



**THE COUNCIL OF EUROPE CONVENTION ON COUNTERFEITING OF
MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS
TO PUBLIC HEALTH
(MEDICRIME CONVENTION)
COUNTERING THE SPREAD OF COUNTERFEIT MEDICAL PRODUCTS**

International High-Level Conference

**CONVENTION DU CONSEIL DE L'EUROPE SUR LA CONTREFAÇON
DES PRODUITS MÉDICAUX ET LES INFRACTIONS SIMILAIRES
MENAÇANT
LA SANTÉ PUBLIQUE
(CONVENTION MEDICRIME)
CONTRER LA PROPAGATION DES PRODUITS MÉDICAUX
CONTREFAITS**

Conférence internationale à haut-niveau

ПРОГРАММА


**КОНВЕНЦИЯ СОВЕТА ЕВРОПЫ ПО ФАЛЬСИФИКАЦИИ
МЕДИЦИНСКОЙ ПРОДУКЦИИ И СХОДНЫМ ПРЕСТУПЛЕНИЯМ,
УГРОЖАЮЩИМ ЗДОРОВЬЮ НАСЕЛЕНИЯ
(КОНВЕНЦИЯ МЕДИКРИМ)
ПРОТИВОДЕЙСТВИЕ ФАЛЬСИФИКАЦИИ МЕДИЦИНСКОЙ
ПРОДУКЦИИ**

Международная конференция высокого уровня

Moscow, Moscou, Москва 26-28 Oct. октября 2011

SLIDES SESSION III


Federal Agency for Medicines and Health Products



Federal Agency for Medicines and Health Products (FAMHP)

Multisectorial co-operation based on the CoE model of a network of single points of contact SPOCs


Roy Vancauwenberghe, FAMHP Belgium
 MEDICRIME CONVENTION Conference Moscow, Russian Federation, 26-28 october 2011



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Federal Agency for Medicines and Health Products

- Medicrime Convention: Art. 17 & Art.22
- Network of SPOCs model: targets & obstacles
- Purpose
- Objectives of network, tasks of SPOCs
- Reporting National / International
- Realisation of SPOC network
- SPOCs Network in Belgium



Federal Agency for Medicines and Health Products

Medicrime Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health


www.coe.int/t/DGHL/StandardSetting/MediCrime/Default_en.asp

Article 17 - National measures of co-operation and information exchange

3 a. receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

Article 22 - International co-operation on prevention and other administrative measures

2. The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.



Establishing a SPOC network

Targets:

- (in)formal operational network structure
- National secretariat, regular meetings
- International database of national SPOCs
- International reporting and collaboration



Establishing a SPOC network

Obstacles may be :

- exchange of information barriers ...
 - legal reasons ...
 - political reasons ...
 - priority reasons ...
 - Capacity reasons ...



Network of SPOCs concept

- * Created by Ad Hoc Group of Counterfeits „Co-operation structures and model procedure“, Feb 2006
- * „National and International Co-operation: a model for network and SPOCs“ adopted by Ad Hoc Group of Counterfeits, June 2007
- * Document adopted by Heads of Medicines Agencies' Working Group of Enforcement Officers HMA-WGEO, Sep 2007
- * Adopted by PFIPC and WHO IMPACT.



Purpose of model

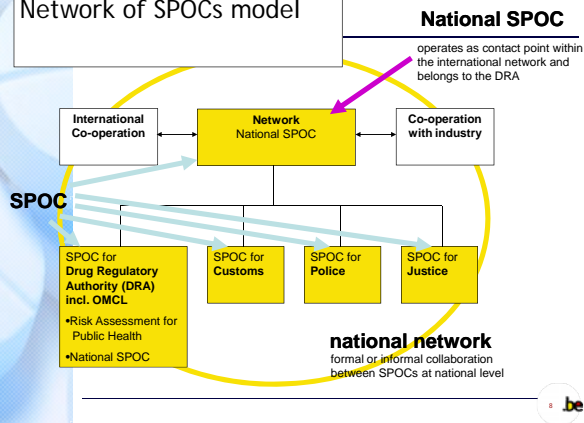
Model should be basis for countries:

- **establishing** the SPOC network at national level
- or checking their **existing networks**

National network should be set up by and **between the main national authorities** who are competent for handling pharmaceutical crime.



