

**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 28 February to 2 March 2011 in Geneva and was chaired by Ambassador H.E. Darlington Mwape (Zambia) with the following vice-chairs: Paul Orhii (Nigeria), Bruno Neves (Brazil), Javad Aghazadeh Khoei (Iran), Konstantin Keller (Germany), Lucky Slamet (Indonesia) and Ruth Lee Choo Ai (Singapore). The session was attended by 93 Member States and one regional economic integration organization.

2. The Working group examined the following matters from a public health perspective:

- (a) WHO's role in measures to ensure the availability of quality, safe, efficacious and affordable medical products;
- (b) WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/false-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations;
- (c) WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce;
- (d) any issue or issues raised in the proposals contained in documents, A63/A/Conf.Paper No.4 Rev.1, A63/A/Conf.Paper No.5 and A63/A/Conf.Paper No.7,2 starting with those issues referred to in subparagraphs (a)–(c) above.

3. For the purpose of this Working Group it was agreed that the term medical products refers to medicines, vaccines and in-vitro diagnostics¹.

3bis The Working Group discussed two major areas of work for WHO: promoting access and availability, and promoting quality, safety and efficacy.

4. The Working Group decided to focus the discussion on identifying principles.

WHO's role in measures to ensure the availability of quality, safe, efficacious and affordable medical products.

5. Some Member States stressed that the improvement of access to affordable, quality, safe and efficacious medicines is an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy.

6. Overall, WHO should continue to focus on and intensify its measures to make medical products more affordable, strengthening national regulatory authorities and health

¹ This may also include medical devices at an appropriate time in the future.

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.

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.

7. Some Member States expressed their desire to set up an intergovernmental negotiating body to draw up legally binding instrument at the international level designed to prevent the manufacture, export, import, or trade of counterfeit medical products on international markets and in international trade and regulate and oversee supply and distribution networks.

8. Some Member States stressed that the improvement of access to affordable, safe and efficacious medicines is an important element in the effort to prevent medicines with compromised quality, safety and efficacy.

9. With regard to substandard medical products, the Working Group discussed the current WHO definition, developed by the last Expert Committee on the Specifications of Pharmaceutical Preparations of October 2010.²

10. With regard to falsified medical products, some Member States proposed the following non-exhaustive elements of a definition: a falsified medical product gives a false representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medical products.

10bis Differences remained among Member States on the appropriate terms to be used to represent medical products of compromised quality, safety and efficacy.

² "Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications. Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing." (45th WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2010)

11. The Working Group then considered the future role of WHO in the areas of substandard and SFFC medical products under three headings:

Information and awareness creation

12. For substandard medical products, WHO should be a global convener for information exchange and awareness creation, including through the International Conference of Drug Regulatory Authorities.

13. In addition, for SFFC products, WHO should also promote and support awareness raising among regulatory authorities, political decision makers, health professionals and consumers; create a global surveillance and alert system, gathering and disseminating reliable and objective data on SFFC products; and act as a global convener dedicated to combating other SFFC products from a public health perspective.

Norms and standards

14. For substandard medical products, WHO should develop/update/promote tools and guidelines for quality assurance and GMP, especially addressing the issues of bioequivalence and inter-changeability, biosimilars and COPP certificates. WHO should intensify activities on prequalification of products and quality control laboratories, including specialized laboratories as centres of excellence.

15. In addition, for SFFC products, WHO should develop/update/promote tools and guidelines for combating SFFC medical products, including tools for sampling and surveillance of the market and guidelines for good distribution practices for internet sales, importers and brokers.

Technical support to countries

16. For substandard medical products, WHO should continue the programme of supporting the assessment of national regulatory authorities, leading to plans of action for strengthening them and monitoring their progress. WHO should increase its efforts to build national and regional regulatory infrastructures and capacity, including the national capacity to implement and enforce the regulations. Technical assistance should focus on quality assurance, safety and pharmacovigilance systems. Technical support to national regulatory authorities should be expanded in the areas of good governance and transparency issues including use of IT-enabled systems, and strengthening national medicine quality control laboratories. WHO should also continue to support regional and sub regional harmonization initiatives and expand their scope to cover aspects of implementation and enforcement of regulations. Training programmes should focus on good manufacturing practice (GMP) and pharmacovigilance. In undertaking the above activities, WHO should intensify its international cooperation and collaboration.

17. In addition, for SFFC products, WHO should also assist countries in identifying gaps in national legislation and regulatory structures, training programmes, support to linking national regulatory structures with other national organizations involved in fighting SFFC medical products, and providing support for the establishment and accreditation of national and international quality control laboratories able to analyse SFFC medicines.

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

18. Following a general discussion there was no consensus on WHO's relationship with IMPACT. The positions ranged from disengagement from to continued engagement with IMPACT. Some Member States suggested a moratorium on WHO's involvement in IMPACT activities until this issue is duly assessed by the Working Group, while other Member States supported WHO's continued involvement. Some Member States proposed an intergovernmental mechanism to discuss the issue of SFFC. Some Member States acknowledged the need to reform IMPACT. However, it was noted that WHO cannot unilaterally change the terms of reference of IMPACT.

19. Several Member States recognized that there have been benefits to some countries; several Member States, however, expressed their concerns about the controversial nature of the work of IMPACT and confusion between public health goals and commercial interests.

Next Steps

20. In view of the need for further deliberations in order to make specific recommendations, the Working Group requests that the World Health Assembly consider extending the period set out in Decision 63(10) in order to allow the Working Group to complete its work as soon as possible, building on the work thus far achieved.

21. WHO should continue its programmatic work related to WHA mandates contained in resolution WHA 41.16, resolution WHA 47.13 and resolution WHA 61.21. These resolutions are not related to IMPACT.

22. Mechanisms adopted by WHO to fulfil its mandate should ensure transparency and inclusiveness in their conception and composition, avoiding the emergence of conflicts of interest in the actors involved and should guarantee oversight of its activities and accountability.