
Pharmaceutical Policy in Independent Mozambique: the first years

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In most countries with market economies, the flow of pharmaceuticals is dominated by the major drug producers and their agents, whose main interest is profit [Lazio 1977; Muller 1982]. With few exceptions, the regulatory control of health authorities is very weak and, in Third World countries, is often almost non-existent. Doctors are under strong pressure from the industry's promotional activities, and they are bombarded by printed advertising material and visits by drug-company representatives [Galice 1974; Yudkin 1978; Medawar 1979; Brudon 1981; Melrose 1982]; in some Third World countries, representatives are as numerous as one to every three doctors [Silverman 1976].

In this situation, the market is flooded by thousands of pharmaceutical products, many of which are ineffective, unnecessary, or even harmful [de Brabant 1979; Wolfe et al 1981; November 1981; Health Action International 1982]. The actual number of useful drug substances does not exceed a few hundred, and this unnecessary profusion of pharmaceuticals is the result of:

- brand-named drug combinations, which in most cases have no therapeutic advantage (they may even be quite irrational) and are more expensive than the individual drugs marketed separately;
- imitative drugs, which result from minor changes to known compounds and which generally have no substantial advantages over the existing drugs, being introduced only to bypass patent protection;
- drugs of unproven efficacy, marketed singly or in combination;
- multiplicity of brands for the same drug substance;
- fancy formulations of any of the above, with unproven advantages and usually exorbitant prices.

[UNCTAD 1980; Yudkin 1980; Marzagão and Segall 1983]

In pre-independent Mozambique, these were among the many problems that characterised the pharmaceutical sector.

Pharmaceutical Chaos during the Colonial Period

Before independence in June 1975, Mozambique's pharmaceutical market was flooded by some 13,000 products, which were promoted by drug-company representatives, of whom there were about one for every five doctors. Promotion was targeted especially on the 500 or so doctors then working in the country, most of them in private practice at least part time. As in other Third World countries, the doctors and medical facilities were greatly concentrated in the urban areas. The settler population — a colonial bourgeoisie, most of whom also lived in the towns — constituted the main drug market. As a well-to-do class they could afford to pay for pharmaceuticals, and some of them were also covered by health insurance schemes which included drug costs. The distribution of retail pharmacies was also an indication of the discriminatory nature of medical services. Of the 80 pharmacies then existing in the country, 45 were in the capital city and all the others were in the towns where the settlers lived. The mass of the population had little access to medical and pharmacy facilities, and especially in the rural areas, the supply and marketing of drugs was very irregular, poorly planned and uncontrolled.

There was no pharmaceutical industry in the country and all drugs were imported in the finished state. The six main supplying countries were Portugal, Switzerland, West Germany, South Africa, France and the United Kingdom. The manufacturers included the major pharmaceutical transnational corporations (TNCs), and some drugs were imported as virtual monopolies of certain firms. Over-invoicing of drug imports was a common practice, which created very high prices and drained the country's scarce foreign exchange. During the last few years of the colonial period, all local subsidiaries of the TNCs showed financial deficits, which were the result of transfer-pricing manoeuvres to channel hidden profits to the parent companies abroad.

In 1974, the last colonial year, the government drug budget was about US \$1 mn for a population of some

9 mn, an average expenditure of only US\$0.11 per person.¹ The government had little bargaining power in relation to the TNCs for reducing the cost of drugs, since it did not have a central procurement agency; indeed, it had almost no regulatory role in the import, marketing and use of pharmaceuticals. Importation was in the hands of private agencies representing various manufacturers or specific TNCs. Import licences were required as a formality, but there was no effective import control. (The only drug ever refused admission to the market was thalidomide.) There was in fact a financial incentive for importers and retailers to deal in expensive products, since their mark-up was calculated as a fixed percentage of the price.

