their activities. The benchmarks relate to company policies and practices in pricing, patents, joint public/private initiatives, research and development and the appropriate use of medicines. Within the 2 years that followed, the industry was considered according to that standard to have made “substantial progress” in reforming its attitude to the Third World.

In seeking to move forward, pharmaceutical companies were also sometimes receiving encouragement from their own shareholders – a considerable shift in thinking from the days of *Dodge v. Ford Motor Company*:

In September 2004 the Pharmaceutical Shareowners Group, which united fourteen large international institutional investors, completed a study of the policies and plans of seven of the leading drug companies. The study had been sparked in 2001 by the legal action in South Africa in which 30 major firms attempted to prevent the Government from obtaining AIDS from low-cost sources. Alongside the TRIPS Agreement, which appeared certain to maintain high drug prices in much of the world, the case had in the view of shareholders brought about “marked shifts in societal perceptions” about the industry. According to the group: “A view has emerged that pharmaceutical companies have not been playing their part in tackling the public health crises.” In so far as senior management had begun to respond to the world’s needs, its response had virtually been limited to very tightly defined disease areas in which the industry had been subjected to heavy outside pressure. (Boseley 2004)

At least in their declarations of intent, if not always in their acts, corporate managers have in recent years begun to accept that in their various fields of activity they indeed owe positive duties to developing countries:

As a leading international pharmaceutical company we can make a real difference to healthcare in the developing world. We believe this is both an ethical imperative and key to business success. Companies that respond sensitively and with commitment by changing their business practices to address such challenges will be the leaders of the future.
A number of basic principles underpin our contribution to improved healthcare in the developing world:

- **Sustainability**: Our long-term commitment is to make contributions to world health that are sustainable. This applies equally to the research and development we carry out, the preferential pricing arrangements we make and our community based partnerships.

- **Appropriateness**: We are sensitive to the diversity of countries and regions and the differing needs of populations in terms of existing healthcare infrastructure levels. In all the countries where our products are available, in both the developed and the developing world, we have a duty to do what we can to ensure they are used in a clinically appropriate way. It would be wrong to sell our products in circumstances where they cannot be used with the right clinical supervision or where they are at risk of being misused.

- **Support for innovation**: Patents stimulate and fundamentally support the continued research and development of new and better medicines, including those for diseases prevalent in the developing world.

- **Partnership**: The significant barriers that stand in the way of Access to Healthcare in the developing world must be tackled as a shared responsibility by all sectors of global society. The pharmaceutical industry can play an important role, but it does not have the mandate, expertise or resources to deliver healthcare unilaterally to developing countries. Our activities are undertaken in partnership with organisations that have relevant specialised knowledge, such as governments, international agencies, charities and academic institutions.

- **Reporting**: We aim to communicate our overall intentions, activities and progress on an annual basis, as well as to provide regular updates on specific programmes and policies.

- **Sharing responsibilities**: We are seeking the establishment of regulatory, legislative and other mechanisms to minimise diversion of preferentially priced products to developed markets, so that patients most in need receive the treatments intended for them and the company generates sufficient revenue to fund future R&D.

One may wince at a few turns of phrase, but in many respects it would be difficult to find a better formulation of the obligations which rest on a multinational pharmaceutical corporation in the Third World and the extent to which these are formally acknowledged by industry itself.

To sum up: Humanitarian considerations alone would suggest that much of society – and certainly all players in the international pharmaceutical field – should be concerned with these problems of the Third World; the situation results in a vast loss of life and much suffering, more particularly among the poor and underprivileged, and it is in blatant contradiction to the fundamental principles of human rights in health considered in Chapter 2. Even if one were to set humanitarian considerations
aside; however, the extent of disease across the world can be shown to result in serious damage to the economy and to the functioning of society in the world as a whole. While the consequences of the situation, in terms of permanent invalidism, suffering and large-scale mortality, are felt most immediately in the developing world, the ability of many forms of infectious disease to travel so rapidly means that they represent a threat to all parts of the world. Some of the causes of disease in the developing world may seem so remote that a western pharmaceutical company might consider itself within its rights to set them aside, confining its own activities to those parts of the world with which it was more familiar. In fact, however, any individual or party engaged in drug issues might fairly be regarded as having a moral obligation to contribute at least something to solving the crisis.

8.3. Industrial Performance in the Third World

In defining proper standards, and in looking ahead to their attainment, it is not productive to dwell at length on the less creditable aspects of drug company performance in the Third World; many authors have done that in detail (see for example Medawar 1979, Silverman 1982, Ahmad 1990, Chetley 1990, Chowdhury 1996) and activist organizations continue to document the record. As Medawar summarized the scene a quarter of a century ago:

Between them, the drug companies have been accused of virtually every sin that transnational corporations (in the non-extractive industries) are known to be able to commit – short of attempting to overthrow a democratically elected government. In particular, they have been associated with some of the most extortionate cases of overcharging and profiteering; they have been involved in sometimes indecently aggressive marketing activity; and their emphasis on marketing has given them control over technology which, in many developing countries, is virtually complete. On top of this, a significant proportion of their products – probably upward of one third – are authoritatively described as either undesirable or unnecessary, or both. (Medawar 1979 at p. 111)

Entirely in contrast to this are some much-publicized and entirely creditable activities developed in recent years, ranging from long-term drug donations and heavy discounting agreements to participation in WHO-based public–private development partnerships.

