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DRUG CONTROL AND DISTRIBUTION IN BANGLADESH
A CASE STUDY

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1 The Director-General acknowledges with appreciation the contribution of this case study by the Government of Bangladesh.
DRUG CONTROL AND DISTRIBUTION IN BANGLADESH

Sources, types and availability of information

1. The main sources of information relating to the rational use of drugs are the Ministry of Health and Population Control, the Directorate-General of Health Services, the Directorate of Drug Administration, the Bangladesh Medical Association, the Bangladesh Dentist Association, and the Chemist and Druggist Association. The Ministry of Health and Population Control is concerned with all types of information that may be required, the Directorate-General of Health Services with the procurement and distribution of the drugs required for Government hospitals and Ghana health complexes.

2. The Bangladesh Chemist and Druggist Samity, the association for retail drug shops, can give information about drugs prescribed by the doctors and the supply position of all types of drugs manufactured in the country or imported from abroad.

3. The drugs used include essential drugs and other newer drugs specially for the bigger medical college hospitals of the country. The Directorate of Drug Administration, under the Drug Act, 1940, the Drug Rules, 1945, and the Drug (Control) Ordinance, 1982, is responsible for the control of the manufacture, sale, and distribution of all type of drugs in the country through a licensing system covering both manufacturers and pharmacies. There are at present some 15 500 licensed retail drug stores in the country. New licences are issued on the recommendation of district drug licensing committees. A drug licence is granted only if the premises proposed for the drug shop are suitable and the sale and stock of medicines can be supervised by a registered pharmacist. There is a system of registration for each product either manufactured in or imported into the country. Two government drug testing laboratories in the country test drugs for safety and efficacy.

4. The standard of private hospitals and clinics is upheld by the Directorate-General of Health Services. These private hospitals and clinics play an important role in the medical care of the people, particularly those living in metropolitan areas. The Bangladesh Medical Association plays a vital role in maintaining the professional standard of doctors. This body sometimes transfers professional information among doctors through its services and symposia. There is another important body called the Bangladesh Medical and Dental Council, responsible for the registration of doctors and dentists. There are eight medical college hospitals which provide medical education side by side with medical care. Apart from these medical colleges, the Institute of Post Graduate Medicine and Research is the highest centre for medical education. There is a diabetic hospital exclusively for the treatment of diabetic patients. The International Centre for Cholera and Diarrhoeal Disease is located in Bangladesh.

Drug control and distribution

5. A company has been set up by the Government to produce essential drugs for the hospitals and health complexes of the country. Another company is under construction for the same purpose. There are 150 essential drugs produced in Bangladesh. The selection of essential drugs is based on the WHO list of essential drugs. The Government encourages all the manufacturers to produce essential drugs. As compared with that for specialized drugs, the process of registration for essential drugs is simplified.
Drug marketing

6. Drug marketing in Bangladesh falls into a number of categories. The pharmaceutical industry distributes its own products, which are either manufactured locally or imported from abroad. Some local companies work as agents on behalf of foreign pharmaceutical firms. Drugs are distributed by the Central Medical Stores to the government hospitals and thana health complexes. This is exclusively a government distribution. Drugs are also distributed by the Social Marketing Department, particularly contraceptives for the family planning programme of the country. Various charitable or missionary hospitals procure drugs either locally or from abroad. Finally, international agencies provide drugs as a gift to be distributed among the people of the country according to need.

Review of national health legislation relating to drug control and distribution

7. The concept of health has undergone tremendous change over the last few decades. Health is no longer regarded as merely the absence of disease but is now considered to be an essential component of physical, mental, and social wellbeing.

8. Bangladesh is committed to ensuring minimum medical care for every citizen with a view to achieving the national objective of Health for all by the year 2000. With the development of medical science and technology as well as of the concept of health, the National Health Service has to assume a progressively expanding role in terms of its content and its links with other sectors.

9. In any country the importance of health legislation as an instrument for providing legal coverage to health activities, including drug control and distribution, can hardly be overemphasized. Appropriate and effective legislation providing adequate coverage for all health activities is necessary for the protection of the people from disease and health hazards, for the promotion of health, and for drug control and distribution. Most of the health laws inherited by Bangladesh, enacted long ago, were inadequate to cope with the demands of the present day.