Medicines were sold to the public with little control, and even drugs theoretically requiring a prescription could be obtained easily over the counter in a retail pharmacy or, in the rural areas, even in a general store. In the absence of proper medical care, especially for the mass of poor people, a great deal of uninformed self-medication occurred, as well as over-the-counter medication by pharmacists or even by pharmacists' assistants (who were in most cases very poorly qualified). Only drugs of addiction were controlled.

The lack of pharmaceutical regulation also allowed the occurrence of promotional malpractices, which were particularly common for the more expensive products. As in many other Third World countries [Medawar 1979, 1980a,b; Brudon 1981; Medawar and Freese 1982; Muller 1982; Silverman et al 1982], side-effects, contraindications and warnings were often minimised or omitted, while the range of indications was frequently exaggerated.

A Health Care Revolution

One month after independence, in the context of far-reaching political, social and economic changes, the health care sector was nationalised and private medicine was abolished. In 1977 a comprehensive and integrated national health service (NHS) was set up. Preventive care and inpatient treatment became free of charge. Only ambulatory curative consultations were subject to the payment of a token registration fee, which was intended to discourage people from seeking attention when they did not really need it. Even for outpatient treatment, basic drugs for treating the most common problems were free. Families earning less than the equivalent of US\$125 per month (which applied to more than 90 per cent of the population) had to pay only 5 per cent of the cost of other drugs available through the health service.

¹ This is according to the official colonial figures. Post-independence census data indicate that the population in 1974 must have been greater than the colonial estimate, so the *per capita* drug expenditure was actually less.

Some key features of a new health policy were defined [FRELIMO 1977; Ministério da Saúde 1978a], with two major characteristics. First, priority was given to prevention and, within this strategy, primary prevention was given priority over secondary and 'tertiary' prevention. Secondly, the primary health care approach was adopted — before the Alma Ata conference² — as national policy. This included the following priority programme components: environmental hygiene, health and nutrition education, quality control of water and food, mother and child health (including family planning), school health, occupational health, oral health, and mental health. Emphasis was placed on extending health care coverage in the rural areas by means of newly-defined health teams, which included medical assistants, rural medical aides and preventive health cadres. Community participation in health promotion was fundamental to the approach [Martins et al 1977] and was organised utilising the new social structures that were being created; in the rural areas these included above all the 'communal villages' where peasants, living and working together, selected some of their members for training as village health workers.

The Main Principles of the New Pharmaceutical Policy

In setting up a new pharmaceutical policy, five main principles appeared paramount:

- Pharmaceutical policy should be part of the overall health policy aimed at serving the mass of the population without discrimination.
- The new NHS, as the sole authority in the health sector, should develop adequate structures for the management of pharmaceuticals, including their regulation, procurement, production, promotion, distribution, and utilisation.
- The new pharmaceutical regulatory system should end the flow of ineffective, harmful and unnecessary products onto the market, and so create the conditions for the proper utilisation of useful drugs, thereby improving the quality of medical practice in the interest of public health.
- The scarce resources available for pharmaceuticals should be used economically, and the drug management mechanisms should be capable of obtaining as many appropriate drugs as possible for a given amount of money, so that the people could have the right product available at the right place at the right time.
- The new pharmaceutical policy should reinforce national economic independence.

² The WHO/UNICEF international conference on primary health care held at Alma Ata, USSR, in September 1978.

Early Steps and Institutional Changes

Guided by these principles, several major measures were taken immediately after independence. First, within a reorganised Ministry of Health, a new Pharmaceutical Service was created in August 1975 directly subordinate to the Minister of Health. Then in September 1975, a Therapeutics and Pharmaceuticals Expert Committee (CTTF)³ was created with technical advisory functions. Its membership was drawn from clinicians, pharmacologists and pharmacists, and it included officials of the Ministry's Pharmaceutical Service. The tasks of this committee were to:

- define the pharmaceutical products which may circulate in the country;
- revise and update the national formulary for health service use;
- advise on product selection in the procurement of pharmaceuticals;
- disseminate scientific information on the use of drugs and the choice of therapeutic agents;
- advise on all aspects of pharmaceutical policy.