Merck Inc. introduced the antiparasitic and anthelminthic agent ivermectin (Mectizan) into veterinary practice in the U.S.A. prior to 1980. By 1982 there was
evidence that it could be effective in human onchocerciasis (river blindness), a hitherto untreatable condition affecting many millions of patients in the poorest areas of Africa. It was however clear that virtually no patients could afford to buy the drug, and funding from donors or other agencies was unavailable. In 1987, Merck announced that henceforth it would donate “as much Meclizan as necessary, for as long as necessary, to treat river blindness and help bring the disease under control as a public health problem.” The programme has continued up to the present in collaboration with international agencies which have helped to create a distribution system.

The Chief Executive Officer of Merck made direct reference to ethical considerations, speaking of “doing the right thing” and remarked in a later interview on “… the research people – how disappointed they would be if the drug never reached the people that would benefit…” (Hawthorne 2003 at pp. 16–17)

Turning back to the other extreme of behaviour one must recall the events of 2001 when 39 major companies lodged a legal case in Capetown against the Government of South Africa to prevent it from importing from India and elsewhere low-cost generic copies of their patented AIDS drugs. The originating companies had already agreed, after tortuous negotiations with WHO and other agencies, to provide considerable discounts on their own AIDS products, but it had become clear to the Government that by using the still cheaper generic copies the available funding could provide treatment to many more sufferers. Legal experts were generally of the opinion that the Government was acting entirely legally under a statute of 1997, and at the last moment the industry group withdrew its case without going to court. While a tactfully worded “settlement” was published it was clear that the industry had capitulated. The attempt which it had made to suppress low-cost treatment for an entire population was regarded worldwide as both tactless and unethical (Hawthorn 2003 at pp. 208–214).

The industry’s record in the developing world thus remains a chequered one, even within a single company. The fact is that, while the international industry has taken some major steps towards recognizing and meeting its moral obligations towards the Third World, too little effort has been made to eliminate concurrent malpractices, large or small:

The German company M withdrew an ineffective and potentially dangerous aphrodisiac from European markets in 1994. The same firm announced in 2002 that it was joining in a WHO-based public–private development partnership in Africa. In 2004, newly-minted batches of the aphrodisiac were still found on sale in a Cairo street market. On enquiry it was found that, at the time of withdrawal in Europe, M had licensed the product to its subsidiary in Cyprus so that production could continue for non-European markets. (Personal notes)
It is clearly necessary that if a corporation accepts a global obligation it should be both willing to ensure and capable of ensuring that its intention is carried through at all the levels at which the firm exercises authority. Having made various efforts to raise or restore its reputation in the Third World, the industry cannot now afford to engender the suspicion that its good works are no more than a facade behind which misbehaviour continues.

8.4. An Overview of Obligations

Bearing in mind that the industry’s obligations to society in developing countries rest on a broad ethical basis rather than on specific legal rules it can be helpful to summarize them in general terms before considering some of them in more detail.

A corporation which wishes to meet its obligations to the developing world, or to some chosen part of it should at least set out to ensure that, whatever the formal legal requirements:

- its products meet international standards for quality, efficacy and safety
- the products are accessible, particularly in terms of price
- its research programmes take account of third world needs
- the information which it provides is adequate and dependable
- its clinical investigations adhere to accepted standards.

Within a given country, many of these matters lie within the national jurisdiction to which the industry will be subject if it is physically present, and there is no question of a company modifying these obligations. It will however often be faced with a national administration that is weak, inexperienced, understaffed and perhaps corrupt, a situation which one might readily be tempted to misuse. Instead, the challenge is to act decently, and to assist others to do the same. As in other matters one must respect the law and the regulations and, where these are deficient, act according to the standards which ideally should be in place (Jayasuriya 1985, WHO 1988).

As an effective senior regulator in an East African country put it in 2003:

Please look on the absence of an effective regulatory regime in some of the countries around us as no more than a temporary blemish on the road to development; no individual and no institution with an ethical sense should use it as an excuse for persisting in commercial or other practices which have clearly had their day.

(Interview 3)
One recurrent difficulty is that presented by corruption. Corrupt practices in the administration, the trade and the professions are entirely illegal everywhere, yet in very many parts of the world virtually universal. An experienced country manager in the pharmaceutical industry offered a practical view:

It is really no use you people telling us not to give bribes. It’s a way of life anywhere south of Milan and you can’t ignore it unless you want to find yourself out of a job. Yes, I have bribed doctors to prescribe and regulators to sign pieces of paper that were just lying on their desks and I gave Ministers an incentive to change their minds. In some instances I knew I was simply helping them to get a living wage. What I have not done is to bribe them to do anything improper. If I get someone to use a recent and well-documented drug that way, then I have nothing on my conscience. If I didn’t do it people would simply get a similar drug from the competition, probably much less reliable. Provided I do this with a conscience I think I’m doing some good in this devious way... (Interview 24, translated and abridged).

8.5. Quality, Safety and Efficacy

Since the bulk of drugs required for use in the developing world are not manufactured there, foreign firms exporting to these countries clearly have a marked influence on the nature and acceptability of supplies. As noted in Chapter 3, the regulatory authorities in industrialized countries have in recent decades to a large extent assumed much of the de facto responsibility for ensuring that the medicines available to their populations attain satisfactory standards as regards their quality and the suitability for the purpose for which they are to be sold. Their role is however essentially to verify the manufacturer’s attainments in this regard; the legal (de jure) and moral responsibility in these matters remains firmly with the manufacturer or the national licensee (see Section 3.5). This distinction, all too easily overlooked in a fully regulated system, is of crucial importance when one considers those many developing countries where a fully effective system of national regulation has not been attained. Public facilities for quality control are commonly deficient or lacking entirely, and with limited human and other resources it is commonly impossible to evaluate regulatory files relating to efficacy, safety or to other matters; even frontier inspections of imports are as a rule far from comprehensive. Only exceptionally can a bilateral donor or an international agency financing and organising supplies be in a position to provide all the necessary assurances.

