

Third IMPACT General Meeting 3-5 December 2008 Hammamet, Tunisia Summary report

This summary report outlines the main points of discussion and outcomes of the Third IMPACT General Meeting and related Working Group meetings that took place in Hammamet, Tunisia, from 3rd to 5th December 2008.

Overall, there was good participation, with government representation from 34 countries. Participants included representatives from INTERPOL, WCO, European Commission, Council of Europe, FIP, PSI, as well as associations representing pharmaceutical manufacturers (EGA/IPGA, IFPMA, WSMI), wholesalers (GIRP, IFPW) and IAPO.

All powerpoint presentations will be available on IMPACT's web site (www.who.int/impact) from January 2009. This report is therefore limited to broad issues.

1) IMPACT Chair, Vice-chairs, Chairs of Working Groups and Rapporteur

As established in IMPACT Terms of Reference, the meeting renewed the above-mentioned positions as follows:

| | |
|--|--|
| Chair: | Dr Carissa Etienne, Assistant Director-General, Health Systems and Services, WHO |
| Vice-Chair | Prof. Dora Akunyili, Minister of Information, Nigeria |
| Vice-Chair | Ms Ruth Lee Choo Ai, Health Sciences Authority, Singapore |
| Chair, Legislative and Regulatory Infrastructure Working Group | Dr Konstantin Keller, Federal Ministry of Health, Germany |
| Chair, Regulatory Implementation Working Group | Dr Ilisa Bernstein, Director, Pharmacy Affairs, Food and Drug Administration, USA |
| Co-Chairs, Enforcement Working Group | Ms Aline Plançon, INTERPOL Mr Eric McIntosh, Therapeutic Goods Administration, Australia |
| Chair, Technology Working Group | Ms Alicia Greenidge, Director General, International Federation of Pharmaceutical Manufacturers and Associations |
| Chair, Communication Working Group | Mr Ton Hoek, Secretary General, International Pharmaceutical Federation |
| Rapporteur | Dr Domenico Di Giorgio, Italian Medicines Agency, Italy |

The above nominations are valid for two years, with the exception of the Rapporteur who, according to IMPACT Terms of Reference, is nominated for one year.

The meeting modified IMPACT's Terms of Reference to include the Rapporteur in the Planning Group.

As a result, the Planning Group is now comprised of the above mentioned persons plus Dr Sabine Atzor, DG Enterprise, European Commission and Dr Valerio Reggi, Executive Secretary, IMPACT, WHO.

2) IMPACT Secretariat

Funding remains a major issue; the meeting recommended that WHO should improve its fundraising strategy and give priority to the hiring of staff for the Secretariat (particularly urgent: a communications officer).

3) Working groups topics

LEGISLATIVE AND REGULATORY INFRASTRUCTURE

The document Principles and Elements for National Legislation against Counterfeit Medical Products endorsed at IMPACT Second General Meeting, Lisbon, December 2007, was revised to include language that addresses a) counterfeit medical devices, and b) concerns raised by some WHO Member States at the 61st World Health Assembly in May 2008. The revised document was discussed and a draft endorsed in principle. After editorial work, this draft will be posted on IMPACT web site to seek further comments and input from a broad constituency. It is envisaged that comments will be received until June 2009. Then a revised text consolidating all comments will be made available and discussed at a face-to-face meeting of IMPACT's Legislative and Regulatory Infrastructure Working Group at a date to be determined.

The meeting heard updates from specific initiatives undertaken, separately, by the European Commission and the Council of Europe. The European Commission is working at legislative measures aimed at combating counterfeit medical products in the member countries of the European Union. The process started in March 2008 with a public consultation and is expected to continue and hopefully be completed before June 2009 with a final co-decision made by both the European Parliament and the Council of the European Union (which is the decision-making body gathering the 27 competent ministers of the member states of the European Union). When completed, this process will result in legislation applied in all 27 member states of the European Union.

Separately, the Council of Europe (which is not a structure of the European Union) is working at drafting a "Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health".

REGULATORY IMPLEMENTATION

The draft text proposing revisions to WHO's Good Distribution Practices endorsed in December 2007 at the Second General Meeting was submitted (early 2007) to the WHO's Expert Committee on Specifications for Pharmaceutical Preparations (EC) with a request for consideration. The EC met in October 2008 and decided that the text should be discussed and hopefully finalized at a joint meeting of interested EC members and members of IMPACT's WG on Regulatory Implementation. Such meeting will be convened by WHO in the first semester of 2009.

