IMPACT
International Medical Products Anti-Counterfeiting Taskforce

First ASEAN-China Conference on Combating Counterfeit Medical Products
Jakarta, 13-16 November 2007
Crowne Plaza Hotel, JL. Gatot Subroto Kav. 2 - 3, Jakarta, Indonesia

Summary report

The World Health Organization (WHO) has launched an International Medical Products Anti-Counterfeiting Taskforce, IMPACT, which is the response that the international community is giving to the growing concerns caused by the expansion of the number of cases of and countries affected by counterfeit medical products. A number of international organizations and other stakeholders are actively participating in this taskforce. IMPACT's core principle is that no one sector alone can effectively combat counterfeit medical products and that improved collaboration among concerned parties at the national, regional and international level is essential for curbing this disturbing problem.

The ASEAN Secretariat has requested WHO support to develop an ASEAN-wide initiative to combat counterfeit medical products. In response to this request the ASEAN Secretariat , WHO, and INTERPOL, with the support of the national medicines regulatory authority of Indonesia, Badan POM, and Singapore, HSA, have organized a conference in Jakarta from 13 to 16 November 2007 with the following objectives:

- To provide an opportunity for all participating countries' stakeholders to share information and experience regarding combating counterfeit medical products;
- To intensify collaboration with WHO-IMPACT in view of obtaining technical advice and ensuring that ASEAN Member Countries are aware of international initiatives and involved in specific action as required;
- To discuss and identify specific actions to be taken at the regional level to address this problem and propose a plan for their implementation.

The conference has been the first event gathering all ASEAN member countries and China to discuss strategies to combat counterfeit medical products. National medicines regulatory authorities, police, customs and associations representing health professionals, pharmaceutical manufacturers and wholesalers have been invited to attend. The conference programme and list of participants are provided in attachments 1 and 2.

This report and the presentations made at the conference are available on IMPACT web site (www.who.int/impact and www.impactglobalforum.org).

The meeting heard and discussed presentations from ASEAN countries, China, Australia and Japan. The meeting then split into 4 groups and discussed some key aspects of international collaboration in combating counterfeit medical products. The conclusions of the groups were merged and appear in the notes here below.

A separate report will be prepared by INTERPOL on the meeting that took place on 16 November to discuss a joint operation involving China and selected ASEAN member countries.

DEFINITIONS

Counterfeit medical product

IMPACT is discussing the possible revision of the established WHO definition of counterfeit medicine. The purpose of this revision is to expand the definition to encompass all medical products. The current proposed definition is as follows:

> ***Counterfeit medical product:***
> *A medical product is counterfeit when there is a false representation in relation to its identity (name, composition, strength, or any other element that may influence the judgement of health professionals, patients or consumers about the identity of the product) or source (manufacturer, country of manufacturing, country of origin, marketing authorisation holder, or any other element that may influence the judgement of health professionals, patients or consumers about the source of the product). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components[1] or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.*

The meeting agreed that, for the purpose of collaboration and exchange of information among the participating countries, the established WHO definition published in the 1999 Guidelines[2] will be used, this definition reads:

> *a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients[3] or with fake packaging.*

The meeting also agreed that, for the purpose of collaboration and exchange of information among the participating countries, the definition should not be used to address the so-called 'imitations', i.e. products that imitate names, shapes, logos, colours or other characteristics of other brands, without violating national trade mark protection laws and regulations.

Broker: see Operator of the distribution chain
Distributor: see Operator of the distribution chain
Exporter: see Operator of the distribution chain.
Importer: see Operator of the distribution chain.

Manufacturer

[1] this refers to ingredients or any other component of a medical product
[2] Guidelines for…..
[3] The Guidelines identified the need to take into account the fact that counterfeit medicines can contain either insufficient or excess active ingredients; this would require amending the definition and specify: *incorrect amounts of active ingredients.*

IMPACT is discussing a definition of manufacturer to encompass all activities that are relevant in a strategy aimed at combating counterfeit medical products. The current proposed definition is as follows:

Any natural or legal person who:
2.1. produces the medical products;
2.2. engages in any part of the process of producing the medical products or of bringing the medical products to their final state. This includes any of the following: purchase of materials, processing, assembling, packaging, labelling, storage, sterilizing, testing and releasing for supply of the medical products or of any component or ingredient of the medical products as part of that process;
2.3. has the medical products designed or manufactured (as defined above) by a third party;
2.4. re-packages or re-labels medical products (as defined above).

