

I. Internationally controlled drugs and the unregulated market

A. Background

1. The international drug control treaties, particularly the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol¹ and the Convention on Psychotropic Substances of 1971,² seek to ensure a delicate balance between making narcotic drugs and psychotropic substances available for medical and scientific purposes and preventing their abuse or non-medical use. That delicate balance can be achieved through a carefully worked out international and national system of controls with regard to the manufacture, importation, exportation, distribution, prescribing, dispensing and use of narcotic drugs and psychotropic substances.

2. Obligations imposed by the international drug control treaties must be translated into national legislation, and most States have enacted domestic legislation for that purpose. Some States have also introduced control systems that are in line with what is prescribed by the treaties, but with modifications to suit local conditions.

3. The international drug control treaties were conceived as a response to widespread drug abuse and as an attempt to reduce to a minimum the medical, public health and other problems emerging in the wake of the misuse of drugs while, at the same time, not reducing the availability of drugs for medical and scientific purposes. The drafters of the treaties were conscious that there would be attempts to defeat whatever control systems that would be in place. Accordingly, the drafters introduced several measures to minimize the possibility of the treaty objectives being undermined.

4. Notwithstanding the drug control regime prescribed by the international drug control treaties and related national laws and regulations, there have been reports of the diversion, misuse or abuse of drugs. The problem has assumed more significant dimensions with regard to psychotropic substances under international control. In more recent times, however, there have been growing concerns that the unregulated market – in general, for medicinal products, and in particular,

for some narcotic drugs and psychotropic substances – may be becoming too ubiquitous in certain parts of the world and that the underlying contributory factors need to be identified and remedial measures taken.

5. The concerns of the International Narcotics Control Board stem from reported incidences of the availability of internationally controlled drugs in the unregulated market. For example, benzodiazepines, amphetamines and other internationally controlled drugs can be easily obtained in street markets in several developing countries. Even in developed countries, there are reports of the abuse or misuse of controlled drugs originating in the unregulated market. Through Internet pharmacies, internationally controlled drugs such as benzodiazepines, opioids, stimulants and barbiturates can be obtained without a prescription. According to estimates of the World Health Organization (WHO),³ at least 10 per cent of the world's drugs are counterfeit.

6. The Board therefore decided that it would be timely to have the unregulated market as the special theme of its report for 2006. The unregulated market is examined in the present chapter primarily in relation to narcotic drugs and psychotropic substances under international control.

B. Selected features of the unregulated market for drugs

7. The unregulated market for drugs has evolved and exists in different forms in different parts of the world. Given the wide variation in the forms of unregulated markets and in the ways they operate, the phrase “unregulated market for drugs” is commonly used in a generic sense. From a more technical perspective, an unregulated market for drugs can be considered to exist where:

(a) Unlicensed individuals and/or entities⁴ trade in drugs that they are not authorized or entitled to deal

¹ United Nations, *Treaty Series*, vol. 976, No. 14152.

² *Ibid.*, vol. 1019, No. 14956.

³ World Health Organization, “Counterfeit medicines”, *Fact Sheet No. 275*, February 2006.

⁴ The term “entities” covers manufacturing establishments, pharmacies, clinics etc.

with or in contravention of the applicable laws, regulations and norms; or

(b) Licensed individuals and/or entities trade in drugs that they are not authorized or entitled to deal with or in contravention of the applicable laws, regulations and norms.

8. The situation described in subparagraph 7 (a) above would include, for instance, the case of a person who is not a registered pharmacist selling a controlled drug at a village fair. The situation described in subparagraph 7 (b) above would include, for example, the case of a registered pharmacist selling a controlled drug in a pharmacy but without a prescription as required by law. Both situations cover legally manufactured or imported drugs, as well as counterfeit⁵ or substandard drugs, which cannot be the subject of legitimate commerce. They also cover unauthorized Internet sales. The phrase “trade in” is intended to apply to all commercial transactions in relation to such drugs.

