The menace of substandard drugs

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Numerous small pharmaceutical manufacturers in Bangladesh are marketing substandard drugs, often deliberately using inadequate levels of active ingredients. Stricter application of the national drug policy is necessary, notably in regard to the issuing of licences and the sanctions applied to firms breaking the law.

In 1982 a national drug policy and a drug control ordinance came into effect in Bangladesh, taking account of internationally accepted norms for primary health care and the need for essential drugs. One of the provisions of the ordinance is that manufacturers and vendors of substandard drugs are punishable by imprisonment or fine, yet no such action has been taken even though spurious and substandard medicaments have been produced and marketed. For instance, paracetamol was recently marketed in a syrup formulation containing diethylene glycol, a toxic compound. Firms contravening the law in this way have merely been obliged to announce the withdrawal of substandard products in the press; regrettably, these notices have become less and less prominent.

A survey conducted in the period 1988–91 found that 66 of the 198 licensed pharmaceutical manufacturers were each producing between 1 and 16 substandard drugs. Among these items, 49% were over-the-counter (OTC) drugs and 6.3% were injectables (the remainder being non-injectables on prescription). About 36% and 41% of these OTC products consisted of paracetamol and antacids respectively. The principal deficiency was an insufficient content of active ingredients.

However, the companies producing substandard drugs have only a small share of the market. The top five companies control 49.9% of the market and the top 15 have an 88.7% share of the market. Some 30 companies have major production units.

In 1992, analyses were made of paracetamol tablets, ampicillin capsules, cotrimoxazole tablets and suspensions, vitamin B-complex tablets/capsules and injectables, and vitamin B-2 tablets obtained from retail shops in various parts of the country (1–3). While the analyses took into account disintegration of tablets, the results given here are on the basis of the level of active ingredients. A total of 137 brands were examined, of which 37 were found to be substandard, all of them manufactured by small companies. Of the 16 brands of paracetamol tablets and 10 of ampicillin capsules that were substandard, 11 and eight respectively had previously been assessed by the regulatory authority as being substandard. This was also true of the two brands of cotrimoxazole suspension found to be substandard. All of the analysed products of 13 of the top 15 companies were up to the required standards; the remaining two companies did not have any of the analysed products on the market at the time of the study.

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In almost all cases of substandard production of paracetamol, ampicillin and cotrimoxazole it appeared that active ingredients had been deliberately kept below the required levels, and that the companies concerned had continued making such batches of drugs even after warnings from the regulatory authority. On the other hand, it seemed that negligence was largely responsible for the substandard manufacture of the less costly vitamin B products: most of the small firms had inadequate quality control facilities. All the substandard vitamin B-complex preparations contained all four active ingredients, but the quantities of one or two of these were often too small.

The quality of marketed drugs should be continuously monitored. If a particular item produced by a company is found to be substandard on two occasions in a two-year period the licence to produce medicines should be revoked. Furthermore, the sale of capsules supposedly containing ampicillin or tetracycline, when in fact they contain only flour or some other non-medicinal material, should be vigorously suppressed. Such products are not usually prescribed by registered physicians, but are sold directly to patients by quacks and in druggists’ shops.

Substantial numbers of poor rural people make significant sacrifices in order to purchase substandard drugs and then suffer the consequences. Dealing with this situation requires the primary care system to be improved. At present the government health centres in the rural areas cannot cope with the needs of poor people. These centres should have a steady supply of medicines of good quality. Qualified doctors are required, and health promoters should be available so that the people can be made aware of the importance of basic hygiene and sanitation. International agencies could perhaps play a vital role in helping to develop the rural health care system and to promote high quality and rational use of drugs. The government authorities should be even more vigilant in rural areas than in the cities in their efforts to eradicate substandard drugs.

The national drug policy is sound but is in danger of failing through poor implementation owing to lack of appropriate administrative and legislative mechanisms. In particular, licences should not be issued to small firms without restriction but should only be granted on a selective basis, for instance in respect of OTC tablets. No licences should be issued to small firms for the manufacture of life-saving drugs. Similar recommendations were made in 1982 but have not been put into effect; despite pressure from different lobbies and interest groups, the big firms were interested only in making profit. Another possibility would be to establish regional quality control centres for small firms.

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