Under such circumstances a developing country may remain very much at the mercy of foreign industry and trade and the latter’s willingness and ability to provide reliable warranties in these matters. Once again: the
ethical standard which a firm needs to adopt is clear; irrespective of whether or not an importing developing country is itself able to impose standards or exercise controls, the firm is morally bound to ensure that products attain and maintain in every batch the standards which would be demanded (and in most cases already have been imposed) by a reputable agency elsewhere.

For the bulk of international producers with their own facilities for evaluation, production and quality assurance and control, this norm is readily attainable, the goods commonly being produced in the same plant and under the same conditions as when they are supplied to other parts of the world. Shortcomings can however occur where such a manufacturer has licensed a factory elsewhere to produce the quantities required for certain markets, without himself ensuring sufficient standards:

A European manufacturer X franchised to an Indian subcontractor B the production and quality control of certain items intended for export to East Africa. No provision was made for inspection by the franchiser X, but samples taken from certain batches, selected at random, were to be forwarded periodically to X for rechecking in Europe. Illegally and unbeknown to X, the Indian firm entrusted the manufacture of one product, a dextran-based blood substitute, to another Indian firm Z, making no provision for batch control. During its use in hospitals in the African country D, the product proved to be contaminated and fatalities resulted. X acknowledged only moral responsibility, but provided some financial compensation to the victims’ families and ensured that future supplies would be shipped directly from the European plant. (Interview 126)

8.6. Access, Prices and Affordability

The serious problem of lack of access to drugs in developing countries was examined by a Working Group of the United Nations Millennium Project in 2003–2005. (Millennium 2005) Although many of the causes of impaired access lie within these countries, one major impediment has been and remains, as noted earlier, that of price. The problem is a longstanding one, which for a time appeared insoluble; the background needs to be understood.

By the eighties of the twentieth century, the west’s science-based industry had settled into a stable pattern of business and financing. The income of the multinational corporations, with ample margins for profit and research, was being very largely derived from the western economy, where prices were high and sometimes very high indeed. Whatever was earned from sales to the poorer markets, comprising what had long been “the colonial world”, was a secondary bonus which hardly featured in planning and accounting. For simplicity of operation, many a major firm
established for each of its products a single global “export price” for such markets; because of the need to cover administration costs, insurance costs, freight charges and import duties as well as the agent’s fees the C.I.F. charge was commonly higher than in the firm’s domestic price.

We were running a commodities import house in Lagos in the sixties, dealing in all sorts of packaged items including medicines, for which we had contacts with various drug houses in England, America and sometimes France and Denmark. To keep it simple we generally used their home catalogues and added on thirty per cent or so for charges. That put the medicines even further out of reach of most people around Lagos, but we supplied the Ministers and the Ambassadors and some businessmen and suchlike, and it paid off. (Interview 24)

In this situation there was clearly no serious intention of dealing with most major public health problems. Some examples briefly illustrate the situation that pertained, and that in many parts of the world still exists:

a. Treating HIV/AIDS in the Ivory Coast and Uganda: 2000 (UNAIDS 2000). By the end of the century, HIV/AIDS affected more than 36 million people, while a further 21.8 million were estimated to have died since the epidemic began. (CDC 2001) Of all AIDS deaths since the epidemic began, 83 per cent had been in Sub-Saharan Africa. (Adu-Bonna 2001) The only reasonably effective treatment capable at the time of containing the disease and saving life involved lifelong administration of three different retroviral drugs, one of these being didanosine. In the Ivory Coast, the costs of using didanosine alone amounted to $3.48 daily. However, the GNP per head of population was only $1.94 daily, and the public health services could provide only some $0.03 per capita daily ($10.95 annually) in drug funding, which by African standards was relatively high. Obtaining the drug at current prices would therefore have involved spending twice the average patient’s total income and a hundred times as much as the country had to date been able to afford. To give three drugs would vastly multiply the problem; Efavirenz was 80 per cent more expensive than didanosine and idinavir 160 per cent more expensive. The situation in Uganda, where by 2000 some 5 per cent of the population were suffering from HIV infection, was even more serious. Didanosine was on sale at a price equivalent to $5.26 daily, while the GNP per head was only $0.87 daily, and public drug funding amounted on average to only $0.01 daily.
b. *Treating resistant malaria in Indonesia* (EDM 2001). In Indonesia, malaria is commonly due to the highly resistant *falciparum* parasite. Life-saving treatment was available using malarone. However, a curative course of treatment, if the drug was purchased at the usual global price, cost some $42. This had to be set against the fact that the Gross National Product per head towards the end of the century was only $1.60 daily, and that total annual drug expenditure per head in 1990 was only US$5.80.

c. *Treating cryptococcal meningitis in Thailand* (EDM 2001). *Cryptococcal meningitis* is likely to demand lifelong treatment with fluconazole. The original product as supplied by the company holding the patent was in 2001 sold at a price equivalent to US$14.00 per treatment day. However, the Thai per capita GDP was only $5.47 per treatment day.