The meeting recognized that it is important to adopt an operational definition of manufacturer that is consistent with the declared need to combat counterfeit medical products and therefore all activities related to manufacturing should be adequately included in order to ensure that they are covered by appropriate regulation and compliance oversight. However, the meeting considered that this matter should be raised and discussed at an ACCSQ-PPWG meeting, which is the proper forum for this kind of discussion and decision. The meeting agreed that, for the purpose of collaboration and exchange of information among the participating countries, the established ACCSQ-PPWG definitions will be used. These definitions read:

Manufacturer: A company that carries out at least one step of manufacture as well as the final release of the finished product.
Manufacture: all operations starting from the purchase of materials and products through to production, quality control, release, storage, and shipment (from storage related to the manufacturing site) of finished products, and the related controls. Manufacture includes re-packaging and re-labelling operations".

Operator of the distribution chain:

For the purpose of combating counterfeit medical products, this term encompasses all persons involved in all the different professional and commercial activities concerned with purchasing, selling, procuring, storing, distributing, importing, exporting medical products, with the exception of dispensing/providing medical products to the end users. This refers, as applicable, to ownership or possession of the medical products. Depending on national legislation, operators of the distribution chain will be referred to by different terms (e.g. distributor, wholesaler, full-line wholesaler, parallel trader, short-line wholesaler, broker, importer, exporter, sales representative, sales agent, etc.) reflecting specific activities and licensing or authorisation requirements. All these activities are grouped under one definition because they should all be subjected to the same requirements and accountability in relation to counterfeit medical products.

Other operators involved:

This term encompasses all persons involved in all the different activities concerned with advertising, providing platforms for trade, providing Internet and other communications services, transportation, storage, providing assistance in commercial and financial transactions, providing forwarding and logistics services. This refers, as applicable, to ownership or possession of the medical products. All these activities are

grouped under one definition because they should all be subjected to the same requirements and accountability in relation to counterfeit medical products.

Retailer:

This term encompasses all the different activities concerned with procuring (in the sense of obtaining through any means) and storing medical products in order to sell, supply or dispense them to the end users. This refers, as applicable, to ownership or possession of the medical products

Sales agent: see Operator of the distribution chain
Sales representative: see Operator of the distribution chain
Wholesaler: see Operator of the distribution chain

Establishment of Single Point of Contact (SPOC) System

The meeting discussed a document describing a model developed by the Permanent Forum on International Pharmaceutical Crime (PFIPC) for the establishment of a international network of Single Points of Contact (SPOC) based on national SPOC systems.

The meeting amended the PFIPC document as shown here below and unanimously agreed that, in order to improve the capacity to combat counterfeit medical products:

a) a SPOC system among ASEAN countries and China is a desirable initiative, and
b) WHO and Interpol should formally request ASEAN countries and China to appoint an international SPOC and establish national SPOC systems.