In the same month a Central Agency for Medicines and Medical Supplies was established under the authority of the Pharmaceutical Service to centralise the procurement and distribution of all drugs and supplies in the NHS. Construction of new premises was started in the city of Beira, a port situated centrally in the country. (In subsequent years, some provincial and district medical stores were created, and strong efforts were made to develop their functional capacity and their coordination with the central agency.)

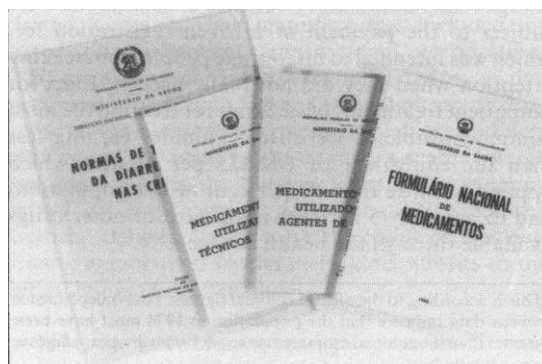
A first reduction in the number of pharmaceutical products on the market was effected by means of an unofficial 'gentlemen's agreement' between the Ministry of Health and the private drug agencies and representatives. A new law was passed in October 1975 obliging all importers and distributors to re-register the pharmaceutical products that they wanted on the market. For each product registered they were obliged to pay a fee, which was calculated in such a way as to discourage the registration of products with low demand. The drug firms were informed that the Ministry of Health wished to see as few products as possible on the market, but the law did not oblige the firms to reduce the number of preparations; they could register whatever drugs they wanted. Any compliance with the Ministry's wishes would be entirely voluntary — an arrangement that the companies very much wanted to preserve. It turned out that the firms reduced the number of products on the market from

about 13,000 to some 2,600⁴ (from the commercial standpoint this in fact rationalised the companies' operations and allowed them to concentrate their efforts on a smaller number of better-selling items). This important result was thus achieved simply — without conflict with the pharmaceutical industry — within a few months of independence, before the expert CTTF had even got started. The system also allowed the revision of the disorganised colonial system of drug registration and the updating of product records, and it earned the government about US \$70,000 in registration fees. When attempting to achieve radical transformation, it is important to know that progress takes place in stages and to judge how to set the pace of change.

A New National Formulary

As indicated earlier, the major thrust of the pharmaceutical policy was to improve the quality of medical practice. To attain that goal it was essential to reduce the number of available drugs by eliminating inappropriate products and to impede promotional misinformation. This also had its economic aspect, above all to prevent the waste of scarce resources on unnecessarily expensive branded preparations.

Attention to the quality of medical care was an urgent necessity in the early post-independence years. There had been a mass exodus of medical personnel, and at independence the country was left with just 85 doctors, of whom only 32 were Mozambicans. It was foreseen that most of the remaining Portuguese practitioners would also leave in subsequent years (as in fact transpired), and that doctors would come from very many other countries to fill the breach. In fact by December 1979 there was a total of 317 medical practitioners from more than 40 countries (by then 101 of the doctors were nationals). The question was: how would doctors from all these different countries — used to drugs designated by the particular trade names of their homelands — be able to relate to each other



³ Comissão Técnica de Terapêutica e Farmácia.

⁴ The number of products on the market was reduced further in 1980 to about 1,200.

and to the pharmaceutical situation in Mozambique? How would it be possible to achieve some uniformity in prescribing out of this medical anarchy?

It was clear already in 1975 that a new national formulary (NF) should be compiled as soon as possible for use in the developing health service. This formulary would:

- include all products necessary for the prevention, diagnosis and treatment of all diseases found in the country, and include also second- and third-line drugs, since the aim was (and should be seen to be) medicine of the highest quality;⁵
- list drugs by international nonproprietary names and abolish trade names in the health service, including for prescription;⁶
- be used as the basis for all aspects of drug management.

