

WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/false-labelled/falsified/counterfeit medical products

1. WHO's activities in the prevention and control of substandard/spurious/false-labelled/falsified/counterfeit medical products form a part of its work in the area of quality and safety of medicines.¹ The establishment of the present working group was mandated in May 2010 by the Sixty-third World Health Assembly.²

SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS – THE EXTENT OF THE PROBLEM

2. Counterfeiting can apply to both branded and generic products; substandard/spurious/false-labelled/falsified/counterfeit medical products may include those with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging. Although the number of reported cases of substandard/spurious/false-labelled/falsified/counterfeit medical products – with their serious health repercussions, especially for the poor – continues to rise, the exact magnitude of the problem is unknown. Many Member States are showing more interest in quantifying the problem, and are conducting analyses of the trend in the form of market studies.³ WHO's most recent studies were carried out in Myanmar and Viet Nam.⁴

3. The diversity of sources of information makes compiling statistics a challenge. 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, especially sampling, used in the studies and the varying approaches to preparing reports compound the difficulties in compiling and comparing data. Furthermore, studies can only give snapshots of the immediate situation. Counterfeiters, by contrast, are extremely flexible in the methods they use to mimic products and prevent detection of their

¹ See document A/SSFFC/WG/2, Figure.

² See decision WHA63(10).

³ Examples can be found on the web sites of national medicines regulatory authorities, including those from Thailand, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania and United States of America.

⁴ See document WHO/EDM/QSM/99.3, available online at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed 12 January 2011).

activities. They can change their methods rapidly, so that the results of a study about such activities may be outdated even at the moment of release. In addition, information about a case under legal investigation is sometimes made public only after the investigation has been concluded and the case closed. This can mean lengthy periods of time that substandard/spurious/falsely-labelled/falsified/counterfeit medical products remain available; additionally, it can mean that the professionals (such as the health professionals and regulators) are not taking required action to protect patients because information, or the availability of information, can be compromised.

4. 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 not always possible to trace the source of the problem. 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 substandard/spurious/falsely-labelled/falsified/counterfeit medical products in recent years.

5. In some countries, 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 trend is the common availability of substandard/spurious/falsely-labelled/falsified/counterfeit medical products 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. Counterfeiting is primarily motivated by its potentially huge profits. The success of counterfeiters is, at least in part, a function of their capacity both to adjust quickly to different contexts and products, and to change their focus of interest swiftly, according to where the most money can be made. Many factors facilitate the production or circulation of substandard/spurious/falsely-labelled/falsified/counterfeit medical products, including lack of equitable access to essential medicines; the presence of outlets for unregulated medicines; a lack of appropriate legislation; absence or weakness of national medicines regulatory authorities; inadequate enforcement of existing legislation; and weak penal sanctions.

7. Most countries have mechanisms in place enabling regulatory authorities to take measures against substandard medicines and their manufacturers, but, as counterfeiters usually work in unauthorized settings, within international networks and with the intention of hiding their identity, such law enforcement measures taken by national and regional regulatory procedures may be only partially successful. Thus, the normal regulatory approach for legally manufactured but substandard medicines cannot be effective if undertaken in isolation. There is a need for national and international collaboration with other governmental institutions, such as legislative bodies, enforcement agencies and courts.

A GLOBAL PROBLEM NEEDS A GLOBAL SOLUTION

8. The problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products can be divided into five distinct areas.

Lack of awareness

9. There is a lack of awareness on the part of both professionals and patients with regard to the extent of the problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products and the potential dangers of buying medicines from unlicensed distributors or through the Internet. There is a similar lack of awareness of what to do in the case of suspected substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

Lack of technology, tools, standards and procedures

10. Global consensus has not been reached on a definition for the various types of substandard/spurious/falsely-labelled/falsified/counterfeit medical products. Further, sampling and testing protocols to detect substandard/spurious/falsely-labelled/falsified/counterfeit medical products, and robust statistical methods to assess and report the problem are also lacking. The research-based pharmaceutical industry is investing heavily in tools and technologies to prevent, deter and detect substandard/spurious/falsely-labelled/falsified/counterfeit medical products, and to create procedures that can assist health-care professionals and patients to identify genuine products. However, the international regulatory and professional collaboration required to ensure that such mechanisms be successfully implemented and expanded is often lacking.

Lack of legislative and regulatory infrastructure

11. Legislation to combat substandard/spurious/falsely-labelled/falsified/counterfeit medical products is insufficient, inadequate or non-existent in many countries. That which is available varies widely from country to country, in terms of definitions and sanctions. In many countries the only legal instrument available to deal with the public health aspect of substandard/spurious/falsely-labelled/falsified/counterfeit medical products is legislation related to intellectual property rights, which fuels the global confusion between public health and the objectives of intellectual property rights. Similarly, supportive regulations and regulatory mechanisms are often missing, and sanctions are ineffectual or non-existent. As a result, very few countries have adequate legal and regulatory means to combat effectively the public health aspect of substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

Lack of regulatory implementation

12. Many countries fail to ensure good procurement practices and effective regulation of distribution chains, which readily opens opportunities for substandard/spurious/falsely-labelled/falsified/counterfeit medical products to enter the regular supply system. Most countries also lack procedures to assess and report the extent of the problem or monitor trends over time. As mentioned, the definitions of substandard/spurious/falsely-labelled/falsified/counterfeit medical products are widely divergent. National statistics are often inconsistent and cannot be compared or combined to provide regional or global figures. Mechanisms of information exchange among neighbouring countries are largely absent, and even when such information is received, most countries do not have adequate mechanisms in place to make effective use of it.