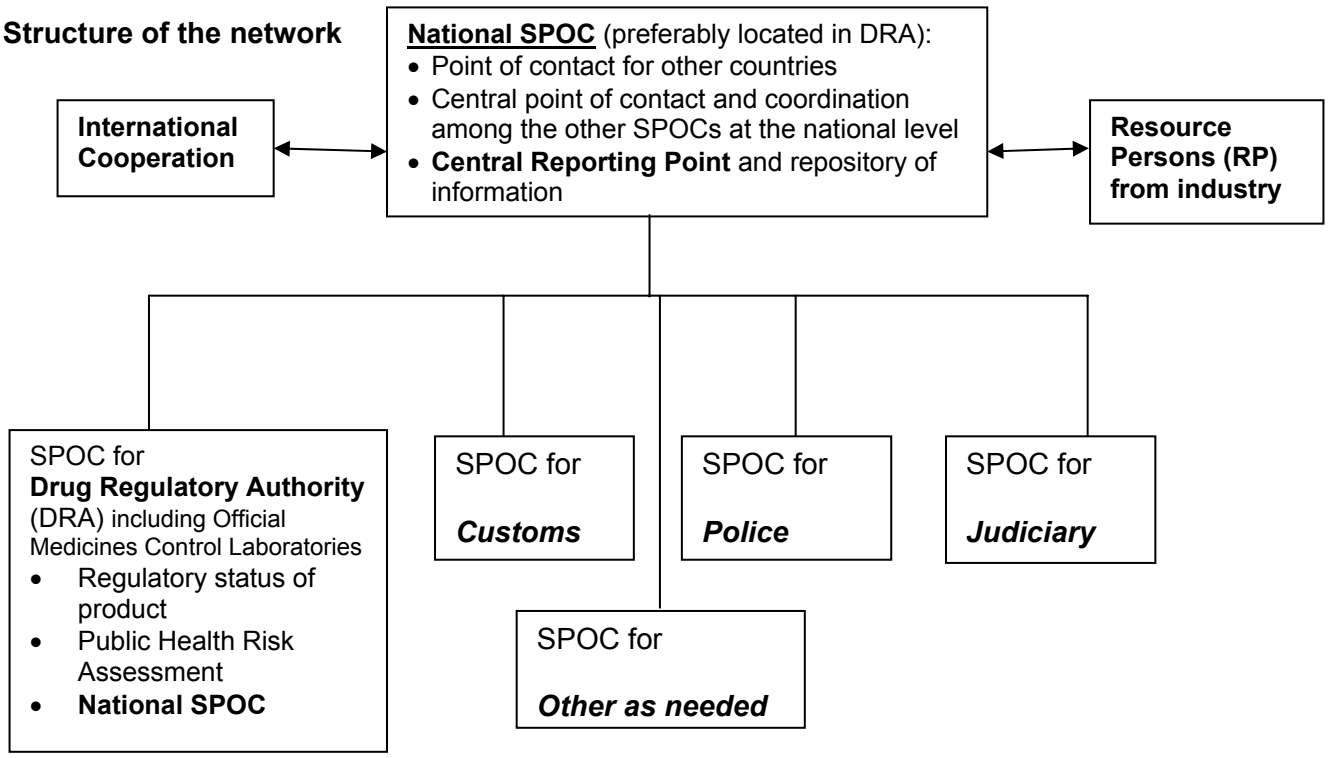
STRENGTHENING NATIONAL AND INTERNATIONAL COLLABORATION TO COMBAT COUNTERFEIT MEDICAL PRODUCTS:
A MODEL FOR A NETWORK BASED ON SINGLE POINTS OF CONTACT (SPOCs)

Combating counterfeit medical products requires a multi-disciplinary, multi-sectoral, cross-border approach. The basic principles of a successful approach are good collaboration and clearly-defined roles and responsibility among several concerned parties both at the national and international level.
Collaboration can be set up *ad hoc* for isolated cases but, in order to ensure effective and sustained action, collaboration should be structured into a stable network with defined roles and procedures. The establishment of single points of contact (SPOCs) in each one of the concerned parties is crucial for ensuring effective communication and collaboration within national and international networks.

The purpose of networks based on SPOCs is to streamline effective collaboration among concerned parties at the national and, where necessary, international level, in view of taking the necessary urgent action for protecting public health and disrupting supply of suspect/confirmed cases of counterfeit medical products.

A model for a network based on SPOCs is presented in this document. This model is the conceptual basis for establishing or strengthening national and regional collaboration systems based on SPOC networks.

Structure of the network



SPOCs and network are inseparably linked with each other. As shown in the above model, a national network should be set up by and between all the main national authorities who are competent for handling pharmaceutical crime. For most countries the official authorities are indicated here in a simplified form as: the national drug regulatory authority (DRA), Police, Customs and Justice. Depending on specific national situations, each one of these can correspond to different specific institutions and definitions. It is proposed that the National SPOC is located within the DRA. The DRA encompasses all technical and administrative functions related to drug regulation and control, which also includes quality control laboratories.

Operation of the national network

1. Regular and *ad hoc* meetings should be organised and a secretariat installed. All information should be collected and stored in a structured secure database at the level of the appropriate SPOC and accessible, as and if required, by other SPOCs of the network. The network uses a Rapid Alert Form[4] if necessary. The network shall create national procedures for handling suspect cases of counterfeit medical products and other pharmaceutical crime signals (e.g. theft of medical products, internet post office parcels) and develop training opportunities.
2. The network will be based on appropriate informal or formal agreements between the participating institutions and with external concerned parties such as industry and health professionals.
3. The network is responsible for preparing an annual report which reflects all data collected in relation with pharmaceutical crime, the recognition of new trends in pharmaceutical crime, initiatives taken for improving legislation and regulations, training programs set up for the different network partners, and awareness programs aimed at different audiences.

