COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 4 March 2008 PC-S-CP (2008) 08
pc-s-cp/3ème reunion/documents/pc-s-cp (2008) 08 – e English only

EUROPEAN COMMITTEE ON CRIME PROBLEMS
(CDPC)

GROUP OF SPECIALISTS ON COUNTERFEIT PHARMACEUTICAL PRODUCTS
(PC-S-CP)

A MODEL FOR A NETWORK OF SINGLE POINTS OF CONTACT (SPOCs) TO COMBAT COUNTERFEIT MEDICAL PRODUCTS

Note by the Secretariat :

The document "A model for a network of Single Points of Contact (SPOCs)" was adopted by the Council of Europe Ad hoc Group on Counterfeit Medicines at its 11th meeting, 6-7 June 2007.
("….with a view to avoiding duplication and with reference to the advanced state of the activity, agreed to follow the suggestion of Mr Reggi, WHO IMPACT Secretariat, to drive the development of SPOCs and networks in the frame of the IMPACT WG Enforcement…)

At its 12th meeting on 9-10 October 2007, the Council of Europe Ad hoc Group on Counterfeit Medicines supported the submission of the above SPOCs model for endorsement at one of the forthcoming General Meetings of the WHO IMPACT.

Council of Europe Ad hoc Group members, members of the Permanent Forum on International Pharmaceutical Crime (PFIPC), presented the model to PFIPC, members of the WHO IMPACT working group enforcement, and at the Asean-China Conference on Combating Counterfeit Medical Products before the 2nd General Meeting of the WHO IMPACT.

The 2nd General Meeting of the WHO IMPACT, Lisbon, 12-13 December 2007, endorsed the SPOCs model including comments from the above organisations and the Asean-China Conference on Combating Counterfeit Medical Products.

The document "A model for a network of Single Points of Contact (SPOCs) to combat counterfeit medical products",version, REV (4), 13 December 2007 includes comments received from PFIPC, members of the WHO IMPACT working group enforcement, and at the Asean-China Conference on Combating Counterfeit Medical Products and underwent language review.

The WHO IMPACT Secretariat and the Chairs of the WHO IMPACT working group enforcement were informed about and had no objections to the use of version REV (4) at the 3rd meeting of the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP).

A MODEL FOR A NETWORK OF SINGLE POINTS OF CONTACT (SPOCs) TO COMBAT COUNTERFEIT MEDICAL PRODUCTS

REV (4) 13 DECEMBER 2007

INCLUDING COMMENTS RECEIVED FROM PFIPC MEMBERS, OTHER MEMBERS OF IMPACT'S ENFORCEMENT WORKING GROUP, AND ASEAN-CHINA CONFERENCE ON COMBATING COUNTERFEIT MEDICAL PRODUCTS

This version is based on a document developed by some members of PFIPC for the Council of Europe's Ad hoc Group on Counterfeit Medicines.

Background

Counterfeit medicines and pharmaceutical crime in general are fast upcoming phenomena which directly involve public health and do need a multidisciplinary, multisectorial and cross-border approach. The basic principles of an adequate approach are collaboration and responsibility among several concerned parties both at the national and international level.

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Collaboration can be set up *ad hoc* for isolated cases but in order to ensure effective and sustained action, collaboration should be structured within a network with defined roles and procedures. Within networks, single points of contact (SPOCs) should collaborate to meet the pre-set objectives.

In the conclusions of the Council of Europe 2005 and 2006 international conferences on counterfeit medicines the participants called for the establishment of a network of Single Points of Contact for speeding up effective co-operation and public health protection in the case of suspect/confirmed cases of counterfeit medicines.

The Council of Europe Ad hoc Group on Counterfeit Medicines developed a model for a network and SPOCs which has been the basis for this document.

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.

Definitions

Central Reporting Point: located at the SPOC authority 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 pharmacists, patients) should be channeled 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 organized in an international network[a], are important partners and should be involved on a regular or *ad hoc* basis.

Pharmaceutical crime: any crime with medicinal products or health products comprising counterfeiting, adulteration, tampering, manufacture/distribution and possession of unlicensed medicines, or otherwise unlawful medical products, diversion, trafficking, peddling and unlawful activities through the internet

Signal: any appearance of a problem with medicinal or health products which can be considered as pharmaceutical crime