9. The unregulated market ranges from ad hoc or makeshift outlets in village fairs or markets where drugs are sold along with other commodities, such as balms, tonics and creams, to more organized systems operated by unscrupulous manufacturers, importers, retailers, wholesalers and health-care professionals.

10. Any activity on the unregulated market is unlawful; in some countries such activity may be part of a much larger criminal operation transcending national frontiers, particularly where counterfeit or banned or substandard drugs are manufactured or imported or exported. The possibility of making a substantial profit drives such markets. Such profits are particularly enhanced where the quality of drugs is compromised; where customs or import duties are avoided; where taxes are not paid on the turnover; or where price control systems are undermined.

⁵ “A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging” (“Counterfeit drugs: report of a WHO/IFPMA workshop, 1-3 April 1992” (WHO/DMP/CFD/92), p. 1).

11. Drugs enter the unregulated market through a number of channels. These vary from one country to another and sometimes even from one geographical area within a country to another. For its supplies the unregulated market depends on two principal sources: official sources (regulated channels) and “other sources”:

(a) Official sources (regulated channels):

(i) Drugs may be stolen from licensed manufacturers, wholesalers or retail distributors. Unscrupulous manufacturers may manufacture and sell products for which they have no licence or may sell products in contravention of the conditions of their licence. Drugs that are substandard or recalled by the manufacturer because they have expired or have quality defects may be sold and find their way into the unregulated market;

(ii) Imported drugs or drugs for export may find a way into the unregulated market through theft or unauthorized sales;

(iii) Drugs may be diverted from health-care institutions and/or health service providers, again through theft or unauthorized sales;

(iv) Controlled drugs obtained legitimately by retailers or by health-care institutions, for example, may be stolen and diverted to the unregulated market; in some cases, individuals who have obtained such drugs using prescriptions may sell them for profit;

(b) Other sources:

(i) Counterfeit drugs may be manufactured or imported or distributed and supplied to the unregulated market, as well as to the regulated market. Unscrupulous manufacturers, importers, exporters, pharmacists, distributors and brokers have been implicated in such operations;

(ii) Drugs that are stolen from prescription holders may find their way into the unregulated market;

(iii) Through the Internet, even drugs for which prescriptions are required can be obtained relatively easily.

C. The demand for the unregulated market

12. The unregulated market is driven by several factors; the underlying dynamics vary from situation to situation. Some of the more common factors that have created demand for an unregulated market or responded to demand from an unregulated market are described below.

Limited access to health-care facilities

13. In countries with limited access to health-care professionals, hospitals, clinics or pharmacies, unauthorized or unregulated outlets are more likely to exist. Such a situation is particularly common where a person may have to travel a long distance to consult a health-care professional or where drugs are in short supply in established or formal health-care outlets, such as hospital or community pharmacies, or where there is a long waiting period to consult a service provider.

Cost of drugs

14. The price of most medicinal products found on the unregulated market is likely to be lower than the price of those products in regulated pharmacies. In the case of counterfeit drugs, there are significant profits for the illicit manufacturer, as counterfeit drugs cost much less to manufacture and distribute than genuine drugs. Drugs smuggled into a country or diverted from licit channels may be cheaper, as customs or import duties and other applicable taxes are usually evaded.

15. On the other hand, the price of certain internationally controlled drugs available through the Internet may in fact be higher than the price of those products in regulated pharmacies, and the consumer might not be aware of this. However, the price may not necessarily deter some individuals from obtaining such drugs.

Privacy

16. The ability to obtain controlled drugs through the Internet offers a degree of privacy, as there are no medical records indicating that the person has been taking a course of treatment for an ailment or illness, which might pose problems regarding that person's current or prospective employment or health insurance.

Lack of public awareness

17. Unscrupulous individuals or entities may exploit individuals who are not aware of the dangers of buying drugs on the unregulated market or who are not able to distinguish between registered and unregistered sales outlets or practitioners. Where law enforcement is weak because of poor planning, a shortage of inspectors or corrupt practices, such individuals or entities will be able to carry out their illegal activities with impunity.

18. Aggressive promotion and advertising to the general public, in contravention of the treaty obligations, may influence public perception about the availability of drugs on the unregulated market.

