Essential drugs: economics and politics in international health

Michael R. Reich
Department of Health Policy and Management, Harvard School of Public Health, Boston, MA, U.S.A.

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Summary

The World Health Organization since the mid-1970s has expanded its activities on essential drugs from a concept to a list to policies, establishing the Action Program on Essential Drugs and Vaccines in 1981. The global social and political environment, especially the emergence of an international consumers movement, created favorable conditions for acceptance of the concept of essential drugs, despite initial resistance by the pharmaceutical industry. The WHO achieved a major accomplishment in getting other organizations to accept the WHO's evolving definition of essential drugs as legitimate. But the relationship between public and private sectors remains a key issue in achieving the objectives of essential drugs policies, an issue the WHO has not fully or directly addressed. Potentials for conflict and collaboration between the WHO and the industry exist around three topics: the extent of regulation, the role of the market, and local production. The case of essential drugs illustrates a new pattern that has emerged for setting the international health agenda, with open participation in international organizations by industry associations and by consumer groups. These changes in the international agenda-setting process influence national policy but still leave difficult problems of implementation at the country level.

Essential drugs; World Health Organization; Pharmaceuticals; International health; Multinational corporations; Consumer organizations

Background on WHO's Action Program on Essential Drugs

In 1975, the WHO's Director-General, Halfdan Mahler, issued a report to the annual meeting of the World Health Assembly that identified national drug poli-
cies as a top priority for developing countries. The report called for drug policies that would meet health needs and economic priorities, and stressed the essential drugs approach as an effective means to improve health conditions in poor countries [1]. That document built on a history of concern at the WHO with various aspects of pharmaceuticals, expressed as early as the first World Health Assembly in 1948 [2]. But the report in 1975 marked a clear step toward creating a new campaign on pharmaceuticals, focusing on the concept of essential drugs, with the goal of influencing domestic policy in poor countries.

This concept of essential drugs emerged from a growing realization of the gap between the potential of modern drugs to control basic diseases and the limited capability of health systems in poor countries. At all levels of the health system — from the national to the hospital to the patient — many poor countries lack modern drugs in sufficient quantities [3]. But limited resources alone do not explain the gap between what can be done and what is done. The gap results from multiple problems in the interaction of pharmaceutical companies with the social organization of poor countries. Some companies, both domestic and international, have engaged in irresponsible business practices, including product dumping, misleading advertisements, and aggressive product promotion and gift-giving to physicians and pharmacists [4,5]. Inadequate social infrastructure has exacerbated the problems of procurement, distribution and prescription, due to a lack of government policy, implementation difficulties, poor training of physicians and pharmacists, and ineffective management capacity [6–8]. As a result, available drugs often are not appropriately prescribed or used [4]. The practice of selling prescription drugs over the counter, the problems of assuring patient compliance, and the lack of laboratory facilities to assess drug quality contribute to the complex web of pharmaceutical problems in poor countries.

Many of these problems relate to difficulties of resource allocation in conditions of scarcity. Who should receive existing supplies of drugs? Which drugs should be purchased with a limited budget? How can drugs best be provided to the periphery and to the urban poor? How can a nation reduce its expenditures of limited foreign exchange on imported drugs? How can the training of health personnel be improved? The concept of essential drugs sought to address these questions, as a single solution to multiple problems, and promised to extend access, reduce costs, and improve treatment — all at the same time.

The WHO defined essential drugs in 1975 as "those considered to be of the utmost importance and hence basic, indispensable, and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society" [9]. In 1977, to make this concept more specific, the WHO prepared and published a Model List of Essential Drugs, including about 200 drugs and vaccines, by generic name. Most products on the list were known to be therapeutically effective and were no longer protected by patent rights [10]. That step, according to the current WHO Program Manager of essential drugs, marked the start of "a peaceful revolution in international public health" [11].

The concept of essential drugs has introduced major changes in the ways of thinking about pharmaceuticals in poor countries. Indeed, the concept represents
Table 1
Chronology of major WHO actions on essential drugs

1975 28th World Health Assembly:
Director-General’s Report reviewed main drug problems in poor countries, presented possible new drug policies, and noted experiences of some countries with approaches using basic or essential drugs to improve access to appropriate drugs.

1975 28th World Health Assembly:
Resolution WHA28.66 (2) requested WHO Director-General ‘to develop means by which the Organization can be of greater direct assistance to Member States in advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs’.

1975–76 World Health Organization:
Two consultants prepared a working document that: (a) described how lists of drugs are used; (b) defined terms related to basic or essential drugs and drug policy, economics and evaluation; (c) proposed criteria of drug selection; and (d) provided a preliminary list of drugs. The report was then circulated for comment and revised.

