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

1. This report focuses on WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce.¹

ESTABLISHMENT OF THE TASKFORCE

2. In early 2006, in view of a prevailing lack of agreement among Member States on the need for an international convention on "counterfeit" medicines,² consideration was given to the idea of starting an action-oriented international taskforce led by WHO. The view was that the participants in that taskforce could, despite their different individual mandates, identify and work towards a common goal under WHO's leadership, namely that of defending public health principles and countering activities characterized by a lack of quality assurance that puts patients in danger.

3. In 2006, an international conference entitled "Combating Counterfeit Drugs: Building Effective International Collaboration" was convened by WHO and hosted by the Government of Italy (Rome, 16–18 February). The Declaration of Rome, adopted by the 160 participants at the conference, stated that WHO should lead the establishment of an International Medical Products Anti-Counterfeiting 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 together with the conceptual framework for the Taskforce's work in order to ensure that public health interests were met.³ Two months later, 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.

4. The participants at the next planning meeting, entitled "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

¹ See documents A/SSFFC/WG/2 and A/SSFFC/WG/3.

² The term "counterfeit" is used throughout this document to refer to "substandard/spurious/falsely-labelled/falsified/counterfeit".

³ Details of officers of the Taskforce are available online at:
http://www.who.int/impact/resources/IMPACTthirdgeneralmeeting_%20report.pdf (accessed 26 January 2011).

manufacturers and wholesalers, adopted the Taskforce's terms of reference. Most importantly, these terms of reference defined participants who could be collaborating parties in the Taskforce, as follows:

- (a) intergovernmental organizations and institutions, such as WHO, the European Union, 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).

5. On 21 August 2006 the Acting 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. Later that year, a Circular Letter, dated 25 September, was sent to all Member States and Associate Members to announce the establishment of the Taskforce. The Acting Director-General further invited Member States and Associate Members 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. At the meeting in Bonn the then Assistant Director-General for Health Technologies and Pharmaceuticals was elected Chair of two annual general meetings.

WHO'S MANDATE FOR INVOLVEMENT IN THE TASKFORCE

6. WHO's activities in relation to "counterfeit" medicines in general, and with the Taskforce in particular, have been guided by the resolutions and recommendations set out below.

- **The Conference of Experts on the Rational Use of Drugs (Nairobi, 1985).** The Conference "*considered that governments should take the action necessary to prevent drug counterfeiting, which was characterized by several participants as a criminal act that all drug regulatory authorities must try to combat. It was recommended that WHO, with other international and nongovernmental organizations, should study the feasibility of setting up a clearing-house to collect data and inform governments about the nature and extent of counterfeiting.*" The Director-General stated that WHO should be "*studying with other*

appropriate bodies ways of providing information to combat the criminal offence of counterfeiting.”¹

- **Resolution WHA41.16 on rational use of drugs (1988).** The Health Assembly requested the Director-General, inter alia, “*to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeit or substandard pharmaceutical preparations, and to cooperate with the Secretary-General of the United Nations in such cases when provisions of the international drug treaties are violated.*”
- **Resolution WHA47.13 on rational use of drugs and the WHO Action Programme on Essential Drugs (1994).** The Health Assembly requested the Director-General, inter alia, “*to support Member States in their efforts to ensure that available drugs are of good quality, and in combating the use of counterfeit drugs*”.
- **11th International Conference of Drug Regulatory Authorities (Madrid, 16–19 February 2004).** The Conference, which was co-hosted by the Government of Spain and WHO, recommended, inter alia, that “*WHO in collaboration with other stakeholders, should develop a concept paper for an international convention on counterfeit drugs. WHO should convene a meeting of national regulatory authorities to discuss further the concept paper and related issues before the next ICDRA [International Conference of Drug Regulatory Authorities].*”
- **WHO-convened international conference entitled “Combating Counterfeit Drugs: Building Effective International Collaboration” (Rome, 16–18 February 2006).**

See paragraph 3 above.