Drug control regulations and enforcement

19. Some countries have drug control laws and regulations with provisions that go beyond treaty requirements without necessarily preventing abuse or misuse. Overly stringent prescription requirements is one such example. This may lead to a situation where certain controlled drugs are more readily available on the unregulated market. In the absence of effective law enforcement, particularly through inspections and reporting systems, outlets selling such drugs will be able to operate outside the regime of legal controls.

Consumer demand for illicit drugs

20. The unregulated market caters to individuals, including persons who are dependent on drugs of abuse and who are unable to obtain them without a prescription. In addition to recreational use, some individuals may seek access to performance-enhancing drugs that are available only with a prescription.

D. Some emerging issues

Counterfeit drugs

21. Though the existence of counterfeit drugs is not new, their availability was first formally acknowledged as a problem only in the mid-1980s and has since assumed alarming proportions, not only in developing but also in developed countries. According to WHO, an estimated 25-50 per cent of the medicines consumed in developing countries are believed to be counterfeit. The use of certain counterfeit medicines can be fatal: a

counterfeit vaccine used in the Niger in 1995 resulted in 2,500 deaths.⁶

22. Some counterfeit drugs are easy to manufacture. Such drugs may closely resemble genuine products in terms of their packaging and labelling. Controlled narcotic drugs and psychotropic substances may be present in products without any mention of such drugs or substances on the labels or package inserts. This has been a problem in some countries with herbal or traditional medicines.

23. The manufacture and distribution of counterfeit drugs on a larger scale often involve unscrupulous manufacturers, pharmacists, wholesalers, retailers and brokers. In many countries, brokers facilitate international trade in drugs and remain largely invisible to the authorities. Contrary to treaty requirements, brokers in some countries are not regulated by national drug control legislation.

Internet orders

24. Internet pharmacies that are properly regulated serve a useful purpose, especially in underserved areas, making drugs available to the population. However, in many countries, Internet pharmacies have not been regulated yet.

25. A recent survey of 185 Internet pharmacies in one Member State revealed that 84 per cent of them sold benzodiazepines, 68 per cent sold opioids, 8 per cent sold stimulants and 1 per cent sold barbiturates. Eighty-nine per cent of the Internet pharmacies did not require a prescription, and 8 per cent of them accepted a prescription sent by telefax (allowing customers to easily use forged prescriptions or to obtain medicine from several Internet pharmacies with a single prescription). Only 3 per cent of the Internet pharmacies indicated that, before dispensing medicine requiring a prescription, they would request for the original prescription to be mailed or would contact the prescribing doctor.⁷

26. The risks involved in buying a medicinal product through an illegal Internet pharmacy are high: (a) the

medicinal product may be marketed on a website using incorrect or fraudulent health claims; (b) the medicinal product may be issued without a valid prescription or the proper supervision of a pharmacist or medical professional; (c) the product may be counterfeit or of substandard quality or the expiration date of the product may have elapsed; (d) the price of the medicinal product may be higher than in legal pharmacies; and (e) the buyer's privacy or the security of the buyer's credit card or medical data may be compromised.

27. Internet pharmacies are dependent on postal services to deliver drugs, some of which are of an illicit nature, to end-users. The huge numbers of parcels pose challenges in scanning, identifying and intercepting parcels with illicit drugs. In one country, the law enforcement authority examined 1,153 imported parcels containing medicinal products during a three-day operation in 2003. The overwhelming majority of the products (88 per cent) were illegal imports – drugs not registered or supplied without the required prescription. The products included over 25 different internationally controlled substances, including narcotic drugs such as codeine and psychotropic substances such as diazepam.⁸

28. Websites that provide advice and consultations with so-called “cyberdoctors”, recommending medicinal products for use and facilitating access to the “prescribed drugs”, are a matter of increasing concern, particularly in cases where there are no proper clinical consultations. The costs of using such websites vary; in fact, there are hidden costs, such as fees for consultations with “cyberdoctors”, and handling and packaging fees.

