

**IMPACT General Meeting
12-13 December 2007
INFARMED, Lisbon, Portugal
Summary report**

This summary report outlines the main points of discussion and outcomes of the IMPACT General Meeting and related Working Group meetings that took place in Lisbon from the 10th to the 13th December 2007.

Overall, there was good participation, with government representation from about 40 countries. Participants included representatives from INTERPOL, WCO, WIPO, WTO, European Commission, Council of Europe, FIP, PSI, Pharmaciens Sans Frontières, ReMeD, as well as associations representing pharmaceutical manufacturers (EGA, IFPMA, WSMI), wholesalers (GIRP, IFPW) and the medical devices industry.

All powerpoint presentations are available on IMPACT's web site (www.who.int/impact and www.impactglobalforum.org). This report will therefore be limited to broad issues.

1) IMPACT Chairmanship and future

Dr Howard Zucker, WHO's Assistant Director General for Health Technology and Pharmaceuticals chaired the Lisbon meetings, but announced his departure from both the WHO and IMPACT positions. He assured the WHO's commitment to the continued work of IMPACT.

Funding remains an issue; IMPACT members recommended the WHO secretariat to improve their fundraising strategy and give priority to the hiring of staff for the Secretariat (fundamental: a communications officer; but ideally, one staff person for each working group).

2) Working groups topics

LEGISLATIVE AND REGULATORY INFRASTRUCTURE

The draft document Principles and Elements for National Legislation against Counterfeit Medical Products was discussed in detail in a separate meeting on 10 and 11 December 2008. The resulting document was then endorsed in the plenary session of the General Meeting on 12 December 2008. The final version is available on IMPACT's web site (www.who.int/impact and www.impactglobalforum.org).

Key issues discussed:

- The addition of specific reference to international legal instruments on human rights has been deferred, only a brief reference was added to the introduction.
- The text was revised to clarify that counterfeiting is a criminal offence regardless of the volume or value of seized counterfeit products.
- Language on the desirability of transparency in providing information on status/outcome of prosecution was added.

- There was some debate about the definition of a counterfeit medical product in the context of the legislation principles document. It was agreed that the new definition was more appropriate since a) it encompassed all medical products and not just medicines, and b) by avoiding the terms ‘deliberately and fraudulently’ relieved the investigators of the onus of proving the voluntary possession of counterfeit medical products by transferring the burden of proving their good intentions on those found in possession of counterfeits.
- The issue of manufacturers who deliberately manufacture and sell sub-standard versions of their own products - sort of “counterfeiting themselves” - was raised. The meeting agreed that substandard products or other aspects of non-compliance with GMP requirements were better covered by GMP regulations. The investigation of GMP non-compliance cases permits to reveal deliberate non-compliance and this situation is covered by the definition of counterfeit medical product included in the legislative principles document and identified as a criminal act, including when perpetrated by the legitimate manufacturer.

Next steps:

- IMPACT Planning Group will ensure final editing of the text. The resulting paper will be a living document that will be revised on the basis of experience and feedback from IMPACT stakeholders and others.
- Experts for medical devices will revisit the text and propose specific amendments to meet the specific terms and requirements of this class of products.
- During 2008 IMPACT will encourage national/regional parliaments to debate legislation on counterfeit medical products on the basis of IMPACT’s principles. This has been made possible by funding made available by the European Commission. One approach to be explored is for WHO to send a hard copy of the document to all WHO Member States with an official request to provide feedback on its contents and on action that could be taken to improve the legal framework at the national level, if necessary.
- A comparative study of implementation of anti-counterfeiting legislation is being conducted by the Max Planck Institute and a report will become available in 2008.
- There is a need for IMPACT to further develop the specific issue of sales of medical products through the Internet.
- The legislative working group and IMPACT Secretariat will review language in existing international legislation (including on human rights) that may be applicable to the specific work of IMPACT.