Legislation on drugs

10. Whereas the major problems of drug regulatory control in developed countries are related to the introduction of new drug entities, their testing in animal and man in clinical trials, the monitoring of adverse reactions, etc., Bangladesh, like most other developing countries, was struggling primarily to ensure for its population the availability of essential drugs in good quality at a reasonable price. The Drug Act, 1940, as amended from time to time, the basic drug law in the country, was enacted to regulate the manufacture, import, export, sale, and distribution of drugs. Control over the import and export of drugs was made the responsibility of the then Central Government, control over manufacture and sale the responsibility of the provincial governments. The same practice continued in Pakistan. By the time Bangladesh emerged as a sovereign republic the situation had changed with the rapid developments in the pharmaceutical and medical sciences; the administrative and legal procedures laid down in the Drug Act, 1940, had become virtually ineffective. After years of litigation in the country, manufacturers of spurious drugs, including injectable ones, often got away scot-free or with a nominal fine. A drug licensed earlier could not be withdrawn unless it could be proved to be harmful or substandard. It was the view of the experts that the Act of 1940 had lost its effective force with the passage of time and was no longer suitable for an independent drug policy in a sovereign country. The people of Bangladesh were denied the benefits of effective drug control and protective
measures in law. The result was that alcoholic, harmful, and substandard products achieved registration and were widely sold through successful advertising methods. This caused immense harm to people in general and the poverty-stricken population in particular. On the other hand, a lot of money accumulated in the hands of manufacturers and traders out of the profits from those products; a phial of gripewater used to cost the manufacturer not more than one taka whereas it used to be sold at 10 to 15. It was estimated that, out of the total expenditure by the people on drugs, nearly one-third was spent on unnecessary and useless ones. Moreover, drug policy did not protect the national interest. There were 177 licensed pharmaceutical manufacturers, but drug production was dominated by eight multinational companies that manufactured about 75% of the products.

11. Homoeopathic, unani, and ayurvedic drugs were exempted from control under the Drug Act. As a consequence, unethical, harmful, and useless products multiplied. There was no control over the price of pharmaceutical raw materials or packing materials, which constituted more than 60% of the trade price. These materials were imported from different sources by different manufacturers at widely varying prices. In conformity with the recommendation of WHO, essential drugs were required to be made readily available at reasonable cost with a view to achieving the national objective of Health for all by the year 2000. The worldwide strategy designed by WHO to achieve that objective is considered to be a rationalization of the manufacture, marketing, and sale of pharmaceutical drugs. A WHO document states: “While drugs alone are not sufficient to provide adequate health care, they do play an important role in protecting, maintaining and restoring the health of the people”.

12. In view of the situation, the present Government, soon after assuming power, convened an expert committee to advise on a new drug policy. The expert committee’s report began: “Recognizing the right of every citizen to enjoy the highest possible level of health care, there is an urgent need to mobilize and make economic and effective use of all available resources for improving the state of health of the people. Drugs, being most essential tools for health care, cannot be treated just as any other commercial product. At present not more than 20% of the population have access to even the most essential drugs for their health care and yet the market is flooded with hundreds of useless or non-essential products”.


14. The Committee recommended that the Drugs Act 1940 should be revised or replaced by new drug legislation incorporating the following provisions:

- a system of registration for all medicinal products including ayurvedic, unani, and homoeopathic medicines
- enforcement of good manufacturing practices
- full control of labelling and advertising
- control of the prices of finished drugs and pharmaceutical raw materials
- prescription control of toxic and habit-forming drugs
- summary trial for offences in special drug courts
- heavy penalties including confiscation of equipment and property for the manufacture and/or sale of spurious and substandard drugs
- departmental adjudication for fines up to Taka 10 000.00
- heavy penalties for possessing or selling drugs stolen from government stores, hospitals, and dispensaries
- regulation of technology transfer and licensing agreements with foreign concerns
- restriction of ownership of retail pharmacies to professional pharmacists
- control of the manufacture and sale of unani, ayurvedic, and homoeopathic drugs
- revision of the patent laws in respect of pharmaceutical substances.

Guidelines for evaluation of drugs

15. The expert committee also drew up guidelines for the evaluation of all registered/licensed drugs and recommended that registration should be granted only on the basis of the guidelines. They are as follows:

16. In general, combination drugs should be accepted only where no alternative single drug is available for the purpose or where the single drug is not cost-effective. Exceptions should be made for oral rehydration salts, certain antimalarials, co-trimoxazole, iron with folic acid for use in pregnancy, combined oral contraceptives (containing up to 35 mcg estrogen), and formulations specified by the licensing authority for multivitamin (B complex) tablets and paediatric drops, hydrocortisone with antibiotic skin preparations, and a haemorrhoid preparation.