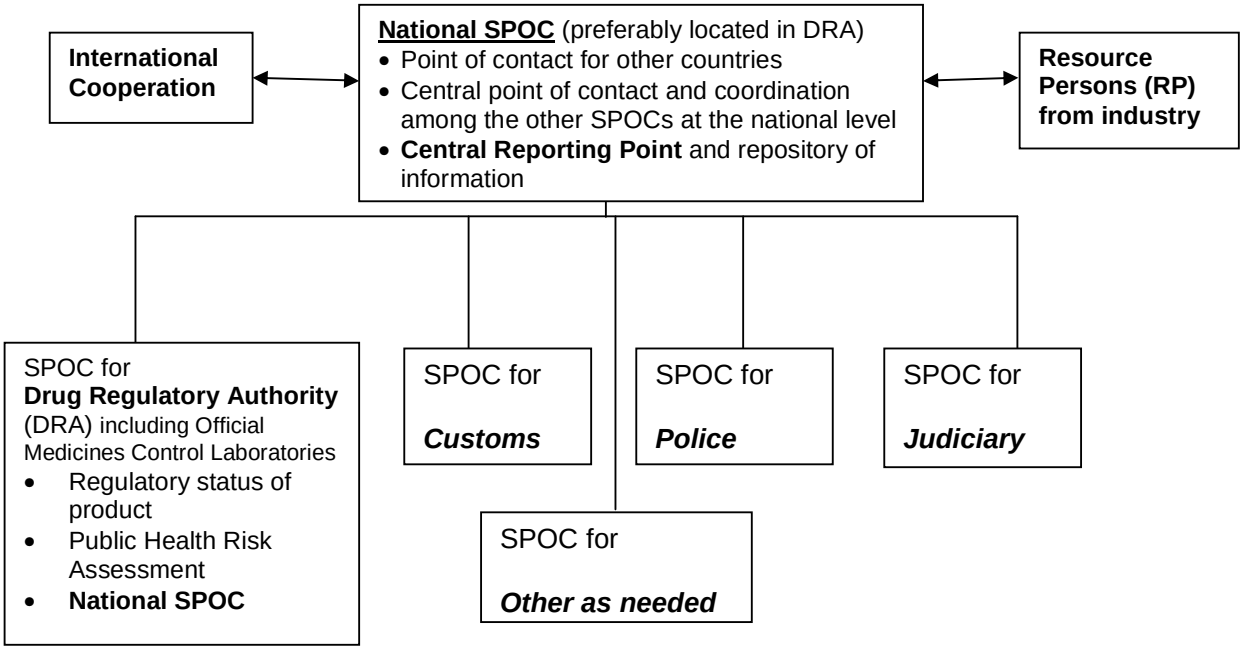
Single Point of Contact (SPOC): an entity responsible for the operational management of a signal in their own area of responsibility and the exchange of information

Responsible person or SPOC for industry (RP): the pharmaceutical industry is part of the network but has no enforcement authority. Pharmaceutical industry staff is often an important part to the case and are involved on an *ad hoc* basis. Each company should provide a RP or SPOC

[a] An example of a network of Official Medicines Control Laboratories (OMCL) is the OMCL Network co-oridnated by the European Directorate for the Quality of Medicines (EDQM) and Healthcare Link : News of the European Directorate for the Quality of Medicines - Pharmacopoeia on the WWW

Purpose
This model should be the basis for
- establishing the concept of a SPOC network at regional and global levels;
- countries checking their existing networks or establishing new SPOC networks at regional and global levels.

Structure of the network - (Agree to prefer DRA as National SPOC; however some countries don't have strong DRA and may need choose another entity as a National SPOC)



SPOCs and a network are inseparably linked with each other. A national network should be set up by and between the main national authorities who are competent for handling pharmaceutical crime. For most countries the official authorities are 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

Objectives 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 SPOC and the network. The network uses a Rapid Alert Form[b] 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.

[b] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

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 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, training programs set up for the different network partners and awareness programs at different audiences.

4. The network actively updates its references at international level and sets up procedures for co-operation, information exchange, data collection and management.

5. Stakeholders should notify any signal/ suspected case to the Central Reporting Point who informs the network if necessary.

Profile and function of a SPOC within a national network

It is desirable that the National SPOC should have or have access to the following knowledge:

1. The SPOC should have a broad knowledge on medicinal products.

2. The SPOC should be experienced in enforcement in the area of pharmaceutical crime (including field investigation in pharmaceutical crime).

3. The SPOC should have a good knowledge of medicines legislation and intellectual property rights.

4. The SPOC should have a basic knowledge in criminal law, investigation and procedure (e.g. handling of evidence).

All SPOCs should have the following competences and tasks:

1. The SPOC represents its institution as contact point within the network.

2. The SPOC manages incoming and outgoing information and - if required- reports a case to the other national SPOCs on a need to know basis.

3. The SPOC handles the information flow in accordance with the applicable legislation on data protection legislation. Confidential information such as patient names and/or names of notifiers etc should not be included in the information database but managed according to specific procedures.

4. The SPOC develops and applies a model procedure for managing counterfeit cases and pharmaceutical crime cases within his/her authority.

5. The DRA SPOC co-ordinates the risk assessment of pharmaceutical crime 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.

6. The operational SPOC takes the lead in investigation when appropriate.

7. The SPOC may set up a Pharmaceutical Crime Unit consisting of an operational and an intelligence section.

8.The SPOC has the competence of giving detailed information to other SPOCs in the international and national network. 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 having regard to 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, but also 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 medicines on a national level has been described in the "Guidance of the management of counterfeit medicines – Co-operation structures and model procedure": diagram, see Attachment.

At international level, the national SPOC may use a Rapid Alert Form[c] for reporting pharmaceutical crime to other National SPOCs.

Network implementation

With a view to effective implementation of a network at regional and global levels it is recommended to
1. establish a list of National SPOC's
2. list of all SPOC's for each country
3. prepare a list of all SPOCs for each participating country

[c] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

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