The prohibitive influence of price in such situations is evident. While some spokesmen for the pharmaceutical industry advanced arguments to the effect that the non-availability of treatment primarily reflected other obstacles, ranging from failure of distribution to incompetent diagnosis or prescribing, activists were quick to suggest that such explanations only reflected the lack of experience of the pharmaceutical industry in the African situation. It was exchanges such as these which, around the turn of the century, began to result in negotiated measures to alleviate selected problems. Even though progress was to be punctuated by such dramas as the AIDS debacle in Africa, advances were booked:

By 2001 some initial agreements had been concluded between independent bodies and individual firms to supply specified drugs to particular markets at exceptionally low (“equity”) prices. The International Planned Parenthood Federation, UNFPA and the Rockefeller Foundation were among those who signed early supply agreements, one of which provided for the delivery of hormonal (and other) contraceptives at prices as little as 1% of those being charged for the same products in the United States. Even some advanced biotechnical products were incidentally covered; in January 2004 Médecins sans Frontières concluded negotiations for supplies to Sudan of injectable liposomal amphotericin B (AmBisone), a life-saving treatment for visceral liposomiasis (kala azar) which kills some 50,000 patients yearly. The original price was $3750 for a complete course of treatment; with a 90% discount this was reduced to $350, a reduction sufficient to make the drug accessible at least to severely ill patients who would be unable to tolerate an older and more toxic drug. (Healy 2004)

Agreement by manufacturers to price reductions of this extent may be welcomed enthusiastically or greeted with a degree of suspicion, particularly
since they sometimes raise questions regarding the calculation of the original price level. MSF now periodically issues overviews of the offers agreed to date and the terms to which they are subject (MSF 2002). In some cases the conditions set for a developing country are devious, and it can be difficult for an outsider to determine whether such a price reduction represents a genuine attempt to provide assistance or a symbolic public relations gesture having limited practical value or perhaps even masking a commercial ploy. It is at least obvious that if a relief programme is publicly announced it should be regarded as a commitment and implemented:

In July 2004, an AIDS coalition reported that, when the Pfizer Corporation introduced its donation programme for fluconazole in South Africa, it had under prolonged activist pressure agreed to introduce a similar programme in Latin America and had publicized the fact. In fact, according to the coalition, no such programme had been introduced and sufferers from severe fungal infections accompanying AIDS continued to die as a result. (ACT-UP 2004)

The effect of reducing prices to affordable levels has often been dramatic both in terms of drug usage and public health:

In Brazil, for example, where a Presidential Decree declared that compulsory licenses on drugs could be issued in the event of a national emergency, the AIDS epidemic was declared to constitute such an emergency. Generic AIDS drugs were then made by government laboratories and given free of charge to all HIV-positive persons. The effect of this policy was to almost halve the number of AIDS deaths between 1996 and 1999, as well as to reduce the incidence of opportunistic infection by between 60 to 80 per cent over the same time period. (Teixeira 2001)

Conversely, one can quantify the degree of deprivation resulting from high prices in particular situations. In Brazil, as a consequence of the above-mentioned generic initiative, 1000 people with HIV/AIDS can for a given sum of money be treated with the triple combination AZT/3TC + NVP (excluding the cost of diagnostics and other expenses), while with the same amount of money in Thailand, where the same combination of medicines are not available as generic products, it is possible to treat only 350 people, leaving 650 to die. (Perez-Casas 2000)

It could very well be that the pharmaceutical industry is moving towards an altogether broader policy of “equity pricing” in much of the Third World, thereby providing far broader access for the poor to much-needed medicines and opening a door to what in the future may become more lucrative markets. What level of pricing will be sustainable in the long run is still uncertain. Figures reviewed above and in Chapter 6 show that for older drugs which are out of patent the cost reductions achieved can be little short of sensational. For newer medicines still under patent it
is unclear how much can be achieved, but the statistics suggest that in many situations the income obtainable by selling to a larger patient population at a lower price can equal or exceed that earned from very limited sales at world prices. All current thinking as regards the future of pricing may however need to be revised as the provisions of TRIPS (see Section 2.2.4) come into force worldwide, with the possibility that generic supplies will be less readily available than hitherto.

The principal legal obstacle arising during negotiations for differential prices has been the desire to find firm guarantees that a medicine supplied to a developing country at a sharply reduced price will not be diverted illegally to a high-priced market. (GSK 2004, Ghana 2003, EC 2002) This has on occasion occurred, though well-designed contracts of supply generally prevent any significant loss; it is currently recommended that goods supplied under such agreements be provided with distinctive packaging so that they are much less likely to be accepted in normal trade channels (DFID 2005).

8.7. Research and Development

As noted in Chapter 5 and above, the possibilities for drug treatment of many diseases existing in the developing world are gravely limited by the fact that they have hardly been the subject of drug innovation. The remote prospects of an adequate financial return from poor countries mean that science-based companies see little temptation to enter these areas with well-financed and viable research projects, even where the patient population is large and sometimes massive. Western governments too for a long period saw little reason to induce the industry to move further in this direction, having a greater interest in the profitable growth of exports to markets where world prices could be demanded (MSF 2005a). MSF has contrasted the stagnation in this field with the massive and immediate effort which was unleashed in the United States to tackle the supposed anthrax threat in 2003 or the international effort which in that same year produced within weeks a diagnostic kit for SARS (Severe Acute Respiratory Syndrome) (MSF 2005a).

Chapter 7 considered possible future changes in the process of funding and stimulating research in order to achieve a greater degree of innovation, and several of the approaches considered there could benefit developing countries. Some of the approaches most widely discussed in recent publications are summarized in Table 8.A; they are not mutually exclusive.
A possible approach in an alternative direction would be for science-based companies to create links with selected centres working in the field of traditional medicines. The use of entirely traditional remedies in Africa and Asia is vast, and is based very largely on native plants. Traditional medicine of this type is as a rule practised independently of western medicine, and many of its remedies have not been systematically examined. Bearing in mind however the extent to which pharmaceuticals used in modern medicine are still those based on (or derived indirectly from) plant sources similar to those used by traditional healers it is indeed likely that, in some instances where synthetic chemistry fails to provide an approach, inspiration will be found in this direction.

