INTERNATIONAL MEDICAL PRODUCTS ANTI-COUNTERFEITING TASKFORCE (IMPACT)

TERMS OF REFERENCE

Mission: **To promote and strengthen international collaboration to combat counterfeit medical products.**

1. Preamble

The need for greater international cooperation in combating counterfeit medical products has been recognized by the World Health Assembly in resolution WHA41.16 of 1988 and reiterated through resolutions WHA47.13 (1994), WHA52.19 (1999), and WHA57.14 (2004).

The establishment of an International Medical Products[1] Anti-Counterfeiting Taskforce, IMPACT, has been proposed by WHO[2] and endorsed by 160 participants at an international conference in Rome in February 2006, representing 57 national drug regulatory authorities, 7 international organizations, 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers. The Rome conference issued a set of principles and recommendations, enshrined in the Declaration of Rome[3], calling for WHO to lead the establishment of IMPACT and set the conceptual framework for IMPACT's work.

On 5 April 2006, the 12th International Conference of Drug Regulatory Authorities in Seoul, Republic of Korea, welcomed the establishment of IMPACT and congratulated WHO on the establishment of IMPACT Secretariat.

The IMPACT is a voluntary grouping of governments, organisations, institutions, agencies and associations from developing and developed countries aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of fighting counterfeit medical products.

IMPACT aims at ensuring appropriate regional representation, including in particular from developing countries.

2. Goals

Consistent with the above-mentioned World Health Assembly resolutions, IMPACT will aim to achieve the following main goals:

- Improve collaboration among governments, organisations, institutions, agencies and associations engaged in combating counterfeit medical products at the national, regional and/or international level;
- In light of the global dimension of counterfeiting, raise awareness among international organisations and other stakeholders
- Raise awareness among national and regional authorities and decision-makers with a view to calling for effective legislative measures in order to combat counterfeit medical products;

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[1] The term 'medical products' encompasses medicines, vaccines, blood derivatives, other biologicals, diagnostics, medical devices and items, as well as their combinations and their components.

[2] The rationale for the establishment of an International Medical Products Anti-Counterfeiting Taskforce is provided in the document 'Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration' http://www.who.int/medicines/events/FINALBACKPAPER.pdf

[3] http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf

- Establish mechanisms for the effective exchange of information and to provide assistance on specific issues pertaining to combating counterfeit medical products;
- Develop technical and administrative tools to support the establishment or strengthening of international, regional and national strategies;
- Encourage and facilitate coordination among different anti-counterfeiting initiatives.

3. IMPACT Objectives

The IMPACT Participants agree to collaborate in facilitating progress in the following areas:

a) securing political will and commitment, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement;
b) inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools;
c) creating an awareness about the severity of the problem among stakeholders and providing information to the health system and the public;
d) development of technical competence and skills in required areas;
e) development of appropriate mechanisms for ensuring vigilance and input from patients' groups, healthcare professionals, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers), and the public.

4. Nature of IMPACT

IMPACT is a task force administered by WHO which provides the participants the opportunity to discuss matters which fall within these Terms of Reference and, where appropriate, to formulate proposals and recommendations to be adopted through a consensus-based approach and made public. Such proposals and recommendations and working plans do not commit the participating governments, organisations, institutions, agencies and associations in any way, but constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility, and according to the prerogative, mandate and internal rules and procedures of each such participating governments, organisations, institutions, agencies and associations.

IMPACT is not a legal entity, and cannot therefore undertake any action, without the explicit agreement in writing of each participating governments, organisations, institutions, agencies and associations. In line herewith, IMPACT cannot be represented by individual participants at any other fora, unless all participating governments, organisations, institutions, agencies and associations have explicitly agreed to be represented in such a manner.

IMPACT Participants are encouraged to conduct activities which are consistent with the above-mentioned objectives under their own responsibility and according to their respective policies and principles. Fund-raising efforts of IMPACT Participants for their own activities will be subject to their own respective policies and principles.

