Outside Europe

Pharmaceuticals Management in Ceylon

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As in the case of many developing countries Ceylon has suffered an adverse balance of trade for some years, and the deficits have been covered by hard currency loans. By 1970 the adverse trade balance plus the servicing of foreign debts had amounted to about £100 million. For a small island that depends on a "ship-to-mouth existence" this was a foreign exchange crisis of serious proportions, and the Government was compelled to impose severe import restrictions, especially from hard currency areas; it also attempted to stimulate exports and to expand bilateral trade agreements with the countries of Eastern Europe and China. When the time came for applying these procedures to pharmaceuticals the Prime Minister of Ceylon assigned this task to us.

We were asked to inquire into the present practices of import, manufacture, and distribution of drugs and to recommend steps to ensure that drugs are available to those who need them in adequate quantities and at reasonable prices. The task was to overcome some prevailing drug shortages by importing more but without increasing the foreign exchange allocation for drug imports. The report¹ was presented to the Prime Minister in March 1971, and at the time of writing it was being implemented. It contains proposals relevant to the practice of medicine which are likely to be of interest to countries wishing to rationalize and thus economize on drug usage.

Cost and Sources of Drugs

The practice of modern medicine in Ceylon is divided into a State sector, which is administered by the Department of Health, and a private sector, where general practitioners charge fees for service. The general, district, and rural hospitals are State-run institutions, and drugs for this sector are imported in bulk at competitive prices by the Civil Medical Stores after calling for world-wide tenders. The private sector runs a few small hospitals but is predominantly an outpatient dispensary practice. Drugs for this sector are supplied by the traditional pharmaceutical manufacturers in Britain, Western Europe, and North America through their agents in Ceylon, who operate very much as they do in Britain—through pharmaceutical representatives, promotional literature, distribution of samples, advertising, and other practices familiar to medical practitioners in Britain.

The report compares the quantities and costs of drugs imported by the private and State sectors on the basis of data supplied by them. It is shown that if the same or equivalent drugs now imported by the private sector are imported at Civil

Medical Stores prices the private sector drugs could be obtained at one-third their present cost. The remaining two-thirds of the money could be used to purchase more drugs and thus make available drugs in adequate quantities and at reasonable prices without increasing the present foreign exchange allocations. The report gives three pre-requisites for obtaining drugs (now imported by the private sector) at prices comparable to Civil Medical Stores prices: (1) a reduction in the number of pharmaceutical preparations imported and used in the private sector, (2) an amendment to the patent laws governing drugs, and (3) the importation of drugs in bulk quantities and in large packs.

An example to illustrate this is the five varieties of tetracyclines imported by the private sector in 1970. It imported 13 million capsules for £100,000, which is about £8 per 1,000 capsules. The Civil Medical Stores price of tetracycline is £3.50 per 1,000 capsules, so that if the Civil Medical Stores had imported 13 million capsules it would have cost £45,000. Small quantities of drugs in small packs obtained from several sources are more costly than bulk imports of one tetracycline from one source. In practice it would mean that oxytetracycline, chlortetracycline, doxycycline, demethylchlortetracycline, and methacycline would be replaced by tetracycline, and the evidence is that this would suffice when a tetracycline is indicated.

The annual cost of all antimicrobials (penicillins, chloramphenicol, tetracyclines, streptomycin, etc.) imported by the private sector is £250,000, and the same quantity could be obtained by the State for £120,000.

The private sector imports about 3,000 pharmaceutical preparations, all of which are administered by medical practitioners in the private sector. The Department of Health imports and uses only 800 preparations in Government institutions, with no detriment to patient care. For example, the private sector imports five kinds of tetracycline from 37 sources, and the same therapeutic effects could be obtained by the use of one tetracycline imported in bulk from one source. The private sector imports and uses 10 different kinds of thiazide diuretics, whereas two thiazides would suffice for all therapeutic situations. Eighteen kinds of antihistamines used in the private sector could easily be reduced to three.

Medical practitioners are unlikely to become enthusiastic about proposals that would interfere with the prescribing of their accustomed brand of thiazide or antihistamine or antimicrobial. This raises the question of priorities in prescribing practices. If the patient's interest is paramount the medical profession would have to select the drugs of choice on the basis of available evidence and restrict prescribing to them. The selection of an approved list of drugs is no easy task. British persuasions towards better prescribing take place through such channels as the *British National Formulary*, *Prescribers' Journal*, *Drug and Therapeutics Bulletin*, *British Medical Journal* ("Today's Drugs," and "Therapeutic Conferences"), the *Practitioner*, and other journals. In addition the Committee on the Safety of Drugs issues warnings wherever appropriate.

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Reduced List of Preparation

The situation in Ceylon is complicated by foreign exchange difficulties and by the fact that all pharmaceuticals have to be imported, with several months intervening between indenting for drugs and their receipt. By 1960 the profusion of drugs had led to a confused situation in the State medical services, which then requested the University Department of Pharmacology to advise on rationalizing drug usage. As a result a hospital formulary was produced, and only the drugs in the formulary could be used in State hospitals. In effect this became an approved list of drugs for the State institutions, and the approval was made by a formulary committee whose membership included clinical consultants, general practitioners, pharmacologists, and pharmacists.