Network of SPOCs model



Objectives of national network

- Regular / ad hoc **meetings**, secretariat
- structured secure **database** at the level of the SPOC and the network
- **procedures** for handling routine pharmaceutical crime **signals**
- **procedures** for **co-operation, information exchange, data collection and management**
- Stakeholders **notify** any signal to the National SPOC who informs the network if necessary
- Set up **training**
- Annual **report**



Profile of National SPOC (in DRA)

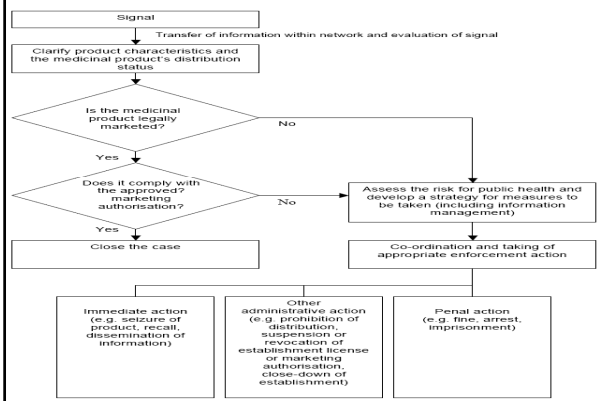
- Broad knowledge on medicinal products
- Experience in enforcement in area of pharmaceutical crime
- Knowledge of medicines legislation and Intellectual Property Rights
- Basic knowledge in law and investigation, handling of evidence

Tasks of a SPOC

- * **represents** the co-operation partner within the network
- * **manages** incoming and outgoing information, reports a case
- * **handles** the information flow, except confidential information
- * **develops** and applies a model procedure for managing pharmaceutical crime cases within his/her authority.
- * DRA SPOC **co-ordinates** the risk assessment of pharmaceutical crime signal (identified, analysed, evaluated, treated).
The risk management procedure shall be continuously reviewed and improved.

Protection of public health has priority.

National Reporting & managing CM



International Reporting

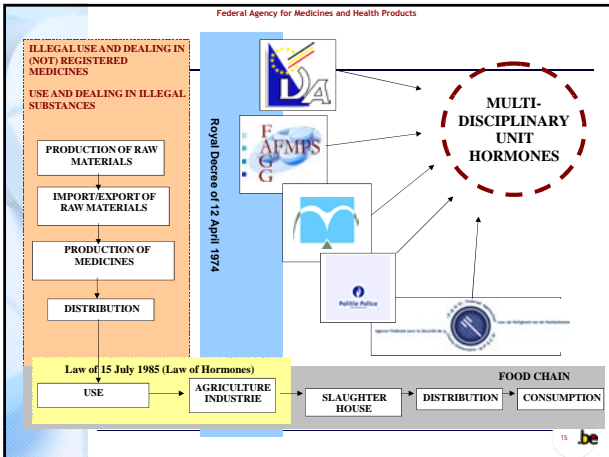
Reference: Rapid Alert System RAS system operated by EMA and PIC/s.

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

Belgian Multidisciplinary Hormone Cell

- **Informal network:** Police, Customs, Medicines agency, Food Agency, Justice
- Initially fight against Illegal hormonal treatment of cattle
- Extended to **PHARMACEUTICAL CRIME:** doping in sports, illegal medicines, counterfeit medical products, internet ..
- **Collaboration script** (no procedures yet)
- **Meeting** every two weeks, meeting reports, secretariat
- **Database**
- **Training & lectures**
- **Annual report**



