

**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 (Iran), Ambassador Gaudenz Silberschmidt<sup>1</sup> (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 focussed on developing specific recommendations.

3. The Working Group agreed not to discuss the definition of "SSFFC medical products". However, it recalled the discussion that took place at the first session in which the issues of substandard medical products and SSFFC medical products were dealt with separately.

4. During its deliberations the WG considered the following:

**WHO's role in measures to ensure the availability of quality, safe, efficacious and affordable medical products (Document A/SSFFC/WG/2/2)**

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 of 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.

**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 considerations (Document A/SSFFC/WG/2/3)**

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 "SSFFC medical products".

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<sup>1</sup> Elected Vice-Chair following the resignation of Professor Konstantin Keller (Germany)

**Advance, Unedited Version**

9. There was also discussion about establishing a new Member State mechanism to address "SSFFC medical products", which would draw on expert advice and collaborate with the International Conference of Drug Regulatory Authorities (ICDRA) and other stakeholders, as appropriate.

10. The Working Group agreed to recommend that the World Health Assembly set up such a mechanism to address "SSFFC medical products" (see annexed a proposed draft resolution and proposed goal and objectives).

**WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce** (Document A/SSFFC/WG/2/4)

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 65<sup>th</sup> session of the WHA.

13. It was agreed that the proposed new Member State mechanism should promote effective collaboration among Member States and WHO, and would draw on expert advice and collaborate with ICDRA and other stakeholders, as appropriate in order to address "SSFFC medical products" and associated activities.

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

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