17. The combination of an antibiotic with another antibiotic or with corticosteroids or other active substances should be prohibited. Antibiotics harmful to children (e.g. tetracyclines) should not be allowed to be manufactured in liquid form.

18. The combination of analgesics in any form is unacceptable as there is no, or only trivial, therapeutic advantage and such combinations increase toxicity, especially in the case of kidney damage and overdoses. The combination of analgesics with iron, vitamins, or alcohol is irrational and unacceptable.

19. The use of codeine in any combination form is not acceptable, as it carries no advantage and may be subject to abuse.

20. Vitamins should be prepared as single-ingredient products with the exception of the vitamin B complex. Vitamins of the B complex, with the exception of B12, may be combined into one product. B12 should always be produced as a single-ingredient injectable product for use by specialists only. Other members of the B complex may be produced as single-ingredient products (e.g. B1). Vitamins should not be allowed to be combined with non-vitamins, e.g. minerals or glycerophosphates. Vitamins should be in tablet, capsule, and injectable form only. The reason why no liquid forms should be permitted is the wastage of financial resources and the tremendous misuse that has occurred. An exception should be made for paediatric liquid single and multivitamin preparations (without vitamin B12, vitamin D, vitamin E and vitamin K and/or minerals) in bottles up to 15 ml with droppers.
21. No multiple-ingredient cough mixtures, throat lozenges, gripe water, antacids, etc. should be accepted (either locally manufactured or imported), as they offer no therapeutic advantages to outweigh their cost.

22. The sale of tonics, enzyme mixtures/preparations, and so-called restorative products flourishes on consumer ignorance. Most are habit-forming and, with the exception of pancreatin and lactase, are of no therapeutic value. Henceforth local manufacture or importation of such products should be discontinued. However, pancreatin and lactase should be allowed to be manufactured and/or imported as single-ingredient products.

23. Some medicines are being manufactured with only trivial differences in composition from other products but with a similar action. Such duplication confuses both patients and doctors and should not be acceptable in future.

24. Products whose therapeutic value is doubtful, trivial, or absent and products that are judged harmful or subject to misuse should be banned.

25. Prescription medicines and galenical preparations not included in the latest edition of the British Pharmacopoeia, the British Pharmaceutical Codex, or the United States Pharmacopoeia should be prohibited, unless there is enough evidence of need and of efficacy.

26. Certain drugs, having a favourable risk-benefit ratio, in spite of known serious side-effects and the possibility of misuse, should be permitted for restricted use by specialists.

27. Where a drug or a close substitute is produced in the country importation should not be allowed, as a measure of protection for local industry. This condition may be relaxed in some individual cases where local production is insufficient.

28. A basic pharmaceutical raw material that is locally manufactured should also be given protection. The role of multinational enterprises in providing medicines for this country is acknowledged with appreciation. In view of the manufacturing and technical know-how they possess for producing important and innovative drugs for the country, the task of producing antacids and vitamins should be entrusted to national companies, leaving the multinationals free to concentrate their efforts and resources on preparations not so easily produced by smaller national companies. Multinationals should, however, be allowed to produce injectable vitamins as single-ingredient products.

29. No foreign proprietary medicines should be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available/manufactured in Bangladesh, as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

30. No multinational enterprise without its own factory in Bangladesh should be allowed to market its products by manufacturing them in another factory in Bangladesh on a toll basis.

The Drugs (Control) Ordinance, 1982

31. The Drugs (Control) Ordinance, 1982, was promulgated on 12 June 1982, but the Drug Act, 1940, was not repealed. This means that the Ordinance is in addition to
the provisions of the Drug Act, 1940, and the Drug Rules, 1946. The provisions of
the Ordinance may be summarized as follows. Out of a total of about 4000 brands of
registered allopathic drugs, the registration or licence of 1666 brands of locally
manufactured or imported drugs was cancelled. Under the Ordinance 299 brands are
listed in a schedule as harmful. These were destroyed by 12 September 1982. Under
schedule II of the Ordinance 127 brands were to be reformulated by 12 June 1983.