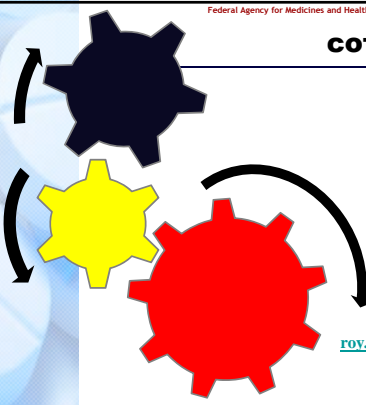
Collaboration Protocol DRA - CUSTOMS : example

- 1)Reference to legislation
- 2)Purpose of collaboration agreement
- 3)Competences
- 4)Scope
- 5)Collaboration: Legislation
 - : Information exchange
 - : Surveillance policy
 - : Surveillance
 - : Training
 - : External communication
- 6)Monitoring mechanism

- Respect for each others competences and expertise
- Understanding each others competences and expertise
- Exploring each others competences and expertise
- Listening to each other
- Sharing information not withholding

сотрудничество

спасибо



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**Multisectorial Assistance Programmes in the fight against counterfeit medical products
The Portuguese Experience**



Helder Mota Filipe
INFARME I.P.
International High-Level Conference
MEDICRIME CONVENTION
Moscow, 28-29 October 2011

Summary

- The collaborating countries
- Internal Support
- Building a SPOCs network
- Strategies
- Conclusion

Bilateral Agreements

- Angola
- Cabo Verde
- Brasil
- Mozambique

Angola

- 3 Cooperation Agreements (2009)
 - National Directorate for Medicines and Equipments (DNME)
 - National Directorate for Inspection and Investigation of Economic Activities (DNIAE)
 - General Health Inspectorate (IGS)
- Domains
 - Regulatory ; Scientific Assessment, Inspection, Licensing , Enforcement, Quality Control
- Actions
 - Alert network
 - Drafting of legislation /procedures
 - On the job training
 - Specialist workshops

Brasil

- Cooperation Agreements
 - MoU (2006); Brasilia Protocol (2007); Joint Infarmed/Anvisa Action Programme (2008)
- Domains
 - Generics, Clinical Trials, GMP Inspections, Counterfeits/Falsified products, Medical Devices, Cosmetics
- Actions
 - Alert network
 - Regulatory dialogue (exchange of information, legislation procedures, requirements)
 - Specific Advisory Groups
 - Specialist workshops

Cape Verde

- 2 Cooperation Agreements
 - General Pharmacy Directorate (2004)
 - National Agency for the Regulation and Supervision of Food and Pharmaceutical Products (2011)
- Domains
 - Regulatory, Scientific Assesment, Inspection, Licensing, Enforcement, Quality Control, Pharmacovigilance, Pharmacoecconomy
- Actions
 - Alert network
 - Drafting of legislation /procedures
 - On the job training
 - Specialist workshops

Mozambique

- Cooperation Agreements
 - MoU (1997)
- Domains
 - Regulatory, Scientific Assessment, Inspection, Licensing, Enforcement, Quality Control, Pharmacovigilance, Medical Devices, Cosmetics
- Actions
 - Alert network
 - Drafting of legislation /procedures
 - On the job training
 - Specialist workshops

Exchange of Information

- Guiné Bissau
 - Alert network
 - Training
- S. Tomé e Príncipe
 - Alert network
 - Training


Multilateral Cooperation

- EAMI (Ibero-american medicines authorities)
 - Coordination of working group on falsified /counterfeited products
 - Member of Permanent Secretariat
- Actions
 - EAMI Portal
 - Specific platform for exchange of information on counterfeits (e-rooms)
 - SPOC network almost finalized



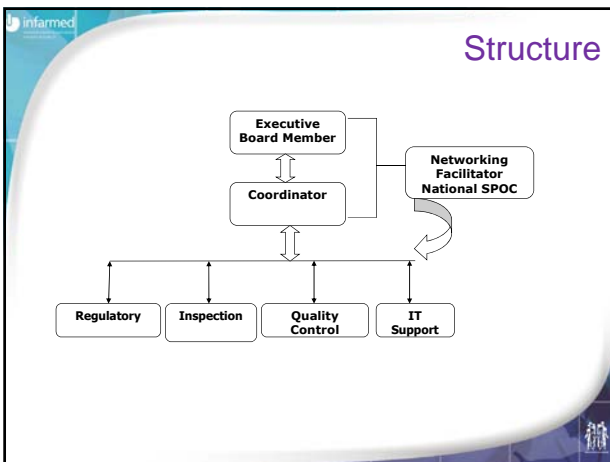
www.portaleami.org

Internal Support



3C infarmed
Autoridade Nacional
do Medicamento
e Produtos de Saúde I.P.

