



Counterfeit medical products

Report by the Secretariat

1. Counterfeiting medical products, from their manufacture to their supply to patients, is a serious crime that puts human lives at risk and undermines the credibility of health systems. Counterfeit medical products jeopardize progress achieved in public health and threaten the effectiveness of major initiatives aimed at priority diseases.
2. Resolutions WHA41.16 and WHA47.13 on the rational use of drugs, and resolution WHA52.19 on the revised drug strategy recognize the threat posed by counterfeit medical products and requested the Director-General to support Member States in their efforts to combat the manufacture, trade and use of counterfeit medical products. In response to these requests, the Secretariat has organized international consultations, intensified collaboration with Member States and other organizations, and issued guidelines for the development of measures to combat counterfeit drugs.¹
3. The context in which anti-counterfeiting strategies are implemented has changed markedly over the past decade. Intensified international commerce, the rapid expansion of the Internet and its commercial use, the widespread use of “free zones” in international trade, and the increasingly easy access to sophisticated technologies such as those for printing and manufacturing, have made it more difficult for governments and other concerned parties to combat counterfeiters of medical products effectively.
4. The extent of counterfeiting is impossible to quantify. However, the number of incidents detected in 2007 increased to over 1500 (that is on average more than four cases a day), roughly a 20% increase with respect to 2006 and a 10-fold increase compared with 2000. These increases reflect improved detection and reporting capacity, but also indicate that the problem is growing in numbers.
5. Counterfeiting affects all medical products: from medicines and pharmaceutical ingredients to medical devices and diagnostics. The consequences of their use can be extremely dramatic, as even the smallest cases concern at least one production batch, which amounts to thousands of tablets. In 2006, a counterfeit pharmaceutical excipient caused more than 100 deaths in Panama. A collaborative study conducted in 1999–2006 by the WHO Regional Office for the Western Pacific, the International Criminal Police Organization (INTERPOL) and other stakeholders has shown that about half the

¹ Document WHO/EDM/QSM/99.1.

samples of antimalarial medicines collected in the Mekong subregion contained no or insufficient amounts of active substances.¹

6. In addition to direct harm to patients and therapeutic failure, the presence of counterfeit medical products weakens public confidence in the entire health system, affecting the reputation of manufacturers, wholesalers, pharmacists, doctors, private organizations and government institutions alike.

7. Counterfeit medical products have been detected in most of WHO's Member States and in all its regions. Cases have involved widely-used medicines such as atorvastatin and paracetamol, limited-use medicines such as growth hormone, paclitaxel, and filgrastim, erectile dysfunction medicines, and medical devices such as contact lenses, condoms, surgical mesh, and diagnostic test strips used by diabetic patients to monitor their blood glucose concentrations. Both expensive products and cheap ones, generic and branded products are being counterfeited with the result that they appear in community pharmacies and hospitals, as well as other less-regulated settings.

8. Although organized crime and individuals acting alone have been associated with the manufacture of, and trade in, counterfeit medical products, in most cases counterfeit products appear to have been internationally traded between previously unconnected groups or individuals. This fact puts an equal responsibility on importing and exporting countries.

9. Many factors of varying importance between Member States contribute to creating an environment in which manufacture of, and trade in, counterfeit medical products can thrive:

- governments' unwillingness to recognize the existence or gravity of the problem
- inadequate legal framework and penalties
- weak administration and coordination, with measures not focused on fighting counterfeiting
- ineffective control of manufacturing, import and distribution of medical products
- ineffective collaboration among bodies and institutions, such as health authorities, police, customs and the judiciary, involved in regulation, control, investigation and prosecution
- ineffective collaboration and exchange of information between public and private sector
- insufficient international collaboration and exchange of information.

10. Besides the ubiquitous corruption, several other socioeconomic factors, many of which are specific to some countries or particular areas inside a country, undermine efforts against counterfeiting:

¹ Newton PN et al. A collaborative epidemiological investigation into the criminal fake artesunate trade in south-east Asia. *PLoS Medicine*, 2008, 5:e32 (<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050032>, accessed 10 March 2008).

- national drug policies that prioritize economic over public health aspects of medicine manufacturing, with the result that exporting takes priority over compliance with good manufacturing practices
- extreme fragmentation of distribution channels involving an unnecessarily large number of transactions, thereby increasing the opportunities for counterfeiters to infiltrate the normal distribution system
- existence of “extraterritorial” trade zones which largely escape from regulatory and enforcement oversight and goods and their accompanying documentation can be manipulated
- inadequate access to health services and reliable pharmaceutical supply channels that creates opportunities for “informal operators” who establish “informal supply systems” purportedly to meet populations’ real needs
- absence of or insufficient social security coverage in countries that do not regulate prices; the resulting search by patients for better prices often leads to fierce competition among vendors and opens opportunities for counterfeiters who can offer unbeatable prices
- illiteracy and poverty, which put patients at a particular disadvantage
- unregulated Internet trade, where unscrupulous sellers can hide their identity and the true origin of traded medical products
- third-party manufacturing, which, if not properly and carefully supervised, may lead to the unauthorized use of manufacturing techniques and packaging materials.