The issues discussed by the WG and reported to the plenary include:

- a. Involve **pharmacovigilance systems** in reporting of suspect counterfeit cases. This requires contacting the relevant WHO unit and CIOMS to adapt, as necessary, CIOMS reporting form and some other aspects (obtaining samples of the suspected product remains a major issue). There is need to identify volunteers to draft guidance for DRA's re: identifying signals within their pharmacovigilance system.
- b. Completing the **Internet guidance** document on the basis of the input received before and during the Hammamet meeting. Particular attention will be given to the experience of the Portuguese Regulatory Agency (Infarmed). A first draft should be ready for circulation for comments by May 2009. IMPACT Communication working group to develop consumer

- education campaigns** regarding buying medical products online that can be used by DRA's and stakeholders in a variety of languages.
- c. Creation of **Toolkit**/Update of 1999 guidelines. There is still work to be done to identify what needs to be done. The current plan is to envisage updating in 2010.
 - d. Develop **Rapid Response guidance** based on the outlined presented at the meeting. A first draft should be ready for circulation for comments by May 2009.
 - e. Finalize draft of **assessment tool to identify regulatory and legislative gaps** in national situations. This shall be based on the field testing carried out this year in 8 countries. A draft should be ready for circulation for comments by May 2009.
 - f. Further develop **sampling strategy** document adding introductory discussion to better describe the purpose, add watch list examples (e.g. MHRA list), add reference to laboratory network. A new draft should be ready for circulation for comments by May 2009.
 - g. Identify volunteers to draft strategies re: **exporting** pharmaceuticals. This document should address two main areas: a) procedures to monitor/regulate exportation, and b) mechanisms for international communication and exchange of information between relevant authorities.
 - h. **Printed packaging materials guidelines**. The purpose and outline of the existing draft were clarified and the draft will be further circulated for comments in February 2009.

ENFORCEMENT

The meeting heard a report on the three main operations carried out in 2008: Operation Mamba (Uganda and Tanzania), Operation Storm (PR China, Myanmar, Thailand, Lao PDR, Cambodia, Vietnam, Singapore, Indonesia), and Operation Pangea (on Internet sites).

The focus of the Enforcement WG in 2009 will be on the following areas:

- Set-up further operations in different regions
- Organize 8 to 10 training initiatives on counterfeit medicines:
 - In the regions where operations take place
 - Western Africa : INTERPOL IPR Training Seminar and Workshop
 - Ad hoc training seminar in Southern Africa
- Create an advanced version of the Crime Investigation Manual:
 - Intelligence gathering / Informants handling
 - Money flow
 - Internet investigation / test purchase
 - Customs Risk Analysis

The meeting heard a presentation outlining the mission and activities of the Permanent Forum on International Pharmaceutical Crime (PFIPC). The PFIPC was established in 1998 and is a network of enforcement officers from 15 countries aimed at protecting public health and safety through the exchange of information and ideas to foster mutual cooperation in combating pharmaceutical crime.

COMMUNICATION

- The meeting endorsed the updated "Communication Strategy" and reiterated that this is to be considered a "living document" open to further expansion and periodic updates.
- The meeting endorsed the call for the urgent hiring of a communication officer for the IMPACT Secretariat.
- A revised Rapid Alert System allowing member states to report cases and receive alerts when new cases are reported is being developed for a global audience, based on the RAS developed

by WHO's Western Pacific Regional Office.

TECHNOLOGY

The WG considered necessary to:

- continue within the working group's mandate but also to improve connections with the overall WHO IMPACT and the broader WHO context.
- focus work on concrete contributions to help awareness and address needs of members, especially developing countries.
- reiterate that the effort towards harmonization of certain technological approaches to combating counterfeiting should take into account the fact that technology cannot solve the problem alone and that there is a need to factor in supply chain integrity, legislation, and other aspects on a country by country basis.