Guidelines for product selection were drawn up. They included the criteria of efficacy and safety (the benefit/risk ratio), cost and quality. In making a selection these criteria should be weighed up one against the other, and a balanced judgement made. Drug combinations were to be chosen only on those few occasions when there was a recognised therapeutic advantage, and fancy formulations of unproven value, especially when expensive, were to be excluded.

With these terms of reference, the CTF started work and in December 1976 — about 10 months before the WHO expert committee on the selection of essential drugs presented its first report [WHO 1977] — the NF was approved. It was published in January of the following year [Ministério da Saúde 1977a], and at the same time prescription by generic name became compulsory in the health service. The NF listed 640 items, comprising 430 therapeutic substances in different dosage forms and strength, 20 diagnostic agents and 14 dressings. The NF is subject to revisions and a second version has been published [Ministério da Saúde 1980]. It contains only 502 items, comprising 343 therapeutic substances in different dosage forms and strengths, 19 diagnostic agents and 12 dressings.

Limited Formularies and Lists

In a country like Mozambique, where not only doctors but also lesser-trained health workers prescribe medicines, it is extremely important to define which

⁵ This concept of an all-embracing national formulary differs from the restricted sense in which 'essential drugs lists' are sometimes understood. For example, though drugs with serious side-effects would not be included when less toxic alternatives existed, they would be included if they were the only weapons against certain diseases, including rare ones.

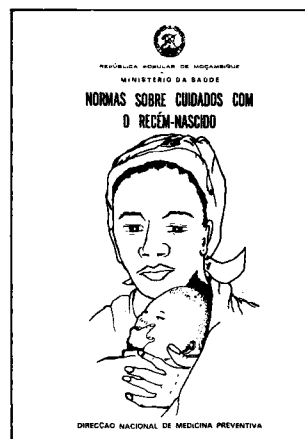
⁶ As a compromise with public demand, pharmaceuticals for sale over the counter in retail pharmacies still include some popular brand-name preparations, which are mostly placebos.

drugs the latter cadres may use. Therefore, limited formularies for medical assistants, medical aides and other categories of health workers have been published and updated [Ministério da Saúde 1977b, 1981a,b].

Another measure to help make basic pharmaceuticals available to the mass of the rural population was the definition by the Ministry of Health in 1977 of those drugs which could be sold without prescription by general stores in areas where there were no retail pharmacies.⁷ The updated list of 1981 contained 56 generic products.

Drug Information, Therapeutic Guidelines and Compliance in Prescribing

Although the establishment of an effective NF is the most important measure for rationalising prescribing practices, it is not a panacea for solving all therapeutic 'ills'. Drugs can still be used incorrectly. For example, items included in the NF for the treatment of rare diseases or for highly specific indications can be misused for other purposes, and products included as second- or third-line drugs can be prescribed as first-line therapy, with negative medical and economic consequences. Thus one of the main tasks became to educate doctors, other health care personnel (including pharmacists and pharmacy assistants) and the general public, on the purposes and use of the NF, and to provide information on rational therapeutic policies.



⁷ This liberalisation of the sale of non-prescription drugs was accompanied by a more strict control on the sale of prescription drugs.

The few medical representatives still remaining in the country at that time continued to pressurise doctors and other health workers to prescribe drugs that were not in the NF or to prescribe by trade name, under the pretext that only the branded products of their companies were of good quality. However, the adoption of the NF and of compulsory generic-name prescribing, as well as other measures to control pharmaceutical imports, soon provoked the virtual disappearance of the pharmaceutical industry's promotional activities, as these became no longer worth while economically.

The main task was thus to replace the previous system of commercial misinformation with one that would show prescribers that better quality medicine would result from the acceptance of discipline in prophylactic, diagnostic and therapeutic practice. Especially during 1977 and 1978, soon after the publication of the NF, a great deal of effort was put into the production and distribution of printed material, and into other educational activities, to provide unbiased, scientifically-sound, pharmacological and therapeutic information.