5. IMPACT Collaborating Parties and Structure

5.1 Collaborating Parties:

IMPACT is open to the following collaborating parties involved in combating counterfeit medical products:

Participants

(a) Intergovernmental organizations and institutions, such as the World Health Organization; the European Commission; the Commonwealth Secretariat; the ASEAN Secretariat;

(b) Governmental institutions and agencies;

(c) WHO Collaborating Centres competent in combating counterfeit medical products;

(d) International non-governmental organizations, with an active involvement in combating counterfeit medical products;

(e) international associations/umbrella organizations representing health professionals such as physicians, pharmacists, nurses, dentists;

(f) international associations/umbrella organizations representing patients and consumers;

(g) international associations/umbrella organizations representing manufacturers, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers) of medical products.

Invited experts

The General Meeting and the Working Groups may invite individual experts, with outstanding experience and active internationally in the fight against counterfeit medical products, to participate in certain meetings of IMPACT, for the purpose of sharing information and/or advising the Participants on matters within the sphere of their competence. Invited experts will not, however, be considered as Participants.

Observers

The General Meeting and the Working Groups may furthermore invite governments, organisations, institutions, agencies and associations who do not meet the criteria for participation, but are involved in activities which are relevant to all or part of the goal and objectives of IMPACT to attend all or certain designated meetings of IMPACT, as observers. .

Observers will not, however, be considered as Participants. Upon invitation of the Chairperson, they may, however, make a statement to present their views or positions on the issue under consideration.

5.2 General Meeting

IMPACT will be guided by the General Meeting. The Secretariat will develop guidance principles and a practical mechanism to ensure the effective operation of the General Meeting, the necessary geographical balance, a balanced representation of governmental and non-governmental participants, and the regular presence of relevant international organizations and representatives of patients' and health professionals' organizations. The General Meeting will review and decide on the final principles and criteria developed by the Secretariat. The list of participants to the General Meeting as well as the proceedings will be publicly available. The General Meeting is expected to meet at least once a year.

The General Meeting will review the reports and proposals presented to it by the Planning Group (see 5.3) and, where appropriate, will recommend all or part of their content for endorsement by the respective IMPACT Participants, in light of the IMPACT goals and objectives. The responsibilities of the General Meeting will furthermore be to put forward proposals and make recommendations on matters within the IMPACT goal and objectives to IMPACT Participants.

The General Meeting will also be responsible for establishing ad hoc Working Groups to address and advise the General Meeting on issues relevant to IMPACT´s goal and objectives, including the coordination of country focused initiatives.

The General Meeting will perform its responsibilities through a consensus-based approach. The General Meeting will biennially elect a Chairperson and a Vice-Chairperson to act for a two-year term. A Chairperson and Vice-Chairperson may not act for more than two consecutive terms without a one term hiatus. The General Meeting will annually elect one Rapporteur, to act for a one-year term.

The General Meeting will select a maximum of participants to participate in the Planning Group for 2-year terms, i.e. in addition to the Chairperson, Vice-Chairperson and WHO, as ex-officio participants in the Planning Group.

5.3 Planning Group

The Planning Group shall be comprised of the Chairperson and the Vice-Chairperson of the General Meeting, the Chairs of the Working Groups, the Secretariat and other Participants appointed by the General Meeting. The responsibilities of the Planning Group will consist of the following:
(a) coordination of reports and proposals of relevant collaborating parties for review by the General Meeting;
(b) review and overall presentation of the output/reports of the Working Groups to the General Meeting;
(c) review and acceptance of applications for participation as experts or observers in IMPACT;
(d) identification of the need for invited experts (as described above) to support the achievement of the IMPACT objectives;
(e) identification of the need for the establishment of ad hoc Working Groups to address and advise IMPACT participants on specific issues relevant to the IMPACT goal and objectives (for confirmation by the General Meeting); and
(f) submission of proposals for nomination of candidates for Chairperson, Vice-Chairperson and Rapporteur to the General Meeting.

The Planning Group will operate by consensus, and will meet at least once a year.

