

Counterfeit medical products

International Medical Products Anti-Counterfeiting Taskforce

Report by the Secretariat

1. In January 2009 the Executive Board at its 124th session considered a report by the Secretariat on counterfeit medical products, and requested the Director-General to prepare an information document about the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), including information about the role, function and public health interests of the members of the Taskforce. This report responds to that request.¹
2. The Secretariat's activities to support Member States in strengthening their medicines regulatory authorities and avoiding the negative impact of substandard medicines on their populations, are described in a separate report.² That document also relates WHO's activities in response to the previous Health Assembly resolutions that focus specifically on combating counterfeit medical products.³
3. The complex issues raised by the counterfeiting of medicines have necessitated the involvement of various parties and international organizations outside the health sector, including the police, customs and judiciary. It is against this background that the Taskforce was launched by WHO in 2006. The intent was that the partner and member organizations of the Taskforce could, despite their different individual mandates, identify and work towards a common goal under WHO's leadership, namely to defend public health principles and counter those whose actions put patients in danger.
4. The Declaration of Rome adopted by the 160 participants attending the WHO international conference on Combating Counterfeit Drugs (Rome, 16–18 February 2006) stated that WHO should take the lead in establishing the Taskforce. The participants represented 57 national medicines regulatory authorities, seven international organizations, and 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers. The Declaration also contained a set of principles and the conceptual framework for the Taskforce's work in order to ensure that public health interests were met.⁴

¹ Document EB124/2009/REC/2, summary record of the ninth meeting.

² Document A62/13.

³ Resolutions WHA41.16 (Rational use of drugs), WHA47.13 (Rational use of drugs; and the WHO Action Programme on Essential Drugs), WHA52.19 (Revised drug strategy), and WHA57.14 (Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS).

⁴ See WHO web site (www.who.int) under Programmes and projects, International Medical Products Anti-Counterfeiting Taskforce.

5. The 12th International Conference of Drug Regulatory Authorities (Seoul, 3–6 April 2006) welcomed the establishment of the Taskforce and WHO's provision of secretariat functions.

6. The participants in a meeting on Making IMPACT operational (Rome, 25–26 July 2006), representing seven national medicines regulatory authorities, six international organizations, and 14 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers, adopted the Taskforce's terms of reference.¹ Most importantly, these terms of reference defined participants who can be collaborating parties in the Taskforce as follows:

- (a) intergovernmental organizations and institutions, such as WHO, the European Commission, the Commonwealth Secretariat and the ASEAN Secretariat;
- (b) governmental institutions and agencies;
- (c) WHO collaborating centres competent in combating counterfeit medical products;
- (d) international nongovernmental organizations, with an active involvement in combating counterfeit medical products;
- (e) international associations or umbrella organizations representing health professionals such as physicians, pharmacists, nurses and dentists;
- (f) international associations or umbrella organizations representing patients and consumers;
- (g) international associations or umbrella organizations representing pharmaceutical manufacturers, the medical product supply chain, and other parties concerned with medical products (including technology and service providers).

7. On 21 August 2006 the Director-General wrote to all Regional Directors about establishing a consultative mechanism and seeking advice on attendance by Member States at the Taskforce's first general meeting in Bonn (Germany) in November 2006.

8. Later that year, a Circular Letter was sent to all Member States and Associate Members to announce the establishment of the Taskforce. The Director-General also invited them to express interest in joining as participants and in participating in one or more working groups (by nominating experts) and to nominate individuals who could be considered by the general meeting for the roles of Chair and Vice-Chairs of the Taskforce and Chairs of each working group. A senior WHO staff member was elected Chair of two general meetings.² Currently, five working groups have been established.

9. All WHO's Member States are eligible to become collaborating parties in the Taskforce on a voluntary basis. Currently, the parties include some 30–40 Member States, representatives of the International Criminal Police Organization (INTERPOL), OECD, World Customs Organization, WIPO, WTO, the European Commission, Council of Europe, the Commonwealth Secretariat, the

¹ For details see WHO web site, under Health topics, IMPACT.

² For details of officers of the Taskforce, see web site:
http://www.who.int/impact/resources/IMPACTthirdgeneralmeeting_%20report.pdf.

ASEAN Secretariat, and numerous nongovernmental organizations. In line with WHO's mandate, WHO's main role in the Taskforce is to ensure focus on patients' safety and public health, and several departments and regional offices contribute.

10. There is clear consensus among the Taskforce's partners that "counterfeit" medicines should not be confused with issues relating to medicines that are not authorized for marketing in a given country, nor with trademarks or related intellectual property rights issues. Health-related aspects of counterfeit medical products fall within WHO's remit, and the other aspects come under the mandates of other bodies or international organizations.