[4] Reference is made to any applicable RAS system (e.g. the ASEAN PMA system or the RAS system operated by EMEA and PIC/s. For example see http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

4. The network actively updates its references at international level and sets up procedures for co-operation, information exchange, data collection and management with its international counterparts.
5. External concerned parties should notify any signal/suspected case to the Central Reporting Point who will liaise with the other SPOCs as necessary.

Operation of the international network

An appropriate international mechanism should be set up to ensure those SPOCs lists are regularly updated, for example by a periodical questionnaire to the National SPOCs requesting to update/confirm contact details. The regularly updated contact lists will then be distributed to the SPOC's through appropriate, secure means.
The gradual establishment of a global network needs to be undertaken through the establishment and proper support to national and regional networks.

Resources

The effective functioning of a SPOC system, including regular training and performance of investigation work, requires specific financial and human resources. These need to be identified through appropriate national and international financing mechanisms. Ideally, an international fund could be established to support specific operations and complement national budgetary provisions where needed.

Desirable profile and function of a SPOC within a national network

The National SPOC should have the following knowledge, or such knowledge should be gradually built through appropriate training:

1. broad knowledge on medical products,
2. experience in enforcement in the area of pharmaceutical crime (as defined at the end of this document),
3. good knowledge of medicines legislation and basic understanding of Intellectual Property Rights issues.

All SPOCs should have the following competences and tasks:

1. Each SPOC represents its institution as contact point within the network.
2. Each SPOC manages incoming and outgoing information and, if required, reports cases to other SPOCs on a need-to-know basis.
3. Each SPOC handles the information flow in accordance with the applicable legislation on data protection. Confidential information such as patient names and/or names of notifiers should not be included in the general information database but managed according to specific procedures.
4. Each SPOC develops and applies a model procedure for managing pharmaceutical crime cases within his/her authority.
5. The DRA SPOC co-ordinates the public health risk assessment of suspected cases. The suspected cases shall be identified, analysed, evaluated, and treated. The risk management procedure shall be continuously reviewed and improved. In any case, the protection of public health has priority on any other concern.
6. For each case, one of the SPOCs of the network is identified as **operational SPOC** (see definition below). The operational SPOC takes the lead in investigation, as appropriate.
7. A SPOC may set up a Pharmaceutical Crime Unit consisting of an operational and an intelligence section.
8. Each SPOC has the competence of giving detailed information to other SPOCs in the national and, where appropriate, international networks. Regarding information flow, it is important to differentiate between information (analysed and interpreted

data) and evidence (information being relevant for proceedings and which may be used in court). Information should only be exchanged between SPOCs and between countries within applicable privacy laws and legal procedures. However, no legal procedure should prevent fast information exchange in life threatening situations.

9. When providing information to other SPOCs, each SPOC should ensure that it is adequate and can be effectively used to take appropriate action.

A SPOC needs not necessarily to be a single person; it may be an entity such as a group or a department within an agency. If the SPOC consists of several persons, then only one e-mail address and one phone/fax number needs to be indicated in order to ensure precise contact and to avoid unclear responsibility.

Reporting procedure for SPOCs

The model procedure on how to manage counterfeit medical products at the national level is schematically summarized in the diagram on the next page.

