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Organization**

**EXECUTIVE BOARD
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Substandard/spurious/falsely-labelled/falsified/ counterfeit medical products: report of the Working Group of Member States

The Director-General has the honour to transmit to the Executive Board the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products, established by decision WHA63(10), which met in Geneva from 25 to 28 October 2011 (see Annex).

ANNEX

**REPORT OF THE WORKING GROUP OF MEMBER STATES ON
SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/
COUNTERFEIT MEDICAL PRODUCTS**

1. The Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products met from 25 to 28 October 2011 in Geneva and was chaired by Ambassador H.E. Darlington Mwape (Zambia) with the following Vice-Chairs: Mr Hashim Ubale Yusufu on behalf of Dr Paul Orhii (Nigeria), Mr Bruno Neves (Brazil), Mr Javad Aghazadeh Khoei (Islamic Republic of Iran), Ambassador Gaudenz Silberschmidt¹ (Switzerland), Ms Lucky Slamet (Indonesia) and Dr Ruth Lee Choo Ai (Singapore). The session was attended by 90 Member States and one regional economic integration organization.
2. Under each of the substantive agenda items, the Working Group focused on developing specific recommendations.
3. The Working Group agreed not to discuss the definition of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”. However, it recalled the discussion that took place at the first session in which the issues of “substandard medical products” and “spurious/falsely-labelled/falsified/counterfeit medical products” were dealt with separately.
4. During its deliberations the Working Group considered the following subjects.

WHO’s role in measures to ensure the availability of quality, safe, efficacious and affordable medical products²

5. The Working Group expressed unanimous support for WHO’s fundamental role in measures to ensure the availability of quality, safe, efficacious and affordable medical products.
6. The Working Group expressed concern regarding the lack of sufficient financing for WHO’s work in the area of quality, safety and efficacy of medicines.
7. The Working Group agreed to the continuation and the importance of strengthening of WHO’s activities in this area.

¹ Elected Vice-Chair following the resignation of Professor Konstantin Keller (Germany).

² See document A/SSFFC/WG/2/2.

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 from a public health perspective, excluding trade and intellectual property considerations¹

8. The Working Group considered the possibility of establishing a subcommittee of the WHO Expert Committee on Specifications for Pharmaceutical Preparations to give technical advice on “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”.

9. There was also discussion about establishing a new Member State mechanism to address “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”, which would draw on expert advice and collaborate with the International Conference of Drug Regulatory Authorities and other stakeholders, as appropriate.

10. The Working Group agreed to recommend that the World Health Assembly set up such a mechanism to address “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” (see annexed a proposed draft resolution and the proposed goal, objectives and terms of reference).²

WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce³

11. The Working Group considered WHO's relationship with the Taskforce and discussed three options, as contained in document A/SSFFC/WG/2/4.

12. There were divergent views expressed with regard to WHO's involvement in the Taskforce and the options proposed. A way forward on this specific issue could emerge when the new mechanism is considered at the Sixty-fifth World Health Assembly.

13. It was agreed that the proposed new Member State mechanism should promote effective collaboration among Member States and the Secretariat, and would draw on expert advice and collaborate with the International Conference of Drug Regulatory Authorities and other stakeholders, as appropriate in order to address “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” and associated activities.

14. The Working Group recommends that the Executive Board adopt the attached draft resolution for consideration by the Sixty-fifth World Health Assembly.

¹ See document A/SSFFC/WG/2/3.

² In the present document these are found in, respectively, Appendix 1 and Appendix 2.

³ See document A/SSFFC/WG/2/4.

Appendix 1

DRAFT RESOLUTION**Substandard/spurious/falsely-labelled/falsified/counterfeit medical products**

The Executive Board,

RECOMMENDS to the Sixty-fifth World Health Assembly the adoption of the following resolution:

The Sixty-fifth World Health Assembly,

PP1 Having considered the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products and its recommendations;^{1,2}

PP2 Welcoming the outcome of the sessions of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

PP3 Reaffirming the fundamental role of WHO in ensuring the availability of quality, safe and efficacious medical products;

PP4 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;

PP5 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;

PP6 Recognizing the need, as expressed in the Rio Political Declaration on the Social Determinants of Health (2011),³ 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;

PP7 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”;

¹ Document EB130/22, Annex.

² A definition of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” has yet to be endorsed by the governing bodies.

³ See subparagraph 11.2 (xii).

PP8 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”;

PP9 Expressing concern regarding the lack of sufficient financing for WHO’s work in the area of quality, safety and efficacy of medicines;

PP10 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 which includes 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 operative paragraph 4 after three years of operation;

6. URGES Member States¹ to:

(1) participate in and collaborate with the Member State mechanism referred to in operative paragraph 4;

(2) provide sufficient financial resources to strengthen the work of the Secretariat in this area;

¹ And, where applicable, regional economic integration organizations.

² Attached in Appendix 2 of the present document.

7. REQUESTS the Director-General:
- (1) to support the Member State mechanism referred to in operative paragraph 4;
 - (2) to assist Member States in building capacity to prevent and control “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”.

Appendix 2

Member State mechanism on substandard/spurious/falsely-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/falsely-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/falsely-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/falsely-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/falsely-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.

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

(8) To promote cooperation and collaboration on surveillance and monitoring of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”.

(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.

¹ And, where applicable, regional economic integration organizations.

Transparency and conflict of interest

- (1) The Member State mechanism, including all invited experts, should operate in a fully inclusive and transparent manner.
- (2) Possible conflicts of interest shall be disclosed and managed in accordance with the policies and practice of WHO.

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