

## An overview of the IMPACT Working Groups' documents and activities (updated 2 April 2009)

	Title of document	Brief Description	Current Status	Future Plans
LEGISLATION	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. 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.	The document was endorsed at the 2nd IMPACT General Meeting, Lisbon, December 2007, and was revised at the 3rd General Meeting in Hamamet to include language that addresses: (a) counterfeit medical devices; and (b) concerns raised by some WHO Member States of the SEARO region.	After editorial work, this draft will be posted on the IMPACT web site to seek further comments and input from a broad constituency. It is envisaged that comments will be received until June 2009. A revised text consolidating all comments will then 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.
	A comparative study on existing legislation used to combat counterfeiting of medical products	The Max Planck Institute for international and foreign criminal law 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.	Results from a preliminary analysis: *no country uses subjective/mental elements in the national definition of counterfeit medical products; *many countries use in parallel the concept of "counterfeit-like offences", e.g. unauthorized or substandard medicines. Final results of the analysis are expected in spring 2009.	The analysis will be presented to IMPACT's Legislative and Regulatory Infrastructure Working Group and to the IMPACT general meeting for discussion.
	Review of responsibilities of other stakeholders in the distribution chain. For example, the Internet (and other) service providers	This is an analysis review of existing documents and activities, e.g.: *Council of Europe Convention on Cybercrime; *Council of Europe guidelines on distribution of medicines through the Internet; *self-regulating standards by the pharmaceutical industry (e.g. EBay), etc.	This is work in progress.	This initiative will be led by the Council of Europe with assistance from the Working Group (WG) where necessary.

## REGULATORY INFRASTRUCTURE

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A data collection tool to identify regulatory and legislative gaps in national situations.	This assessment tool is designed to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, subregional or regional setting. There are seven parts to this tool: legislation; capacity of national medicines regulatory authorities (NMRAs); market control; documentation and reporting mechanism; awareness programmes; national and international collaboration.	Process of development started April 2007. Discussed during the 2nd IMPACT General Meeting, December 2007 in Lisbon, Portugal. Reviewed by the Regulatory Implementation WG in Rome, 6-8 May 2008. Reported to NMRAs during 13th ICDRA meeting, 16-19 September 2008.	Based on field testing carried out this year in eight countries (Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Uganda and United Republic of Tanzania ). A draft version should be ready for circulation for comments by June 2009.
Sampling strategy guidelines	This document highlights key issues and recommendations for developing an efficient suspect product sampling strategy. Elements of a procedure for collection and testing of samples for the purpose of detecting counterfeit medical products is also described.	The principles of this document were endorsed in the 3rd General Meeting with the intention to continue work on the draft document.	A new draft should be ready for circulation for comments by June 2009.
Guidelines for rapid response plan for national drug regulatory authority for signal of suspect counterfeit	NMRAs must devise pro-active strategies to effectively fight and prevent counterfeit medical products. 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.	The principles in this document were endorsed at the 3rd IMPACT General Meeting with the intention to continue work on this document.	The first draft should be ready for circulation for comments by June 2009.

<p>Developing good security practices for printed packaging material for pharmaceutical products.</p>	<p>Printed packaging materials are the communication interface between drug product quality and the patient. They have a very important role in drug safety as wholesalers, pharmacists, doctors and patients rely on them. Current legislation is not sufficiently mindful of manipulations with printed packaging materials. This document will serve as a guideline focusing on printed packaging materials.</p>	<p>A first draft has been written.</p>	<p>To further consider developing materials and strategies aimed at educating pharmacists, patients and other concerned parties regarding handling and safe disposal of packaging materials, in order to prevent their reuse. The second draft will be further circulated for comments in May 2009.</p>
<p>Create/coordinate a guidance document for combating internet trade of counterfeit medical products.</p>	<p>This document will address efforts to combat counterfeit medical products over the Internet, focusing on characteristics/principles for legitimate online sale, and considerations for regulatory and enforcement authorities.</p>	<p>A detailed outline for the guidance was circulated and discussed at the 3rd IMPACT General Meeting.</p> <p>The Communication WG has been asked to develop consumer education campaigns in several languages regarding buying medical products online that can be used by MRAs and stakeholders. A drafting team has been identified.</p>	<p>A first draft should be ready for circulation for comments by June 2009.</p>
<p>To develop a counterfeit-oriented revision of the WHO guidelines on good distribution practices (GDP).</p>	<p>WHO GDP lay down guidelines for the distribution of pharmaceutical products. The main principles established in this document to secure the distribution chain may also be taken into account for medical devices. Recommendations are made where necessary to strengthen measures to combat infiltration of counterfeit medical products in distribution.</p>	<p>This document was endorsed in principle at the 2nd IMPACT General Meeting. A series of edits and revisions were made by IMPACT and considered by the WHO Expert Committee on Specifications for Pharmaceutical Preparations at its meeting in October 2008. No one from IMPACT was available at this meeting to answer the Committee's questions.</p>	<p>The IMPACT Regulatory Implementation Group will meet with the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 2009 to answer any questions.</p>