11. Against this background, WHO in 2006 launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Based on the principles enshrined in the Declaration of Rome (18 February 2006),¹ this taskforce aims to coordinate action across and between countries in order to halt the production, movement and commerce – both between traders and with consumers – of counterfeit medical products around the globe. It brings together all the major anti-counterfeiting bodies,² including international organizations, nongovernmental organizations, drug regulatory authorities, enforcement authorities, associations representing pharmaceutical manufacturers, wholesalers, health professionals and patients.

¹ <http://www.who.int/entity/medicines/services/counterfeit/RomeDeclaration.pdf>.

² IMPACT stakeholders include representatives from the following organizations: INTERPOL, Organisation for Economic Co-operation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, United States Pharmacopoeia, Commonwealth Secretariat, Association of Southeast Asian Nations Secretariat, International Federation of Pharmaceutical Manufacturers and Associations, International Generic Pharmaceuticals Alliance, World Self-Medication Industry, Asociación Latinoamericana de Industrias Farmacéuticas, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, the Pharmaceutical Security Institute, Pharmaciens sans frontières, ReMeD and International Alliance of Patients’ Organizations.

Five areas of action

12. The common agreement that (a) combating counterfeit medical products requires the coordinated effort of all the public and private stakeholders who are concerned and competent for addressing the different aspects of the problem and (b) effective coordination and cooperation at the international level are essential for regional and national strategies to be more effective was instrumental in the establishment of IMPACT.

13. The Taskforce has identified five areas where action is needed in order to combat counterfeit medical products effectively. Accordingly, five working groups have been created, covering: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology, and communication.

14. The Taskforce has developed “Principles and elements for national legislation against counterfeit medical products”.¹ The text will be disseminated and promoted during 2008 in order to provide support to countries that want to strengthen their legislative infrastructure. IMPACT has also developed recommendations for strengthening WHO’s Good Distribution Practices,² and has submitted them for consideration and appropriate action to WHO’s Expert Committee on Specifications for Pharmaceutical Preparations.

15. A guide to investigating counterfeiting of medical products and other pharmaceutical crimes has been prepared for IMPACT by the Permanent Forum on International Pharmaceutical Crime. The guide will be used in courses for the training of regulatory and enforcement officers. The two complementary goals that IMPACT wants to pursue with its training courses are: to provide training and to contribute to creating the conditions for improved collaboration between health and enforcement authorities in this very specific area.

16. IMPACT has drawn up a communication strategy for creating awareness of the risks created by counterfeit medical products in the supply systems, supporting policy objectives and increasing commitment of those who can influence change. Model materials have been prepared to create awareness among, and foster cooperation of, health professionals. Other materials aimed at enforcement officers are being developed.

17. IMPACT has published a summary assessment of existing technologies used to protect medical products.³ Meetings have been organized for technology developers, manufacturers and wholesalers of pharmaceutical and medical devices, and regulatory authorities in order to facilitate exchange of information and discuss cost, feasibility, specific country needs, and regulatory implications of the use of different technologies.

18. WHO, INTERPOL and the Association of Southeast Asian Nations Secretariat have launched a collaborative project for regulatory and enforcement authorities of all countries in the Mekong subregion: Cambodia, China, Lao People’s Democratic Republic, Myanmar, Thailand and Viet Nam. The project aims to disrupt the manufacture and trade of counterfeit antimalarial agents and antibiotics through intensified cross-border collaboration.

¹ <http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf>.

² <http://www.who.int/entity/impact/events/IMPACT-ACTechnologiesv3LIS.pdf>.

³ WHO Technical Report Services, No. 937, 2006.

Plans for the future

19. The Taskforce's work plans for 2008 are based on the recommendations provided by IMPACT's stakeholders at its second general meeting (Lisbon, 12–13 December 2007). The planned actions include:

- disseminating and promoting existing documents in order to build on consensus and convince decision-makers at all levels of the need to strengthen national capacity to combat counterfeit medical products;
- finalizing technical documents started in 2007, including those on the regulation of packaging materials, strategies for sampling and testing, information gathering for the assessment of national situations, and extending the web-based availability of the Rapid Alert System developed by the WHO Regional Office for the Western Pacific to all regions;
- designing a comprehensive approach to preventing the sale of counterfeit medical products through the Internet that will cover legislative and regulatory measures, investigative and enforcement aspects, collaboration with Internet service providers and electronic trade platforms, and initiatives to warn Internet users of the risk;
- creating initiatives that focus on the specific needs and problems related to counterfeit medical products in sub-Saharan Africa.

20. WHO's role in IMPACT is to work with Member States in order to mobilize all relevant sectors of the international community in support of common strategies against counterfeiting of medical products in line with the Organization's fundamental principles of promoting and protecting public health. This objective will be attained through strategic alliances with other international organizations and stakeholders, promotion of appropriate legal frameworks, effective exchange of information, involvement of health professionals, and building appropriate technical capacity at all levels.

ACTION BY THE HEALTH ASSEMBLY

21. The Health Assembly is invited to note the report and provide further guidance.

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