E. Requirements of a regulatory system

29. Drugs must be effective, safe and of good quality. Every country should therefore have a drug regulatory authority to assess the efficacy, safety and quality of drugs before allowing them to be imported, manufactured or marketed. Countries that do not have the resources to assess all products on their markets

⁶ World Health Organization, “Counterfeit medicines”, *Fact Sheet No. 275*, February 2006.

⁷ National Center on Addiction and Substance Abuse at Columbia University, “‘You’ve got drugs!’ Prescription drug pushers on the Internet: 2006 update”, *CASA White Paper*, June 2006.

⁸ United States of America, Food and Drug Administration, “FDA/U.S. Customs import blitz exams reveal hundreds of potentially dangerous imported drug shipments”, *FDA News*, 29 September 2003.

can rely on the decisions of drug regulatory authorities in other countries with advanced regulatory systems in place. However, there should at least be a provisional authorization process, in order to identify the drugs that can be marketed.

30. To effectively regulate the drug market, national drug regulatory authorities require political will, relevant legislation, appropriate organizational capacity and skilled professionals. They also need to have adequate financial resources, as well as well-structured and motivated drug inspectorate services and international cooperation.

31. The training of health-care professionals should include guidance on how to promote the rational use of drugs in the context of the applicable regulatory requirements. Codes of conduct for associations of health-care professionals, industry and trade chambers should address the issue of the incorrect or improper handling of drugs.

32. The premises on which medicines are stored also need to be controlled. The procurement, storage, distribution and dispensing of medicines must be done according to specific technical standards and guidelines. Most States require such premises to be inspected and licensed by the national drug regulatory authority. Internationally controlled drugs need even more care and require special storage conditions and administrative procedures, in order to reduce the risk of such drugs being diverted into illicit channels.

33. Professional organizations have a responsibility to promote, monitor and ensure ethical behaviour of health-care professionals. In countries with weak regulatory control of medicines, that responsibility is even more important. Ethical conduct is expected of all health-care professionals.

34. In some countries, inadequate legal frameworks and lax law enforcement are areas of concern. In countries where drug control legislation is lacking or obsolete, the regulation of trade in medicinal products, including internationally controlled drugs, is hampered. According to a 2003 study conducted by WHO,⁹ in 30 per cent of countries, drug regulation is either non-existent or very limited. In such countries,

Governments are unable to ensure the safety, efficacy and quality of medicines on their markets. That makes it very difficult to implement the controls required under the international drug control treaties. As a result, patients may be at serious risk. In half of the countries in the world, drug regulation exists but is less than optimal. In such countries, the implementation, supervision and/or enforcement of drug legislation is compromised. This may lead to any of the following undesirable situations: (a) uncontrolled imports, leading to medicines with doubtful efficacy, safety or quality being available on the market; (b) smuggling of medicines; (c) illicit manufacture of internationally controlled drugs; (d) counterfeit medicines infiltrating the licit market; (e) poor storage conditions and administrative controls in the wholesale or retail sector, allowing pilferage or diversion of internationally controlled drugs; (f) repetitive trading of medicines to obscure their source, storage conditions or previous ownership; (g) poor enforcement of the “prescription only” requirement in pharmacies, allowing patients to use potent and even internationally controlled drugs without professional supervision; and (h) sale of controlled drugs to consumers without a prescription at places such as street markets or bus stops. Even the 20 per cent of countries with well-developed drug regulatory systems may experience occasional problems, especially when new technologies are not yet fully understood by drug regulators or adequately regulated in new legislation on, for example, Internet pharmacies.

F. Conclusions

35. The unregulated market exposes patients to serious health risks by providing access to poorly or incorrectly labelled medicines that are ineffective, substandard and, in some cases, even lethal. The problem is compounded when professional supervision is virtually absent and consumers are not able to assess or avoid the risks. This is a serious situation that requires action from all those concerned, including Governments, professional organizations, the pharmaceutical industry and international organizations.

⁹ “Effective medicines regulation: ensuring safety, efficacy and quality”, *WHO Policy Perspectives on Medicines* (Geneva), No. 7, November 2003, p. 1.