1977 Meeting of First Expert Committee on the Selection of Essential Drugs:
Publication of WHO Technical Report Series No. 615, ‘The Selection of Essential Drugs’, 1977. A WHO bestseller, the Report included a model list for adaptation by each country and guidelines on the process for preparing a list of essential drugs. The Report also stressed the need for additional information about drugs to prescribers and patients.

1978 WHO/UNICEF:
Declaration of Alma Ata, which included the provision of essential drugs and vaccines as one of the basic components of primary health care.

1978 WHO Executive Board:
Resolution EB61.R17 proposed the establishment of an ‘action program of technical cooperation on essential drugs’, and noted the need for cooperation with the pharmaceutical industry.

1978 31st World Health Assembly:
Resolution WHA31.32 urged Member States to establish drug lists and adequate pharmaceutical supply systems, enact legislation, and collaborate with WHO and aid agencies to achieve these objectives. The Resolution authorized the WHO to study strategies for reducing the prices of pharmaceuticals, ‘including the development of a code of marketing practices’. WHO’s Director-General was asked to study ways of supporting Member States and of collaborating with the pharmaceutical industry to improve the health status of poor populations.

1979 Meeting of Second Expert Committee on the Selection of Essential Drugs:
The Committee reviewed and updated the model list in the first report, making 13 deletions, 42 additions, and 66 amendments (mostly explanatory notes). The Committee also suggested that seminars be held in developing countries on the selection and use of essential drugs, and emphasized the importance of exchanging information on essential drugs with the pharmaceutical industry.

1979 World Health Assembly:
Resolution WHA32.41 called for the establishment of an Action Program on Essential Drugs, with initial funding from WHO, if necessary.
1981 **WHO:**
Establishment of the Action Program on Essential Drugs and Vaccines in February 1981.

1981 **International Federation of Pharmaceutical Manufacturers Associations (IFPMA):**

1981 **Health Action International (HAI):**
Formation of HAI as a network of consumer and public interest organizations, 'to promote the safe, rational and economic use of pharmaceuticals worldwide,' to promote full implementation of WHO's Essential Drugs Program, and to seek 'non-drug solutions' to health and nutrition problems.

1981 **WHO/UNICEF:**
Collaborative agreement on essential drugs, to promote methods for low-cost procurement.

1982 **WHO Executive Board Meeting, January:**
International Federation of Pharmaceutical Manufacturers Associations (IFPMA) stated that its member firms are ready to supply essential drugs at favorable prices for underserved populations in developing countries, and to assist the WHO in other ways.

1982 **Meeting of Third Expert Committee:**
The model list was revised again, with fewer additions and deletions, and a greater emphasis on clearer explanatory notes. The published report in 1983 stressed usage more than selection, reflected in the title, 'The Use of Essential Drugs'.

1982 **Action Program:**
Initiated a cooperative program with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) for training in quality control for persons from developing countries, with tuition and living expenses provided by IFPMA.

1982 **35th World Health Assembly:**
Endorsed the principles of the WHO Action Program on Essential Drugs and adopted a plan of action for the Program which included the major components of a national drugs policy.

1982–83 **Action Program:**
Organized three demonstration workshops in collaboration with the Government of Kenya to illustrate the use of ration kits to improve the distribution of essential drugs to dispensaries and health centers. Participants included government officials from 30 countries and representatives of other UN organizations and bilateral donors.

1983 **36th World Health Assembly:**
IFPMA requested WHO Member States to submit cases of possible infringements of IFPMA Code of Pharmaceutical Marketing Practices (1981) for review, and offered to report to the Health Assembly on progress in applying the Code.

1984 **International conference at Harvard School of Public Health:**
an innovative and effective strategy by the WHO for mobilizing opinion and resources. How could one oppose 'essential' drugs, especially for the poorest of the poor? The changes, however, have not always been entirely peaceful. The concept has carried with it complex economic, political, and ethical implications, which have not always been directly addressed by the WHO. The crux of the problem, and one ambiguously approached in WHO materials on essential drugs, is the relationship between the public and private sectors to achieve the stated goals. This issue, in turn, touches on fundamental value judgments and material interests of individuals, organizations, and societies.

In the late 1970s, the WHO took additional steps to integrate the concept of essential drugs into broader ideas about health care in poor countries. The WHO's goal of 'Health for All by the Year 2000' included the regular supply of certain essential drugs as a key indicator to evaluate progress. The Declaration of Alma Ata on primary health care in 1978 identified the provision of essential drugs as a basic element [12]. Then, in 1978 and 1979 the WHO took formal steps to establish an Action Program on Essential Drugs and Vaccines, which began operation in February 1981.