- **The 12th International Conference of Drug Regulatory Authorities (Seoul, 3–6 April 2006).** In the ensuing recommendations the Conference welcomed “*the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)*” and congratulated “*WHO on establishment of the IMPACT Secretariat.*” The Conference also expected the Taskforce, inter alia, to “[d]evelop concrete and pragmatic proposals on how to improve national, regional and international strategies to combat counterfeit medicines”; to “[a]nalyse in particular how to improve the sharing of information on cases of counterfeit medicines taking into consideration existing systems, e.g. WHO Rapid Alert System”; and to “[t]ake into consideration existing activities in order to use the synergies of such activities and avoid duplication of effort”. The Conference also called upon WHO “*to provide all necessary support to IMPACT via its Secretariat*” and national and regional authorities “*to fully support IMPACT by providing the necessary resources during its work and by implementing its recommendations.*”

¹ *The rational use of drugs. Report of the Conference of Experts, Nairobi, 25–29 November 1985.* Geneva: World Health Organization, 1987. Available on line at <http://apps.who.int/medicinedocs/documents/s17054e/s17054e.pdf> (accessed on 14 January 2011).

OBJECTIVES OF THE TASKFORCE

7. The Taskforce has the following objectives:

- to create awareness about the severity of the problem among stakeholders, and provide information to the health system and the public;
- to promote intersectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools;
- to develop technical competence and skills in required areas;
- to develop appropriate mechanisms for ensuring vigilance and input from patients' groups, health-care professionals, the medical product supply chain, other stakeholders and concerned parties, and the public;
- to secure political will and commitment, adequate legal frameworks, implementation commensurate with the impact of counterfeiting on public health, and provide the necessary tools for coordinated and effective law enforcement.

ORGANIZATION OF THE TASKFORCE

8. The Taskforce is a voluntary grouping of governments, organizations, institutions, agencies and associations from developing and developed countries that aim to share expertise, identify problems, seek solutions, coordinate activities and work towards the common goal of fighting “counterfeit” medical products. The Taskforce aims at ensuring appropriate regional representation, with a particular focus on developing countries.

9. All WHO's Member States are eligible to become collaborating parties in the Taskforce and its five working groups. Currently, the parties include some 40 Member States, representatives of the International Criminal Police Organization (INTERPOL), OECD, World Customs Organization, WIPO, WTO, European Union, Council of Europe, Commonwealth secretariat, the ASEAN secretariat, and numerous nongovernmental organizations. In line with WHO's mandate, the Organization's main role in the Taskforce is to ensure focus on patients' safety and public health.

10. The Taskforce organizes its work into five working groups, focusing on: legislative and regulatory infrastructure, in order to support the protection of public health and the enforcement of sanctions against “counterfeit” products throughout the medical supply chain; regulatory implementation, in order to promote good distribution, procurement and national assessments; enforcement, in order to coordinate and strengthen operations among participating countries; technology, in order to assess technologies to prevent, deter or detect “counterfeit” medical products; and communication, in order to address health professionals, distributors, patients, enforcement agencies and the media.

WHO'S ROLE IN THE TASKFORCE

11. When the Taskforce was established, WHO was requested to chair its general meetings (with Nigeria and Singapore as Co-Chairs) and to host the Taskforce secretariat. The latter activity also implied managing the web site of the Taskforce and hosting an office of INTERPOL.

12. In its planning and coordinating role, WHO chaired most of the planning meetings between the two Co-Chairs, the rapporteur and the Chairs of the five working groups, and was involved in planning the three general meetings hosted by, respectively, Germany, Portugal and WHO. As a technical partner in the Taskforce, WHO was mostly involved in the work of the working groups on legislative and regulatory infrastructure, and on regulatory implementation. The Organization had less involvement in the work of the working groups on enforcement, technology and communication.

13. The activities of the various working groups are reported and discussed at the annual meetings of the Taskforce. The Taskforce's reports and (draft) documents are posted on its web site, which is managed by its secretariat (and hosted by WHO). Since 2008, a strict distinction has been made between WHO's documents and those belonging to the Taskforce, through a careful use of separate logos and explanatory text where needed.