36. While there is no precise figure on the amount of internationally controlled substances reaching patients through the unregulated market, it is believed to be increasing rapidly. In some regions, people abuse licitly produced prescription medicines in quantities similar to or greater than the quantities of illicitly manufactured heroin, cocaine, amphetamine and opioids that are abused. The Internet allows easy access to internationally controlled substances but is inadequately regulated at the national and international levels. The widespread availability of counterfeit drugs has further compounded the problems associated with the unregulated market. The progress made over the last 40 years in the control of illicit drugs is now being undermined. The Board is greatly concerned about these developments.

G. Recommendations

37. The Board recognizes that the elimination of the unregulated market must be done through a concerted effort involving Governments and relevant parties such as the pharmaceutical industry, wholesalers, retailers, professional associations, consumer and patient groups and international organizations.

Recommendations to Member States in the context of treaty obligations

38. The Board is of the view that much can be achieved to prevent internationally controlled drugs from being diverted to the unregulated market if all the parties concerned strictly enforce the applicable control requirements. In that connection, the Board recommends the effective implementation of the following control requirements and related measures:

(a) Member States need to enforce existing legislation to ensure that narcotic drugs and psychotropic substances are not illegally manufactured, imported or exported and are not diverted to the unregulated market;

(b) In compliance with article 15 of the 1971 Convention, Member States need to conduct inspections of manufacturers, exporters, importers and wholesale and retail distributors, as well as of stocks and records, and to take appropriate action against those who fail to comply with applicable legal requirements and professional codes of conduct.

Activities of market intermediaries such as brokers must be regulated as appropriate;

(c) Member States need to assess their requirements of narcotic drugs and psychotropic substances on a systematic basis to ensure that supplies are sufficient to meet legitimate demand. Records of operations involving manufacture, import, export and distribution must be verified and any discrepancies resolved;

(d) Member States need to take appropriate measures to increase the availability of drugs through legitimate channels, particularly in areas where there is little or no access;

(e) Member States need to take prompt and effective action to implement previous recommendations of the Board¹⁰ on Internet trading and inform it of the actions taken;

(f) Member States need to address the issue of the unregulated market for drugs in national drug control policies and legislation; strengthen the drug regulatory authority and its inspectorate; enlist the assistance of customs, law enforcement and postal services to intercept illegal or unauthorized consignments; and prevent the illegal sale of drugs through effective law enforcement;

(g) Member States need to build the capacity of staff attached to the drug regulatory authority and other agencies concerned;

(h) Member States need to implement effective policies to combat counterfeit drugs and provide a comprehensive legal framework to make trading in counterfeit products a serious criminal offence. Exporting countries must regulate the export of drugs with a view to preventing the export of drugs that are counterfeit or of poor quality. The Declaration of Rome adopted at the WHO International Conference "Combating Counterfeit Drugs: Building Effective International Collaboration", held in Rome in February 2006, should be supported by Member States, and they should actively participate in the work of the new International Medical Products Anti-Counterfeiting Taskforce (IMPACT), as well as other regional initiatives.

¹⁰ *Report of the International Narcotics Control Board for 2005* (United Nations publication, Sales No. E.06.XI.2), paras. 219-236.

Recommendations to international and intergovernmental organizations

39. The Board recommends the following to intergovernmental organizations:

(a) WHO should consider studies to be undertaken at the national, regional and international levels to develop a better understanding of the dynamics underlying the operations of the unregulated market and formulate relevant guidelines;

(b) WHO should consider the development of a guide on best practices in dealing with the unregulated market, to be compiled and widely distributed;

(c) The United Nations Office on Drugs and Crime (UNODC) and WHO should consider providing technical assistance to Member States that require such assistance for building capacity and for updating drug control laws in order to be able to deal more effectively with problems emerging in the wake of the unregulated market;

(d) The pharmaceutical industry and relevant associations need to notify the relevant national and international authorities of any consignments that are being diverted to the unregulated market or of any attempts to manufacture and distribute counterfeit drugs.