Review national strategies regarding export of pharmaceuticals and develop guiding principles for NMRAs.	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.	This is work in progress.	A drafting team needs to be identified.
Develop guidance for ways to adapt current pharmacovigilance systems for counterfeit reporting.	This requires contacting the relevant WHO unit and the Council for International Organizations of Medical Sciences (CIOMS) to adapt, as necessary, CIOMS reporting forms and some other aspects. (Obtaining samples of the suspected product remains a major issue.)	This is work in progress.	Volunteers are needed to work on this.
Update of 1999 WHO guidelines on measures to combat counterfeit medicines.	The technical documents developed by IMPACT reflect the needs of Member States to effectively combat counterfeit medical products in a comprehensive manner. An IMPACT toolkit will be developed as a package of tools, including updated WHO guidelines on measures used to combat counterfeit medical products.	This is work in progress.	The current plan is to update the guidelines in 2010.

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ENFORCEMENT	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.	The guide has been prepared by members of the Permanent Forum on International Pharmaceutical Crime. It is as generic as possible on the basis that each country's medicine and medical product law and regulatory regime will differ.	Create an advanced version of the Crime Investigation Manual: *intelligence gathering/informants handling; *money flow; *Internet investigation/test purchase; *customs risk analysis.
	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 the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines.	Three main operations were carried out in 2008: Operation Mamba (United Republic of Tanzania and Uganda), Operation Storm (Cambodia, People's Republic of China, Indonesia, Lao People's Democratic Republic, Myanmar, Singapore, Thailand, Viet Nam, ), and Operation Panga (on Internet sites).	IMPACT to set up further operations in different regions.
	IMPACT training courses.	The guide to investigate counterfeit medical products and pharmaceutical crime will be used in courses for the training of regulatory and enforcement officers.	In the countries involved in IMPACT operations a systematic partnership between police, customs and regulatory authorities was forged. Training sessions were conducted with translation of the Permanent Forum on International Pharmaceutical Crime (PFIPC). An investigative guide manual was also translated into Khmer and Vietnamese.	Focus on Western Africa and an ad hoc training seminar in Southern Africa in conjunction with some INTERPOL activities.

COMMUNICATIONS

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	IMPACT Communications Strategy.	<p>The communications strategy focuses on two main objectives: increasing awareness of the risk; and promoting policy remedies proposed by IMPACT.</p> <p>IMPACT's overall vision is to fight for the eradication of all counterfeit medicines from supply chains of the developed world and to be reduced by two-thirds in the developing world by 2020. A communications campaign is needed to create awareness of the risk, support programme policy objectives and increase commitment from those who can influence change.</p>	<p>Seven distinct target audiences have been identified. Specific key messages have been selected and tailored to each group for effective communications campaigning.</p> <p>The strategy was endorsed in the 3rd General Meeting when it was reiterated that it is to be considered a "living document" open to further expansion and periodic updates.</p> <p>An internal WHO SharePoint portal was initially setup but there has been no active use and update of this tool.</p> <p>The IMPACT web site needs to be urgently updated.</p>	<p>A more effective internal communication protocol and structure has to be set up between the IMPACT WGs with a view to ensure consistent and regular information sharing, so as to effectively disseminate timely and accurate information to an international audience about counterfeit medicines and the means by which to combat them.</p> <p>A full-time communications officer needs to be established within the WHO IMPACT Secretariat.</p>
	Communications campaign focusing on patients.	<p>Patients and care providers must ensure that they only buy from their legal outlets such as pharmacies and appropriate trained personnel such as pharmacists, and they should be educated about what counterfeit medicine is. The main key message is "Only get your medicines from known and reliable sources".</p>	<ul style="list-style-type: none"> <li>*The World Health Professions Alliance (WHPA) has printed flyers to provide information to patients.</li> <li>*The International Alliance of Patient Organizations (IAPO) has developed a Patient Safety Toolkit for patients' organizations which includes a section on counterfeit medicines.</li> <li>*Discussions initiated with the Patients for Patient Safety programme in the WHO World Alliance on Patient Safety.</li> </ul>	<p>To further develop a multimedia campaign focusing on the personal and public health risks of counterfeit medical products to patients.</p> <ul style="list-style-type: none"> <li>*Collaborate further with WHO World Alliance on Patient Safety.</li> <li>*A patient guideline on buying medical products and services over the Internet will be developed with the Regulatory WG.</li> </ul>
	Communications campaign focusing on the general public.	<p>The general public must ensure that they only buy from their legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists, and they should be educated about what counterfeit medicine is.</p>	<p>The concept of "World Anti-Counterfeiting Day" or "Safe Medicines Day" was proposed, to be further explored by the IMPACT Planning Group and WHO.</p>	<p>Opportunities for a Public Service Announcement on combating counterfeit medical products project will be explored.</p>

