World Health Organization

SIXTY-THIRD WORLD HEALTH ASSEMBLY **A63/23**
Provisional agenda item 11.20 **22 April 2010**

Counterfeit medical products

Report by the Secretariat

1. In January 2009 the Executive Board at its 124th session requested the Director-General to revise the report on counterfeit medical products before its submission to the Health Assembly in order to identify the public health concerns and focus on the Secretariat's support to Member States in strengthening their medicines regulatory authorities and avoiding the negative impact of substandard and counterfeit medicines.[1] The Sixty-second World Health Assembly decided to postpone consideration of the matter to the provisional agenda of the Sixty-third World Health Assembly.[2]

COUNTERFEIT MEDICINES

2. During the discussion of the subject by the Board in January 2009 and the debates on other matters in the Sixty-second World Health Assembly,[3] concerns were raised about the use of the term "counterfeit medicines".[4] Subsequently, the Director-General invited Member States and Associate Members to provide information about their use of this term and/or equivalent in national legislation. Commonly used language includes the terms: falsified, spurious, fake and substandard.

3. The reporting of occurrences 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. Member States are increasingly undertaking studies to quantify the problem. An example was given by Nigeria during the Sixty-first World Health Assembly in 2008.[5] Other examples can be found on the web sites of national medicines regulatory authorities, including those from Thailand, United Kingdom of Great Britain and

[1] See document EB124/2009/REC/2, summary record of the ninth meeting.

[2] See documents WHA62/2009/REC/3, summary record of the first meeting of the General Committee and WHA62/2009/REC/2, verbatim record of the second plenary meeting, section 2.

[3] See document WHA62/2009/REC/3, summary records of the fifth meeting of Committee A, section 2, the tenth meeting of Committee A, section 1, and the third meeting of Committee B, section 3.

[4] The term "counterfeit medicines" was used in several Health Assembly resolutions (see resolutions WHA41.16 on rational use of drugs, WHA47.13 on rational use of drugs: the WHO Action Programme on Essential Drugs, and WHA52.19 on revised drug strategy). The term has subsequently been used in various WHO guidelines, for example those on good distribution practices for pharmaceutical products.

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

Northern Ireland, United Republic of Tanzania and United States of America. In addition, WHO has carried out studies in Myanmar and Viet Nam.[1]

4. The variety of information sources makes compiling statistics a difficult task. Sources include reports from national medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies of specific geographical areas or therapeutic groups. The different methods used in the studies and to produce reports compound the difficulties in compiling and comparing data. Studies can give only snapshots of the immediate situation. Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can rapidly change these methods, so that the results of a study when released may already be outdated. Furthermore, information about a case under legal investigation is sometimes made public only after the investigation has been concluded.

5. WHO also has been collecting data related to counterfeit medicines,[2] 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 hormones, steroids and anticancer medicines and pharmaceuticals related to lifestyle; 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.

6. 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 (which mostly use new technologies to identify their products unambiguously) and enforcement agencies (which use forensic means of analysis) has proved to be effective in tracing and fully identifying counterfeit medicines in recent years.

7. Most countries have mechanisms in place for regulatory authorities to take measures against substandard medicines and their manufacturers, but, as counterfeiters usually work in unauthorized settings, within international networks and are not easily traceable, the above-mentioned national and regional regulatory procedures for law enforcement may be only partially successful. Thus, the normal regulatory approach for legally manufactured but substandard medicines cannot be used alone and there is a need for national and international collaboration with other governmental institutions, such as legislative bodies, enforcement agencies and courts.

8. Counterfeiting is primarily motivated by its potentially huge profits and counterfeiters are adept at quickly adjusting to different contexts and products for which they can make the most money. 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.

[1] Document WHO/EDM/QSM/99.3.

[2] For details see the WHO web site under Health Topics.

WHO'S INVOLVEMENT IN COMBATING COUNTERFEIT MEDICINES

9. 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 with other international and nongovernmental organizations set up a clearinghouse to collect data and to inform governments about the nature and extent of counterfeiting.

10. 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.

11. 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.

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

13. 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.

14. 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, the Secretariat drafted guidelines for the development of measures to combat counterfeit medicines.

15. 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.

16. 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 counterfeit medicines. 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.

17. In order to assist Member States in their discussion on this topic WHO's new anti-counterfeiting programme aims to distinguish clearly between the WHO Secretariat's activities and those of the Taskforce. Two different web sites[1] have been established. A new WHO fact sheet has been issued.[2] Major efforts have been undertaken to mobilize resources for the new programme.