OUTPUTS OF THE TASKFORCE

14. Examples of the outputs of the Taskforce's working groups include the following: the legislative working group (chaired by Germany), has made a detailed review of national legislations on "counterfeit" medical products and has developed a model text for national legislation based on practical experiences from several Member States, intended for national adaptation as needed. The regulatory support group (chaired by the United States of America, notably, through the United States Food and Drug Administration) is developing a standard sampling methodology for national regulatory authorities in order to assist them in measuring the size of the problem in such a way that survey results will be reliable and comparable between countries and over time. The group has also reviewed an existing WHO guidance document on medicine distribution and has proposed improved provisions to prevent "counterfeit" medicines entering the supply chain.

15. The enforcement working group, co-chaired by Australia and INTERPOL, has collaborated with members of the Permanent Forum on International Pharmaceutical Crime¹ in developing a practical guide on the investigation of "counterfeit" medical products. The group has also trained hundreds of officers from national police, customs and medicines regulatory agencies and has worked in close collaboration with national authorities and national police forces supported by INTERPOL, for example in the countries of the Mekong subregion (Operation Storm) and in East Africa (Operation Mamba). The technology working group, chaired by the International Federation of Pharmaceutical Manufacturers and Associations, organized two workshops – in Prague (2007) and Singapore (2008) – in order to bring together regulators and technology developers. The communication working group, chaired by the International Pharmaceutical Federation, developed model information materials for health-care providers and patients. A full list of the achievements and current work of the five working groups is given in the Annex.

¹ A network of enforcement officers from 15 countries (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) established in 1998.

FUNDING SOURCES

16. In the years 2006–2008, funding for the secretariat of the Taskforce amounted to nearly US\$ 2.3 million. The major contributors included the European Union and the Governments of Australia, Germany, Italy and the Netherlands. WHO's fundraising for the Taskforce secretariat was governed by WHO's established policies and principles, and subject to WHO's administrative procedures and practices. A large part of the WHO Secretariat's expenditure has been incurred in relation to Taskforce meetings, offsetting the costs of participants from developing countries and of experts invited to attend.

17. The remaining resources for the Taskforce's related activities are usually not transferred to WHO. For example, some stakeholders (e.g. the International Federation of Pharmaceutical Manufacturers and Associations) have made direct contributions to the activities of working groups without passing through the WHO Secretariat. Numerous Member States and other stakeholders have similarly contributed to the work of the Taskforce through provision of expertise, for instance by sending their experts to meetings, by undertaking collaborative efforts in various working groups and through in-kind funding when hosting general meetings and/or working groups.

MEETINGS — MANAGING THE POTENTIAL FOR CONFLICT OF INTEREST

18. Some 40 Member States participated in the three general meetings in 2006, 2007 and 2008. More than half the participants were representatives of medicines regulatory authorities and other governmental institutions and agencies; participants also included representatives of international organizations and of international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers.

19. From the outset, the view has been that the partner and member organizations of the Taskforce could, despite their different individual mandates, work under WHO's leadership towards the common goal of defending public health principles and countering those whose actions put patients in danger. According to WHO's guidelines on the management of conflict of interest, interests do not have to be declared in meetings whose participants are clearly identified by their affiliation and thus represent the views of their respective organizations. To date, participation in meetings of the Taskforce has not, therefore, required declarations of interest such as the one typically used for meetings of WHO's expert committees and for invited WHO experts. In addition, an external review of the activities and organization of the Taskforce, and of potential conflicts of interest within it, has concluded that through the current terms of reference, WHO's role has been limited, as the Organization is only one of the participants in the Taskforce.

20. Since the re-establishment of its own programme on "counterfeit" medicines in 2009, the Organization has been transparent in distinguishing the Taskforce's documents from WHO's official documents and normative materials. This distinction is ensured through a separation of the respective web sites, a strict policy on the use of logos and the provision of additional explanatory text where needed.