In the months following the appearance of the NF, the first official strategies for the control of four major endemic diseases (malaria, leprosy, tuberculosis and sleeping sickness) were published, and this was followed by later publications on the control and management of schistosomiasis, intestinal parasitosis, and diarrhoea [Ministério da Saúde 1977c,d,e, 1978b, 1979]. These strategies were concluded only after wide professional soundings and much discussion. While they included the setting of norms for the prevention, diagnosis and treatment of individual cases, their main approach was prevention and control through public health measures.

At the same time, suggested and 'compulsory' therapeutic schemes were published for use in routine clinical situations. The 'compulsory' character of some of the more important norms was actually theoretical, since it was impossible to monitor their implementation, but this official-sounding designation was intended to add to their persuasiveness. Information was also provided on the relative costs of drugs — virtually unknown to most health workers — and advice was given on how to prescribe cost-effectively [CTTF 1978; Barker et al 1980].

In 1978, it was decided that much of this pharmaceutical information should be compiled in a single *Therapeutic Guide*. This would be in two volumes, the first giving information on each of the products in the NF (pharmacological properties, indications, contraindications, dosage, side-effects, warnings, etc), and the second giving therapeutic



guidelines for managing the most frequent clinical situations in the country. After laborious work by the CTTF, the *Guide* was finally published [Ministério da Saúde 1981c], and it represents a major step towards establishing scientific and rational therapeutic practice in Mozambique.

Informational material was not only published, it was also widely distributed, explained and discussed. Practical compliance with the NF and the therapeutic schemes has naturally presented problems, especially in the early period, but it has improved with time, actually more rapidly than was expected. The few Mozambican doctors trained during the colonial period were committed to the NF — in the compiling of which many had participated — and new graduates were already educated in the NF system. Some expatriate doctors had difficulties in adjustment in the beginning, but many came to find that the simplified prescribing rules were a welcome relief from the pharmaceutical anarchy in their own countries. They realised that the rules, which included among other things a reduction in the use of placebos, actually improved the quality of their medical practice.

In 1981, four years after the publication of the NF, an assessment of health worker compliance was made [Patel et al 1981]. A study of over 4,000 prescriptions from several health units of different types in Maputo City and province showed that 83 per cent of all prescriptions were in accordance with NF prescribing rules and only 5 per cent employed trade names. Compliance was lowest in the casualty department of Maputo Central Hospital, where there are health workers from various countries and where there is little direct supervision. The average number of drugs per prescription was 2.3, which compares very favourably with reports from other countries [Barnett et al 1980; Maitai and Watkins 1980; Victora et al 1982] and with the previous practice of polypharmacy⁸ in Mozambique.

⁸ The unnecessary prescription of many drugs.

Centralisation of Pharmaceutical Procurement

It was clear from the beginning that substantial savings in foreign exchange could be made by reorganising the drug supply system. As stated earlier, procurement for the NHS had already been centralised in a single agency since 1975, but importation remained exclusively in the hands of the private firms, which were also supplying the retail sector. In 1976, the Ministry of Health began to put out its drug orders for competitive tender on the basis of generic names. The 27 local private importers participated in the tender system, but at the same time the government was also beginning to acquire drugs directly through international tenders. In order to expand this latter activity, a state corporation (MEDIMOC EE) for the import and export of pharmaceuticals, and medical supplies and equipment, was created in 1977 by the merging of five private import companies which had been abandoned by their foreign owners. One of the tasks of the new state enterprise was to increase competition in the tender system by inviting worldwide bids, including bids from producers in socialist countries and in Third World countries like India, Brazil and Cuba.

