WHO OPEN FORUM ON IMPACT
26 March 2010

Meeting summary

Overview

The Open Forum on the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) convened by the World Health Organization (WHO) Essential Medicines and Pharmaceutical Policies department brought together representatives from 47 Member States, the European Union and 19 international development agencies, NGOs and private sector organizations, to share information on the work of IMPACT, and review the feedback from WHO Member States on the use of the term "counterfeit medicines" and/or equivalent in national legislation.

The meeting was open to all Member States and by invitation to: NGOs with an official relationship with WHO and collaborate with WHO and/or IMPACT in anti-counterfeiting activities, including IMPACT partners; associations having previously invited WHO and/or having collaborated with WHO in this area; associations in collaboration with and/or having been involved in IMPACT related matters; donors having previously financed activities relating to anti-counterfeiting.

Hans Hogerzeil, Director Essential Medicines and Pharmaceutical Policies opened the meeting on behalf of Carissa Etienne, Assistant Director-General Health Systems and Services, with the two co-chairs of IMPACT, Paul Orhii (Director General, National Agency for Food and Drug Administration and Control, Nigeria) and Ruth Lee (Health Sciences Authority, Singapore and Member of the Permanent Forum for International Pharmaceutical Crime). The session on the achievements and next steps of IMPACT Working Groups was chaired by Ton Hoek (Secretary General, International Pharmaceutical Federation and Chair of IMPACT working group on communication). The final forum discussion with Member States and NGOs was moderated by Dr Hogerzeil.

The aim of the meeting was to provide factual information in an open and transparent manner and to listen to concerns and respond to questions. The meeting had no intent to pre-empt discussion during the World Health Assembly in May. "Counterfeit medicines" remain a major threat to public health, putting the health of numerous patients at risk and the confidence of patients in their health systems at stake. This is of critical importance for WHO. WHO has been involved in the issue since 1988, and is committed to remaining involved. There are strong links with other WHO activities, such as support for medicines regulatory authorities, quality assurance and other core components of a functioning health system. Collaboration across international and national partners, beyond the health partners, is needed to ensure an effective response to this complex global problem.
Achievements and plans for the future of IMPACT Working Groups:
The five IMPACT working groups reported on their recent activities and future plans.

**Regulatory implementation** - promoting good distribution, procurement, and national assessments (Chair: Ilisa Bernstein, Food and Drug Administration, USA).

The Regulatory implementation Working Group has: contributed to strengthening the WHO Good Distribution Guidelines to address counterfeits and newer supply chain vulnerabilities; developed an assessment tool to evaluate national, regional, sub-regional situations and identify gaps and needs; developed guidelines for rapid response for drug regulatory authority in the event of a suspect counterfeit.

The Working Group plans to: complete sampling/quality control guidelines; promote use of the assessment tool; develop points to consider for combating counterfeits over the internet; update the 1999 *WHO guidelines for the development of measures to combat counterfeit drugs* and create a toolbox, and provide training programs.

**Enforcement Working Group** - coordinating and strengthening operations among participating countries (Co-Chairs: Aline Plançon, INTERPOL and Eric McIntosh, Therapeutic Goods Administration, Australia; Representative of the Permanent Forum for International Pharmaceutical Crime).

The Permanent Forum for International Pharmaceutical Crime (PFIPC) is an international enforcement forum aimed at protecting public health and safety by combating pharmaceutical crime including counterfeit medicines. The PFIPC has 16 member countries and provides technical expertise to the Working Group on Enforcement. INTERPOL outlined the history of its collaboration with WHO in combating counterfeit medicines and the creation in January 2010 of a new INTERPOL unit: Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC).

Recent initiatives of the Enforcement Working Group have included (1) the establishment of a Single Point of Contact model at regional and global level to build the bridge of communication between enforcement agencies and drug regulatory agencies that deal with the pharmaceutical crime to facilitate rapid and effective communication and info exchange between relevant agencies and identify barriers to the exchange of information between countries and ways to remedy them; (2) the development of a Basic Investigative Tool Kit Manual in eight languages and training to provide investigative guidance to countries with little or no enforcement capacity in pharmaceutical crime, specifically counterfeit medical products; operations in eastern Africa, south-east Asia, and the International Internet Week of Action have disrupted counterfeit medicine chains and internet sales of counterfeit medicines.

Next steps for the Enforcement Working Group include: enhancing the multi disciplinary approach to enforcement; developing operational enforcement activities on a regional level, consolidating existing partnerships; continue raising awareness; developing an advanced investigation manual.

**Technology Working Group** - assessing technologies to prevent, deter or detect counterfeit medicinal products (Chair: Eduardo Pisani, Director General, International Federation of Pharmaceutical Manufacturers and Associations).

The Technology Working Group has developed “Anti-counterfeiting technologies for the protection of medicines” and held discussions in Bonn (2006) and Lisbon (2007) followed by

The Working Group plans to: prepare a new chapter in "Anti-counterfeiting technologies for the protection of medicines" to include information about tamper evident closure technologies; supplement/checklist for enforcement authorities on fast tracking authentication of suspect counterfeit pharmaceutical products, complete a comparative analysis of different field testing techniques, with respect to the needs of different user groups (i.e. regulators, rights holders), different locations, and critical success factors.

**Communication Working Group** - increase awareness, disseminate tools, and advocate change by addressing health professionals, distributors, patients, enforcement and media (Chair: Ton Hoek, International Pharmaceutical Federation).

The Communication Working Group has developed and led the implementation of the IMPACT Communications Strategy focusing on raising awareness of counterfeit medical products as a threat to public health worldwide. Together with the World Health Professions Alliance, the Working Group has developed a toolkit for health professionals and patients to support activities to combat counterfeit medical products. The Working Group has assisted the IMPACT Secretariat in maintaining the IMPACT website and promoting external print and electronic materials relating to counterfeit medical products.