5.4 Working Groups

As noted above, IMPACT may establish Working Groups to address and advise IMPACT Participants on specific issues relating to its goal and objectives, including the coordination of country focused initiatives. Working Groups will be lead by a Chairperson, selected by the General Meeting. The Chairperson must be a Participant. For the beginning, 5 Working Groups have been established as outlined at the end of this document.
Working Groups must ensure that Participants and Experts have the appropriate expertise. As long as this is ensured, Working Groups' composition will aim at ensuring representation of the different stakeholders. The Planning Group and the Secretariat will have to ensure that these principles are met.

Each Working Group will develop proposed work plans, report and submit proposals to the General Meeting through the Planning Group.

5.5 Secretariat support for IMPACT

Subject to the availability of sufficient human and financial resources for this purpose, secretariat support for the IMPACT will be provided by WHO, though its Health Technology and Pharmaceuticals (HTP) Cluster at the Organization's headquarters in Geneva.

In this connection, WHO will, among other things,: (a) coordinate the organization of the meetings of the General Meeting, and of the Planning and Working Groups; (b) organise a central repository of information and documents relevant to IMPACT; (c) maintain a database of participants' activities which are completed, ongoing, or planned; (d) inform the participants of activities, ongoing, or planned; (e) prepare and distribute -- in consultation with the Planning Group -- draft agendas, meeting reports, progress reports, and overviews of implementation, etc; (f) create and manage an email list server and an IMPACT internet site (within the WHO domain); (g) receive and submit applications for participation, observership and liaison in IMPACT to the Planning Group and General Meeting, respectively, in accordance with the procedure described above; (h) receive and inform the General Meeting of notices of termination; and (i) take the necessary measures to ensure the confidentiality and protection of materials and information that are provided to WHO with the request to keep them protected from unauthorized access.

IMPACT documents and other output will be issued by WHO and will be disseminated with appropriate disclaimers, including that the content does not necessarily reflect the views or stated policy of the participating organizations, agencies and institutions (including WHO, providing the secretariat support for IMPACT), as well as a clarification of the nature of the proposals/recommendations put forward in such IMPACT documents, along the following lines:

> *" Consistent with the World Health Assembly Resolutions* WHA41.16 (May 1988), WHA47.13 (May 1994), WHA52.19 (May 1999), and WHA57.14 (May 2004)*, and the Declaration of Rome (18 February 2006) IMPACT has been established to improve collaboration among international organizations, agencies, associations and institutions engaged in combating counterfeit medical products. The IMPACT participants have reached a consensus on the proposals and/or recommendations contained in this document. These proposals and/or recommendations may not, however, necessarily reflect the views or stated policy of the participating organizations, agencies or institutions, nor are they in any way binding on, nor do they commit, the organizations, agencies and institutions to whom they are addressed. These proposals and/or recommendations constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility and according to the prerogative, mandate and internal rules and procedures, of each such organization, agency, association or institution authority. The name of IMPACT and the role of any of its participants in it may not be used for, or in conjunction with, commercial purposes without the prior written permission of IMPACT participants or the participant in question, as the case may be."*

6. Financing of, and fundraising for, the day to day operation of IMPACT (including the secretariat support)

Each Participant, observer, and invited expert will, in principle, be responsible for meeting its own expenses in relation to IMPACT (including, but not limited to, travel and subsistence for the attendance of General Meetings, Planning Group meetings, Working Group meetings, country focused initiatives, etc). Subject to the availability of funds, WHO (as a provider of secretariat

support) may, in consultation and agreement with the Chairperson, decide to support the participation of certain developing country Participants and/or of invited experts.

The secretariat support and related day to day operation of IMPACT will be financed by voluntary contributions from Participants. In addition, WHO may raise funds from other sources to support the work of IMPACT, in accordance with WHO's established policies and principles.