REGULATORY IMPLEMENTATION

- A draft text proposing revisions to WHO’s Good Distribution Practices was endorsed. IMPACT Secretariat has submitted it to the WHO’s Expert Committee on Specifications for Pharmaceutical Preparations with a request for consideration. Feedback is expected by June 2008.
- A draft text on Best Practices for Pharmacists and other Healthcare Providers has been endorsed as a “living document” and as additional support for the updating of the FIP/WHO Good Pharmacy Practices (GPP)¹ with respect to preventing and detecting counterfeit medical products.
- The meeting discussed a preliminary draft of tool for the assessment of national situations concerning counterfeit medical products. The tool requires improvement, development of an assessment guide and adequate field testing. The list of stakeholders obligations included in the Principles and Elements for National Legislation against Counterfeit Medical Products is a useful reference to improving the assessment tool. If funding permits, it is hoped that this work will be finalized in 2008.

¹ http://www.fip.nl/www2///subsections/index.php?page=menu_goodpharmacypractice

- A draft document on Rapid Response for National Regulatory Authorities was discussed. It will need to be further improved and revisited in conjunction with the work being done by the Enforcement working group on the establishment/expansion of a SPOC system.
- The update of WHO 1999 “Guidelines for the development of measures to combat counterfeit drugs” was postponed. The current thinking is that this document will focus on general guidance and refer to IMPACT’s toolkit items for deeper discussion of selected topics. For this reason, the finalization of the new version of the guidelines will depend on the actual availability of toolkit items.
- Additional key areas of work for 2008 (and beyond...):
 - Develop a list of governmental institutions that can act as reference/resource, especially quality testing facilities.
 - Develop a document outlining a sampling strategy based on the recognition that a) laboratory testing is expensive and should not be used for routine purposes without a specific strategy and identified outcomes, and b) selection of samples and sampling sites should be risk-based and should aim at maximum consumer protection.
 - Develop a scientifically sound approach to further developing and implementing appropriate screening methods building on experiences such as GPHF’s ‘minilab’ or the ‘mobile labs’ developed by the National Institute for the Control of Pharmaceutical and Biological Products of China.
 - Develop a guidance paper on the management of packaging materials. A first draft is ready and will be circulated to working group members these days.
 - Develop a model for a mechanism to enhance collaboration and exchange of information between countries in order to combat counterfeit medical products in international trade. Such mechanism would rely on the effective establishment of a SPOC network (see below, enforcement working group). A first draft of the paper should be ready in the first quarter of 2008.

ENFORCEMENT

- The meeting endorsed a “Guide to Investigating Counterfeiting of Medical Products and Other Pharmaceutical Crimes” developed by the Permanent Forum on International Pharmaceutical Crime. Some text still needs to be reviewed to explain the connections between counterfeiting of medical products and other types of pharmaceutical crime. The editing is been done by IMPACT’s Enforcement working group. It is still uncertain whether the guide should be openly accessible in its electronic form because some stakeholders consider that it would be a useful tool for unsophisticated counterfeiters and traders in counterfeits. It is envisaged to finalize the text and print enough hard copies to conduct training of regulatory and enforcement officers (only in English for the moment).
- The meeting also endorsed a “Model for a Network of Single Points of Contact (SPOC)”. Some review of the language is still required and is being done by IMPACT’s Enforcement working group. IMPACT shall have to actively promote the establishment of SPOC-based networks in WHO member states and their effective operation. This requires the recruitment of an enforcement officer and a case management officer to assist the IMPACT Secretariat.
- The first “ASEAN + China” conference involving regulatory, police and customs authorities of the 11 countries was held in Jakarta in November 2007. That conference endorsed the SPOC approach and launched a specific joint operation involving 7 countries to be conducted in 2008. Aim of the operation is to improve collaboration among the concerned countries and authorities through ad hoc training and a joint investigation of selected cases.

COMMUNICATION

- The meeting endorsed the “Communication Strategy”. This is to be considered a “living document” open to further expansion and periodic update.
- 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 will be developed for a global audience, based on the RAS developed by WHO’s Western Pacific Regional Office.