Lack of enforcement

13. Counterfeiters hide their identity and the source of substandard/spurious/falsely-labelled/falsified/counterfeit medical products is nearly always unknown. Normal regulatory control mechanisms cannot be used, since they are based on the assumption that the manufacturer or

distributor of a substandard product can be approached. Additional enforcement mechanisms are needed, such as forensic investigations and criminal proceedings. Good national cooperation structures, such as a central reporting point, are necessary in order to make full use of information obtained by professionals, regulators, customs, enforcement agencies and the police. Very few countries have such structures in place; even fewer have mechanisms to deal with the cross-border trade of substandard/spurious/falsely-labelled/falsified/counterfeit medical products. Lack of legal sanctions and lack of enforcement mean that counterfeiting medicines is a low-risk and profitable crime.

DEVELOPMENT OF WHO'S ACTIVITIES FROM 1985 TO 2005

14. The problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products was first discussed at the international level in response to a recommendation by the Conference of Experts on the Rational Use of Drugs (Nairobi, 25–29 November 1985). WHO, 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. In 1988, the Health Assembly adopted resolution WHA41.16, in which the Director-General was requested, inter alia, to initiate programmes for the prevention and detection of export, import and smuggling of falsely-labelled, spurious, counterfeit or substandard pharmaceutical preparations, and to cooperate with the Secretary-General of the United Nations in cases where the provisions of the international drug treaties were violated.

15. One element of this initiative was the first international meeting on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, a workshop organized jointly by WHO and the International Federation of Pharmaceutical Manufacturers and Associations (Geneva, 1–3 April 1992). Participants at this workshop agreed a definition of “counterfeit” medicines.¹ At the same time, comprehensive recommendations were adopted that urged the commitment of all parties involved in the manufacture, distribution and use of medicines, including pharmacists and consumers, to solving the problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

16. The spread of substandard/spurious/falsely-labelled/falsified/counterfeit medical products in many national distribution channels has been rapid, and since 1994, when in resolution WHA47.13 the Health Assembly, inter alia, requested the Director-General to support Member States in their efforts in combating the use of “counterfeit drugs”, the Secretariat has provided support to Member States in their efforts to ensure that available medicines are of good quality and in combating the use of substandard/spurious/falsely-labelled/falsified/counterfeit medical products. In 1995, the Organization, with financial assistance from the Government of Japan, launched the DMP-DAP Joint Project on Counterfeit Drugs. The objective was to support Member States in assessing the problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products and in 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 drugs*.²

¹ Available online at <http://www.who.int/medicines/services/counterfeit/overview/en/> (accessed 10 January 2011).

² Document WHO/EDM/QSM/99.1, available online at <http://www.who.int/medicines/publications/counterfeitguidelines/> (available in English and French) (accessed 10 January 2011).

17. Increasing international trade of pharmaceuticals and sales through the Internet has further facilitated the entry of substandard/spurious/falsely-labelled/falsified/counterfeit medical products into the supply chain. In a meeting before the 11th International Conference of Drug Regulatory Authorities (Madrid, 16–19 February 2004), combating of substandard/spurious/falsely-labelled/falsified/counterfeit medical products was reviewed. The main recommendations were taken up during the Conference itself, which was attended by the regulatory agencies of nearly 100 Member States. WHO was requested to develop a concept paper for an international convention on substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to convene a regulators' meeting to discuss it. The subsequent regulators' meeting and further explanatory work revealed that there was no consensus among Member States upon which to base such a convention. An alternative emerged: to start a wide, action-oriented international initiative led by WHO. In 2006, this led to the launch of the International Medical Products Anti-Counterfeiting Taskforce.

WHO'S ACTIVITIES FROM 2007 TO 2009

18. From 2007 to 2009, the Taskforce became the main conduit for WHO's work on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, resulting in WHO's more active involvement in combating substandard/spurious/falsely-labelled/falsified/counterfeit medical products than in preceding years, with a strong new role for WHO in planning and coordinating the work.¹ In addition, there was more intensive contact among the Secretariat, Member States and the various other stakeholders through the Taskforce's planning committee and its annual meetings, through WHO's hosting of the Taskforce's secretariat, and through its Assistant Director-General's chairmanship of the Taskforce. During those years, WHO and the Taskforce enhanced collaboration among national and interregional medicines regulatory authorities, national and international enforcement authorities, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups.