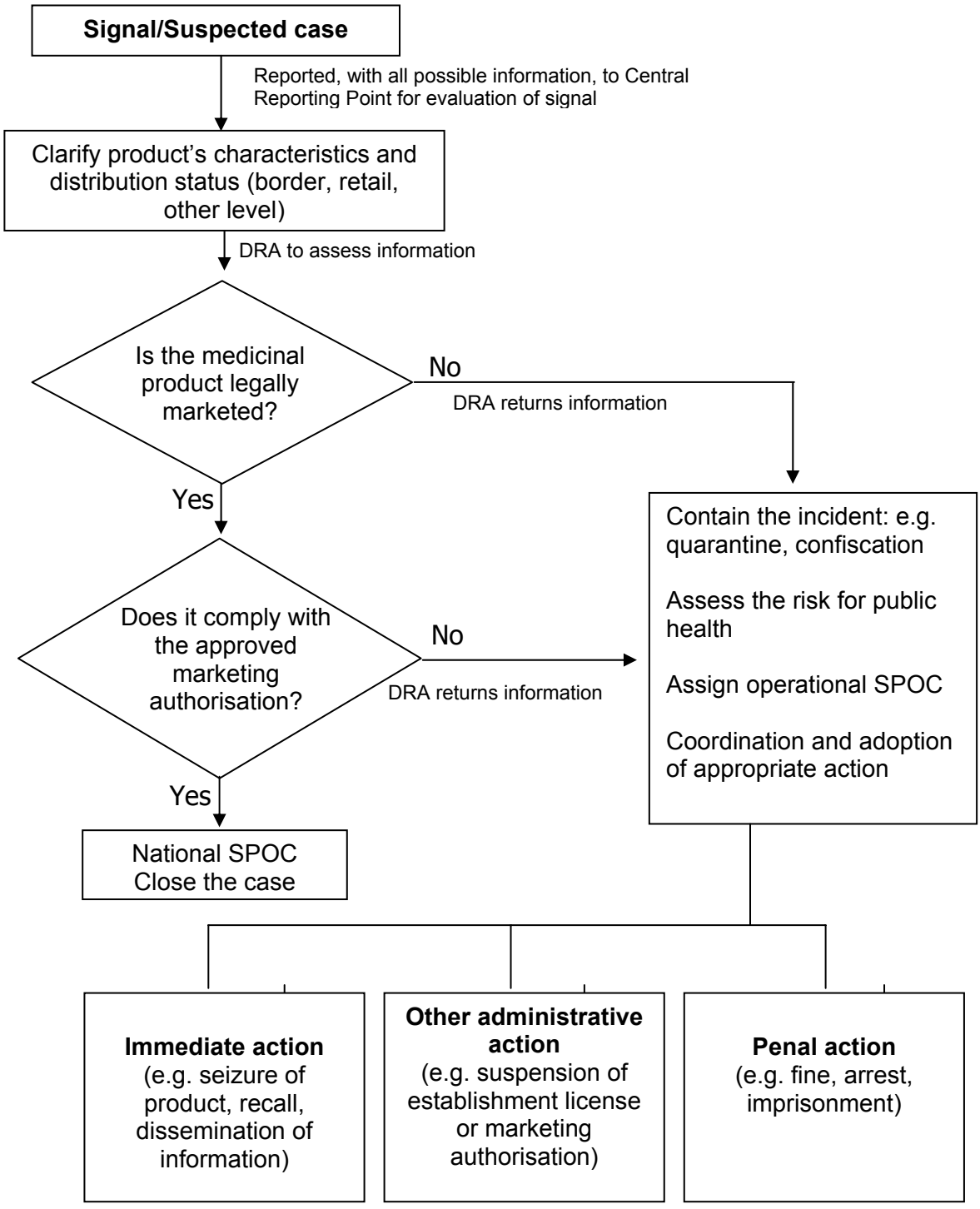
At the international level, the National SPOC may use a Rapid Alert Form for reporting pharmaceutical crime to the SPOCs (or other contact points if a SPOC system is not in place) of other countries.

Network implementation

The first steps to the effective implementation of a network at regional level are:

1. to establish a list of National SPOC's
2. to establish a national SPOC system in each participating country
3. to prepare a list of all SPOC's for each participating country

Model flow of information-for-action for a suspected case of counterfeit medical product



Definitions

Central Reporting Point: the national SPOC should act as point where all information on pharmaceutical crime is centralised and information is disseminated to network partners on a need-to-know basis. Information/signals from stakeholders (such as industry, health professionals and patients) should be channelled through appropriate, fast and effective channels to the national SPOC.

National SPOC: operates as contact point within the international network and, preferably, belongs to the DRA.

Network: formal or informal collaboration between SPOCs at national level.

Networking: activities between network members consisting of operational management and information exchange in relation to pharmaceutical crime

Official Medicines Control Laboratories: national medicines control laboratories. They may be organised in an international network, are important partners and should be involved on a regular or ad hoc basis.

Operational SPOC: the SPOC identified and appointed to manage a case by the network or by the National SPOC. The operational SPOC leads the investigation.

Pharmaceutical crime: any crime involving medical products comprising counterfeiting, adulteration, tampering, manufacture/distribution/possession of unlicensed or otherwise unlawful medical products, diversion, trafficking, peddling, and unlawful activities through the Internet.