Emphatic recommendations for specific projects frequently emerge from the Traditional Medicine Programme of the World Health Programme. For a firm willing both to expand its research in novel directions and to

| Table 8.A Possible Approaches to Expanded Drug Innovation for Developing Countries |
|---|
| Better definition of therapeutic research priorities both by governments and in international fora. |
| Reallotment of resources in research-based industry, with reduction in marketing expenditure and in “me-too” research, but greater emphasis on fully innovative programmes for developing countries |
| Selective pricing policies in all countries to reward innovative products |
| Prioritized registration policies in all countries to reward innovative products |
| Government-funded or EU-supported academic programmes in donor countries, attuned to specific Third World goals |
| Government-subsidized or EU-supported industrial research programmes in donor countries, attuned to specific Third World goals |
| International Public/Private Partnerships for drug development e.g. |
| (1) Medicines for Malaria Venture (MMV) |
| (2) Global Alliance for TB Drug Development |
| (3) International Aids Vaccine Initiative (IAVI) |
| Development of an EU Technology Platform for the Pharmaceutical Industry |
| Creation of independent non-commercial drug research organizations based on philanthropic funding (Model: Oneworld Health) |
| Non-profit research in a collaborating network of institutions, both academic and commercial, with firm central management. (Model: Drugs for Neglected Diseases Initiative) |

Sources: WHO (2004b), Millennium (2005), GSK (2005), DFID (2005), MSF (2001), MSF (2005) and Perlman (2002)
provide direct development assistance, a relatively modest investment in a search for agents derived from traditional tropical medicine could prove both rewarding and prestigious.

8.8. Information and Education

The principles that should govern the provision of information by the pharmaceutical industry in any country have been considered in Chapter 5, and they apply fully in developing countries; information must be adequate, balanced, objective and verifiable. These duties are especially stringent in the developing world where the audience is to such a great extent at the purveyor’s mercy. Lack of education and limited access to literature may render the prescriber and others unusually dependent on the information that the industry provides. Marketing and Advertising Codes which have proved effective in western countries should be carefully respected and promotional material should be in keeping with the Data Sheets or Summaries of Product Characteristics produced by recognized authorities. National authorities in developing countries rarely have the capacity to inspect the flow of promotional material or to maintain standards; in such conditions a mutual system of self-regulation of advertising (Chapter 3), which has proven its value in western countries, could be helpful.

In Chapter 5 of this volume, reasons were adduced for the pharmaceutical industry to abstain from direct involvement in education. It could be argued that this standard, conceived in countries where public and other impartial educational systems are fully in operation, applies with even greater force in developing countries where health and professional teaching systems may be deficient and one therefore needs to be doubly cautious as regards any “educational” process that could carry a commercial message. In situations of underdevelopment however one may need to adapt one’s approach if there is to be any progress at all. The ideal of impartial teaching must be maintained if education is not to be tainted, but there should always be fair opportunities to allow an industry to make its name known. In a number of countries the pharmaceutical industry has found it possible to assist schools and colleges to obtain well-recognized educational materials from abroad, which would otherwise have been inaccessible because of foreign currency restrictions.

8.9. Clinical Investigation in Developing Countries

The question of clinical investigations in developing countries has sometimes led to acrimonious debate, largely because two different issues
have been confused. Criticism in principle of such studies dates largely from a time when it was found that clinical studies of an ethically unacceptable type were being conducted by multinational companies in the developing world in a deliberate attempt to evade the ethical and legal standards that apply to such investigations in the industrialized west. There were similar reports of tainted investigations performed in countries which were at the time behind the so-called “iron curtain”:

In the decade following the thalidomide tragedy in 1960–1, a number of firms were known to have made arrangements for safety investigations of new drugs in human pregnancy using Hungarian women who were on the waiting list for abortion. Such studies could as a rule be carried out rapidly and at low cost, and although the standard was often low the results were used for preliminary in-house screening reviews and on occasion submitted to various authorities in order to obtain early regulatory approval. This type of activity appears to have ceased as international contacts have developed and worldwide norms for clinical work have been established in the literature and in regulation.

The unfavourable publicity likely to be accorded today to such practices by the world media, the consumer movement and other independent monitoring groups could well be sufficient to dissuade any firm from engaging in them.

In much of the developing world, specific legislation and regulation to govern clinical research is still lacking, though the sponsor is often required to notify such studies to the Minister of Health. Whatever the formalities, the standards demanded if trials in human subjects are to be ethically defensible as well as reliable are well defined in the literature and they lay considerable demands on both the sponsor and the investigator (Sections 4.5 and 9.2). Experience (and in some instances specific training and certification) are required. The adoption of these standards in European, American, Commonwealth and Japanese systems of regulation, backed by the Helsinki Declaration of the World Medical Association and by WHO recommendations, has in effect rendered them universally binding, at least in an ethical sense and often in a legal sense as well. The practical problem in many parts of the developing world is that the experience or facilities are lacking to perform these studies in accordance with these standards and thus in a manner providing adequate protection to the trial subject.

