World Health Organization

WORKING GROUP OF MEMBER STATES ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/ FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
Provisional agenda item 4

A/SSFFC/WG/2/3
23 September 2011

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

1. The Secretariat's report presented to the first session of the Working Group on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products outlined WHO's current activities.[1] The report of that session[2] provided a synopsis of a number of activities discussed in the Working Group. The related activities addressing both substandard and spurious/falsely-labelled/falsified/counterfeit medical products were listed under the following main headings: information and awareness creation; norms and standards; and technical support to countries.

2. Most countries have mechanisms in place to enable regulatory authorities to take measures against substandard medicines and other medical products and against their manufacturers. However, some countries may not have the legal framework in place to address spurious/falsely-labelled/falsified/counterfeit medical products. In some countries, this deficiency is being addressed by a joint effort of national authorities and stakeholders. Often such actions call for cooperation with another country or at a global level. In close collaboration with Member States, WHO has initiated the development of a global system to offer support to countries seeking to exchange information about "suspect" medicines in order to protect patients.

3. Recent trends reveal the globalization of pharmaceutical starting materials and finished products manufacture. The implications of such trends include heightened risk with respect to product integrity. These issues need to be addressed in WHO's response, in the form of activities relating to norms and standard-setting, for example, and support to countries.

4. Countries have limited oversight of the pharmaceutical supply systems and distribution channels that relate to imports and exports, and sales via the Internet. Full traceability of procured medical products is a challenge. Therefore, regulatory controls to ensure that a product is safe for use by patients have increased in many countries. This has also triggered the need for new international, regional and national mechanisms which influence WHO's work.

5. Terminology and legal definitions and principles relating to pharmaceutical products differ from country to country. For this reason, a comparison of data and information may be inconclusive.

---

[1] Document A/SSFFC/WG/3 Rev.1.

[2] Document A/SSFFC/WG/5.

6. WHO has a unique role within the United Nations system to address spurious/falsely-labelled/falsified/counterfeit medical products from the public health perspective, and is in a position to complement the work undertaken by other United Nations agencies in this area.

7. Most of the activities undertaken by WHO that specifically relate to spurious/falsely-labelled/falsified/counterfeit medical products have been financed by voluntary contributions; however, few donors would currently invest in this area.

The way forward

8. Four possible approaches are proposed below. They are not intended to be mutually exclusive. Some may be implemented quickly while others may take longer and require substantial human and financial resources:

(1) The WHO Expert Committee on Specifications for Pharmaceutical Preparations was established by the First World Health Assembly in 1948. This Expert Committee is a well-established advisory body to the Director-General. It has met 45 times since its inception.[1] It is suggested that a subcommittee under this Expert Committee be established, by the Health Assembly or the Executive Board, to give technical advice on spurious/falsely-labelled/falsified/counterfeit medical products. Such a subcommittee would enable a transparent advisory function and would rely on existing processes and structures.

(2) A number of United Nations and other intergovernmental agencies are involved in the area of spurious/falsely-labelled/falsified/counterfeit medical products. The creation of a new international cooperation mechanism would allow coverage of the various aspects within the respective mandates of each organization;[2] WHO would represent the public health perspective therein, for organizations including, for example, United Nations Office on Drugs and Crime, World Intellectual Property Organization and World Trade Organization.

(3) Creation of a new intergovernmental mechanism in collaboration with all relevant stakeholders to discuss the issue of spurious/falsely-labelled/falsified/counterfeit medical products with a view to sharing best practices and reaching agreement on policy issues.

(4) Set up an intergovernmental negotiating body to draw up a legally binding instrument at the international level designed to: prevent the manufacture, export, import or trade of spurious/falsely-labelled/falsified/counterfeit medical products in international markets and in international trade; and to regulate and oversee supply and distribution networks.

= = =

[1] http://www.who.int/medicines/services/expertcommittees/pharmprep/ep_44meetingsreport/en/index.html (accessed 16 September 2011) and http://www.who.int/medicines/publications/BrochurePharmaupdatedversion.pdf (accessed 16 September 2011).

[2] See resolution 20/6 contained in the report of the United Nations Commission on Crime Prevention and Criminal Justice (document E/2011/30, E/CN. 15/2011/21).