

International Medical Products Anti-Counterfeiting Taskforce

I M P A C T

Overview of the Working Groups



**World Health
Organization**



Overview of the IMPACT Working Group on Legislative and Regulatory Infrastructure

Preamble:

Medical products are essential to cure diseases and to save lives. If a medical product cannot achieve this goal because of counterfeiting, people's health and lives are put at stake. Counterfeit medicines may contain no or insufficient amounts of active ingredients or even toxic substances. As a rule, patients are not in the position to identify counterfeit medical products, thus they are left without defence. Beyond this risk to individuals, counterfeit medicines pose a threat to public health: low dose antibiotics or anti-malaria medication may lead to resistance and the thrust of consumers in affordable generics or the official distribution system may be undermined. There are good reasons to take action, now.

In many countries, national legislation does not fully address the extremely serious threat to peoples' health and life that is caused by counterfeit medical products. Very often, penalties for counterfeiters are far from being adequate to act as deterrents. Legislation that clearly identifies counterfeiting of medical products as a crime – sometimes with serious consequences for the life/health of patients – will help to empower health officials, police, customs officials and the judiciary to better fight this crime. The legal instruments countries dispose for addressing criminal sanctions against counterfeiters of medical products are extremely heterogeneous. For this reason no "model legislations" that would be appropriate for all legal systems can be drafted. The aim of the working group is to provide Member States with tools and modular proposals for elements of legislation that might be easily adapted to each national or regional system of criminal, pharmaceutical or other law.

Terms of reference:

Currently chaired by Dr Konstantin Keller, from the Federal Ministry of Health, Germany

The Working Group aims to:

- survey existing national and international legislation & requirements for fighting counterfeit medical products;
- assess gaps in existing national and international legislation & requirements on manufacturing, distribution, exportation, and importation;
- develop elements of legislation and legislative principles for establishing or improving legislation against counterfeit medical products;
- develop initiatives aimed at law-makers in order to promote development or adoption of efficient legislation.

Main achievements so far:

1. Developed a draft IMPACT working document on "Principles and Elements for National Legislation against Counterfeit Medical Products". The principles set out in this document focus on public and personal health implications in relation to counterfeit medical products that need to be appropriately addressed in legislation. The document is a toolbox for legislation that may be used by Member States. National and/or regional legislation in the criminal, pharmaceutical, administrative and civil field may need to be enriched by the principles illustrated in this document, which are intended to complement or strengthen other legislation and not to replace it.

Status: Currently under review by the WHO Expert Committee on Specifications of Pharmaceuticals and open for comments on the WHO website. Further development is expected in the area of medical devices and in the promotion of a better understanding of the terms used in the document.

2. Initiated a comparative study on existing legislation used to combat counterfeiting of medical products. The Max Planck Institute for international and foreign criminal law (MPI) is leading this work to compare current forms of legal instruments in countries that can be used to sanction crimes relating to counterfeit medical products.

Key activities 2008-2010:

1. Further refinement of the "Principles and Elements for National Legislation against Counterfeit Medical Products" in order to address in a better way the particularities of medical devices.
2. Based on the replies on the WHO circular letter and on the results from the study by the MPI, clarify definitions and terms used in the "Principles and Elements for National Legislation against Counterfeit Medical Products".
3. Survey and support the national, regional and international use of the "Principles and Elements for National Legislation against Counterfeit Medical Products". Improve and expand, as necessary, the recommendations on the basis of the experiences gathered by WHO Member States.

Overview of the IMPACT Working Group on Regulatory Implementation

Preamble:

Counterfeit medical products pose a significant danger to public health in developing as well as developed countries. Counterfeits may be distributed through different distribution channels such as governmental health systems, hospitals, pharmacies, other legitimate or illegitimate distributors, as well as sold over the internet.

Because counterfeiters are good at what they do, licensed distributors, pharmacists, health care providers or patients are sometimes unable to detect or differentiate between counterfeit and genuine medical products. It has been difficult to assess the extent of the problem of counterfeit medical products around the world. Reasons being among others; lack of resources/skills to detect counterfeit medical products, absence or weak regulatory and enforcement systems, different definitions of counterfeit medical products in different countries worldwide, as well as variation in distribution systems. As a result, estimates on the actual extent of the problem may be incomplete and vary from country to country.

Terms of reference:

Currently chaired by Dr Ilisa Bernstein, Director, Pharmacy Affairs, Food and Drug Administration, USA

The Working Group aims to:

- 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 sampling and quality control laboratories in combating counterfeit drugs;
- develop and promote the use of 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;
- develop guidance for rapid response for national regulatory authorities in the event of suspected counterfeit medicines.

Main achievements so far:

1. Led the revision of the WHO Good Distribution Guidelines. Recommendations are made where necessary to strengthen measures to combat infiltration of counterfeit medical products in distribution.

Status: WHO Expert Committee on Specifications of Pharmaceuticals have met and approved the revised guidelines at its 44th meeting in October 2009.
2. Developed an assessment tool designed to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, sub-regional or regional setting. Field testing has been carried out in eight countries (Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Uganda and United Republic of Tanzania) and will be ready for broader use in 2010.
3. Developed guidelines for rapid response plan for national drug regulatory authority in the event of a suspect counterfeit. This document is intended to provide actions that may be followed by the NMRA in the event of suspect counterfeit medicines in national distribution channels.
4. Held joint meetings with the Technology Working Group to discuss cross-cutting issues regarding the regulatory aspects of anti-counterfeiting technologies and the Enforcement Working Group to discuss and raise awareness of the importance of cooperation among regulatory and enforcement experts.