A brief review of WHO's major activities on essential drugs (in Table 1) indicates a continuously expanding scope. The initial emphasis on the selection of appropriate drugs changed in the late 1970s to stress the use of essential drugs, reflected in a title change of the WHO's basic document [13]. Following the establishment of the Action Program, the scope expanded again to encompass nearly all aspects of national drug policies (as presented in the plan of action approved in 1982 by the World Health Assembly), including selection of drugs, sup-
Table 2
Budget for Action Program on Essential Drugs (US $)

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<td>Country</td>
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<td>Regions</td>
<td>3,228,900</td>
<td>6,176,400</td>
<td>2,619,800</td>
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<td>(and inter-country 1985–86)</td>
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<td>Global and inter-regional activities</td>
<td>1,056,000</td>
<td>1,142,000</td>
<td>1,843,300</td>
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<td>Total</td>
<td>4,284,900</td>
<td>7,318,400</td>
<td>7,613,200</td>
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<td>Extraducetary funds</td>
<td>approx. 3,000,000</td>
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Staff for Action Program on Essential Drugs

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<td>Headquarters</td>
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<td>Professional</td>
<td>4</td>
<td>4</td>
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<td>General service</td>
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<td>Regions</td>
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<td>Professional, including assigned experts</td>
<td>6</td>
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ply of drugs, assurance of quality, manpower training, legislation and regulatory control, and financial resources. The Action Program has also grown significantly, with a doubling in professional staff in Geneva between 1982 and 1986 and a 1.8 times increase in budgetary funds between 1982–83 and 1986–87 (Table 2). Table 1 presents the Program's concerted efforts to spread the word about essential drugs and to include more aspects of drug policy within the Program. In addition, the Action Program has developed an active consulting service on drug policy for national governments. According to the Program's own count, since 1981, 'more than 80 countries have adopted the essential drugs concept and many are operating active programs' [14].

Within the United Nations, a rough division of labor has evolved on topics related to the pharmaceutical industry. The UN Industrial Development Organization (UNIDO) has promoted local production and formulation of pharmaceuticals in developing countries [15]. The UN Council on Trade and Development (UNCTAD) has studied issues related to trade of pharmaceuticals and its implications for domestic production [16]. The UN Centre on Transnationals has examined the global pharmaceutical industry and its role in national development [17]. The Special Program for Research and Training on Tropical Diseases supports the development of new drugs and vaccines for tropical diseases [18]. UNICEF has become actively involved in procurement efforts through international competitive tenders and in packaging essential drugs, at the UNICEF Packing and Assembly Centre (UNIPAC) in Copenhagen [19]. But the WHO can probably claim the greatest success on the conceptual level, through its promotion of the idea of essential drugs — with important potential consequences for pharmaceutical policy and management.
Social and political context for essential drugs

The concept of essential drugs emerged from the WHO, but also reflected larger social and political processes worldwide related to poor countries, multinational enterprises, and consumer organizations. WHO staff can be credited in large part for the surge in acceptance and in controversy over the idea of essential drugs. The global environment in the late 1970s and early 1980s, however, also created favorable conditions for the concept.

 Drugs are a key component of any health system. Drugs serve multiple social, psychological, and political functions; they are not simply used to treat disease. One study identified 27 ‘latent functions’ of pharmaceutical preparations, shown in Table 3, and readers can no doubt think of others. These multiple material and symbolic functions make drugs a potentially powerful and volatile issue in public debate. These traits contributed to the intensity of the controversy over essential drugs.

 The notion of a limited formulary of drugs existed long before the WHO officially adopted the concept of essential drugs. Hospital formularies have been widely

Table 3
Latent functions of pharmaceutical preparations

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<tr>
<td>1</td>
<td>Visible sign of the physician’s power to heal (drug)</td>
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<td>2</td>
<td>Symbol of the power of modern technology (drug)</td>
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<td>3</td>
<td>Sign that the patient is ‘really’ ill (drug)</td>
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<td>4</td>
<td>Legitimizes the long-term illness without cure</td>
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<td>5</td>
<td>Concrete expression that physician has fulfilled his contract</td>
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<tr>
<td>6</td>
<td>Reasonable excuse for human contact with physician</td>
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<tr>
<td>7</td>
<td>Satisfactorily terminates the visit</td>
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<td>8</td>
<td>Fits the concept of modern man that he can control his own destiny</td>
</tr>
<tr>
<td>9</td>
<td>Expression of physician’s control</td>
</tr>
<tr>
<td>10</td>
<td>Indication of physician’s concern</td>
</tr>
<tr>
<td>11</td>
<td>Medium of communication between physician and patient</td>
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<td>12</td>
<td>Forestalls lengthy discussions</td>
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<td>13</td>
<td>Source of satisfaction to the physician</td>
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<td>14</td>
<td>Identifies the clinical situation as legitimately medical</td>
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<td>15</td>
<td>Legitimizes sick role status</td>
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<td>16</td>
<td>Symbol of patient control</td>
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<td>17</td>
<td>Means of patient goal attainment</td>
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<td>18</td>
<td>Excuse for failure</td>
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<td>19</td>
<td>Symbol of patient stability</td>
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<tr>
<td>20</td>
<td>Evidence of physician as an activist</td>
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<tr>
<td>21</td>
<td>Evidence of pharmacist activity</td>
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<tr>
<td>22</td>
<td>Research source of utilization and treatment</td>
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<tr>
<td>23</td>
<td>Political tool</td>
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<tr>
<td>24</td>
<td>Medium of exchange</td>
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<td>25</td>
<td>Sampling medium</td>
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<td>26</td>
<td>Method of clinical trial</td>
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<td>27</td>
<td>Method of differentiating legal drug status</td>
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used in the United States [20]. Recent studies show that hospital formularies can be effective and acceptable to hospital staff and can improve the quality of prescribing while reducing drug costs [21]. Cuba, in the 1960s, adopted a national formulary that reduced the number of registered medicinal products from about 20,000 to just over 600 [22]. In addition, UNICEF and PAHO used limited lists of drugs in supplying countries and assistance programs prior to the 1970s. The WHO’s innovation was to use these ideas to promote national policy for essential drugs in poor countries.

