

Counterfeit medical products

Report by the Secretariat

1. In May 2008, the Sixty-first World Health Assembly considered a report on counterfeit medical products and a draft resolution proposed by several Member States.¹ In the discussion, several Member States said that they required more information on the issue before adopting a resolution and, given the gravity of the subject and the need to reach consensus, it was agreed to refer the matter to the Board for further discussion, including the draft resolution and the comments made by delegates.²
2. Counterfeit medical products are a serious public health problem that puts human lives at risk and undermines the credibility of health systems. They jeopardize progress achieved in public health, and, in addition to direct harm to patients and therapeutic failures, challenge confidence in the entire health system.
3. Counterfeit medical products have been detected in most Member States, and in all regions. Examples have involved widely-used medicines, such as atorvastatin or paracetamol, limited-use medicines such as growth hormone, paclitaxel and filgastrim, other kinds of medicines such as sildenafil and tadalafil, as well as medical devices such as contact lenses, condoms, surgical mesh, and strips used by diabetic patients to monitor their own blood glucose concentrations. Counterfeiting has affected both expensive and cheap products and generic and branded ones. Counterfeit products appear in community pharmacies, hospitals and other less-regulated settings.
4. It is impossible to obtain a precise estimate of the proportion of counterfeit medical products on national markets. However, the number of incidents detected in 2007 increased to more than 1500, that is more than four cases a day. Even minor cases concern at least one production batch, which amounts to thousands of tablets. The 2007 figure represents roughly a 20% increase over that for 2006 and a 10-fold increase over 2000. These increases reflect improved detection and reporting capacity, but they may also indicate that the problem is growing.
5. Although the medicines regulatory authorities of most Member States are aware of the problem, obtaining information is difficult and published reports can sometimes be misleading, even when issued by reputable sources. The most important limitations of the available information are that often no distinction is made between patent violations, patent or trademark disputes, copyright violations and actual counterfeiting, and that information about the role of the source country (e.g. in which

¹ Document A61/16.

² Document A61/2008/REC/3, summary record of the tenth meeting of Committee A.

counterfeit products are manufactured or repacked, or through which they transit) is often not available.

6. Many factors contribute to a political and regulatory environment in which manufacture and trade of counterfeit medical products can thrive. These factors include: governments' unwillingness to recognize the existence or gravity of the problem; inadequate legal framework and insufficient sanctions; weak administrative measures, not focused on fighting counterfeit medical products; ineffective control of manufacturing, importation and distribution of medical products; ineffective collaboration among authorities and institutions involved in regulation, control, investigation and prosecution; ineffective national and international collaboration and exchange of information between the public and private sectors; inadequate access to health services and reliable pharmaceutical supply channels; illiteracy and poverty; inadequate social protection systems; national drug policies that prioritize economic over public health aspects of medicine manufacturing; fragmented distribution channels; extraterritorial trade zones; unregulated Internet trade; and unregulated third-party manufacturing.

7. In 1988 the Health Assembly, in resolution WHA41.16, requested "governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations" and requested the Director-General "to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations".

8. In 1992 a large group of Member States, INTERPOL, the World Customs Organization (at the time known as the Customs Cooperation Council), the International Narcotics Control Board, the International Federation of Pharmaceutical Manufacturers' Associations, the International Organization of Consumer Unions and the International Pharmaceutical Federation endorsed the following working definition:

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.

9. Increasing practical experience has led to the identification of three aspects of counterfeiting that are not satisfactorily covered by the 1992 working definition and that have hampered legal enforcement in some countries. Account needs to be taken of the fact that counterfeiting affects all medical products and not just medicines; that there have been cases where the quantity of active ingredient in a counterfeit product is greater than the amount declared on the label; and that there have been cases in which a licensed manufacturer has masked substandard batches with forged manufacturing documentation.

10. For these reasons, work is continuing to refine the 1992 working definition, with the specific intention that it will serve as a model text for national legislation. The working text that was agreed by the International Medical Products Anti-Counterfeit Taskforce at its Third General Meeting (Hammamet, Tunisia, 3–5 December 2008) reads as follows:

A medical product is counterfeit when there is a false representation¹ in relation to its identity² and/or source.³ This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components,⁴ with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices in legitimate and medical products should not be confused with counterfeiting.

11. Unlike the 1992 definition, the new text clearly indicates that medical products that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

12. Many Member States do not have specific or effective legal instruments for combating counterfeit medical products, and may for that reason resort to non-specific legislation related to trademark protection. However, for several reasons such an approach is not satisfactory, as follows. Legal instruments related to intellectual property rights have a broad scope and are not focused on the protection of public health. Counterfeiting of medical products does not always entail the violation of intellectual property rights. The intellectual property rights approach identifies the rights holder as the main victim of counterfeiters and as the main trigger of enforcement and prosecution while, in the case of medical products, the real victim of counterfeiting is the patient; legislation should therefore enable patients and health authorities to undertake appropriate procedures regardless of the action of the holders of intellectual property rights. The technical complexity of the regulation of manufacture, trade, distribution and dispensing of medical products warrants an approach much wider than one based on intellectual property rights. The new text therefore states clearly that the violations or disputes about patents must not be confused with counterfeiting of medical products.

