

Substandard/spurious/falsely-labelled/falsified/ counterfeit medical products

The Sixty-fifth World Health Assembly,

Having considered the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products and its recommendations;¹

Welcoming the outcome of the sessions of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

Reaffirming the fundamental role of WHO in ensuring the availability of quality, safe and efficacious medical products;

Recognizing that many people in the world lack access to quality, safe, efficacious and affordable medicines and that such access is an important part of a health system;

Recognizing the importance of ensuring that combating “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” does not result in hindering the availability of legitimate generic medicines;

Recognizing the need, as expressed in the Rio Political Declaration on the Social Determinants of Health (2011),² to promote access to affordable, safe, efficacious and quality medicines, including through the full implementation of the WHO global strategy and plan of action on public health, innovation and intellectual property;

Acknowledging the need for improving access to affordable, quality, safe and efficacious medicines as an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy and in the decrease of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”;

Taking note of resolution 20/6 of the United Nations Commission on Crime Prevention and Criminal Justice entitled “Countering fraudulent medicines, in particular their trafficking”;

Expressing concern regarding the lack of sufficient financing for WHO’s work in the area of quality, safety and efficacy of medicines;

¹ Document A65/23.

² See subparagraph 11.2 (xii).

Recognizing the need to enhance support to national and regional regulatory authorities to promote the availability of quality, safe and efficacious medical products,

1. REAFFIRMS the fundamental role of WHO in ensuring the quality, safety and efficacy of medical products; in promoting access to affordable, quality, safe and efficacious medicines; and in supporting national drug regulatory authorities in this area, in particular in developing countries and least-developed countries;
2. REITERATES that WHO should continue to focus on and intensify its measures to make medical products more affordable, strengthening national regulatory authorities and health systems that include national medicine policies, health risk management systems, sustainable financing, human resource development and reliable procurement and supply systems; and to enhance and support work on prequalification and promotion of generics, and efforts in rational selection and use of medical products. In each of these areas, WHO's function should be: information sharing and awareness creation; norms and standards and technical assistance to countries on country situation assessment; national policy development; and capacity building, supporting product development and domestic production;
3. FURTHER REITERATES that WHO should increase its efforts to support Member States in strengthening national and regional regulatory infrastructure and capacity;
4. DECIDES to establish a new Member State¹ mechanism for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in accordance with the goals, objectives and terms of reference annexed to the present resolution;²
5. FURTHER DECIDES to review the Member State mechanism referred to in paragraph 4 after three years of operation;
6. URGES Member States¹ to:
 - (1) on a voluntary basis, participate in and collaborate with the Member State mechanism referred to in paragraph 4;
 - (2) provide sufficient financial resources to strengthen the work of the Secretariat in this area;
7. REQUESTS the Director-General:
 - (1) to support the Member State mechanism referred to in paragraph 4;
 - (2) to support Member States in building capacity to prevent and control "substandard/spurious/falsely-labelled/falsified/counterfeit medical products".

¹ And, where applicable, regional economic integration organizations.

² Attached as Annex.

ANNEX

**Member State mechanism on substandard/spurious/false-labelled/
falsified/counterfeit medical products****Goal, objectives and terms of reference****General goal**

In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and the Secretariat, the prevention and control of substandard/spurious/false-labelled/falsified/counterfeit medical products¹ and associated activities.

Objectives

- (1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of “substandard/spurious/false-labelled/falsified/counterfeit medical products” in order to strengthen national and regional capacities.
- (2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.
- (3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.
- (4) To identify actions, activities and behaviours that result in “substandard/spurious/false-labelled/falsified/counterfeit medical products” and make recommendations, including for improving the quality, safety and efficacy of medical products.
- (5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.
- (6) To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of “substandard/spurious/false-labelled/falsified/counterfeit medical products”.
- (7) To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.
- (8) To promote cooperation and collaboration on surveillance and monitoring of “substandard/spurious/false-labelled/falsified/counterfeit medical products”.

¹ The Member State mechanism shall use the term “substandard/spurious/false-labelled/falsified/counterfeit medical products” until a definition has been endorsed by the governing bodies of WHO.

(9) To further develop definitions of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” that focus on the protection of public health.

Structure

(1) The Member State mechanism will be open to all Member States.¹ The Member State mechanism should include expertise in national health and medical products regulatory matters.

(2) The Member State mechanism may establish subsidiary working groups from among its members to consider and make recommendations on specific issues.

(3) Regional groups will provide input into the Member State mechanism as appropriate.

(4) The Member State mechanism shall make use of existing WHO structures.

Meetings

(1) The Member State mechanism should meet not less than once a year and in additional sessions as needed.

(2) The default venue for the Member State mechanism, and its subsidiary working groups, will be Geneva. Meetings may, however, be held from time to time outside Geneva, taking into account regional distribution, overall cost and cost-sharing, and relevance to the agenda.

Relations with other stakeholders and experts

(1) As needed, the Member State mechanism should seek expert advice on specific topics, following standard WHO procedures for expert groups.

(2) As needed, the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics.

Reporting and review

(1) The functioning of the Member State mechanism shall be reviewed by the World Health Assembly after three years of its operation.

(2) The Member State mechanism shall submit a report to the Health Assembly through the Executive Board on progress and any recommendations annually as a substantive item for the first three years and every two years thereafter.

Transparency and conflict of interest

(1) The Member State mechanism, including all invited experts, should operate in a fully inclusive and transparent manner.

¹ And, where applicable, regional economic integration organizations.

(2) Possible conflicts of interest shall be disclosed and managed in accordance with the policies and practice of WHO.

Tenth plenary meeting, 26 May 2012
A65/VR/10

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