Communications campaign focusing on the media.	Counterfeiting of medical products, including the entire range of activities from manufacturing to provision to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems. The main key message is “Counterfeit medicines are a threat to personal and public health worldwide”.	IMPACT has been approached by a European TV chain (ARTE) to do a spot video on IMPACT.  Five IMPACT Factsheets have been developed, highlighting key messages relating to the five working areas of IMPACT and its stakeholders.	A major goal is to increase media activities on the international level, and where effective, at key national events. There is a need for an international ambassador or spokesperson for IMPACT, especially in expanding TV, radio, newspaper and other media events of IMPACT.
Communications campaign focusing on health professionals.	Health professionals need to consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for. There is also an ethical call for health professionals to play a vigilant role in distribution and use of legitimate medical products themselves and when interacting with patients and their peers.	The WHPA has developed a counterfeit medicines toolkit for healthcare professionals and IMPACT has adopted these materials for its own uses. A wider distribution plan for this toolkit needs to be put in place.	A multimedia campaign will be further elaborated. Initial discussions have started with IMPACT and the International Pharmaceutical Federation (FIP9). Ideally this campaign should be launched at the 4th IMPACT General Meeting. This will be the focus for 2009.
Communications campaign focusing on legitimate pharmaceutical supply chains.	In order to successfully combat counterfeits a coordinated effort of all public and private stakeholders in the pharmaceutical supply chain is required where all share accountability, all bear responsibility, all invest resources.	An IMPACT global forum was organized in Singapore (February 2008), bringing together developers of anti-counterfeiting technologies and key impact stakeholders.	An industry consensus needs to be created amongst manufacturers and wholesalers on the level of individual responsibility required to prevent supply chain infiltration.
Communications campaign focusing on enforcement agencies and officers.	Cooperation, collaboration and sharing of information beyond boundaries between law enforcement agencies are a necessity for effective investigation and prosecution. The main message is “When existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate”.	Two short films were developed in 2008, one in Mali and one in Venezuela. Both films (3 minutes each) describe (in different contexts) an enforcement officer who loses a member of his family due to counterfeit medicines.  A short video has been developed in collaboration with Interpol focusing on illustrating the dangers of the illicit supply chain and the role of IMPACT as a global taskforce to “win the race” in order to save lives.	Further collaboration with the work plan of the Enforcement WG needs to be explored. The role of pharmacists, pharmacy owners and pharmacy national associations can be further explored and integrated within the training and outreach projects of Interpol and WHO.