The 1970s witnessed increasing recognition by established institutions that appropriate drugs are a necessary element of a health system, especially in poor countries [23]. It is impossible to provide good quality care without appropriate drugs. For some diseases, drugs are also a highly cost-effective technology in terms of benefits, in the prevention of diseases through vaccines, and in treatment and further illness avoided, for example, through antibiotics [24]. Shortages of drugs adversely affect the credibility of a health care system and the morale of health workers. On the other hand, a supply of appropriate drugs is not sufficient for assuring the effective operation of a health system. Attention must also be directed to the processes of distribution, prescription, pricing, and use of pharmaceuticals [7].

A second element that contributed to the acceptance of the concept of essential drugs was the growth of an international consumers movement in the 1970s. Established consumer groups in the United States, Britain, Germany, and Japan turned to the environmental and health problems of poor countries. And developing countries began to establish their own consumer and public interest organizations. The selection of a Malaysian president for the International Organization of Consumers’ Unions – the first Third World president – reflected those two processes.

Consumer groups in the late 1970s viewed pharmaceuticals as a major target in efforts to create an international consumer watchdog network, to serve as a countervailing force to multinational corporations [25]. Among the most active organizations were the International Organization of Consumers’ Unions, Social Audit of the U.K., Oxfam, and BUKO, a West German coalition of development action groups. These groups and others collaborated in the formation of Health Action International (HAI) in 1981, an organization of some 50 consumer and other public interest groups, in both rich and poor countries. As its goals, HAI seeks ‘to further the safe, rational and economic use of pharmaceuticals worldwide, to promote the full implementation of the World Health Organization’s Action Program on Essential Drugs, and to look for non-drug solutions to the problems created by impure water and poor sanitation and nutrition’. In working toward these goals, HAI has actively lobbied the annual World Health Assembly since 1982 and engaged in other campaign actions [25].

Another factor that affected the debate over essential drugs was the controversy over infant formula in the 1970s. That controversy focused public attention on multinational firms and health problems in poor countries, and compelled the WHO to address the role of the private sector and the issue of regulation. Various public
health experts and consumer groups identified a decline in breast feeding in poor countries and attributed that trend to marketing practices of infant formula producers. High infant mortality rates were said to be linked to the use of infant formula, often in unsanitary conditions or improper ways (such as the use of contaminated water to prepare the formula), and to the overpromotion of this product. In 1978, the WHO passed a recommendation that member governments take measures to promote breast feeding and to regulate ‘inappropriate sales promotion of infant foods that can be used to replace breast milk’. In 1981, the WHO, under heavy lobbying from consumer organizations, passed as a recommendation an ‘International Code of Marketing Breast-Milk Substitutes’ [26].

The controversy over infant formula held different lessons for the various participants. The Reagan Administration – the only government to vote against the infant formula Code – regarded the Code’s passage as an undesirable event, an over politicization of the World Health Assembly, and a pattern to be avoided again. The Reagan Administration argued that the WHO should not be involved in such regulatory recommendations. Consumer groups, on the other hand, regarded the Code as a success, representing a new-found legitimacy at the international level, raising real problems of marketing practices to public scrutiny, and changing corporate and WHO consciousness about these issues. Individual corporations responded to the infant formula controversy with different strategies. Nestles, the main target of the consumer campaign, underwent a dramatic transformation in its approach from outright rejection to conciliatory bargaining, ultimately agreeing to abide by the WHO Code in all countries that passed a version of the Code [27]. The pharmaceutical industry viewed the events around infant formula, and especially the code, with nothing less than ‘panic’, sensing that drugs were next on the agenda [28]. The formation of the WHO Action Program, and Health Action International, shortly after the 1981 World Health Assembly, seemed to confirm industry fears.