Where however clinical work can be performed adequately there is sometimes good reason to do it, principally when one needs to determine the efficacy of drugs under tropical conditions or in disorders that are rare or unknown in western countries. In addition it can be necessary to perform studies of drug metabolism in differing populations because of racial
variations. There is, for example, evidence that Asians may require smaller
doses of neuroleptic drugs and suffer adverse effects at lower doses than
Caucasians even after adjustments for body weight (Wood and Zhou
1991). For various other drugs it has been found that there are significant
differences in metabolism and therefore in safe dosage levels as between
Chinese/Japanese populations and Europeans (Balant and Bechtel 1994).
Less justifiable, but unfortunately on occasion unavoidable, is repetitious
work which has to be carried out in a particular country merely to satisfy
regulatory demands or accommodate a local situation; in such a situation
the formal requirements of the law may go well beyond what ethical con-
siderations would demand – and indeed create situations which are them-
selves ethically questionable:

Right up to the mid-nineties we were having to set up formal clinical trials just to
please the local people in some countries, especially in Latin America, though it
did happen in Africa and elsewhere. We would turn up with a thousand pages of
sound clinical material which had passed the regulators in Washington or Berlin
with flying colours, only to be told with a smile that we had to provide a number
of local studies in some designated hospital round the corner. Here and there one
also met a genuine belief that you couldn’t believe evidence from over the border,
but as a rule there was an element of prestige or money in it – I recall one case
where we knew that the regulator was splitting the proceeds with the hospital
director. Naturally it was a waste of time, particularly because you often had to
deal with people who had really no idea how to do a trial or didn’t have enough
patients to carry it out properly. The embarrassing thing was when they wanted our
help to publish their results in an international medical journal, and our people
knew that the findings wouldn’t stand up to critical examination. (Interview 4)

Standards established for use in industrialized countries may not
always be adequate in Third World situations. Various attempts have been
made to define the risks which are or might be associated with drug trials in
developing countries and to suggest supplementary precautions. The WHO
has suggested standards (Hubscher 1993) and several major pharmaceutical
companies have developed internal guidelines of their own (GSK 2002). In
part one is dealing with real problems which need to be accommodated, in
part one needs to be prepared to rebuff unjustified criticism. From the point
of view of a sponsoring company there is an obvious risk that the perform-
ance of studies in a developing country’s population by a western industry,
especially if the subjects are relatively uneducated, will be viewed as highly
suspect in the light of current thinking on equity and human rights.

In the local situation it may prove wise to secure clearance of the trial
design not only from the national drug authorities and medical association
but also from international experts familiar with the design and performance of studies in the specialism concerned, for example a clinical pharmacologist attached to a school of tropical medicine. The ethics of the study need to be discussed with whatever local body is likely to be considered most appropriate – if there is no ethics committee, the opinion of community leaders and religious bodies may prove most helpful. Particular care must be taken to inform the trial subjects in a manner which they will understand, given the confines of language and education, and to obtain their fully informed consent; in some parts of the world it is also the custom that consensus be obtained from the extended family or a community group. Whatever payments are made to an investigator or a trial subject should be modest and in keeping with local standards; as in any clinical study it is important to avoid exposing any person to financial temptation to act against his better judgement. Finally, when working in a developing country it may be advisable for the sponsoring company to place its trial monitor close to where the work is to be carried out so that the study can be kept under surveillance and standards maintained.

8.10. Partnerships and Organizational Links

For a long period, the public and private drug sectors in developing countries – and for that matter at the international policy level as well – worked largely in isolation from one another. Within countries, public and non-profit drug supply systems had come into being mainly because of the failure of the private sector to provide nationwide supplies of affordable medicines. Internationally (see Sections 3.5.10 and 8.12), the research-based industry had remained suspicious of government intentions. Relatively recent attempts to develop a measure of collaboration are proceeding cautiously and in particular through a number of public–private partnerships. As noted in Section 2.9 these are best still regarded as experimental, but at their best they could provide a useful way ahead with the two sectors playing complementary roles to serve developing countries’ needs. Promising work is emerging in collaboration with (or under the auspices of) the United Nations and its specialized agencies, notably the WHO. That is entirely logical: western pharmaceutical industries are often not well placed to select and implement themselves the various forms of activity which they could undertake and which the developing world needs. Working however in collaboration with international organizations or bilateral donors which can establish meaningful and well-coordinated programmes of assistance in the pharmaceuticals field for particular countries
or in special diseases areas they can achieve a great deal. For the firm, its involvement in such a programme may at the outset appear to comprise little more than humanitarian or charitable aid but, quite apart from the issue of duty, such activities could well serve as a transitional step to closer business involvement with these countries in the future.

Various initiatives taken to date (ABPI 2002, APG 2005, MSF 2005a) suggest that, given appropriate safeguards, collaboration of this type can be productive. Examples relating to drug development and supply include:

The *Accelerating Access Initiative* in which Merck Inc and other firms have cooperated since 2001 with UNAIDS, the WHO, UNICEF, UNFPA and the World Bank as well as with other bodies to broaden access, affordability and appropriate use of medicines in HIV infections and AIDS-related conditions (UNAIDS 2003).

The *Global Alliance for TB Drug Development*, formed to accelerate discovery and development of effective and affordable tuberculostatics for TB-endemic. A broad alliance works with commercial R&D pharmaceutical companies to identify promising substances and move them along the development pipeline.

The *Global Alliance for Vaccines and Immunization* (GAVI), seeking to improve the delivery of Hepatitis B, *Haemophilus influenzae* and Yellow Fever vaccines at a low level of development. GAVI involves international organizations, recipient governments, the vaccine industry, research institutions and service delivery NGOs.

The *International AIDS Vaccine Initiative* (IAVI), designed to support early discovery and development of an effective HIV vaccine. IAVI receives major financial support from a number of major philanthropic foundations, the World Bank and nine national governments.