TECHNOLOGY

- The meeting welcomed the document “Anti-counterfeit Technologies for the Protection of Medicines” which is now available on IMPACT’s web site (www.who.int/impact and www.impactglobalforum.org).
- The working group reiterated the statements issued after the meeting held in Prague on 13 March 2007 (available on IMPACT’s web site) and announced the agenda for the joint Regulatory - Technology working groups’ conference in Singapore 13-15 Feb 2008 “1st IMPACT Global Forum: Using Technology to Combat Counterfeit Medical Products - Technology developers meet manufacturers, wholesalers and regulators” (see www.impactglobalforum.org).

3) Cross-cutting issues

MEDICAL DEVICES

- The meeting decided that the most appropriate approach was to involve experts from the medical devices area into all existing working groups instead of creating a separate one.
- All IMPACT documents will be reviewed by experts in order to adapt the language making it applicable to medical devices or to propose specific addenda focusing on medical devices.
- IMPACT Secretariat looks forward to receiving expert names from IMPACT stakeholders in view of including them in the relevant working groups lists.

INTERNET

- Ebay and the Portuguese Regulatory Agency (Infarmed) presented their experience on the trade of medicines through the internet. INFARMED strategy encompasses both regulatory and communication aspects. A new law, August 2007, allows medicines to be bought from internet pharmacies but delivery takes place at the pharmacy and the patient shows the prescription at that point. No on-line (or any other) advertising of prescription medicines is allowed in Portugal. In addition, the Portuguese government has launched a campaign to raise awareness of the dangers of receiving counterfeits when purchasing from the internet, but also the opportunity to order legal medicines on-line. Ebay’s representative explained the efforts the company makes to prevent the illegal sale of pharmaceuticals on their platform. There are clear policies on what type of products can and cannot be sold, and medicines are not allowed. However, official pharmacies may offer their services, if national legislation allows. Filters identify entries which might be infringing. Over 2,000 staff are employed worldwide looking for sales of illegal goods. Companies can register and then send Ebay a warning if products are being sold illegally.
- It was recognized that e-trade requires a multi-pronged approach and this encompasses several IMPACT working group areas. It was decided that a single IMPACT document/guide addressing the advertisement/sale of medical products through the internet will be prepared with input sought from each working group.
- The key areas to be addressed are:
 - legal framework governing the advertisement and sale of medical products through the internet and legal responsibility of internet service providers (in part outlined in the legislative principles document),

- regulatory aspects of advertisement and sale of medical products through the internet,
- investigation, identification and prosecution of illegal sites/activities,
- monitoring the internet to collect information on practices in order to build appropriate advocacy and information activities/campaigns,
- developing and implementing a communication strategy to warn internet users about the risks of purchasing medical products from unknown/unreliable sources.

COUNTRY PRESENTATIONS

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

4) Closing remarks

- Apart from the Singapore conference (regulatory + technology), no other working groups have scheduled face to face meetings for 2008.
- The meeting decided that a specific initiative should be organized in 2008 focusing on the situation in Sub-Saharan Africa, but no date/venue have been identified yet.
- The date and place of the third General Meeting of the IMPACT has not yet been decided (but likely to take place outside Europe)
- The General Meeting made a number of recommendations which are outlined as follows:
 - Strengthen IMPACT Secretariat – improve resources (both human and material)
 - Obtain list of Medical Devices experts in order to include them into the WGs
 - Co-opt European Commission in Planning Group
 - Organise regular meetings/teleconferencing amongst WGs and Chairs
 - Improve IMPACT website
 - Determine date/venue of next General Meeting ASAP
 - Ensure implementation of the WGs' deliverables and monitor/update on WGs' progress
 - Launch Internet-related activities
 - Develop and launch Sub-Saharan Africa project
 - Include matters relating to Medical Devices in IMPACT's agenda