Signal: any appearance of a problem with medical products which can be considered or related to pharmaceutical crime.

Single Point of Contact (SPOC): an entity responsible for the operational management of a signal in his/her own area of responsibility and for the exchange of information within the network (as defined above).

Resource person from industry (RP): the medical products industry should be in contact with the network but it has no enforcement competence. Companies are often an important part to a case and can be involved by the DRA and/or the operational SPOC on an ad hoc basis. Each company should provide one or more resource persons to provide technical advice in the investigation as required. A resource person is called RP.

Pilot project

Mechanism to enhance collaboration between countries in order to combat counterfeit medical products in international trade

Objective:
To enhance the capacity to detect sources of counterfeit medical products through an operational mechanism enabling countries to trigger investigation by other country's authorities in suspected cases of counterfeit medical products.

Expected benefits:
Operation of the proposed mechanism will enable countries to:

- enhance their capacity to identify sources of counterfeit medical products,
- promote international joint investigations,
- strengthen their capacity to combat counterfeit medical products,
- disrupt and dismantle illegal distribution chains,
- establish and field-test an international collaboration scheme based on a SPOCs system.

Elements of the proposed mechanism

a) types of cases
Cases to be reported within the scope of this project include all those that fall under WHO definition of counterfeit medicine, i.e. "a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source". Other quality complaints shall have to be addressed under the provisions of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

b) Reporting/signaling cases
In the context of this project, reporting cases is aimed at triggering investigative action. A separate mechanism, such as a Rapid Alert System, shall be used for raising alerts of public health relevance and trigger related action, especially for cases where there are no clues that can help to identify an exporting or manufacturing country and therefore seek investigation collaboration.
Cases to be included in this project should be reported exclusively to the designated action point/SPOC appointed by participating countries. Reports should include at least the documentation and information described in the documents/templates that the project will develop. It is envisaged that these could include: regulatory status of product and importer in importing country, copy of commercial and shipment transactions, copy of packaging, certificates of analysis, description of circumstances that lead to discovering case, pictures of suspect products and original product, culprit/offenders in question, samples of products,

laboratory test results from an official testing laboratory, other product information relevant to investigative work.
Cases shall be reported by teleconferencing, electronic or other appropriate means depending on the nature of the problem and other circumstances.

c) investigating cases

Upon reception and verification of the required documentation, the SPOC/designated action point will trigger appropriate procedures to investigate each case in cooperation with appropriate national authorities at the required levels. The country leading the investigation may request the involvement of the importing or other countries. It is likely that, at the beginning of the project, cases that importing countries would be best placed to follow-up will be those involving goods found at border control where documentation hinting at country of origin is available.
All participating countries are expected to strengthen and streamline their capacity to gather information and their procedures of investigation. However, these procedures are a national prerogative and cannot be the object of this project.

d) reporting results of investigations

Upon completion of investigation, designated focal points will communicate the outcome of investigations to the country that has triggered the international collaboration mechanism through the appropriate channels (e.g. through the SPOC system).

Tentative plan for the implementation of the proposed mechanism

STEP	ACTION	PROPOSED DEADLINE
Identification of action points/SPOC	Participating countries will indicate name and contact details of counterpart to work with IMPACT in the development of the proposed mechanism Group A	End January 2008
Finalization of written procedures	Designated action points and WHO will develop procedures to be used by importing countries to report cases. National authorities will finalize written procedures for investigating cases	End March 2008
Evaluation of trial phase	Trial phase will be conducted as long as it will be necessary in order to complete the investigation of at least five cases	Unpredictable, possibly end 2008 dependent on written procedures phase
Establishment of the new system and training of concerned officials	Based on the experience gained in the trial phase participating countries will either prolong the testing or establish the routine implementation of the new system, including the necessary training of concerned officials	Unpredictable dependent on evaluation phase
Dissemination of information on proper use of the new system by importing countries	IMPACT will lay down the appropriate messages and dissemination strategy to enable all importing countries to make effective use of the newly established system	Unpredictable
Monitoring and evaluation of routine use	Participating countries and IMPACT will jointly monitor and evaluate the effectiveness of the system both from the point of view of importing countries and other concerned parties	Unpredictable
Periodic revision	On the basis of the experience acquired, participating countries and IMPACT will periodically revise the system in order to constantly improve its effectiveness	Unpredictable