18. After reports had been received about the increased occurrence of counterfeit medicines during the pandemic of influenza A (H1N1) 2009, WHO issued an alert to warn about the purchase of antiviral agents without a prescription, including purchase over the Internet.[3]

19. In response to the Director-General's request (paragraph 2) for information on use of the term "counterfeit medicines" and related definitions, 55 Member States and the European Commission have so far provided answers, and a preliminary summary was presented to the Member States at an open forum held in Geneva on 26 March 2010. An analysis and subsequent inputs will be presented to the Expert Committee on Specifications for Pharmaceutical Preparations for further discussion. The Expert Committee's recommendations will be set forth in its report and the Director-General will submit a report on its meeting to the Executive Board in line with the Regulations for Expert Advisory Panels and Committees.[4]

20. In October 2009 the Expert Committee on Specifications for Pharmaceutical Preparations at its forty-fourth meeting recommended the revision of the WHO guidelines on good distribution practices for pharmaceutical products, building on the input from the Taskforce's working group on regulatory implementation.[5]

QUALITY

21. 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.

22. The comprehensive guidelines for quality assurance include recommendations that cover the development and production of medicines through to their distribution to patients.[6] Development of quality assurance standards is usually triggered by resolutions adopted by the Health Assembly and

[1] http://www.who.int/medicines/services/counterfeit/en/index.html and http://www.who.int/impact/en/index.html.

[2] http://www.who.int/mediacentre/factsheets/fs275/en/index.html.

[3] http://www.who.int/medicines/publications/drugalerts/Alert_122_Antivirals.pdf.

[4] *Basic documents*, 47th edition. World Health Organization, Geneva, 2009.

[5] See document EB127/10.

[6] The guidelines can be found on the WHO web site under Health Topics.

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.

23. 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.

24. 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 collection tools and methodology. To date, 44 assessments have been made of 40 regulatory systems with the involvement of regional offices and in close collaboration with the capacity-building teams from the WHO 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.

25. 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.

26. 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

27. Weak medicines regulatory authorities and proliferation of illicit medicines 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. At a two-day regional conference on combating counterfeit medical products (Johannesburg, South Africa, 9 and 10 November 2009), organized by

[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.

the International Criminal Police Organization and WHO under the auspices of the International Medical Products Anti-Counterfeiting Taskforce, representatives from the invited 15 national medicines regulatory authorities, police and customs reviewed the situation regarding counterfeit medicines across southern Africa, particularly within members of the Southern African Development Community. The meeting concluded with several recommendations for enhancing cooperation between the various agencies involved. Participants agreed to establish a proper legal framework to support prosecutions, the creation of national multi-agency taskforces with links to the Taskforce, and the expansion of combined enforcement activities.

28. African medicine regulators met in Maputo, Mozambique (23–26 November 2009) to discuss ways of improving the availability of essential medicines that meet safety, efficacy and quality standards. The regulators also discussed strategic approaches to strengthening WHO's Harmonization of Medicines Regulation in Africa project. This Second African Medicines Regulators Conference was organized to strengthen national capacities for effective medicine regulation, including prevention of circulation of counterfeit and substandard medicines in this Region.

29. 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 for use in evaluating 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. In late 2008, the Regional Office for the Americas issued a document on the situation on Prevention and Combat of Counterfeit Medicines in the Caribbean Countries. The Working Group on Combating Drug Counterfeit of the Pan American Network for Drug Regulatory Harmonization organized three national meetings for supporting the establishment of national anti-counterfeiting task forces. These meetings were attended by the different parties concerned (customs authorities, police, legislative and enforcement authorities, universities, consumers associations and health ministries) and aimed at building national groups with the participation of the aforementioned stakeholders and to design a brief working plan. The meetings were held in Panama (2008), Plurinational State of Bolivia (2009) and Jamaica (2009). The first direct consequence has been in Panama where an interagency agreement to combat counterfeit medical products has been set in place.

30. 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 recommendations and outcomes of the Taskforce's meetings with medicines regulatory authorities. In addition, a review of different national situations concerning counterfeit medicines has been completed and a detailed assessment is planned for at least two countries in the period 2010–2011.

31. In the **European Region**, the Regional Office works together with the regulatory authorities of Member States on combating counterfeit medicines, and provides support especially to the countries of south-eastern Europe and the newly independent states, including Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Ukraine and Uzbekistan. In addition, the Regional Office is closely following the efforts undertaken by the Council of Europe in the preparation of an international convention to combat counterfeiting. This convention is currently under discussion in the Council's Committee of Ministers and is expected to be agreed later this year. The convention would specifically enlarge the legal possibilities for combating counterfeiting crimes. At the same time the European Commission and the European Union's Member States are also

discussing new legislation on counterfeit medicines, which is also expected to be passed in the next months.

32. In the **South-East Asia Region** combating counterfeit medicines/medical products was discussed by the Regional Committee in 2008.[1] Member States reiterated the importance of a public health focus in combating counterfeit medicines, emphasizing quality, safety and efficacy and separating this from intellectual property rights issues. Concern was expressed at the seizure in transit of consignments of generic medicines meant for developing countries. In order to promote cooperation and strengthen regional and international collaboration on these issues, a staff member from the Regional Office participated in the African regional conference on combating counterfeiting medical products (see paragraph 28).

33. 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) and Operation Storm II (2009) to undertake criminal investigation and legal enforcement. An expert consultation was undertaken in Manila (February 2010) in order to strengthen the surveillance and alert system for combating counterfeit medicines.

ACTION BY THE HEALTH ASSEMBLY

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

= = =

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