

Counterfeit medical products

Report by the Secretariat

1. In January 2009 the Executive Board at its 124th session considered a report from the Secretariat on counterfeit medical products and agreed to request the Director-General to revise the report in order to identify the public health concerns and focus on WHO's support to Member States in strengthening their medicines regulatory authorities and avoiding the negative impact of substandard and counterfeit medicines.¹

COUNTERFEIT MEDICINES

2. The occurrence of counterfeit medicines with their serious health repercussions, especially for the poor, is still increasing, although the exact magnitude of the problem is unknown; nonetheless, even a single case of counterfeiting is unacceptable.

3. Member States increasingly undertake studies to quantify the problem. An example was given by Nigeria during the Sixty-first World Health Assembly in 2008.² Other examples can be found on the web sites of national medicines regulatory authorities. In addition, WHO has carried out studies in Myanmar and Viet Nam.³

4. WHO has also been collecting counterfeit medicines-related data,⁴ as no accurate data on the extent of the problem exist and any type of product can be counterfeited. In some countries occurrence of counterfeiting relates to expensive lifestyle medicines, hormones, steroids and anticancer medicines; in others it may relate to inexpensive generic medicines. In developing countries the most disturbing occurrence is the common availability of counterfeit medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. Experience has shown that vulnerable patient groups who pay for medicines out of their own pocket are often the most affected.

5. The basic investigational elements of studies aimed at identifying the magnitude of the problem of counterfeiting in a national market are sound laboratory testing and verification of information available from national medicines regulatory authorities. Despite such measures, it is hard to trace the source. Close collaboration with the original manufacturers – who mostly use new technologies to identify their products unambiguously – as well as with enforcement agencies – using forensic means

¹ Document EB124/2009/REC/2, summary record of the ninth meeting.

² Document WHA61/2008/REC/3, summary record of the tenth meeting of Committee A.

³ Document WHO/EDM/QSM/99.3.

⁴ For details see the WHO web site under Health Topics.

of analysis – has proved to be effective in tracing and fully identifying counterfeit medicines in recent years. Nevertheless, the full extent of the problem is unknown.

6. Counterfeiters are criminals, usually working within international networks and not easily traceable. The normal regulatory approach for legally manufactured but substandard medicines cannot, therefore, be used alone and there is a need for collaboration with governmental institutions, such as legislative bodies, enforcement agencies and courts.

7. Counterfeiting is primarily motivated by its potentially huge profits and criminals are adept at quickly adjusting to where the most money can be made. Factors that facilitate the production or circulation of counterfeit medical products include lack of appropriate legislation, absence or weakness of national medicines regulatory authorities, inadequate enforcement of existing legislation and weak penal sanctions.

WHO'S INVOLVEMENT IN COMBATING COUNTERFEIT MEDICINES

8. In response to a recommendation by the Conference of Experts on the Rational Use of Drugs (Nairobi, 25–29 November 1985), at which the problem of counterfeit medicines was first discussed at the international level, WHO, together with other international and nongovernmental organizations, set up a clearing house to collect data and to inform governments about the nature and extent of counterfeiting.

9. As requested by resolution WHA41.16 in 1988, the Director-General initiated programmes for the prevention and detection of the export, import and smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations.

10. The first international meeting on counterfeit medicines, a workshop organized jointly by WHO and the International Federation of Pharmaceutical Manufacturers and Associations, was held from 1 to 3 April 1992 in Geneva in response to this resolution. The participants agreed on the following 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 or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.

11. The workshop also adopted comprehensive recommendations which urged the commitment of all parties involved in medicines manufacture, distribution and use, including pharmacists and consumers, in solving the problem of counterfeit medicines.

12. Given the rapid spread of counterfeit medicines in many national distribution channels, and following the adoption by the Health Assembly of resolution WHA47.13 in 1994, the Secretariat has provided support to Member States in their efforts to ensure that available medicines were of good quality and in combating the use of counterfeit medicines.