The *Medicines for Malaria Venture* (MMV), intended to select, guide, fund and further research undertaken done by others to discover new antimalarials and ensure their availability. MMV works in partnership with research institutions, ministries of health, disease control programmes, the R&D pharmaceutical industry, academia and non-governmental institutions to improve the availability of safe, effective and affordable antimalarials.

The *Drugs for Neglected Diseases Initiative* (DfND), sponsored by Médecins sans Frontières and others; the Initiative deserves
special mention since it has created what is still a unique form of collaboration between organizations of differing nature and offers a remarkable opportunity for the pharmaceutical industry to participate at very little expense to itself in health development (Pécoul 2004). In these various ways it distinguishes itself from other partnerships, where the effort is directed primarily to disorders such as malaria and tuberculosis which are prevalent both at higher and lower levels of development, and where success would thus provide a reasonable basis for future earnings. DfND is by contrast directed purely to the needs of the poorest countries concentrating its efforts on conditions such as the kinetoplastid diseases (leishmaniasis, trypanothione, and Chagas disease) where lack of purchasing power has formed a serious deterrent to commercially orientated drug research. Designed to profit from the fact that so many pharmacological compounds which could bear promise in rare diseases are, as noted earlier, lying unused on laboratory shelves, DfND aims to secure non-commercial rights to these and examine them further through the participation of a chain of participating state-funded laboratories in different countries. The corporations making these compounds available will be invited and entitled to participate in the final stages of development so that eligible compounds can be put into production and made available rapidly for medical use. Using these and other approaches, DfND currently bears substantial promise. One measure of the pharmaceutical industry’s social commitment in the coming years could well be the extent to which it provides practical assistance to DfND and whatever like-minded ventures may coming into being.

Finally, one may note that the larger pharmaceutical companies have in recent years all established their own Foundations or collaborative agreements, involved in various forms of philanthropic or development work.

Examples include Abbott Global Care Initiatives, the BMS Foundation and the Lilly MDB-TB Partnership (dealing with multiple drug-resistant tuberculosis). (APG 2005)

Without a full insight into the activities and financing of these bodies it is however in some instances not possible to measure the extent of their philanthropic involvement as contrasted with their role in image-building for the parent company.
8.11. Donations

It has become customary for major pharmaceutical companies to make donations, generally of drugs but also in kind, to developing countries, while similar donations may also be provided as part of the relief effort in states of emergency occurring in any part of the world. The total global extent of such donations is not known with any certainty, particularly since many are not quantified or listed with any recognized aid agency. In 2004 the UN Millennium Commission’s Working Group on Access to Drugs was informed by industry participants that since 1998 10 major companies in the “Partnership for Quality Medical Donations” had donated products worth $2.7 billion to developing countries, this figure being exclusive of all other donations to the Third World. In principle, aid in kind can be of particular value since the drugs can be put to use at once, the source is usually unimpeachable and because the goods are obtained at low cost from source the extent of the aid is likely to be larger than if financial support were be provided.

By 2003 Merck Inc. had through its ivermectin project for river blindness (see above) made treatment available to more than 40 million patients yearly in 34 countries, and the programme had been expanded to other conditions. (IFPMA 2004)

The principal problems which have been experienced with donations arise when they are inappropriate to their purpose (Autier 2002); the choice may well have been made to suit the convenience of the donor rather than the recipient. At worst the donation may have served a purpose other than that of providing assistance:

A U.S. company donated a large supply of a vaccine to a Western African country, the supply being handed over to the Ministry of Health at a ceremony attended by representatives of the U.S. Embassy. Quality control tests shortly afterwards found the entire supply to be life-expired and it was necessary to discard it. An internal investigation revealed that the firm had become entitled to obtain a substantial tax rebate by donating surplus stock to charity before its expiry date was attained. The donation had been publicised by the corporation’s public relations department as a demonstration of its humanitarian activities. (Interview 11)

In Uganda in 1993 two full-size containers were found to be full of donated drugs which were unusable because of inadequate quality, life expiry or their unsuitability for existing needs; destruction would involve major expense for which no funds were available.

In 1996 the WHO, having examined the various abuses of the donation system, whether involving commercial or other donors, drew up a set of
guidelines for its member states, which are now widely respected and have in some countries been adopted into law (DAP 1996). A basic principle was that donations of medicines and medical supplies would henceforth be accepted and their importation permitted only if there had been adequate prior consultation with the health authorities. A licence would be granted only if the product met an existing need, was formulated in accordance with scientific principles and held recognized national licences, and would have a sufficient period of validity to allow for import and distribution. A number of national regulations have added a requirement regarding appropriate labelling or accompanying leaflets. There seems no doubt that any company proposing or undertaking donations in kind should respect the rules in force nationally or, should these be lacking, the principles laid down by the WHO.

A particular problem to be solved is that of language:

In 1996, during a consultancy inspection of national drug storage facilities in Ulan Bator, Mongolia, a large batch of antibiotics was encountered which had been supplied for emergency relief by a major European drug supplier and was intended for immediate distribution throughout the country. Both the packaging texts, inserts and background materials were found to be in German, which is not an accessible language in Mongolia. (Interview 42)

A practical solution would be to ensure that supplied or donated medicines are always accompanied by information materials in sufficient quantities to meet the needs of most users, printed in one or more widely accessible languages; in the case of emergency supplies, where there is no opportunity for repackaging in the correct language, translated material in sufficient quantities might be supplied separately.

Unique preparations. On occasion a reasonable demand arises for a drug or drug combination which is not (or is no longer) regarded acceptable by most regulatory agencies in industrialized countries.