The acceptance by WHO of any contributions for IMPACT from the participating governments, organisations, institutions, agencies and associations, as well as from other sources will be subject to WHO's established policies and principles and to WHO's Financial Regulations and Rules, administrative procedures and practices. WHO will administer any such financial contributions through an allotment entitled "IMPACT". This allotment will be administered in accordance with WHO's Financial Regulations, Rules, administrative procedures and practices and will be subject to WHO's normal programme support costs. WHO will provide the participating organizations, agencies and institutions with an annual summary financial report, including information on contributions received for the IMPACT secretariat support and other activities.

7. Applications

Applications to become a Participant or Observer will be submitted to WHO for presentation to the Planning Group and the General Meeting, in accordance with the procedure described above.

8. Termination

Any participant, observer, and invited expert may decide to terminate its involvement in IMPACT by providing written notice to WHO as the IMPACT secretariat. WHO shall remove the organization, agency or institution or individual in question from the list of participants, observers, liaisons and co-opted experts, and inform the General Meeting accordingly.

In addition, it should be noted that:

- the involvement of observers and invited experts extends only for as long as they are invited by the General Meeting; and that
- the involvement of any Participant shall terminate (on a voluntary basis or by consensus of the General Meeting), if and when this Participant ceases to meet the criteria set forth in the first paragraph of section 5.1 above or no longer subscribes to the goal and objectives of IMPACT as described above.

9. Amendments

These Terms of Reference may by modified by consensus at a General Meeting.

IMPACT WORKING GROUPS ESTABLISHED AS OF 26 JULY 2006:

- LEGISLATIVE AND REGULATORY INFRASTRUCTURE
- REGULATORY IMPLEMENTATION
- ENFORCEMENT
- TECHNOLOGY
- COMMUNICATION

LEGISLATIVE & REGULATORY

INFRASTRUCTURE

- survey existing national and international legislation & requirements;
- assess gaps in existing national and international legislation & requirements on manufacturing, distribution, exportation, and importation;
- develop model legislation;
- develop initiatives aimed at law-makers in order to promote adoption of new legislation
- requirements for the distribution system
- assess existing national best practices and develop model best practices

REGULATORY IMPLEMENTATION

- promote implementation of Good Manufacturing, Good Distribution and Good Pharmacy Practice guidelines and quality assurance systems to ensure supply chain integrity;
- develop model training materials aimed at improving quality assurance within and supervision of distribution chain;
- develop guidance on the role of quality control laboratories in combating counterfeit drugs;
- develop data collection tools and methodologies to assess national regulatory and enforcement systems in order to identify gaps and measures needed;
- at the request of national authorities develop ad hoc projects to improve capacity to combat counterfeit medicines;
- promote secure exchange of information and alerts among regulatory and/or enforcement officials as appropriate
- promote networking and collaboration among national drug regulatory authorities
- develop guidance for pharmacovigilance systems to include reporting and investigating suspected cases of counterfeit medicines

ENFORCEMENT

- develop advocacy materials to increase resources available for enforcement
- promote multi-country initiatives to improve coordination and information exchange among enforcement institutions and officers;
- Develop projects aimed at improving communication and collaboration between regulatory and enforcement officers
- develop training materials and manuals to improve skills of enforcement officers
- Identify gaps in existing legislation, need for resources and propose solutions

TECHNOLOGY

- assess (including piloting when feasible and necessary) technologies to prevent, deter, or help to detect counterfeit products taking into account: a) cost, b) scalability, c) specific country needs and situations, d) feasibility, e) regulatory implications;

- facilitate exchange of information on technologies and their implementation

- disseminate information and recommendations on the merits and limitations of technologies

COMMUNICATION

- develop agreed messages and ensure IMPACT presence, as appropriate, at important national and international events;
- develop advocacy, risk communication and education strategies and materials taking into account the need to address specific target groups such as patients and health professionals;
- develop more effective collection and analysis of information on suspected and confirmed cases of counterfeit medical products and dissemination of confirmed cases as appropriate;
- develop initiatives to communicate risks of purchasing medicines from unknown sources (e.g. Internet);
- assist national authorities to develop risk communication and advocacy materials