Overview of the IMPACT Working Group on Enforcement

Preamble:

Today, nothing short of a global approach to inhibiting the flow of potentially deadly counterfeit medical products is required. Every country around the world suffers the same problems. The global trade in medicines and medical devices necessitates that countries actively work together and commit to reducing the international trade in counterfeit medical products. Organized criminals trading in counterfeit medical products have well developed worldwide networks which do not recognize any borders between countries. Working with well informed law enforcement officers at a global level makes a difference, more importantly it will have a positive impact in your country.

By working with INTERPOL, World Customs Organization and an international network of enforcement officers such as the Permanent Forum on International Pharmaceutical Crime, IMPACT aims at improving contact and mutual understanding among enforcement officials of different countries in order to improve coordination of operations and rapid exchange of information. IMPACT is also a platform for enforcement officers to establish communication with health authorities and other stakeholders, including industry and health professionals to combat the trade in counterfeit medical products.

Terms of reference:

Currently chaired by Ms Aline Plançon from INTERPOL and Mr Eric McIntosh from Therapeutic Goods Administration, Australia.

The Working Group aims to:

- 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.

Main achievements so far:

1. Developed a guide to investigate counterfeit medical products and pharmaceutical crime. The intent of this guide is to provide processes and techniques to countries developing an investigative capacity to combat pharmaceutical crime, in particular identifying, investigating and prosecuting individuals and companies that import, manufacture, supply and export counterfeit medical products into, within and from countries.
2. Established a “Model for a Network of Single Points of Contact (SPOC)”. The aim of this initiative is to facilitate operational collaboration at the international level as well as to streamline collaboration among the different national institutions and other stakeholders involved in investigating, and taking proper timely action when confronted with a case of counterfeit medical product. This builds upon the work done by the Council of Europe’s Ad hoc Group on Counterfeit Medicines.
3. Trainings and Operations in 2009:
 - a. Eastern Africa:
Mamba II : August 2009
Organised two Trainings and joint action amongst 3 countries involving multiple agencies,
 - b. South East Asia:
Storm II : July 2009 – January 2010
Organised two Trainings and joint action amongst 8 countries involving multiple agencies,
 - c. International Internet Week of Action:
Pangea II : 16 – 20 November 2009
Operation coordinated among 25 countries to alert the public of the danger to buy counterfeit and illicit medical products over the Internet.

Overview of the IMPACT Working Group on Technology

Preamble:

There are many anti-counterfeit technologies available to manufacturers and brand owners, ranging from the very simple but effective to the highly sophisticated and extremely secure. The majority can be implemented on one or more of the packaging components, but some features can even be applied at the product level.

The purpose of an anti-counterfeit feature is primarily to enable the authentication of an item. The second function may be to act as a deterrent to anyone considering counterfeiting a product based on the difficulty or cost involved set against the likelihood of detection, and therefore prosecution. It must be stressed that anti-counterfeit features on packaging components provide no assurance as to the authenticity of the contents, which may have been substituted or adulterated. They can also be subject to imitation and counterfeiting attempts. Anti-counterfeit features alone do not reduce counterfeits, but are on the one hand designed to make them easier to detect and on the other hand increase the hurdle for potential counterfeits. They are most effective when used as part of a holistic approach.

Terms of reference:

Currently chaired by Mr Eduardo Pisani, Director General, International Federation of Pharmaceutical Manufacturers and Associations.

The Working Group aims to:

- 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.

Main achievements so far:

1. Developed a guide on “Anti-counterfeit Technologies for the Protection of Medicines” for IMPACT. This document assesses existing technologies to prevent, deter or help to detect counterfeit medicinal products. A new chapter is being developed, to include information about tamper evident closure technologies.
2. Development of a supplement/checklist for enforcement authorities on fast tracking authentication of suspect counterfeit pharmaceutical products.
3. Development of a comparative analysis of different field testing devices, with respect to:
 - a. Needs of different user groups (i.e. regulators, rights holders),
 - b. Needs in different locations,
 - c. Critical success factors.
4. Organised a series of workshops bringing regulators and technology developers together. These workshops facilitate experience sharing among regulators with the objective to better inform regulators on decision-making regarding technology solutions.
 - a. The Second IMPACT meeting for regulators on anti-counterfeiting technologies “Using Technologies to Combat Counterfeit Medical Products” was held in Singapore, February 13-15, 2008.

Overview of the IMPACT Working Group on Communications

Preamble:

The infiltration and sale of counterfeit medicines in the legitimate supply chain can cause death and misery to tens of thousands of patients around the world. Failure to act to prevent this criminal activity would be a fundamental breach of the trust placed in public health structures by patients. Any effective solution must drive immediate change, be effective in the long term and receive the support and active engagement and collaboration of all stakeholders managing the medicines supply chain.

Risk communication can be only considered effective if it alerts the target audience as to what is hazardous, the extent of the danger and what should be done to protect oneself. Specific key messages that are based on accurate and timely information on counterfeit medicines will invoke action in the appropriate target audience.

In communicating the key messages, IMPACT needs to promote responsible media reporting by encouraging and assisting in information provision to ensure accurate and non-sensational coverage.

Terms of reference:

Currently chaired by Mr Ton Hoek, CEO and Secretary General of the International Pharmaceutical Federation

The Working Group aims to:

- 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.

Main achievements so far:

1. Developed and led the implementation of the IMPACT Communications Strategy. The communications strategy focuses on raising awareness of counterfeit medical products as a threat to public health worldwide in a safe and coordinated way that leads to action and providing a platform that reflects and communicates the objectives and actions of the IMPACT and all its working groups.
2. Collaborated with the World Health Professions Alliance (WHPA) in developing a toolkit for health professionals and patients to support activities to combat counterfeit medical products.
3. Collaborated with WHO and INTERPOL in developing media campaigns focussing on various key messages to different target audience.
4. Maintained the IMPACT website and promote external print and electronic materials relating to counterfeit medical products.