13. In 1995, WHO, with financial assistance from the Government of Japan, launched the Project on Counterfeit Drugs. The objective was to support Member States in assessing the problem of counterfeit medicines and designing measures to combat counterfeiting. As one of the first outcomes

of these efforts, WHO drafted guidelines for the development of measures to combat counterfeit medicines.

14. Increasing international trade of pharmaceuticals and sales through the Internet has further facilitated the entry of counterfeit products into the supply chain. In a meeting before the eleventh International Conference of Drug Regulatory Authorities (Madrid, 16–19 February 2004), combating of counterfeit medicines was reviewed. The main recommendations were taken up in the Conference and WHO was requested to develop a concept paper for an international convention on counterfeit medicines and to convene a regulators' meeting to discuss it. The regulators' meeting and further explanatory work revealed that there was no consensus among Member States for such an international convention; thus the idea to start a wide action-oriented international partnership led by WHO emerged.

15. In 2006 this led to WHO's launch of the International Medical Products Anti-Counterfeiting Taskforce, which has become the main conduit for WHO's work on counterfeits. Following discussions at the Sixty-first World Health Assembly and the 124th session of the Executive Board, the Secretariat has established a programme to coordinate its work to combat counterfeit medicines, including coordination with the members of the Taskforce and providing it with secretariat functions.

QUALITY

16. The tools and systems for quality assurance of medicines developed under the auspices of WHO's Expert Committee on Specifications for Pharmaceutical Preparations help many public health actors to work towards ensuring that all essential medicines, including those used in treating large populations, are safe, effective and of good quality. The norms, standards and guidelines reviewed by the Committee are prepared through a rigorous consultative process involving WHO's Member States, national authorities and international agencies such as UNICEF. They are submitted to WHO's governing bodies for information and subsequent implementation by Member States.

17. The comprehensive guidelines for quality assurance include recommendations that cover the development and production of medicines through to their distribution to patients.¹ Development of quality assurance standards is usually triggered by resolutions adopted by the Health Assembly and Executive Board and by the biennial International Conference of Drug Regulatory Authorities. These international guidelines have also contributed to the improvement of medicines regulation at country and global levels. Besides setting norms and standards, WHO supports countries in building national regulatory capacity. These activities have also been endorsed and supported by the Health Assembly through numerous resolutions.

18. The core functions of WHO's medicines regulatory support programmes include the provision of direct country and regional support for strengthening medicines regulation; developing and continuously improving tools to assist regulatory work; facilitating communication; and promoting harmonization among medicines regulatory authorities.

19. Country support involves assessing medicines regulatory systems to identify needs, prepare institutional plans, and provide financial support and capacity building, based on WHO's data

¹ The guidelines can be found on the WHO web site under Health Topics.

collection tools and methodology. To date, 44 assessments have been performed on 40 regulatory systems with the involvement of regional offices and in close collaboration with the capacity-building teams from WHO's Secretariat. Technical assistance has also been given to regional harmonization initiatives and for supporting the participation of bodies such as the Southern African Development Community, East African Community and the Caribbean Community.

20. WHO has organized the International Conference of Drug Regulatory Authorities every two years since 1980 with the objective of promoting harmonization, exchange of information, and finding collaborative approaches to problems of common concern to medicines and biological regulatory authorities worldwide.

21. In addition, the Prequalification of Medicines Programme forms part of WHO's activities in this area. This service aims to facilitate access to medicines that meet unified international standards of quality, safety and efficacy for HIV/AIDS, malaria, tuberculosis and reproductive health. Established in 2001, it was originally intended to promote consistency across United Nations procurement systems such as those of UNICEF and UNAIDS, and to present them with a choice of high-quality medicines. The Programme draws on the expertise of some of the leading national regulatory authorities to provide a list of prequalified products that comply with unified international standards.¹

REGIONAL ACTIVITIES ON COUNTERFEIT MEDICINES

22. Weak medicines regulatory authorities and proliferation of illicit medicine in many countries of the **African Region** are major challenges. An interregional meeting on combating counterfeit medical products (Abuja, 29 and 30 October 2008) was attended by medicines regulatory authorities, police and the customs authorities of 13 countries in the Region. It was proposed that WHO should continue to support countries to develop initiatives focused on the specific needs and problems related to counterfeit medical products; undertake country studies to quantify the magnitude of the problem; and draw up information, education and communication strategies on the dangers of counterfeit medical products for health workers and the general public.

