World Health Organization

WORKING GROUP OF MEMBER STATES ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/ FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
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WHO's role in measures to ensure the availability of good-quality, safe, efficacious and affordable medical products

1. An overview of the activities carried out by WHO within the context of measures to ensure the availability of good-quality, safe, efficacious and affordable medicines[1] was provided during the first meeting of the Working Group (see document A/SSFFC/WG/2).[2] During that meeting, Member States made a number of recommendations which were included in its report (see document A/SSFFC/WG/5).

2. In performing its role of setting standards and supporting countries, WHO faces a number of internal and external challenges. It is important that the Organization be responsive to current trends and developments in its work with Member States to improve access to safe, effective, quality medicines as part of overall health systems.

3. For most countries, the processes associated with the manufacture of starting materials and finished products have shifted beyond their borders. This results in more complex regulatory processes that have acquired an international dimension. In addition, scientific knowledge is continuously evolving. Both trends result in procedures and processes of assessment and inspection that are more technically demanding. This has implications for the normative work of WHO as well as for the technical support it offers to countries.

4. In response to the need and demand for enhanced collaboration with national regulatory authorities, WHO provides a platform to facilitate networking through the International Conference of Drug Regulatory Authorities, and facilitates regional harmonization efforts, such as the Pan American Network for Drug Regulatory Harmonization.

5. Significant budget constraints have been imposed on most national regulatory authorities, resulting in decreased input as well as reduced human and financial contributions to WHO. This has direct implications when WHO seeks the support of experts for the development of norms and standards, or capacity-building activities.

6. The change in procurement practices and the shift of production sites for some medicines may have repercussions on access to medicines, as some medical products may be temporarily unavailable.

[1] http://apps.who.int/gb/ssffc/pdf_files/A_SSFFC_WG5-en.pdf (accessed 14 September 2011).

[2] "Medical products" was the term agreed at the first Working Group to refer to medicines, vaccines and in vitro diagnostics (and in the future may include medical devices).

WHO is working with the Global Fund to Fight AIDS, Tuberculosis and Malaria, for example, to find interim solutions, such as the Expert Review Panel procedure (which is a transitional process for much-needed medicines that are undergoing prequalification or that are not yet authorized by a stringent regulatory authority).

7. The Organization's activities in the area of standard-setting and regulatory support are increasingly dependent on extrabudgetary resources (including the fees attracted by, for example, vaccine prequalification programmes and the International Nonproprietary Names programme) and donors, such as Member States, the Bill & Melinda Gates Foundation and UNITAID. This leads to the risk of a loss of independence and may adversely influence its capacity to address the priorities defined by its Member States. Lack of core budget funding may lead to delays in the implementation of some projects and may put at risk the sustainability of some programmes. Furthermore, increased reporting demands are placing an added administrative burden on the Organization.

The way forward

8. Improved access to affordable, safe and efficacious medicines is a critical element in efforts to achieve universal health coverage.

9. In line with the recommendations of the first session of the Working Group, WHO is requested to continue to enhance the following activities in collaboration with its Member States, partners, nongovernmental organizations and other agencies:

- to provide support to countries wishing to strengthen their national and regional policies, health systems and regulatory authorities in order to ensure access to safe, effective, quality-assured medical products through good distribution and supply practices;

- to develop and maintain up-to-date international tools, guidelines and standards through WHO expert committees;

- to promote national and international policies that favour the procurement and rational use of multisource (generic) medicines;

- to encourage the efficient use of resources through prequalification of both starting materials (for example, active pharmaceutical ingredients and excipients) and finished products, and quality control laboratories combined with enhanced collaboration and the exchange of information between the prequalification programmes and national regulatory authorities;

- to provide technical assistance and capacity-building support to countries to achieve the above; and

- to act as a global convener in facilitating the exchange of information, as well as coordinating bilateral and multilateral cooperation.

10. Continued emphasis on increased collaboration with international donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and with financial institutions, including the World Bank and regional development banks, is imperative. Further, it is important for the Organization to strengthen its activities related to improving access to affordable, safe and efficacious medical products.

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