Challenges and concerns identified by the Working Group include: the use of counterfeit medicines can result in treatment failure leading to drug resistance or even death; public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit medicines; there aren't any reliable global estimates on extent of counterfeiting of medical products; and both branded and generic products are subject to counterfeiting.

The Working Group plans to: enhance advocacy, risk communication and education strategies and materials to address specific target groups such as patients; assist national authorities to develop risk communication and advocacy materials; and develop more effective collection and analysis of information on suspected and confirmed cases of counterfeit medical products and dissemination of confirmed cases as appropriate.

**Legislative and regulatory infrastructure Working Group** - to protect public health by improving the legal framework against counterfeit medicines throughout the development and distribution chain (Konstantin Keller, Federal Ministry of Health, Germany)

“Principles and Elements for National Legislation against Counterfeit Medical Products” has been developed and is currently available on the WHO website for additional consultation prior to discussions during the WHO Expert Committee on Specifications of Pharmaceuticals.

A comparative study on existing legislation used to combat counterfeiting of medical products, “Options and Limitations in Legislation against Counterfeit Medical Products”, is being undertaken by the Max Planck Institute for International and Foreign Criminal Law (MPI) to compare current forms of legal instruments in 11 countries that can be used to sanction crimes relating to counterfeit medical products.

The Working Group plans to refine the "Principles and Elements for National Legislation against Counterfeit Medical Products" to address the particularities of medical devices and make improvements based on the experiences gathered by WHO Member States; clarify the
definitions and terms used to address counterfeit medicines based on the responses to the WHO circular letter and the study by the MPI; survey and support the national, regional and international use of the "Principles and Elements for National Legislation against Counterfeit Medical Products".

**Update on WHO's survey of national counterfeit medicines legislation**
Meeting participants were briefed on the preliminary results (subject to further confirmation) of WHO's global inventory of national counterfeit medicines legislations. Sixty Member States plus the European Union have responded to WHO's Note Verbal\(^1\). Responses have been received in many languages (Table 1) and require careful translation and legal analysis, which is under way.

<table>
<thead>
<tr>
<th>Language of response</th>
<th>Countries submitting response</th>
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<tbody>
<tr>
<td>English</td>
<td>Australia, Austria, Bangladesh, Belarus, Botswana, Brazil, Cambodia, China, Croatia, Czech Republic, Estonia, Finland, Germany, Georgia, Hungary, Iraq, Latvia, Liberia, Malaysia, Maldives, Malta, Netherlands, New Zealand, Oman, Philippines, Poland, Saudi Arabia, Suriname, Sweden, Switzerland, Tanzania, Thailand, Turkey, Ukraine, United Kingdom, USA, European Union</td>
</tr>
<tr>
<td>Spanish</td>
<td>Argentina, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, México, Nicaragua, Perú, Venezuela</td>
</tr>
<tr>
<td>French</td>
<td>Belgium, Burundi, Congo DR, France, Haití, Morocco, Niger, Senegal</td>
</tr>
<tr>
<td>Russian</td>
<td>Moldova, Russia, Ukraine, Uzbekistan</td>
</tr>
<tr>
<td>Other</td>
<td>Egypt (Arabic), Serbia (Serbian)</td>
</tr>
</tbody>
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A preliminary review of responses reveals that the majority of Member States use the word "counterfeit" (34) in their national legislation. Other terms used are "falsified", "illicit", "illegal", "unregistered", "unauthorized" "adulterated" and others. The types of national legislation in which counterfeit medicines are addressed include: medicines regulation (31); intellectual property (8) and crime (6). Twelve Member States indicate that they have no legislation at all dealing with counterfeit medicines; six indicate that legislation is in preparation. The initial conclusion of the survey results is that the majority of Member States use the word "counterfeit" in their national laws, and use it in a medicines regulatory (quality and safety related) context.

The next steps for the preparation of the results of the global inventory include:
Step 5: Second independent review and analysis from health/medicines regulatory perspective
Step 6: Consolidation of both reviews into a comprehensive analysis
Step 7: Validation of information (final checks against original responses)
Step 8: Finalization of analysis as a report
Step 9: Publication on the WHO web site
Step 10: Feedback to WHO Expert Committee (October 2010)

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\(^1\) Additional responses are still being received during the preparation of this summary
**Forum discussion**

A "Frequently asked questions with answers" document, based on the written comments received from Member States, was presented. After all questions and answers were read out in the meeting, and handed out in hard copy, the floor was open for further questions and comments.

The following Member States were among those making statements and asking questions: Argentina, Bolivia, Brazil, Chile, Egypt, India, Madagascar, Monaco, Senegal, Sudan, United States of America, and European Union. Some of the questions asked included: WHO's mandate for involvement in IMPACT, limiting the term "counterfeit" to intellectual property related issues, evidence of the occurrence of "counterfeit" vs "substandard" medicines, budget needs for activities compared to bigger problem of substandard medicines, and potential conflict of interest in IMPACT and its developing "guidance".

**Conclusion**

Participants were thanked for their contributions and were assured that the findings of WHO's survey of national counterfeit medicines legislation would be shared as soon as they are finalized. Documents that will be tabled at the World Health Assembly in May 2010 have been updated to reflect the comments and issues raised during 2009 and the Executive Board in January 2010.

The agenda, list of participants, presentations, and Questions and Answers for the Open Forum on IMPACT are available through the following link: [http://www.who.int/medicines/services/counterfeit/open_forum/en/index.html](http://www.who.int/medicines/services/counterfeit/open_forum/en/index.html).