23. Within the Pan American Network for Drug Regulatory Harmonization, the Working Group on Combating Drug Counterfeit was set up in 1999. A regional study was conducted to determine the situation of medicines counterfeiting in the countries of the **Region of the Americas**. It revealed that drug counterfeiting was a problem that existed in varying degrees in most countries of the Region. To bring greater focus to the problem, the Working Group created a road map to evaluate the cycle of implementation by each country's focal point and to implement prevention and combating of medicines counterfeiting as part of their national health authorities.

24. The **Eastern Mediterranean Region Office** supports Member States in the Region by strengthening national medicines regulatory authorities; building the capacity of national quality control laboratories; encouraging medicines regulatory authorities to participate in meetings and the work of the International Medical Products Anti-Counterfeiting taskforce; and by sharing

¹ WHO gratefully acknowledges the assistance provided in 2008 by staff from the medicines regulatory authorities of Australia, Austria, Brazil, Canada, China, Estonia, Ethiopia, France, Germany, Ghana, Hungary, Italy, Kenya, the Netherlands, Poland, Singapore, South Africa, Spain, Sweden, Switzerland, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania and Zimbabwe.

recommendations and outcomes of the Taskforce's meetings with medicines regulatory authorities. In addition, a review of different national situations concerning counterfeit medicines is under way.

25. In the **European Region**, combating counterfeit medicines is part of WHO's work on strengthening regulatory authorities, and special projects are currently being carried out in Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Kazakhstan, Kyrgyzstan, Montenegro, Republic of Moldova, Russian Federation, The former Yugoslav Republic of Macedonia, Ukraine and Uzbekistan. In addition, close collaboration on counterfeit medical products is ongoing with the Council of Europe.

26. In the **South-East Asia Region** combating counterfeit medicines/medical products was discussed by the Regional Committee in 2008.¹ The Committee re-emphasized the importance of the public health focus in combating counterfeit medicines and separating them from intellectual property rights issues. The necessity for effective mechanisms of cooperation between medicines regulators, police, customs, prosecutors and, where applicable, health professionals, manufacturers, wholesalers, retailers and consumers' organizations was noted. These mechanisms should extend to cooperation between countries for effective combating of counterfeiting.

27. Combating counterfeit medicines is a high priority in the **Western Pacific Region**. Technical support for both intercountry activities and individual country-specific activities has been provided over the past 10 years. These activities have included, among others, intercountry workshops on combating counterfeit medicines (Cambodia, 2001; Thailand, 2002; Viet Nam, 2003; Philippines, 2005); national training on improving inspection capacity (Lao People's Democratic Republic, Philippines, Viet Nam); intensified surveys (Cambodia, Lao People's Democratic Republic, Mongolia, Philippines); and public advocacy activities (Cambodia, Mongolia, Philippines). A regional rapid alert system was introduced in 2004 as an early warning mechanism, involving focal points from countries and partners in the Western Pacific and South-East Asia Regions. WHO has collaborated with the International Criminal Police Organization and other partners to investigate the distribution of fake artesunate in the Greater Mekong subregion in Operation Jupiter (2006), followed by the region-wide Operation Storm (2008) to undertake criminal investigation and legal enforcement.

ACTION BY THE HEALTH ASSEMBLY

28. The Health Assembly is invited to note this report.

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¹ See document SEA/RC61/27 and Report of the Sixty-first session, Part 3, paragraphs 176–182.