Documented examples relate inter alia to:

a. An obsolescent drug for tuberculosis possessing relatively high toxicity, but available at a price within the reach of large populations who would otherwise have no access to treatment. (Interview 88)

b. A fixed combination of antibiotics, to be used in emergency situations or where facilities for bacteriological typing are not available; the manufacturing country proposed to refuse an export licence on the grounds that treatment without laboratory testing would irresponsible. (Interview 88)

c. A request for commercial supplies of a still experimental drug which appeared promising in the treatment of a hitherto resistant and commonly fatal parasitic infection involving children. (Interview 9)
No procedural and ethically sound solution appears to exist for such situations. What would seem advisable is that a pharmaceutical company avoids taking decisions itself in such problematical matters but instead seeks and accepts authoritative advice from an impartial source, for example, that of the relevant technical programme or regional office of the WHO. Whatever solution is adopted it is likely to prove controversial, and no suspicion should be allowed to arise that it has been taken primarily on commercial grounds.

8.12. Essential Drugs

The “Essential Drugs” initiative of the WHO, developed from 1977 onwards, was (and remains) a strikingly successful initiative to improve the situation of medicines in the third world, and one in which the research-based pharmaceutical industry could have played a major role from the start. That it did not do so can only be attributed to an initial lack of foresight in some quarters:

The initiative was built around a simple concept: the setting of strict priorities in drug selection so as to ensure good use of the funds which could be mobilized to provide drugs for developing countries. In the first instance a group of experts brought together by WHO developed a model list of Essential Drugs – initially 230 items defined as “those which satisfy the health care needs of the majority of the population”; all were well established and available at low cost. Member states were encouraged to develop their own lists according to local needs. Initiatives in later years included training courses for prescribers, based on the use of such a basic list, regular revision of the model list, programmes to promote efficient procurement and in 2002/3 publication of a WHO Model Formulary providing reliable prescribing information (WHO 2003b). In the early phases there was hope within WHO that the International Federation of Pharmaceutical Manufacturers’ Associations (IFPMA) would collaborate, encouraging its associated firms to provide massive supplies of drugs to the third world at low cost. In 1977 however the Federation viewed the programme as one which would destroy innovation and seek to limit the range of drugs available, perhaps worldwide:

An industry spokesman described the WHO initiative as “ill-advised and counter-productive” . . . the industry was “strongly opposed to the concept” – According to IFPMA, if essential drug lists were taken up by governments they would “result in substandard rather than improved medical care and might well reduce health standards already attained.” (Cited by Melrose 1982 at p. 180)

The programme therefore sought the bulk of its supplies elsewhere, stimulating rapid growth in the generic industry.

In the 40 years since the Essential Drugs Programme came into being, support to drug supplies has been provided largely through public
aid programmes. Bilateral and international support from much of the world has created national chains to deal with the procurement, storage and distribution of medicines; assistance has been given in writing laws and regulations, staffing regulatory agencies, building warehouse and transport systems and publishing drug compendia and bulletins to guide prescribers. In the meantime, the sale of branded “specialities” from multinationals remained very much on a secondary plane, with limited urban distribution to the affluent and sale through private pharmacies. The realization within “big pharma” after the initially negative reaction from IFPMA that the developing world could provide an important entry into an extremely large future market that merited cultivation led major manufacturers to revise their views, and many multinational firms have in later years supplied medicines at negotiated prices to procurement centres working according to Essential Drugs principles.

8.13. Counterfeit and Substandard Drugs

The issue of counterfeiting has been considered above primarily in connection with trademark protection (Section 2.2.4). The practice is extensive in many developing countries and often involves international trading between them; it is only likely to be countered effectively by close international collaboration and inspection, coupled with firm controls in the recipient countries. The latter is a further example of a situation in which there can be valuable collaboration between industry and the health authorities in the developing world.

8.14. Perspectives

Development is a long process, with its ups and downs at every stage; so long as it is still in progress, which is likely to be a question of many decades, one population will continue to enjoy a much higher degree of wealth and health than another. Fortunately, it is also a characteristic of the world of the early twenty-first century that societies work together and that one society provides aid to another; to that end, money, goods, finance and knowledge constantly pass across frontiers for purposes other than that of seeking direct financial reward. By coming to recognize that it has certain duties to the developing world, the pharmaceutical industry has already engaged to some extent in that process.

To return to the issue raised at the beginning of this chapter: it should be clear today that practical and constructive reactions such as the
above to the needs of developing countries are rather more than purely voluntary or charitable acts. All rights create obligations; the existence of the right to health (like all human rights) can be regarded as imposing a series of obligations on all parties engaging in the sector. Those rights, meriting respect by the industry just as by all other parties have been summarized as comprising:

- The right to *respect*, and to *freedom from unwarranted interference*; this has been interpreted to mean that those who are in the business of providing preventive, curative or palliative care must ensure that it is indeed provided when needed. Services once provided, whether commercial or professional, must be continued or further developed.
- The right to *protection*; this goes along with an obligation to the providers to ensure that the weak as well as the strong find their way, all having equal access to health, and that sudden emergent needs are promptly met.
- The right to *fulfilment* brings with it an obligation on others “...to facilitate, provide and promote processes ensuring the preservation of the right.”

To those more accustomed to the exact technological terms in which drug law and regulation are usually phrased, such standards may seem amorphous and vague, but they represent a roof under which more is constantly growing. Under any of these headings one can find a reflection of the principles of common decency and loyalty, as well as those of honesty and social awareness. Above all, when one has over a long period assumed a task which is supposed to serve society well, has carried it out in the past with some success and proclaimed loudly that one can safely be entrusted with it in the future, one will thereby have made a promise and assumed a duty. That is the essence of the obligations which are now progressively being accepted by the pharmaceutical industry in the developing world.