The concern with essential drugs also reflected increasing awareness in poor countries about the need to manage the process of economic growth with appropriate government intervention, to avoid possible negative consequences. The spread of environmental regulations during the 1970s illustrates this trend [29]. Environmental protection was no longer seen as a luxury of rich countries, but a necessary element to assure quality along with growth in poor countries. The broader acceptance of national regulation helped to promote reforms of pharmaceutical policy, in efforts to control the safety and efficacy of drugs available in the market.

The economic crisis of the 1980s provided a final element to promote the concept of essential drugs. In poor countries, government expenditure on drugs represents a significant portion of the health budget, often ranging between 20% and 40%, and in some cases reaching 60% (although data are scarce and of variable quality) [30]. Moreover, teaching hospitals tend to promote the prescription of relatively high-cost brand-name drugs, while rural dispensaries lack essential drugs such as penicillin, chloroquine, and iron tablets, indicating serious problems of equity and the lack of training in cost-effective prescribing [31]. In addition, as Brian
Abel-Smith noted, 'In many developing countries even relatively poor spend more on the health services they buy than the government spends on providing them with services' [32]. One study of drug expenditures in poor countries without production facilities calculated the per capita average in 1975 as $1.32 (both government and personal costs). The author wrote that the rate of growth of such expenditures has been 'extremely high. In most less developed countries, medicines expenditure has been a rising proportion of total health expenditure... Most striking of all, in most less developed countries expenditure on medicines has been rising very much faster than the rate of growth of the economy' [33].

These trends have encouraged health ministries to search for ways to reduce their drug costs. The debt crisis in the 1980s, which is squeezing the foreign exchange reserves and earning capacity of many poor countries, puts additional pressure on governments around the world to reduce import expenditures, including energy, food and drugs. Even rich countries, including Britain and Japan, have imposed cost control measures on drug expenditures, reflecting budgetary constraints, the high costs of drugs, and the relative administrative ease of cutting drug costs [34,35]. Poor countries have felt even greater pressure to decrease total drug costs – particularly when the International Monetary Fund has required adjustment measures, such as currency devaluations and import reductions, to guarantee additional loans – making the cost-effective promises of an essential drugs policy especially attractive.

**Accomplishments and remaining issues**

The major accomplishment of the WHO’s Action Program has been to transform the concept of essential drugs into a major issue on the international health agenda of multiple organizations around the globe, to transform the nature of discourse on pharmaceutical policy and poor countries. Topics related to essential drugs have been debated at international conferences and at national workshops by policy makers in national governments, international agencies, private corporations, industry federations, consumer groups, donor organizations, and educational institutions. The scope of the issue has expanded from a concept to a list to a policy, now seeming to include all aspects of a national pharmaceutical system. This expansion represents a successful form of conceptual marketing by the WHO, getting other organizations to accept the WHO’s evolving definition of essential drugs as legitimate. The WHO in effect outmarketed the industry.

But the WHO’s actions on essential drugs have rarely occurred without controversy. The measures have been criticized by the pharmaceutical industry, by conservative critics [28], and by the Reagan Administration, all seeking to protect the private market from the restrictions of national formularies, constrain the WHO program to the public health system in poor countries, and keep the WHO from becoming an international regulatory agency. Criticisms have also emerged from consumer groups such as Health Action International, which seeks to push the WHO to accept HAI’s principles of real medical need, significant therapeutic value,
acceptably safe, and satisfactory value for money, as applicable to private as well as public health systems and to rich as well as poor countries. Moreover, while industry staunchly has opposed a WHO marketing code [36], HAI and others steadfastly demanded one (at least until 1984).

The WHO, in response, has sought to maintain some intentional ambiguity in its recommendations on essential drugs, perhaps to solicit the continued support from industry groups as well as consumer groups and to meet the diverse ideological demands of different governments within the WHO. The intentional ambiguity involves the definition of essential drugs, and related policies, especially whether they are designed to promote essential drugs or to exclude certain ‘non-essential’ drugs and whether they apply only to the public health system or also to the private sector. These ambiguities allow for vastly different ethical, political, and economic interpretations concerning the role of national governments in regulating and controlling private firms and individual decisions. The ambiguities may be necessary, however, to contain the level of controversy and provide a measure of consensus within the WHO and within the World Health Assembly, the annual gathering of country representatives (usually the minister of health) who vote on WHO reports and resolutions.

This point reflects a common problem in international agencies: developing a global recommendation for policies that require national implementation. The more directly a recommendation relates to diverse national values and potentially controversial issues, the more ambiguity may be necessary to gain acceptance by different parties. While the ambiguity may be functional for the international organization, it does not help national policy makers who must make difficult choices.