THE TASKFORCE AND INTERNATIONAL TRADE IN LEGITIMATE GENERICS

21. There is clear consensus among the Taskforce's partners that issues surrounding "counterfeit" medicines should not be confused with those relating to medicines that are not authorized for

marketing in a given country (e.g. generic medicines registered elsewhere), nor with violations or disputes concerning patents; and that any measures against “counterfeit” medical products should not jeopardize the international trade in legitimate generics. This is most clearly expressed in the Taskforce’s draft “definition,” which was agreed at the third General Meeting of the Taskforce, held in Hammamet, Tunisia, in December 2008. The agreed definition defines a “counterfeit” medical product as a product with a false representation of its identity and/or source.¹ This applies to the product, its container or other packaging or labelling information. The definition goes on to state that counterfeiting can apply to both branded and generic products, and that “counterfeits” may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but that are authorized elsewhere are not considered “counterfeit”. Finally, substandard batches of legitimate medical products and quality defects in such products or their non-compliance with good manufacturing or good distribution practices must not be confused with counterfeiting.

¹ The full definition is available online at <http://www.who.int/impact/activities/IMPACThamammetreport.pdf> (accessed 14 January 2011).

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

22. 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 respond to concerns raised at the Sixty-first World Health Assembly in May 2008;¹ it was further discussed and amended at the third General Meeting in Hammamet, Tunisia, in 2008. In November 2009 the amended draft text was handed over by the Taskforce for further review by WHO. The draft text was then sent out by WHO Circular Letter to all Member States, requesting them to review the text and to submit comments and suggestions, together with information on their own legal provisions.

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

23. The Max Planck Institute for Foreign and International Criminal Law (Freiburg, Germany) is leading this comparison of national forms of legal instruments and relevant terminology that are currently used to sanction crimes relating to “counterfeit” medical products. A draft report and any recommendations made therein will be discussed by the working group as soon as the study is ready.

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

24. 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. As soon as the report is finished, any recommendations that it may contain will be discussed by the working group.

WORKING GROUP ON REGULATORY IMPLEMENTATION

A data collection tool to identify regulatory and legislative gaps in national situations

25. This assessment tool has been designed to provide a unified approach to assessing the problem of “counterfeit” medicines in a particular country or subregional or regional setting. It is based on the results of field testing in eight countries in 2008 and in 19 countries in 2009. In total, 27 countries

¹ See document WHA61/2010/REC/3, summary record of the tenth meeting of Committee A.

participated, namely: from the African Region – Botswana, Burkina Faso, Cameroon, Mali, Mauritius, Niger, Senegal, Seychelles, Swaziland, Uganda and United Republic of Tanzania; and from the Eastern Mediterranean Region – Afghanistan, Djibouti, Egypt, Iraq, Jordan, Lebanon, Morocco, Oman, Pakistan, Somalia, Sudan, Syrian Arab Republic, Tunisia and Yemen. The report will be published on WHO's web site.¹ The tool will be revised as appropriate; a draft version is available for comments.

Sampling strategy guidelines

26. Guidance and recommendations are being prepared on key issues for developing an efficient strategy on sampling suspect products. The guidelines will also contain elements of a procedure for collection and testing of samples for the purpose of detecting “counterfeit” medical products. A revised draft is available.

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

27. The guidelines being drafted are intended to provide the basis for actions that may be followed by national medicines regulatory authorities when the presence of “counterfeit” medicines is suspected in national distribution channels. The first draft is ready for review.

Good security practices for printed packaging material for pharmaceutical products

28. Guidelines are also being prepared to ensure that information on printed packaging materials for pharmaceutical products is of good quality. The aim is to include the guidelines as an annex to WHO's guidelines on good distribution practices. A draft is available for review.

Guidance document for combating online trade in “counterfeit” medical products

29. A document is currently being written in collaboration with members of the working group on communication.

Revision of WHO's guidelines on good distribution practice for pharmaceutical products, with a focus on “counterfeit” medical products

30. WHO's good distribution practice guidelines, adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 2006 and approved by the Director-General, were reviewed by the Taskforce's working group on regulatory implementation. Proposed amendments were later submitted to that Committee in October 2008 with a request for consideration. This revision took place as a joint effort on the part of members of the Expert Committee and members of the working group. The final version was adopted by the WHO Expert Committee in 2009² and approved

¹ Document WHO/ACM/3 will be made accessible online at <http://www.who.int/medicines/services/counterfeit/>.