Anti-Counterfeiting Taskforce



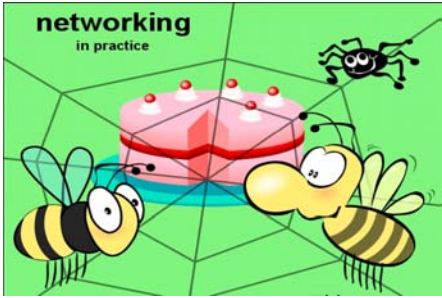
3C Anti-counterfeiting Taskforce
Lines of Action

Approve model and procedures of a future Enforcement (ad hoc at present)
Multidisciplinary
PT SPOC
Management and detection of signals

Support the SPOC system nationally and internationally
Meetings
Exchange of information (webportal)
Regular training

Participate in anti-counterfeiting operations/investigations nationally and internationally
Medifake
Pangea I-V

Building a SPOCs Network



The illustration shows a green background with a spiderweb. In the center is a pink cake with red frosting and white candles. Three bees are present: one on the left, one on the right, and one at the top right. The text 'networking in practice' is written in the upper left of the illustration area.

A Definition

An extended group of people with similar interests or concerns who interact and remain in informal contact for mutual assistance or support.


To interact or engage in informal communication with others for mutual assistance or support.

Ideally.....

- **Involvement of all stakeholders**
 - Multidisciplinary and complementary cooperation
- **Harmonized Best Practices**
- **Sharing of Information and Information Tools**
- **Continuous Training**
- **Sharing of Experience and Expertise**
- **Reduction of Reaction Times**

PT experience - baby steps

- Starting point on long standing MoUs and contact points for cooperation matters
- Indirect awareness to fight against counterfeiting through other regulatory areas (assessment, inspection)
- First exchange of information through "normal" alert network
- Infarmed facilitates flow of information and contacts leading to acknowledgement of geographical implications of phenomena
- Countries begin to contact each other without Infarmed as facilitator



Building a Trust Market towards the effective Implementation of a SPOCs network

Advantages

- Language
- Common history and cultural background
- Regulatory and health professionals graduates from portuguese universities
- Regulatory framework as model
- Easy exchange of information (alert network/contact point for cooperation)
- National SPOCs network
- Infarmed WHO reference lab
- Infarmed website as preferential information feed

Constraints

- Geographical constraints (ie Angola has 1000km border)
- Weak regulatory framework and enforcement structures
- Constant shifts of political nature
 - Difficulty in updating / maitaining contact points
- Absence of national coordinated structures
- Bureaucracy
- Lack of human and financial resources
- IT tools (mails, databases)
- Priority for laboratory infrastructure without legal framework in place

Infarmed **Strategies**

1. Expert Support

- Drafting of legislation
- Drafting of guidelines and procedures
- Short and long term local support to implementing measures
- Local operational support (i.e. inspections)

Infarmed **Strategies**

2. Communication /Information

- **Infarmed's website as preferential communication tool (registered users)**
- **Develop an online Internet Portal to support the SPOCs network**
 - Identification of SPOCs
 - Procedure for Counterfeit Alerts
 - "Forum" type application
 - Links to other applications (KnowIX)

The screenshot shows the Infarmed website interface. At the top, there is a navigation menu with links for HOME, NOTÍCIAS, LINKS, and CAMPANHAS. The main heading is "COMBATE À CONTRAFACÇÃO". Below this, there is an "INTRODUÇÃO" section with placeholder text. To the right, there is a login form titled "ENTRADA" with fields for "NOME DE UTILIZADOR" and "SENHA", and a "OK" button. Below the login form is a "CONTACTOS" section with a list of flags representing different countries. The date "11.03.2010" and "PT/ENG/ESP" are visible in the top right corner.

