

# Personal Perspectives

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## Counterfeits: grappling with the issues

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With the world confronted by the reality or the prospect of large-scale counterfeit production of almost every conceivable consumer product, it is not surprising that drugs are sometimes manufactured in violation of good manufacturing practices and in total disregard of pharmacopoeial standards and requirements for registration and marketing procedures. The difference between most other counterfeit products and counterfeit drugs is that they create a potential for serious public health hazards. If they are of inferior quality, their use can result in either unanticipated adverse reactions or in therapeutic failure. This not only places patients at risk but undermines the confidence of prescribers and consumers in the genuine product.

Policy options and legislative responses to counterfeiting must be considered in the context of local circumstances and experience. Generalizations as to how national policies and laws should be formulated, revised or updated need to be regarded with caution. One basic requirement, however, is that a coordinated approach among the various interested competent authorities is needed at national level, and that these authorities must remain alert to the methods used in other countries to deal with the problems. On occasion, actions taken by a country that is at the hub of a network of exporters of counterfeit products may relieve "importing" countries of the need for an extensive revision of their laws. None the less, "benevolent" legislative changes adopted in exporting countries are to have impact where they are most needed, they should be founded upon carefully conducted bilateral or multilateral consultations and negotiations. Effective solutions cannot be found overnight; there is no simple formula that can be applied to eliminate the problem immediately from the face of the earth.

Progress towards viable solutions needs to be based on four prerequisites. These are political will,

an adequate legislative basis, adequate resources for law enforcement, and effective public education. This implies that wherever counterfeit products are identified, there is a need to review existing policies, procedures, laws, and practices and to identify loopholes that could operate to the advantage of counterfeiters. Where a comprehensive national drugs policy is not already in place, much can be achieved through effective control and rationalization of the drug market.

Counterfeit drugs have been successfully infiltrated into the distribution chain in countries with tightly controlled markets as well as those that remain relatively open. The introduction of counterfeit drugs is, however, much easier where many products are in circulation. When there is no inventory of all available products or when there is no proper system for registration in place, as in some developing countries, the identification of counterfeit drugs is greatly impeded. Developing countries confronted with the problem are well advised to prune out unwanted or unnecessary products from their markets and to introduce a registration system which enables the pedigree of products to be clearly identified. Where domestic manufacturing capability is limited, the need to introduce an import licensing system must be given serious consideration. Such a system, implemented in conjunction with the WHO Certification Scheme, will facilitate monitoring of imported drugs, particularly if these administrative measures are complemented by greater awareness and vigilance among customs officers and import licensing authorities.

### Regulatory prerequisites

Over-regulation needs to be avoided at all costs, and any decision to add a plethora of new controls must be carefully weighed against possible administrative overload, excessive costs, bureaucratic delays and inconvenience. However, in all circumstances, it is important that laws and regulations already in place satisfy the following points:

- counterfeit products should be defined without ambiguity;
- the manufacture, import, export, sale, storage, distribution, advertising and use of counterfeit drugs should be explicitly prohibited;

- the enforcement authorities should be empowered to take such action as is necessary to initiate searches, and to carry out tests with a view to identifying counterfeit drugs;
- procedures should be in place which permit the detection and prosecution of offenders. Where possible, the burden of proving that the product is lawful should be "shifted" to the accused or defendant; a certificate of analysis should be made admissible as prima facie proof of the facts stated therein without the need to summon the analyst; powers should be provided to seize suspect consignments; company accounts and financial dealings should be accessible to the courts; mechanisms should be devised for mandatory notification of the existence of counterfeit drugs to the competent authority; and
- courts should be empowered to deal effectively with: convicted persons and counterfeit products (including mandatory gaol sentences for serious offences); compulsory destruction of counterfeit products; publication of the name and identity of convicted persons and counterfeit products; confiscation of assets.

In addition, powers such as those that devolve upon national enforcement authorities from the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances are necessary if effective action is to be taken against large-scale counterfeiters. Countries may even wish to consider whether the powers that now exist to detect illicit drug trafficking in these specific substances should not be extended to the enforcement agencies dealing with pharmaceuticals in general. However, any conferment of such powers must be carried out with caution and in a way that provides appropriate safeguards against excesses.

Wholesale, retail and pharmacy practices also need to be reviewed, since the professionals working within the distribution chain are of key importance in preventing counterfeit products being marketed through legitimate sales outlets. Codes of practice need to establish unequivocally that dealing in counterfeit products is an unethical practice which is subject to disciplinary action. The elimination of informal sales outlets is a far more complex issue. Such systems are frequently culturally-sanctioned and they provide a service which has gained acceptance as a result of default in providing a comprehensive health system.

### Developing a "counter-counterfeiting" strategy

An assembly of representatives of the pharmaceutical industry, wholesale and retail trade, health care practitioners, health care institutions, patient groups, and police, customs and other law enforcement agencies needs to be established, by a decision of the highest authority of the land, to develop a coordinated response to the problems associated with counterfeit drug trafficking. The drug regulatory agency must also enlist all the support it can mobilize for the purpose. Unless it enjoys a broad base of support, its efforts may fail to yield the exemplary prosecutions required to create a persuasive deterrent. Drug regulatory authorities need to be more open and frank about the problem. Their officials should not feel inhibited to speak out against laxism in the application of rules which hinder counterfeiters, and they should possess the authority to assign specific tasks that fall within their mandate to appropriate agencies within its network. These agencies should be able to enlist the assistance of WHO, INTERPOL, UNDCP, geo-political groupings such as EEC, IFPMA and any other organization with the mandate and resources to help in dealing with the problem.

For far too long, drug regulatory authorities have attempted to deal with the problem in isolation; counterfeiting is a multi-billion, transnational operation, far too complex in character to be effectively dealt with by drug regulatory authorities alone. The full panoply of controls needs to be instituted in a concerted manner.

Each action that is taken to rationalize the market and prescribing and consumption habits, to augment the powers of enforcement authorities, and to work within an international environment of mutual collaboration and support will make its contribution to an effective strategy. It is through modest advances that a foundation will ultimately be built to deal with the problem, although some countries will be able to achieve tangible results within a shorter time-frame than others.

Infrastructure development is probably the single most important strategy for effective control of drugs available in the market place. There are some countries where a counterfeit is available for almost everything, but products like Coca Cola or Pepsi remain largely exempt. The reason for this

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lies in an effective marketing strategy, an extensive distribution network penetrating down to the retail level, and close monitoring of stock movement and products display which hinders any threat of interference with legitimate sales. Feedback is provided through frequent and close contact with wholesalers and retailers.

Because of the complexity and diversity that characterize the pharmaceutical market, it is obviously not possible for manufacturers to maintain a comparable marketing strategy and intelligence system. However, where there are adequate health care institutions, health care

personnel, pharmacies and other retail outlets; where there is an effective system to monitor drug requirements and to ensure that supply matches demand; and where there is an effective mechanism to monitor the movement of drugs, counterfeiters will surely find it more difficult to infiltrate the system. The development of a secure infrastructure is no mean attainment, but it is certainly within reach of the vast majority of countries. In this day and age, the people's 'right to health' includes the right of access to a reliable standard of care and, unquestionably, the right to assurance that the drugs they receive are safe, effective and, not least, genuine.