11. The Taskforce is seen as a unique forum for discussion of measures to combat the counterfeiting of medical products. It is an alliance of partners who might not necessarily otherwise come together, with the goal of protecting patients from buying and taking dangerous and potentially fatal medicines.

Funding sources

12. In 2006–2008 the collaborative work of the Taskforce and its secretariat was funded (nearly US\$ 2.3 million) mainly by the European Commission and the Governments of Australia, Germany, Italy and the Netherlands (altogether 62%) and by WHO (30%). WHO's financing of, and fundraising for, the Taskforce are governed by WHO's established policies and principles and subject to WHO's administrative procedures and practices. The costs for participants from developing countries and invited experts to attend Taskforce meetings have been funded by the Taskforce. It should be noted that not all the funds have been transferred to WHO. For some sources (e.g. The International Federation of Pharmaceutical Manufacturers & Associations), this may also include direct contributions to the Taskforce's meetings or activities. Numerous Member States and other stakeholders have also contributed through expertise, for instance by sending their representatives to meetings of the Taskforce, by collaborative efforts in various working groups, and through in-kind funding when organizing general meetings and/or working groups.

Medical devices

13. In 2008 participants at the General Meeting reiterated the need to involve experts from the medical devices area in all the Taskforce's existing working groups. Although the real extent of counterfeit medical devices is little known, some of the documented cases are serious enough to justify action. The victims are patients or users of medical devices who either suffer direct harm or lose the opportunity to be diagnosed and treated properly in the case of devices used in diagnostic procedures.

Meetings

14. To date, participation in meetings of the Taskforce has not required declarations of interests for WHO experts. This procedure is not normally required for meetings whose participants are clearly identified by their affiliation and thus represent the views of their respective organizations. Participation by Member States in the three general meetings since 2006 has been good (from 28 to 36 countries), with more than half the participants being representatives of medicines regulatory authorities and other governmental institutions and agencies. Participants also included representatives of international organizations and international associations of patients, health professionals,

pharmaceutical manufacturers and wholesalers. The Taskforce has five working groups, and their major outcomes are summarized in the Annex to this report.¹

External review

15. Following the discussions at the Executive Board in January 2009, the WHO Secretariat commissioned an external review of the activities, organization and potential conflicts of interest within the Taskforce. The findings revealed, inter alia, that through the current terms of reference WHO's role has been restricted, as the Organization was identified only as being one of the participants in the Taskforce. The Secretariat is considering the conclusions and practical recommendations, and will report in due course to the Executive Board.

ACTION BY THE HEALTH ASSEMBLY

16. The Health Assembly is invited to note the report.

¹ For details see web site: http://www.who.int/impact/activities/meet_reports/en/index.html.

ANNEX

Activities and outcomes of the Taskforce's working groups**WORKING GROUP ON LEGISLATIVE AND REGULATORY INFRASTRUCTURE****Principles and elements for national legislation against counterfeit medical products**

1. The principles, which focus on public and personal health implications in relation to counterfeit medical products to be appropriately addressed in legislation, have been set out in a draft document, which was endorsed at the Taskforce's second General Meeting (Lisbon, 10–14 December 2007). The text has subsequently been revised to include references to counterfeit medical devices and concerns raised at the Sixty-first World Health Assembly in May 2008.¹ It is intended to post this draft on the WHO web site in order to elicit further comments and input from a broad constituency.

Comparative study on existing legislation used to combat counterfeiting of medical products

2. The Max Planck Institute for International and Foreign Criminal Law (Germany) is leading this comparison of current forms of legal instruments in countries that can be used to sanction crimes relating to counterfeit medical products. Final results of the analysis are expected during 2009.

Review of responsibilities of other stakeholders in the distribution chain, for example, the Internet (and other) service providers

3. This analytical review of existing documents and activities (e.g. Council of Europe Convention on Cybercrime, Council of Europe guidelines on distribution of medicines through the Internet, and self-regulating standards by industry) is a work in progress. The initiative will be led by the Council of Europe with assistance from the working group, where necessary.

WORKING GROUP ON REGULATORY IMPLEMENTATION**A data collection tool to identify regulatory and legislative gaps in national situations**

4. This assessment tool is being designed to provide a unified approach to assessing the problem of counterfeit medicines in a particular country or subregional or regional setting. Based on the results of field testing in 2009 in eight countries (Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Uganda and United Republic of Tanzania), a draft version is expected to be ready for circulation for comments by mid-2009.

Sampling strategy guidelines

5. Guidance and recommendations are being prepared on key issues for developing an efficient strategy for sampling suspect products. The guidelines will also contain elements of a procedure for

¹ Document WHA61/2009/REC/3, summary record of the tenth meeting of Committee A.

collection and testing of samples for the purpose of detecting counterfeit medical products. A new draft should be ready for circulation for comments by mid-2009.

