Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique

AD HOC GROUP ON COUNTERFEIT MEDICINES (P-SP-PH/CMED)

NATIONAL AND INTERNATIONAL CO-OPERATION TO COMBAT COUNTERFEITING OF MEDICINES AND PHARMACEUTICAL CRIMES: A MODEL FOR A NETWORK AND SINGLE POINTS OF CONTACT (SPOCs)

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.
Collaboration can be set up *ad hoc* for isolated cases but should be structured within a network. 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[a] 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 is presented in this document.

The Council of Europe Ad hoc Group on Counterfeit Medicines programme of activities comprises calls for the development of practical tools in the field of counterfeit medicines and other pharmaceutical crimes for authorities and other stakeholders involved in combating counterfeit medicines and other pharmaceutical crimes. The Ad hoc Group is of the view that international co-operation should be facilitated through an operational network of SPOCs and through standard procedures at regional and global levels.

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. Stakeholders (such as pharmacists, patients) should report information to the Central Reporting Point of the Drug Regulatory Authority

National SPOC: operates as contact point within the international network and 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, preferably organised in a supranational network[b], 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, diversion, trafficking and pharmaceutical crime 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

Purpose

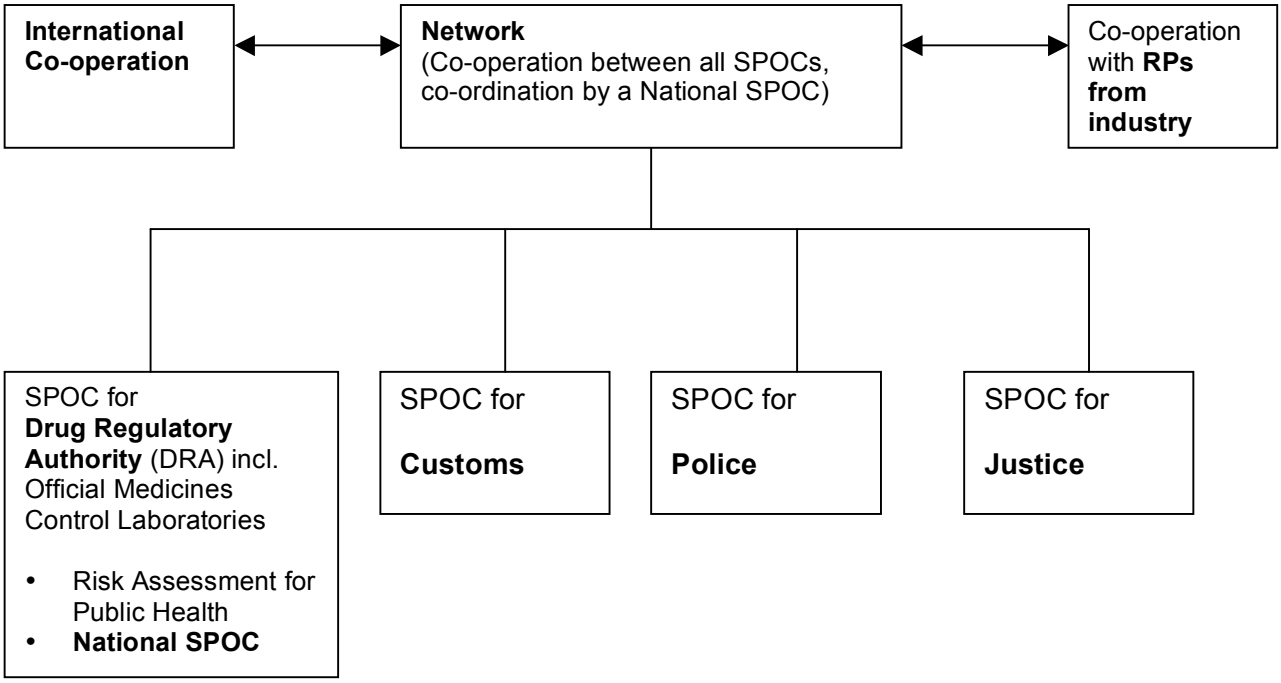
This model should be the basis for

[a] Links : http://www.coe.int/t/dc/press/News/20061107_fin_medicaments_en.asp; Short conclusions_Seminar_CountMed public

[b] An example of a network of Official Medicines Control Laboratories (OMCL) is the OMCL Network co-ordinated 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

- establishing the concept of a SPOC network at regional and global levels;
- countries checking their existing networks or to establishing new SPOC networks at regional and global levels.

Structure of the network



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. It is proposed that the National SPOC is located within the DRA.
The OMCL network is an important partner to the network and should be involved on a regular or ad hoc basis.

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[c] if necessary. The network shall create procedures for handling routine pharmaceutical crime signals (e.g. internet post office parcels) and set up online training by e.g. secure website.

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 to the different stakeholders.

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

[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

5. Stakeholders should notify any signal to the Central Reporting Point of the Drug Regulatory Authorities who informs the network if necessary.

Profile and function of a SPOC within a national network

The National SPOC should have 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 and investigation (e.g. handling of evidence).

All SPOCs should have the following competences and tasks:

1. The SPOC represents the co-operation partner 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.

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 a pharmaceutical crime signal. The signal 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.

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.

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[d] for reporting pharmaceutical crime to other National SPOCs.