WHO'S PROGRAMME FROM 2009 TO THE PRESENT

19. In 2009, following discussions at the Sixty-first World Health Assembly and the 124th session of the Executive Board, and the questions raised about WHO's involvement in the Taskforce,² WHO formally re-established its own programme to combat substandard/spurious/falsely-labelled/falsified/counterfeit medical products within the Essential Medicines and Pharmaceutical Policies Department, in addition to its continuing involvement in the Taskforce. WHO also introduced a clear distinction between the Secretariat's activities and those of the Taskforce; for example, two different web sites were established³ and a new WHO fact sheet was issued.⁴

20. The focus of WHO's activities was in the area of advocacy, norms and standards, and technical support to certain countries and regions that requested assistance. For example, after reports had been

¹ See document A/SSFFC/WG/4.

² See document WHA61/2008/REC/3, summary record of the tenth meeting of Committee A, and document EB124/2009/REC/2, summary record of the ninth meeting.

³ Available online at <http://www.who.int/medicines/services/counterfeit/en/index.html> (accessed 12 January 2011) and <http://www.who.int/impact/en/index.html> (accessed 12 January 2011).

⁴ Available online at <http://www.who.int/mediacentre/factsheets/fs275/en/index.html> (accessed 12 January 2011).

received about the increased incidence of substandard/spurious/falsely-labelled/falsified/counterfeit medical products during pandemic (H1N1) 2009, WHO issued an alert, warning about the purchase of antiviral agents without a prescription, including purchase over the Internet.¹ In October 2009, the 44th WHO Expert Committee on Specifications for Pharmaceutical Preparations recommended the revision of WHO guidelines on good distribution practices for pharmaceutical products, building on the input from the Taskforce's working group on regulatory implementation.²

21. In late 2009, WHO undertook a global survey on the use of the term “counterfeit medicine” and definitions of related words in various national legislations. A preliminary summary of the survey is posted on the WHO web site for additional feedback³ and will be presented to the WHO Expert Committee on Specifications for Pharmaceutical Preparations for further discussion.

22. Since July 2010, WHO's work in this area has continued, but on a sharply reduced scale, owing to limited resources. Its focus is on developing global normative guidance and expansion of the Rapid Alert System in some regions.

FOCUS OF WHO'S FUTURE INVOLVEMENT

23. Globally, substandard medicines constitute the most common type of quality problem, and the one that has the largest negative impact on health. WHO will therefore continue to strengthen its global and country-level activities in promoting the availability of efficacious, safe and affordable medicines of good quality. Strengthening national regulatory systems will also, indirectly, reduce the possibilities for substandard/spurious/falsely-labelled/falsified/counterfeit medical products to enter the market. Since regulatory approaches on their own are not sufficient, as discussed, specific additional actions will be needed to combat the negative public health impact of substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

Advocacy and information

24. In terms of the problem of substandard/spurious/falsely-labelled/falsified/counterfeit medical products, the promotion of awareness of it, including the extent and dangers of it, and the necessary actions against it will be central activities of WHO, together with all relevant stakeholders. The campaign will target governments, health policy-makers, health professionals and the public.

Global norms, standards, tools and procedures

25. In order to foster such awareness and to give meaningful technical support to Member States and other stakeholders, the Secretariat must first be clear and consistent in several areas: the definitions, the recommended actions and the public messages. To this end, WHO will develop the necessary technical definitions, global norms and standards for assessment methods, technologies, and

¹ Available online at http://www.who.int/medicines/publications/drugalerts/Alert_122_Antivirals.pdf (accessed 13 January 2011).

² See documents EB127/10 and WHO Technical Report Series 957. WHO Expert Committee on Specifications for Pharmaceutical Preparations Forty-fourth report, Geneva, World Health Organization, 2010, pp. 71–72; Annex 5, pp. 235–264.

³ Available online at http://www.who.int/medicines/services/counterfeit/WHO_ACM_Report.pdf (accessed 13 January 2011).

legal and regulatory measures for combating substandard/spurious/falsely-labelled/falsified/counterfeit medical products, using the Organization's well-established procedures for the independent development of global standards and policy guidance.

26. In this regard, many experts recognize that the term "counterfeit medicine", while fully appropriate and generally accepted at the time of its first use in 1988, has been overtaken by international developments and is now increasingly perceived as associated with intellectual property rights rather than public health. In order to stress the public health aspect of the problem while developing the global norms and standards, it is proposed that "counterfeit" in WHO's definition be modified to "falsified", and that the term "counterfeit medicine" be reserved for a falsified medicine with a counterfeit trademark, in accordance with existing WIPO definitions.

Technical support to Member States

27. Falsified medicines are more than simply substandard; combating falsified medicines is beyond the normal scope of regulatory control, as the manufacturer or distributor is usually difficult to trace. Combating falsified medicines is therefore a joint responsibility of the regulatory authority and other national organizations, including professional organizations, forensic investigation units, customs and other law enforcement agencies. In supporting Member States in this effort, the Secretariat will focus its activities on the public health aspects of the problem and will continue to support Member States' regulatory agencies and other relevant bodies in developing and implementing the necessary legislation, regulations and procedures.

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