² See WHO Technical Report Series, No. 957.

by the Director-General. The outcome was presented to WHO's Executive Board at its 127th session in May 2010.¹

31. Future activities of this working group will include: reviewing national strategies regarding exporting pharmaceuticals and developing guiding principles for national regulatory authorities; drawing up guidance for adapting current pharmacovigilance systems for the reporting of "counterfeit" medical products; and updating WHO's 1999 guidelines on measures to combat counterfeit medicines.²

WORKING GROUP ON ENFORCEMENT

Guide to investigate "counterfeit" medical products and pharmaceutical crime

32. The guide has been prepared by members of the Permanent Forum on International Pharmaceutical Crime – a network of enforcement officers from 15 countries,³ established in 1998 and aimed at protecting public health and safety through the exchange of information and ideas in order to foster mutual cooperation in combating pharmaceutical crime. The guide aims to provide countries with some necessary tools for combating pharmaceutical crime, including information on investigative processes and techniques.

A model for a network of single points of contact

33. The initiative aims to design a standard model for operational collaboration at the international level and for streamlining collaboration among the different national institutions and other parties involved in investigating "counterfeit" medical products and in taking proper, timely action against them. The initiative builds on the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines.

Training courses

34. The working group on enforcement trained a total of 350 officers from police, customs and medicines regulatory agencies through 10 training initiatives in 2009. In 2010, seven courses were run for a total of 415 such officers in the regions where operations took place, with a focus on West Africa (these figures are provided as at September 2010).

Enforcement actions

35. Several enforcement actions were planned and executed in East Asia (Operation Storm I and II), East Africa (Operation Mamba I, II and III), and a global enforcement action was conducted against Internet sales (PANGAEA II). All these actions are carefully prepared and executed by national law enforcement and national regulatory agencies in the countries concerned, supported by INTERPOL.

¹ See document EB127/10.

² Document WHO/EDM/QSM/99.1.

³ Australia, Belgium, Canada, Germany, Ireland, Israel, Italy, Netherlands, New Zealand, Singapore, South Africa, Spain, Switzerland, United Kingdom of Great Britain and Northern Ireland, and United States of America.

WORKING GROUP ON COMMUNICATION

Communications strategy

36. The communications strategy has two main objectives: to increase awareness of risk and to promote policy remedies proposed by the Taskforce. The strategy was endorsed at the Taskforce's third General Meeting, with provision made for further expansion and periodic revision. Improved internal communication between the working groups is planned, with a view to ensuring consistent and regular information-sharing. This is intended to enhance the dissemination to international audiences of timely and accurate information about "counterfeit" medicines and the means by which to combat them. It was strongly recommended that the Taskforce's secretariat should have a full-time communications officer; however, no action has been taken owing to a lack of resources.

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

37. 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". Tool kits and fact sheets have also been prepared to support the campaigns. Two short films were produced in 2008, one in Mali and the other in the Bolivarian Republic of Venezuela. A short video has also been made in collaboration with INTERPOL in order to explain the role of the Taskforce and highlight the dangers of "counterfeit" medical products and their illicit supply. Further work on a network of national communications contact persons is under way.

The Taskforce's web site

38. The working group on communication has been instrumental in updating the Taskforce's web pages in coordination with the Taskforce's other working groups and secretariat.

WHO's revised Rapid Alert System

39. WHO's Rapid Alert System allows Member States to report cases of "counterfeit" medical products and to receive alerts when new cases are reported. Following experience gained in the use of the System, first at headquarters and then in the Regional Office for the Western Pacific, it is planned to expand the System for global use.

Frequently asked questions

40. The Taskforce's pages on the WHO web site include a section on frequently asked questions, which is regularly updated.

WORKING GROUP ON TECHNOLOGY

Anti-counterfeit technologies for the protection of medical products

41. A document has been prepared that assesses the ability of existing and new technologies to prevent or hinder the production of, and commerce in, "counterfeit" medical products, and to detect

their presence. The document considers the following elements: cost, scalability, country-specific 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

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

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