The formulary committee met at monthly intervals and considered applications for new drugs and deletion of obsolete ones, so that the approved list was amended regularly. There was vigorous debate within the formulary committee, which had the salutary effect of driving members to scientific evidence for decision-making on the efficacy and safety of drugs. For example, the committee succeeded in eliminating phenacetin in favour of paracetamol when the high probability of phenacetin nephropathy became evident; eliminating amidopyrine on account of serious blood dyscrasias; eliminating phenacetin and caffeine from preparations of aspirin, phenacetin, and caffeine; reducing the number of sulphonamides to sulphadimidine, sulphadiazine, and phthalylsulphathiazole; eliminating irrational combinations of drugs; and reducing the varieties of antihistamines, barbiturates, and thiazides. The evidence for these decisions came largely from British publications.

The decisions of the formulary committee are published with reviews on the drug treatment of disease in *Formulary Notes*, which resembles *Prescribers' Journal*. This is the way in which the State institutions have come to use only 800 pharmaceutical preparations. The new task is to persuade the private sector to adopt the procedures and practices of the State sector, with the formulary committee deciding on an approved list of drugs for the country as a whole.

Since the formulary committee invites criticism on its decisions it is necessary to provide adequate information to medical practitioners in the private sector as well. The report states that the departments of pharmacology are preparing information leaflets on the reasons for reducing the number of preparations. Each leaflet will contain a short account of the drugs and many references to publications, so that private medical practitioners can become up to date with information on drugs and be persuaded to accept the reduced list of drugs approved by the formulary committee.

Leaflets are also being prepared for the general public giving information on "over-the-counter" drugs. A good example is the use of the aspirin-type of analgesic drugs. The current consumption of this type of drug is 130 million tablets annually, of which 50 million are used in Government hospitals and dispensaries and 80 million in the private sector. The 80 million is made up of 60 million tablets of Disprin and 20 million of aspirin, Aspro, buffered aspirin, ASC (aspirin, salicylamide, and caffeine) tablets, and paracetamol. Clinical trials indicate that all these preparations do not have appreciable advantages over aspirin with regard to efficacy and adverse reactions. Furthermore, aspirin tablets are far cheaper and more stable than the other analgesic preparations mentioned. Aspirin tablets, therefore, will be adequate to meet situations where

this type of analgesic treatment is required. For a few people who cannot tolerate aspirin, paracetamol tablets will be required. Manufacture and import could therefore be restricted to aspirin tablets and paracetamol tablets, and the price to the public would be greatly reduced. But this requires re-education of the public with regard to pain relieving tablets.

Nomenclature

The report recommends the use of official names and not trade names for drugs. "Pharmaceutical firms promote the use of trade names for drugs, resulting in considerable confusion. For example, Tetrex, Tetracycline, Tetrarco, Hostacycline, Upcycline, Ambramycin, Probacycline, Achromycin, and H-cycline are all trade names under which the antibiotic tetracycline is available. A patient with a prescription for Achromycin will go from one chemist to another and be told that the drug is out of stock, whereas the chemist would have the same drug under other brand names. One patient had a prescription for pentazocine under one of its trade names, Fortral. Since pentazocine is not sold in Ceylon as Fortral a special user's licence was obtained; the drug was flown in only to find that pentazocine had been available all the while under the trade name of Sosegon, manufactured by the same company which sells it as Fortral in other countries."

The report recommends that drug advertising should cease, because the "proper postgraduate education of doctors is through journals and official publications and not from advertisements and brochures from pharmaceutical firms promoting drugs." The distribution of approved data sheets by manufacturers will, no doubt, be encouraged.

Another recommendation is that the patent laws should be modified because at present these provide for patenting the name of a product (product patent) as well as the process of manufacturing it (process patent). As a result Ceylon has not been able to obtain the benefit of cheaper drugs manufactured by processes different from those used by the original patent holder. The private sector imported tolbutamide from the original patent holder at an average price of £15 per 1,000 tablets (£28,000 for 2 million tablets) whereas the Civil Medical Stores purchased this at 80p per 1,000 tablets from Yugoslavia by ignoring the patent law (£1,800 for 2 million tablets). It is recommended that the law be amended so that only process patents apply and not product patents.

It is expected that these radical proposals would be implemented only if the quality of drugs is guaranteed. Ceylon has already established a quality-testing laboratory for drugs, which at the moment is restricted to chemical testing. This would have to be expanded soon to include microbiological and pharmacological tests as well as tests for the factors which influence the biological availability of drugs.

The proposals in the report for purchasing drugs from the cheapest source will not be welcomed by many pharmaceutical manufacturers. But this is a problem that has confronted even the National Health Service hospitals, which have sometimes purchased from cheaper sources in the face of rising drug costs.

Reference

- Wickremasinghe, S. A., and Bibile, S., *The Management of Pharmaceuticals in Ceylon*. Ceylon, Industrial Development Board, 1971.