13. The global nature of counterfeiting warrants an international collaborative approach. The International Medical Products Anti-Counterfeit Taskforce, which WHO launched in 2006, brings together the most relevant stakeholders with the specific aims of promoting international collaboration and coordination and supporting the rapid development and application of new policies and technical approaches. Its funding (nearly US\$ 2.3 million for 2006–2008) comes mainly from the European Commission and the governments of Australia, Germany, Italy, and the Netherlands (altogether 62%) and WHO (30%). WHO's role in the Taskforce is to provide leadership, ensuring that its focus is on the protection of public health. This is facilitated by the fact that the Taskforce's secretariat is housed within the WHO Secretariat. Technical documents that are prepared by the Taskforce's working groups and approved by its members are issued as Taskforce documents. Some selected such documents are submitted for endorsement by WHO, for example, through Expert Committees.

¹ Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed.

² This includes any misleading statement with respect to name, composition, strength or other elements.

³ This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

⁴ This refers to all components of a medical product.

ACTION BY THE EXECUTIVE BOARD

14. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report on counterfeit medical products,¹

RECOMMENDS to the Sixty-second World Health Assembly the adoption of the following resolution:

The Sixty-second World Health Assembly,

Having considered the report on counterfeit medical products;

Recalling resolutions WHA41.16 and WHA47.13 on rational use of drugs and WHA52.19 on the revised drug strategy;

Concerned about the situation in which counterfeit medical products continue to move in international commerce, representing a major threat to public health, especially in the poorer areas of developing countries, and a challenge to the credibility and effectiveness of health systems;

Recognizing that the primary focus of combating counterfeit medical products is the protection of public health and that the main victims of counterfeiters are patients;

Recognizing the importance of ensuring that combating counterfeit medical products does not result in hindering the availability of legitimate generic medicines;

Recognizing that disputes about, or violations of, intellectual property rights are not to be confused with counterfeiting;

Recognizing that medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit;

Recognizing that quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices in legitimate medical products must not be confused with counterfeiting;

Aware of the importance of ensuring effective collaboration among patients, health professionals, the private sector and government institutions to combat counterfeit medical products effectively;

Cognizant of the importance of ensuring international collaboration and exchange of information in order to combat counterfeit medical products effectively;

¹ Document EB124/14.

Noting with satisfaction that the Director-General has intensified activities aimed at strengthening international collaboration to combat counterfeit medical products;

Recognizing the contribution of all parties concerned to the fulfilment of their responsibilities in compliance with the components of resolutions WHA41.16, WHA47.13 and WHA52.19 that specifically focus on combating counterfeit medical products, and encouraging all parties to continue that action;

Commending all parties that have contributed to, and WHO's leadership in promoting, the establishment of the International Medical Products Anti-Counterfeiting Taskforce, based on the Declaration of Rome (16 February 2006), and encouraging them to continue to support its activities;

Inviting bilateral agencies, multilateral bodies inside and outside the United Nations system, and voluntary organizations to support the International Medical Products Anti-Counterfeiting Taskforce and to provide support to developing countries in setting up and carrying out programmes aimed at combating counterfeit medical products, and acknowledging the work of those countries that are already doing so;

Requesting governments, pharmaceutical manufacturers and other concerned parties to cooperate in the detection, investigation and prevention of the increasing incidence of falsely labelled, spurious or counterfeited medical products moving in international commerce,

1. URGES Member States:

- (1) to reaffirm their commitment to develop, implement and monitor national policies and to take all necessary measures in order to ensure access to high-quality medical products;
- (2) to establish and enforce legislation and regulations that prevent counterfeit medical products from being manufactured, exported, imported or traded in international transactions and the regulated distribution system;
- (3) to establish effective mechanisms of coordination and collaboration among health, enforcement and other relevant authorities in order to improve detection, investigation and prosecution of cases of counterfeit medical products;
- (4) to establish appropriate mechanisms enabling international cooperation and exchange of information among relevant authorities involved in detecting and combating counterfeit medical products;
- (5) to alert and promote awareness among health professionals of the risks posed by counterfeit medical products;
- (6) to promote awareness among health professionals and consumers of the risks posed by counterfeit medical products acquired through unregulated outlets or unauthorized Internet sites;

2. REQUESTS the Director-General:

(1) to provide support to Member States in developing and implementing policies and programmes aimed at combating counterfeit medical products, including facilitating the exchange of information at the international level and the development of tools, guidelines, training and awareness initiatives, and methodology for evaluation and monitoring;

(2) to continue the development and dissemination of independent information on instances of counterfeit medical products;

(3) to cooperate with Member States, at their request, and with international organizations and other relevant parties in detecting, monitoring and analysing cases of counterfeit medical products and their impact on public health;

(4) to report to the Sixty-fourth World Health Assembly both on progress achieved and problems encountered in the implementation of the work of the International Medical Products Anti-Counterfeiting Taskforce, with recommendations for action and on progress in implementing this resolution.

= = =