MEDIMOC submitted its first tenders to the Ministry of Health in 1978, competing with the remaining private importers. By the end of that year it was already handling about 60 per cent by value of the NHS drug tenders [Marzagão and Segall 1983] and had a fair management capability, including in market intelligence. An investigation of the private importers' accounts showed that the illegal export of foreign exchange through over-invoicing and other means was still a widespread occurrence. The trading licences of the companies were therefore withdrawn and MEDIMOC was given a monopoly of pharmaceutical imports, for both the NHS and the retail pharmacy sector.

The expert CTF advises MEDIMOC on product selection. Since the introduction of competitive international tendering, the sources of imported drugs have diversified greatly and average prices have declined despite inflationary price increases in the international pharmaceutical market. A comprehensive study of drug imports has demonstrated that in 1979 the drug tender system gave rise to savings of the order of 41 per cent [Pereira and Velasquez in press].

Since 1980, the purchase of pharmaceuticals in small package units for the retail trade has also been effected through international tender. Average prices for these items have also decreased, and the price reductions have been passed on automatically to the consumer. This is an important area where savings can be made. In 1979, the acquisition of these small packages represented about one-fifth of the volume of

pharmaceuticals imported but about a half of the country's drug bill in foreign exchange [Pereira and Velasquez in press].

The Retail Pharmacy Sector

The owners and/or managing pharmacists of many retail pharmacies left Mozambique around the time of independence. Some shops closed and others were left without proper supervision. Although it was not the general policy of the government to take over retail commerce, it had to intervene in this situation. Closure of some of the pharmacies in central urban areas was not such a problem, but closure of the only pharmacy outlets in underserved areas created great hardship. There was also a need to reorganise the whole retail network, since the peri-urban and rural areas were virtually deprived of a pharmacy service.

In 1977 a state corporation (FARMAC EE) concerned with the retail sale of pharmaceuticals and medical supplies was set up. It was to be responsible for supervising and developing the retail network as a whole, taking over and reopening abandoned pharmacies, and representing the interests of the state in those pharmacies in which it acquired a supporting share: Private commercial interests with the legally-required technical capacity to manage pharmacies were encouraged to continue and expand their businesses.

Quality Control

At independence Mozambique did not have a quality control laboratory, and the need to establish mechanisms to assure the quality of imported drugs was realised from the beginning. This was a particular consideration when cheaper generic products were being purchased, since the Ministry of Health, the medical professionals, and the general public alike, wished to be certain of their quality.

In 1979, the country began to participate in the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, and a clause on certification of quality was included in the tender rules. Cooperating governments and quality control laboratories abroad have also helped (free of charge) with the analysis of samples of drugs about which there was suspicion. Quality control tests have now started in Mozambique, at first using the existing facilities in the pharmacology laboratory of the medical school, and more recently in the country's new Water and Food Hygiene Laboratory of the Ministry of Health. At the present time, randomly-selected samples of imported drugs are checked regularly either in Mozambique or abroad, and the quality of products is maintained. Plans are under way to establish a national quality control laboratory.

Local Production

The Third Congress of FRELIMO set the objective of creating a national pharmaceutical industry [FRELIMO 1977]. It was planned to start with a product formulation plant and subsequently to progress towards more complex stages of drug production. Careful preparatory studies have been made and, although implementation has not been as rapid as was first hoped, the development process is under way. A small plant for the production and packaging of oral rehydration salts in sufficient volume to cover the needs of the country has just started operation.

Increasing Volume and Improved Distribution of Pharmaceuticals

Table 1 shows the greatly increased drug expenditure by the government over the years since independence. This increase is even more significant in volume terms, given the general decrease in drug import prices achieved by the new central procurement system.

Table 1

Government pharmaceutical budget*

year	total US \$ (mn)	per head US \$	per cent of health budget
1974	1.0	0.11	8.1
1976	3.3	0.30	12.1
1978	7.6	0.65	17.6
1980	8.9	0.71	16.0
1982	12.5	0.96	20.1

* Calculations made using data from several official sources.