The WHO’s first major controversy in this area focused on the list of essential drugs published in 1977 [10]. The Organization’s leaders may have been unprepared for the complexity of problems and intensity of controversy raised by the list. The list took the WHO into areas in which the organization had limited expertise, including international trade, economic development strategy, and industrial policy. The primary source of opposition was the pharmaceutical industry, especially the research-oriented multinational firms. Medical associations also expressed concern that the list would restrict the physician’s choice of drugs and thereby compromise good care.

In April 1978, the Council of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) adopted an official statement on the WHO’s report on essential drugs, noting ‘serious reservations’ about the policies recommended and deep concern about ‘the manner in which these policies are being represented and promoted’. The IFPMA reported that ‘the pharmaceutical industry is entirely sympathetic to the desirability of improving health care and the access to drugs in developing countries’. But the Federation concluded that ‘adoption of the misguided measures recommended by the WHO Report could severely retard medical care and would discourage investment by the pharmaceutical industry in research’. In 1979, the U.S. Pharmaceutical Manufacturers Association issued a point-by-point rebuttal to the reports from various UN agencies, including the WHO [37]. An evolving dialogue between the industry and the WHO,
however, has helped reduce the sharpness of rhetoric on both sides, although some tensions have persisted. Indeed, the IFPMA changed its position and now supports the concept of essential drugs for the public health sector of poor countries [38].

The WHO’s initial publication on ‘The Selection of Essential Drugs’ seemed to suggest that national policy makers simply needed to produce a list in order to achieve the objectives of availability, low cost, proper dosage, and total coverage [10]. Some countries adopted lists, but exerted little effort on distribution or logistics, and achieved no significant progress toward the stated goals. In countries where attention focused first on excluding unlisted products from import or private sale, without measures to improve distribution, the availability of drugs may even have worsened. In that sense, the industry’s comments about the importance of distributional problems were on target. The first revision of the list in 1979 made only minor changes. But the establishment of the Action Program in 1981 marked a recognition that a list alone would have little positive impact, that countries needed to deal with the broader issues of management and policy – a point reflected in the new title for the 1983 list, ‘The Use of Essential Drugs’ [13], as noted earlier.

In recent years, the Action Program has developed increasing expertise in assisting countries with national policy and management issues. Most of the Program’s staff and budget are now devoted to technical support to countries. Compared to its initial assistance measures, the Program now uses ‘a more flexible pragmatic approach to problems taken if possible in order of priority’ [39].

One innovative measure is the use of drug ration kits in Kenya, in which medicines for 3000 patients are packed centrally and then distributed directly to local health units. This approach was designed with the assistance of consultants from the WHO and the Danish International Development Agency, primarily to improve the distribution of a limited number of essential drugs to rural health facilities. But the measure also sought to improve the quality of drugs supplied, reduce losses in transit, and provide training for health personnel [40]. Kenya’s use of sealed ration kits (provided according to attendance rates at health facilities) has reduced losses from breakage, pilferage and wastage and increased the supply reaching health centers and dispensaries in the periphery [41]. Problems remain, however, in the lack of flexibility for drugs in the ration kits (especially in responding to different incidences of diseases in different areas) and in the difficulties of paying recurrent costs in a health system with free drugs [42]. The ration kits nonetheless seem to provide a more cost-effective distribution, allowing Kenya to achieve ‘more bang for the buck’ it spends on drugs.

The WHO’s efforts to improve the efficiency of the public health management system for drugs, through such measures as Kenya’s ration kits, now meet with little criticism from the private pharmaceutical industry. Indeed, a number of pharmaceutical companies are working with national governments to help improve the management of the public health drug system, including logistics, information, and distribution [43]. But conflict between the industry and the WHO is likely to persist on three points that involve both public and private sectors in policies for
essential drugs: the extent of regulation, the role of the market, and local production. These points are briefly discussed below.

The extent of regulation

Governmental regulation of the pharmaceutical sector covers a broad range of issues. The multinational firms seem to oppose regulation in principle, despite the fact that some kinds of regulation can benefit the research-based multinational firms. Regulation can thus affect different segments of the industry in different ways, benefitting one while costing another. Quality control for safety and efficacy, for example, can remove low-cost producers of poor quality drugs from a market as well as the producers of spurious drugs, and thereby benefit the competitive position of high-quality drugs. The application of quality control to traditional medicines could also benefit international firms. Other examples of governmental regulation that benefit these firms are patent and trademark protection, which represent important elements of research-based firms to protect their products and recoup the costs of research. Of course, the potential benefits of these forms of regulation depend on effective implementation. But these examples suggest that a position opposing regulation in principle and supporting the ‘free’ market does not fully represent the interests of some multinational firms.

The WHO, on the other hand, seems to stress only certain forms of regulation. Quality control is an area that the Action Program recognizes as important for achieving the goals of essential drugs, and as a key component in a national drugs policy, applicable to the private as well as the public sector. But the Program does not explicitly recognize the different problems in assuring quality from small domestic producers in poor countries (which tend to have inadequate quality standards), compared to the major multinational firms of rich countries (which tend to have highly developed quality control systems). The WHO also seems critical at times of the ideas of patent and trademark protection [1]; those elements are certainly not supported in the documents of the Action Program.