32. The import, manufacture, and sale of 1240 brands listed in schedule III were
prohibited after 12 December 1983. In a subsequent ordinance 71 brands and
ointments listed in this schedule were allowed to be manufactured or sold after the
expiry of the above scheduled time limit if they were registered again. The
ordinance prohibits the manufacture of drugs under licence granted by a foreign
company having no manufacturing plant in Bangladesh, if such drug or its substitute
is produced in Bangladesh. However, manufacture of such products under existing
licensing agreements continues till the expiry or termination of the period or
validity of such agreements.

33. The manufacture or sale of any drug without the personal supervision of a
registered pharmacist is prohibited. Under the ordinance a drug control committee
has been constituted. Approval, suspension, or cancellation of registrations of
drugs is now subject to the recommendations of this committee. The ordinance
requires the manufacturer to adopt good practices for manufacture and the quality
control of drugs as recommended by WHO. This makes the manufacturer responsible
for producing drugs of standard quality. Any violation of that provision on the
part of a manufacturer may lead to suspension or cancellation of his manufacturing
licence.

34. The ordinance provides for control of advertisements in respect of drugs, with
punishments for violations. Provision is made to penalize the manufacture or sale
of unregistered, adulterated, spurious, or substandard drugs and the import of any
drug or pharmaceutical material without the prior approval of the licensing
authority. Penalties have been provided in the ordinance for selling or importing
any medicine or pharmaceutical raw materials at prices higher than the maximum
prices fixed by the Government. There is provision too for the punishment of
thefts of drugs that are the property of the Government and of illegal
advertisements and claims relating to medicine. The punishment for the theft of
drugs from government stores or hospitals is rigorous imprisonment for a term that
may extend to 10 years or a fine up to Tk. 2 lacs, or both. Provision has been
made to set up separate drug courts, which will specifically try offences against
the drug ordinance.

35. The ordinance provides for setting up a National Drug Advisory Council to
advise the Government and to coordinate the various ministries. The Council has
been set up, with the Minister for Health and Population Control as chairman.
Provision has been made to fix the maximum prices of drugs and pharmaceutical raw
material to be imported or sold.

36. No medicine of any kind can be manufactured or imported without registration
with the licensing authority.

37. Under the ordinance unani, ayurvedic, homoeopathic, and biochemical medicines
have been declared as drugs and therefore are now under the control of both the
Drug Act, 1940, and the Drugs (Control) Ordinance, 1982. The existing unani,
ayurvedic, and homoeopathic medicines were listed under three schedules as follows:
Schedule I: Permissible drugs

Schedule II: Drugs requiring changes of name


38. The Government adopted the following policy and guidelines in respect of unani, ayurvedic, and homoeopathic medicines: (1) general guidelines for the control of unani, ayurvedic, and homoeopathic medicines; (2) guidelines for the quality control of such drugs; (3) lists of essential, specialised and restricted drugs in the unani, ayurvedic, and homoeopathic systems of medicine; and (4) guidelines for evaluation of the recipes of such drugs. It also laid down that in dosage form no drugs should contain more than 5% alcohol, any metallic element, or any other ingredient proved to be poisonous or harmful. Measures should be taken so that no fungi grew in the product.

39. Within three months of its promulgation the Drugs (Control) Ordinance, 1982, was amended to allow time for certain items banned under the ordinance. It was further amended in July 1984, to remove certain difficulties in initiating legal proceedings against offenders and to provide for appeal from the aggrieved by an order or decision of the licensing authority in respect of registrations of medicines and their cancellation or suspension. The appeal is heard by the appellate authority, already constituted with the Minister for Health and Population Control as chairman and eminent physicians of the country as members. The 1984 amendment also prohibited the prescription of unregistered medicines.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

40. Bangladesh has not yet agreed to participate in the scheme because pharmaceutical raw materials, which are of vital importance, have not been included in it. Moreover, Bangladesh prefers to pursue an independent drug policy, including the quality control of imports and exports. The quality and safety of imported as well as local pharmaceutical products is a most active concern of the Government.

41. For quality control the Government has made provision for the periodic inspection of manufacturing and trading premises, random sampling at various levels of the distribution network, and analyses in the drug control laboratories. Drug testing is required for pre-registration evaluation as well as for post-registration surveillance. Properly equipped drug control laboratories are a prerequisite of a good quality control system. The facilities in the existing laboratories are inadequate. The Government has approved a plan for setting up a national drug control laboratory and several regional ones. These laboratories will require modernization with foreign help.