Parallel with the rising volume of pharmaceuticals has been an attempt to improve their distribution. Allocations to provinces are now made on the combined criteria of population and the availability and level of health care facilities. Improved drug distribution is illustrated by the fact that the proportion of government pharmaceutical expenditure allocated to Maputo Central Hospital, with some 12 per cent of the country's hospital beds, has fallen from about 50 per cent during the colonial period to about 10 per cent since 1978. However, a more rational, equitable and efficient distribution system is still needed.

Problems, Achievements and Conclusions

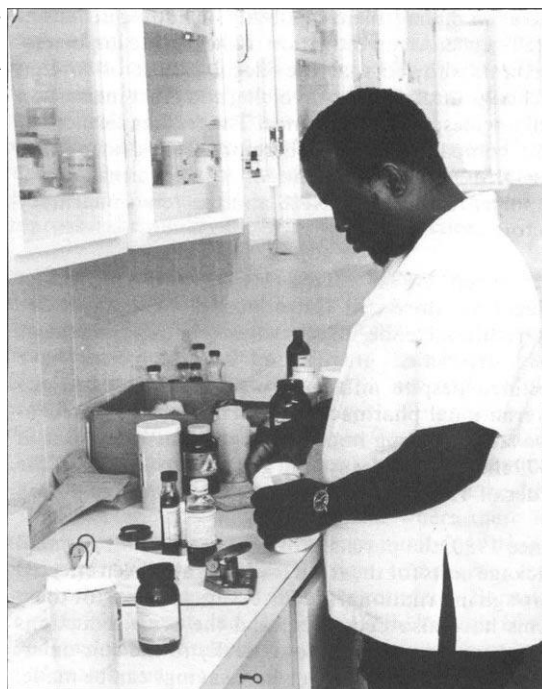
Many problems still exist. Although there have been large increases in the pharmaceutical budget and reductions in the prices of drug imports, shortage of foreign exchange (as in many Third World countries)

is a persisting obstacle to making essential drugs available to the whole population, especially in the rural areas. Despite improvements in drug management difficulties still continue, particularly in relation to stock handling at different levels, transport, storage and distribution; drugs intended for the provinces and the rural areas may arrive only after considerable delays. As mentioned, pharmaceutical production is much behind schedule. Also, despite all the educational efforts already made, the flow of therapeutic information is still below the level it should be; and drug legislation is not yet complete.

However, very important achievements have been attained in the few years since independence. In Mozambique the pharmaceutical sector is rid of ineffective, unnecessary and harmful drugs. Prescribers are no longer faced with a confusing plethora of products, which complicates prescribing decisions. They receive unbiased and scientifically-sound therapeutic information about defined essential drugs, and prescribing patterns have correspondingly improved in quality.

The most important factors accounting for these achievements have been: compulsory generic-name prescribing; the publication of the *National Formulary*, the *Therapeutic Guide*, and other norms and suggestions for the prevention, control, diagnosis and

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In Mozambique drugs are now more likely to be available at peripheral health units than ever before.

treatment of disease; and the creation of a state system of procurement and distribution. Because medicine has been nationalised and private practice abolished, these measures have had nationwide application, with the positive side-effect that drug-company representatives and promotional malpractices have disappeared spontaneously.

Although the main reason for the pharmaceutical policies was to improve the quality of prescribing, their adoption has also resulted in important economic gains. Drug prices have decreased, and the national economy has been defended against the illegal export of foreign exchange through company over-invoicing. Health workers have been educated, not only to prescribe better, but also more economically: and the two are not incompatible. In Mozambique drugs are now more likely to be available at health posts and rural health units than ever before [Hanlon 1983], and this availability is better than in many developing countries. It is the result of the savings made in drug imports, the increase in the government's pharmaceutical budget, and a more equitable system of distribution.

It is hoped that Mozambique's experience in the pharmaceutical sector may be of interest to other countries, both developing and developed.

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