Infarmed

Strategies

2. Communication /Information

- Promotion of awareness/information campaigns (2008-2010)
 - Public
 - Media
 - On line
 - Institutional
- Internet survey
 - Involvement of media- press conference

Infarmed

Viral Campaign PANGEAIII

- Web only
 - Microsite campanha.infarmed.pt at infarmed.pt
 - Mrec video
 - National web portals
 - Social networks (facebook, twitter, youtube)
 - Google addwords
 - Online survey

Infarmed

Microsite w/mrec video

Combate à venda ilegal de medicamentos online


Comprar em farmacia

Comprar em farmacia

Comprar em farmacia

Comprar em farmacia

Online survey



1. Did you buy medicines through the internet?
 2. Have you checked the website authenticity?
 3. What do you think about the information provided here? (not important, very important)
 4. After reading this will you buy medicines on the internet?

Strategies

3. Analytical Support

- Annual Market Surveillance Plan
 - includes samples from African countries
- Emergency analysis
 - urgent cases referred by African countries
 - WHO prequalification designation to facilitate access

Continuous cooperation

Cape Verde (MRA)

- 16 samples (since 2009).
- Anti-inflammatory , antibiotics ,anti-cough
- 95 tested parameters

Angola (Economic Police)

- 25 samples (2008-2010)
- 14 samples (2011-ongoing).
- antimalarial, anti-inflammatory, antibiotics, anti-cough, vitamin supplements
- 89 tested parameters

Angola (Health Inspectorate)

- 15 samples (2011-7 ongoing)
- anti-inflammatory, anti-cough, antifungal, vitamin supplement
- 26 tested parameters

Infarmed

Strategies

4. Training

- Participation in conferences, workshops and seminars organised by Infarmed
- Participation in local training actions (brazil 2008, cape verde 2008-10; angola 2008/9)
- Medium and long duration on-the-job training at infarmed
- International training actions
 - International workshop on counterfeited medicines (feb.2009)
 - EDQM/INFARMED Lisbon Regional Training (jan. 2010)

Infarmed

Incentive I

International workshop on Counterfeited Medicines, Lisbon, February 2009

Objective: to focus on the state of play of on counterfeit medicines and discuss key strategies and actions to combat counterfeiting and reduce risks to public health.



Infarmed

International workshop on Counterfeit Medicines


Key conclusions

- Need for coordinated strategies to combat counterfeit and reduce risks to public health;
- Foster intense national and international cooperation between stakeholders
- Promote regular information campaigns to inform citizens on risks of buying medicines on non-licensed websites;
- Support global information exchange networks as communication tool at international level;
- Develop specific training programmes involving all stakeholders in the combat to counterfeiting

Incentive II

Regional Training Working Across Disciplines and Borders-Best Practices to combat counterfeiting of medicines an to protect public health, January 2010

Objective: to define concrete areas for cooperation and collaboration; strengthen international relations, identify and apply harmonised good practices, update knowledge and procedures, lay the basis of a future spocs network



Regional Lisbon Training

Key Conclusions

- Need for National and International SPOC Network
 - Use of specialized networks (OMCL/Who reference labs)
- Relevance of international legally binding penal instrument to support enforcement authorities
- Importance of Continuous Training
- Strengthening of Regulatory Systems
- Efficient use of resources
- Increase in Intelligence

Spocs Network



In Our View

- Promote awareness
 - Training Initiatives
 - “Push” information
- Political Support
 - Ask for Involvement
 - Face to face meetings
- Offer Expert Assistance
 - Regulatory
 - Operational

EYE ON THE FUTURE

- Support a portuguese speaking counterfeited medicines area
 - Networking
 - Worksharing
 - Trust building
- Make use of WHO *pre-qualification designation*
- Develop web portal to increase and facilitate exchange of information
- Actively support and engage in training actions

Muito Obrigado!