The issue of regulation provides an arena for direct conflict between governments and the private sector, and represents an expression of national values regarding politics, economics and society. Neither the WHO nor the industry can decide what forms of regulation are most appropriate for a particular country. Those decisions are the prerogative of national sovereignty. But there is some ground for convergent interests between the industry, the WHO, and national governments, which could be pursued through joint programs. One example is the training program in quality control for government employees in poor countries – funded by several pharmaceutical manufacturers [44]. That program reflects an implicit recognition that regulation is not in principle bad but can benefit certain segments of the pharmaceutical industry, as the regulation affects the structure of competition in the market.
The role of the market

The role of the market in the pharmaceutical sector represents another key area for conflict between the WHO and the industry as well as an important expression of national identity. The market for drugs usually reflects a nation's larger political and economic strategies for development. This point tends to produce positions just the opposite from regulation. The WHO seems hesitant to recognize the market as a potentially efficient or effective mechanism for allocating resources, while the industry seems to suggest that the market can and should do everything. Yet here again some complexities in the positions exist.

While the WHO is ambiguous about the role of the market in the domestic pharmaceutical sector, the Organization has supported the use of the international market for procurement. The WHO collaborative program with UNICEF promotes the use of international competitive bidding to obtain the best price for good quality generic drugs. This use of the international market, of course, requires a certain level of sophisticated strategy and bargaining ability on the part of national governments, which UNICEF and the WHO seek to upgrade through technical support. The approach represents a form of selective national linkage with the international market, perhaps with broader implications for development strategy. Industry generally encourages this effort to increase the efficiency of national procurement for the public sector through essentially market mechanisms, so long as a private market is allowed to operate as well. Indeed, some tenders have been filled by generic products manufactured by research-based multinationals or their subsidiaries. And some firms have actively pursued this emerging market for essential drugs, reflecting different corporate strategies to meet the changing global market [45].

The role of the market in the domestic economy, however, is more controversial. The WHO is ambiguous about whether its list or its concept should apply to the market while the industry is adamant that it should not. Efforts to apply a list to the market and thereby exclude drugs from commerce and import, rather than to apply a list to the public health sector and thereby promote the use of certain drugs, have apparently met with mixed success in achieving the objectives. The Bangladesh Drug (Control) Ordinance of 1982, for example, has generated substantial controversy by banning about 1700 drugs from production or sale and by taking measures to promote local manufacture and restrict sales by foreign firms [46]. A PMA-supported study of the Bangladesh policy reported vast problems of implementation, scarcity and smuggling [47]. On the other hand, a government perspective presented significant progress in reducing imports and prices while increasing national self-reliance [48].

On a more limited scope, the WHO seems reluctant to consider uses of the market that could promote the distribution of essential drugs to peripheral geographic areas. For example, social marketing techniques (the use of marketing to influence the acceptability of social ideas) might be effective in promoting a small number of essential drugs through the private distribution system [49]. Or using economic incentives, a government might provide subsidies to certain private pharmacies, to
assure that essential drugs are available in the periphery. The drug policy of Norway (one that the Action Program likes to cite as a successful case of a restricted national formulary in a rich country) uses such subsidies to assure availability of drugs at restricted cost in remote areas [50,51]. This approach might be an area of convergence of interests for the WHO, the industry and national governments.

Local production

The issue of local production provides a third area for conflict between the WHO and the industry in pharmaceutical policy. The question of 'make or buy?' represents a fundamental decision in any business organization, to meet the objectives of procurement: 'to obtain the right materials, at the right time, in proper quantities, and at as little cost as possible' [52]. This statement is remarkably similar to the objectives of the WHO's essential drugs concept, reflecting broad similarities between private and public decisions over whether to make or buy. Yet conflict has commonly arisen among the WHO, the industry, and national governments on make-or-buy questions for pharmaceuticals, indicating different interests and perspectives on the issues involved.

Statements in the 1970s on the new international economic order called for local production of all goods possible in the Third World. UNIDO and UNCTAD, for example, argued that poor countries should develop a local pharmaceutical industry to reduce drug costs, cut foreign exchange expenditures, and provide employment opportunities at home, as part of a broader strategy of import substitution and economic development [53]. But the objectives of local production can conflict with the objectives of essential drugs, especially if local production costs more than imported goods (due to economies of scale, high capital start-up costs, inadequate trained staff, poor quality controls, etc.). In this way, domestic economic policy can conflict with domestic health policy. Moreover, if a government seeks to promote local production through subsidies and restrict imports through taxes and duties, conflicts can arise between domestic and foreign producers.