<p>Communications campaign focusing on governments and other international nongovernmental organizations (NGOs) and civil society groups.</p>	<p>There is a need to raise the awareness of IMPACT among international organizations and national legislative, regulatory and enforcement authorities in order to strengthen international action against counterfeit medicines. The main message is “Medicines should not be traded as a commodity and when existing laws are not adequately and rigorously enforced, crimes such as counterfeiting tend to perpetrate”.</p>	<p>FIP organized a briefing for IMPACT at the 61st World Health Assembly in May 2008 on the role of governments, NGOs and other international organizations in combating counterfeit medicines.</p>	<p>FIP will lead an initiative to constructively engage the most relevant NGOs and Civil Society groups in strengthening political commitments so as to bring about unified international actions to combat counterfeit medical products. Communications with the diplomatic missions based in Geneva will be conducted.</p>
<p>Prepare a proposal to hire an IMPACT communications officer.</p>	<p>A dedicated communications officer is critical to support the above-mentioned work plans and the various IMPACT communication campaigns.</p>	<p>An outline of key tasks for this portfolio has been developed. Funding efforts have begun.</p>	<p>WHO is to investigate the possibility of supporting a full-time communications officer at the WHO IMPACT Secretariat.</p>
<p>Revised WHO Rapid Alert System.</p>	<p>A revised WHO Rapid Alert System (RAS) allowing Member States to report new cases and receive alerts is being developed for a global audience, based on the RAS developed by the WHO Western Pacific Regional Office.</p>	<p>Specifications for a request for tender have been drafted based on the required purposes of a global RAS. To enable registered users to: (a) report and store in a shared database cases of counterfeit medical products, (b) receive alerts when selected reports are recorded in the system; (c) browse the reports database; (d) download selected reports; (e) obtain contact details of other users of the system; (f) provide and update user profile; (g) monitor use of the system and record activities.</p>	<p>WHO IMPACT Secretariat to follow up.</p>
<p>Revise and update IMPACT FAQ sheet.</p>	<p>The existing FAQ draft needs to be reworked in accordance to the needs of its audience.          *General FAQ on IMPACT is required.          *Specific FAQ regarding the development of the “WHO definition” of a counterfeit medical product.          *Translate some of the useful information of this document into an internal “technical guidance for IMPACT stakeholders on communications and procedures” .</p>	<p>This is work in progress.</p>	<p>Updated external IMPACT FAQ needs to be made available on the WHO IMPACT web site.           An internal IMPACT FAQ needs to be developed and shared among all IMPACT stakeholders and WG members.</p>

## TECHNOLOGY

Title of document	Brief Description	Current Status	Future Plans
Anti-counterfeit Technologies for the Protection of Medicines.	This document assesses existing and new technologies to prevent, deter or help to detect counterfeit medicinal products taking into account: (a) cost; (b) scalability; (c) specific country needs and situations; (d) feasibility; (e) regulatory implications.	This is a "living" document of the WG and is continuously updated with regards to new trends and lessons learnt from implementation in countries. Two versions are available: one only for regulators (with specific information on the level of security of each technology assessed) and one for the general public (with less detail, to avoid giving important information to counterfeiters). Last version updated November 2007.	Next version of the papers (planned for 2009) to include:  (1) conclusions and recommendations from "Regulators Meeting on Technology Developers", events (Prague, 2007 and Singapore, 2008); 2) elements related to tamper-evident outer pack closure system.
Collect and provide information on new developments in technologies, including 2D barcodes and serialization.  Continue series of workshops bringing regulators and technology developers together.	Need to better understand regulator needs, in particular in developing and least developed countries. Based on learning, the WG will aim at collecting and providing information on: - costs of technology (and effect on final prices; - key elements on implementation of technologies support to MRAs on how to launch specific pilot projects; - effects of the Internet as a source of counterfeits. These workshops facilitate experience sharing among regulators, and between regulators and technology developers. Objective is to better inform regulators on decision-making regarding technology solutions.	This is work in progress; the only information available to IMPACT until December 2008 was on 2D-sterilization proposal in Europe.  Two workshops were held in Prague (2007) and in Singapore (2008) with logistical support from FIP.	The WG would like to invite other developing countries to share their experiences with new technologies.  The WG would also like to invite generic manufacturers, over-the-counter (OTC) manufacturers, distributors, wholesalers and other relevant partners to share their experiences.  Based on previous experience, the WG would like to hold a similar workshop in 2009, but giving more priority to sharing of regulators' needs and experiences.
A review of existing and new field-testing models	To review new developments in Minilab and Chinese Mobile labs, if any. Start looking at experiences with new technologies (Raman spectroscopy) and assess effectiveness and implications.	This is work in progress (WHO approached by USP for project on Raman spectroscopy).	Once more information is available, a note is to be produced and shared with WHO Member States and with regulators.

Develop a technology supplement to the WG Enforcement guide to investigate counterfeit medical products and pharmaceutical crime.	Review the Investigation Guide and SPOC model with a view to proposing supplementary information to help to fast-track investigations for purposes of authentication. The supplement could be a set of critical elements to help investigators facilitate product authentication (e.g. a checklist).	This is work in progress.	Volunteers to review the SPOC need to be identified.
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