The WG will update the document "Anti-counterfeit Technologies for the Protection of Medicines" which is now available on IMPACT's web site (www.who.int/impact) taking in consideration the following aspects:

- Better understand regulators' needs, in particular developing and least developed countries.
- Invite more countries to share experiences with the WG and between each other.
- Invite further input from generic manufacturers, OTC manufacturers, distributors, wholesalers, and other relevant partners.
- Based on lessons learnt, collect and provide information on, inter alia:
 - Costs of technology (and effect on final prices) and cost/benefit ratios
 - Key elements in implementation of technologies, including guidelines on how to launch a pilot project in technologies
 - Effects on Internet as a source of counterfeit products

The WG intends to:

- review the experience gained with the use of the Minilab and Chinese mobile labs.
- start looking at experiences with new technologies, specific company arrangements, and assess effectiveness and implications.

These will result in a note to be produced and shared with IMPACT stakeholders, WHO and with particularly regulators.

The WG will try to organize another meeting "regulators meet technology developers" on the basis of the following guiding principles:

- Priority should be on the needs of and experiences from countries (to better frame which technology developers DRAs would like to hear from).
- Better facilitate knowledge sharing and effective decision-making regarding technology solutions.

4) Cross-cutting issues

PROFESSOR DORA AKUNYILI APPOINTMENT

The meeting was pleased to learn that IMPACT Vice-Chair, Professor Dora Akunyili, has been appointed Minister of Information and that she intended to continue as IMPACT Vice-Chair. The meeting expressed its congratulations to Professor Akunyili and felt that she will be able, in her new position, to put the issue of combating counterfeiting of medical products high on the political agenda.

MEDICAL DEVICES

Although efforts have been done with mitigated results in 2008, the meeting reiterated the need to involve experts from the medical devices area into all existing working groups.

APPROPRIATE ACTION TO COMBAT COUNTERFEITS IN SUB-SAHARAN AFRICA

The meeting heard the feedback from the conference held in Abuja, Nigeria in October 2008. The meeting endorsed a proposal to focus activities in sub-Saharan Africa on the following aspects:

- to include IMPACT activities into existing drug regulatory harmonisation initiatives.
- to advocate the establishment of "IMPACT desks" in all member states to enhance international collaboration and exchange of information.
- to conduct country level assessments using the IMPACT assessment tool in at least 50% of member states.

COUNTRY PRESENTATIONS

It was reiterated that country presentations should be included as regular part of IMPACT meetings agenda, providing a platform for interchange of information and experience.

5) Recommendations and closing remarks

The meeting closed on 5 December 2008 endorsing the work plans presented by the working groups and issuing the following recommendations.

WHO should:

1. Strengthen IMPACT Secretariat by improving resources and recruiting a Communication Officer*
2. Improve IMPACT website*
3. Organize regular meetings/teleconferencing amongst WGs*
4. Draft an IMPACT Master Plan including all IMPACT work plans and activities
5. Post all drafts considered ready for commenting by the Planning Group or the General Meeting on IMPACT web site to seek input/comments from the largest number of interested parties
6. When appropriate, post documents endorsed at IMPACT meetings on IMPACT web site as 'working documents', pending their formal endorsement through appropriate procedures, in order to facilitate their utilization by interested parties

** = Recommendations adopted in Lisbon and reiterated in Hammamet*

All IMPACT stakeholders should:

7. Identify experts in the medical devices area to be involved in all Working Groups
8. Prioritize finalization of drafts on GDP, sampling, assessment tool, internet guidance, updated legislative principles document, safe management of printed packaging materials, Q&A, rapid response.
9. Identify resources to ensure implementation of recommendations and work plans developed by working groups
10. Promote the following principles:
 - The primary focus of combating counterfeit medical products is the protection of public health and that the main victims of counterfeiters are patients;

- Ensure that combating counterfeit medical products does not result in hindering the availability of legitimate generic medicines;
- Patent violations or disputes must not be confused with counterfeiting of medical products;
- Medical products (whether generic or branded) that are not legally marketed in a given country but legally marketed elsewhere are not considered counterfeit.

General issues:

11. The following definition was agreed:

The term counterfeit medical product describes a product with a false representation ^(a) of its identity ^(b) and/or source ^(c). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components ^(d), 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 authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

Notes:

^(a) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed.

^(b) This includes any misleading statement with respect to name, composition, strength, or other elements

^(c) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution

^(d) This refers to all components of a medical product

12. Tentative date/venue of next General Meeting: 1-3 December 2009, Mexico City

13. IMPACT Terms of Reference, as updated at the Hammamet meeting, will be posted on IMPACT web site.

14. IMPACT ToRs will be further revised at the 2009 General Meeting.