The information exchange procedure is based on this model procedure and describes the conditions for communicating a case or signal of counterfeit medicines to an international SPOC network of National SPOCs:

- Counterfeit medicine(s) reached legal distribution channels;
- Counterfeit medicines' batches were distributed internationally.

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

SPOC system – how is it kept alive

A successful example of a well maintained network is the Rapid Alert Database of representatives of each country to whom alerts/ defective product recall notifications are addressed. This list is regularly updated by fax by the inspections sector of EMEA.

Once established, the SPOCs list should be updated regularly by a supranational body, for example by a periodical questionnaire asking to update the coordinates to the National SPOC's. The updated contact list will then be distributed to the SPOC's either through fax transmission through access to a secure database.

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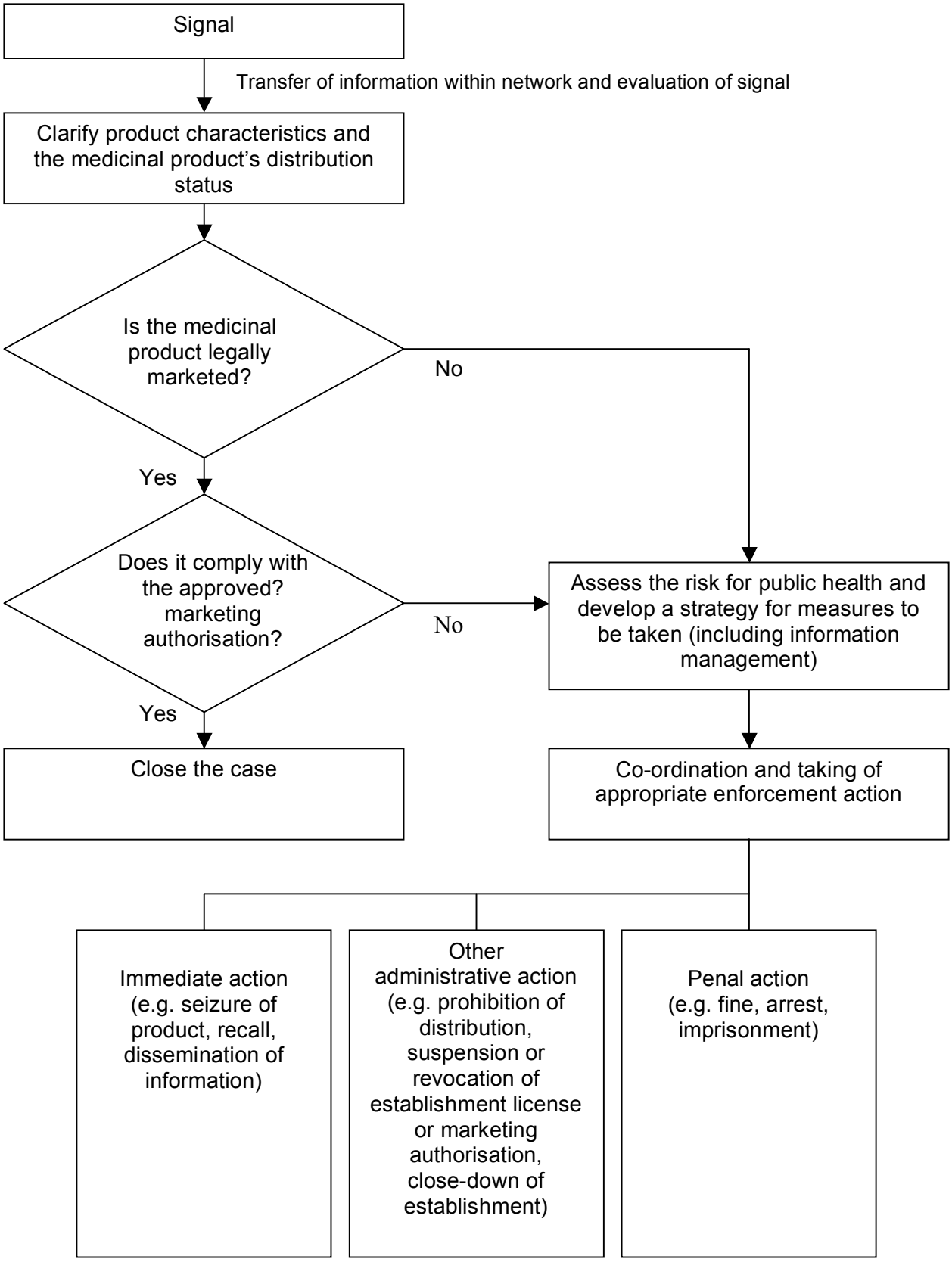
[d] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

Attachment


Signal
Transfer of information within network and evaluation of signal
Clarify product characteristics and the medicinal product's distribution status
Is the medicinal product legally marketed?
No
Yes
Does it comply with the approved? marketing authorisation?
No
Yes
Assess the risk for public health and develop a strategy for measures to be taken (including information management)
Close the case
Co-ordination and taking of appropriate enforcement action
Immediate action (e.g. seizure of product, recall, dissemination of information)
Other administrative action (e.g. prohibition of distribution, suspension or revocation of establishment license or marketing authorisation, close-down of establishment)
Penal action (e.g. fine, arrest, imprisonment)