Potentials for cooperation in this area also exist. A government might aim to promote different levels of production – from packaging and formulation, to production of simple products, to complex manufacturing – depending on local resources and manpower available. Foreign corporations might cooperate in local production, depending on market access for other products, the size of the market (with potential economies of scale), as well as other factors that affect profitability. The industry recognizes the 'enormous potential for market increase' in the Third World, a majority of the world population which consumes about 15% of the global drug market [54]. The industry is also aware, therefore, of the need to promote economic development, as a means of long-term market development.

On the make-or-buy question, the WHO now takes a reasonably conservative and explicit position. As one recent document put it: 'It is generally accepted today that the establishment of formulation plants to produce essential drugs at competitive prices requires careful study of technical and economic feasibility' [55]. Broad recognition exists today that the pharmaceutical industry needs economies
of scale to reduce costs per unit produced, and that international competitive bidding is generally cheaper than local production (which often requires importing raw materials). A review of how the WHO reached its current position, with an analysis of successful and problematic case studies, could be quite useful.

Nairobi and beyond

In late November 1985, the WHO convened a Conference of Experts on the Rational Use of Drugs, known as CONRAD, in Nairobi, to bring together specialists from widely different perspectives, including industry, consumer groups, academics, and national policy makers. In the words of the WHO's Director-General, the meeting sought to stress the 'importance of cooperation rather than confrontation' [56]. Overall, however, CONRAD was marked by disagreements, postures, and consensus.

Conflicts of opinion among the participants occurred on various topics, reflecting the divergent views and interests represented at the meeting. The topics of disagreement included the role of a medical needs clause, the idea of a WHO marketing code, and the relation of an essential drugs list to the market. As anticipated, disagreement arose mainly between the industry group and the consumer group, each of which maintained a support organization outside the closed conference. The points of disagreement are not covered here, since they have been briefly described in earlier sections of this paper.

The WHO organized the conference so that most interventions took the form of statements to the chair rather than discussion among experts, resulting in a good deal of posturing among the limited number of participants. This format, not unusual for such international meetings, may not have been the most productive approach for substantive discussion of the issues. But the statements did produce a record of the diverging viewpoints on numerous topics related to the rational use of drugs, as reported by the WHO [57].

Remarkably, the meeting also produced consensus on a number of topics. Dr. Mahler's summary remarks offered something positive for each of the major groups at the meeting, as he covered issues of drug information, national drug regulatory programs, ethical advertising for drugs, the need to assure access to drugs for all individuals, rational prescribing, better training, and a proposal to study ways to contain costs and recover costs. He stressed that the WHO was not an implementing or enforcing agency, not a supranational regulatory agency, but would serve a coordinating and catalytic role. Dr. Mahler reviewed the responsibilities of six groups involved in making drug use more rational, and stated that no contradiction should exist between working for social equity and for an expanding market.

The WHO Action Program on Essential Drugs has now operated for over five years since its establishment in February 1981, and it is a critical time to evaluate its accomplishments, limitations, and future directions. While it is still too early to assess the consequences of essential drugs policies for health status, the WHO has
accomplished major changes at the level of ideas, expressed in policy and management of drugs. This paper raised issues important to the WHO and the pharmaceutical industry, and suggested trends in the actions of both parties. As illustrated by the Nairobi meeting, the potential for increasing cooperation exists, while the likelihood of continued conflict persists. An unavoidable tension may reside in the fundamental objectives of the two sides: the WHO’s mandate to improve health conditions, especially in poor countries, and to stress equity and health; and the industry’s mandate to use health resources as a means to achieve organizational growth and profit. The concept of essential drugs provides an area for overlap between these objectives, especially when the concept is used to stress principles of managerial efficiency in the public sector, which can directly and indirectly benefit the private sector.

Ultimately, pharmaceutical policy is predominantly domestic policy, and therefore the prerogative and responsibility of the government to decide and implement. As described in this paper, however, national policy takes shape in an international environment of unequal distribution of economic and political power, and in a national context of competing demands for scarce resources. The industry, the WHO, and governments must deal with the complex relationships between the public and private sectors in pharmaceutical policy, if they are to work effectively toward the objectives of the essential drugs concept.

The experiences with essential drugs illustrate two broader themes. First, a new pattern has emerged for setting the agenda of international health issues, with open participation in international organizations by industry associations and by consumer groups. The pattern is still evolving, but it represents a significant change and poses a complex challenge to the leadership of international agencies. The more open participation also raises questions about whose interests are being represented and whose interests should be represented at agencies such as the WHO.

Second, changes in the international agenda-setting process may influence national policy but will still leave difficult problems of implementation at the country level. The evaluation of the new agenda’s impact on policy, services, and health conditions poses complex and controversial problems. Who decides whether the new policies are helping? According to which criteria? How can an evaluation obtain legitimacy from the various parties involved, so that the objectives of improving the health of poor people in poor countries can in fact be achieved?

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