Guidelines for rapid response plan for national medicines regulatory authorities for signalling suspect counterfeits

6. The guidelines being drafted are intended to provide the basis for actions that may be followed by national medicines regulatory authorities in the event of suspect counterfeit medicines in national distribution channels. The first draft should be ready for circulation for comments by mid-2009.

Good security practices for printed packaging material for pharmaceutical products

7. Guidelines are also being prepared to ensure quality of information on printed packaging materials for pharmaceutical products with the aim to include them as an annex to WHO's guidelines on good distribution practices.

Guidance document for combating online trade of counterfeit medical products

8. A document is currently being written in collaboration with members of the Working Group on Communication.

Counterfeit-oriented revision of the WHO good distribution guidelines

9. A revised version of WHO's guidelines on good distribution practices, adopted by the Expert Committee on Specifications for Pharmaceutical Preparations in 2006 and approved by the Director-General, has been elaborated by the Working Group on Regulatory Implementation and was submitted to that Committee in October 2008 with a request for consideration. The revision process is continuing as a joint effort by members of the Expert Committee and members of the Working Group on Regulatory Implementation.

10. Further areas to be covered by this Working Group will be: reviewing national strategies regarding exporting pharmaceuticals and developing guiding principles for national regulatory authorities; drawing up guidance for adapting current pharmacovigilance systems for counterfeit reporting; and updating WHO's 1999 guidelines on measures to combat counterfeit medicines.¹

WORKING GROUP ON ENFORCEMENT

Guide to investigate counterfeit medical products and pharmaceutical crime

11. The guide has been prepared by members of the Permanent Forum on International Pharmaceutical Crime, a network of enforcement officers from 15 countries,² established in 1998, aimed at protecting public health and safety through the exchange of information and ideas to foster

¹ Document WHO/EDM/QSM/99.1.

² Australia, Belgium, Canada, Germany, Ireland, Israel, Italy, the Netherlands, New Zealand, Singapore, South Africa, Spain, Switzerland, United Kingdom of Great Britain and Northern Ireland, and United States of America.

mutual cooperation in combating pharmaceutical crime. The guide aims to provide countries that wish to have the capacity to combat pharmaceutical crime information on investigative processes and techniques.

A model for a network of single points of contact

12. The initiative aims to design a standard model for operational collaboration at the international level and streamlining collaboration among the different national institutions and other parties involved in investigating and taking proper timely action when confronted with a case of counterfeit medical product. It builds on the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines.

Training courses

13. The Working Group on Enforcement trained a total of 350 officers from police, customs and medicines regulatory agencies. It is envisaged that another 8 to 10 training initiatives will be organized in 2009 in the regions where operations take place, with a focus on western Africa.

WORKING GROUP ON COMMUNICATION

Communications strategy

14. The communications strategy has two main objectives: increasing awareness of risk and promoting policy remedies proposed by the Taskforce. The strategy was endorsed at the Taskforce's third General Meeting, with provision for further expansion and periodic revision. An improved internal communication between the working groups is planned, with a view to ensuring consistent and regular information sharing as the basis for dissemination of timely and accurate information about counterfeit medicines and the means by which to combat them to international audiences. It was strongly recommended that the Taskforce's secretariat should have a full-time communications officer.

Communications campaigns focusing on governments, patients, health professionals, enforcement agencies and officers, the media, international nongovernmental organizations and civil society groups

15. The main messages for these campaigns are "Only get your medicines from known and reliable sources" and "Counterfeit medicines are a threat to personal and public health worldwide", and supporting tool kits and fact sheets have been prepared. Two short films were produced in 2008, one in Mali and one in the Bolivarian Republic of Venezuela. A short video has been made in collaboration with Interpol in order to explain the role of the Taskforce and to highlight the dangers of the counterfeit medical products and their illicit supply.

16. Further work on a network of national communications contact persons is under way.

WHO's revised Rapid Alert System

17. WHO's Rapid Alert System allows Member States to report cases of counterfeit medical products and to receive alerts when new cases are reported. Based on the experience of the WHO Regional Office for the Western Pacific in the use of this system, it is being expanded for global use.

Frequently asked questions

18. The Taskforce's pages on the WHO web site include a section on frequently asked questions. It is intended to update this resource and also to prepare an internal version for all the Taskforce's stakeholders and Working Group members.

WORKING GROUP ON TECHNOLOGY

Anti-counterfeit technologies for the protection of medical products

19. A document has been prepared that assesses existing and new technologies for preventing, deterring or helping to detect counterfeit medical products, taking into account: cost; scalability; specific country needs and situations; feasibility; and regulatory implications. The Working Group will regularly update the text in the light of new trends and lessons learnt from implementation in countries.

Workshops bringing together regulators and technology developers

20. Two workshops were conducted in Prague (2007) and Singapore (2008).

= = =