

The Importance of Networking – The Council of Europe SPOCs Model

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Ms Monika MACISOWICZ, Main Pharmaceutical Inspectorate



Overview

- Intentional manufacture, distribution outside the regulatory system compromising **medical product safety**
- **Benefits of networking** among the competent authorities within a country/across borders
- **Experiences and activities of Council of Europe member states** with a Single Points of Contact (SPOCs) approach
- Ways forward to **better medical product safety, public health and security**
- Conclusion

Intentional manufacture, distribution outside the regulatory system: what does this mean?

Passing off a product with intent as genuine medicine when - in fact - it is not: no authorisation by a medicine regulatory authority for being marketed and used for treating/diagnosing a disease.

The above and related acts may not yet be criminal or otherwise unlawful under your domestic law as per today

Intentional manufacture, distribution outside the regulatory system (1)

Cases stirring up regulators in Europe

Counterfeit/falsified medicinal products for treatment of :

- Heart and cardiovascular problems (PLAVIX®)
- Mental bipolar disorders/ schizophrenia (ZYPREXA®)
- Cancer (GLIVEC®)

Intentional manufacture, distribution outside the regulatory system (2)

The **international criminal network** comprised production and packaging, labelling, storage in **Asia** (production “affiliate” also in US)

Europe-based company to transport to wholesalers in the **European Economic Area**
bank transfers organised by the head of the criminal network, **national of a EU member state**
financial operations **off-shore**

Lessons learnt? (1)

Benefits of networking among the competent authorities within a country/across borders

International crime involving counterfeiting/falsifying medical products needs **international cooperation among** health authorities, police, customs, justice

Lessons learnt? (2)

Need for multidisciplinary operational case management

- signal detection, investigation and prosecution together with public health risk assessment, risk prevention
- through cyber agents, criminal analysts, financial and specialised investigators in public health offences, drug enforcement and public health risk prevention **within a state and across borders**

Lessons learnt? (3)

Implement into national and international law provisions for permitting multi-sectorial cooperation within a state and across borders (e.g. Council of Europe MEDICRIME Convention)

How to find the needle in the haystack?



Networking among Single Points of Contact (SPOCs)...basic concepts (1)

SPOCs network **within states and at international level** helps protecting public health, preventing health damage of patients

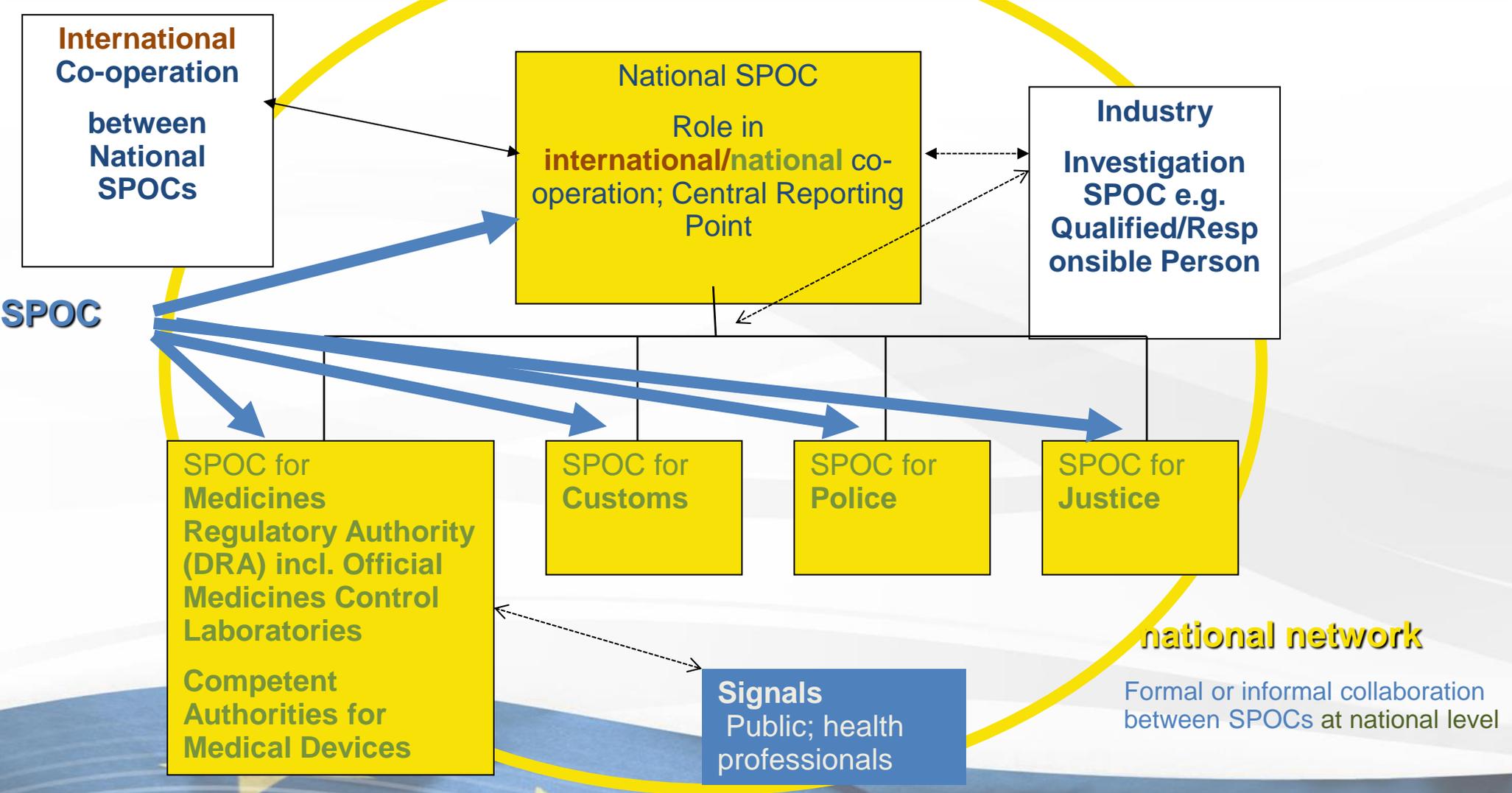
Networking among Single Points of Contact (SPOCs)...basic concepts (2)

- Two-sided cooperation approach:
within an individual state: a network among SPOCs within the different competent authorities;
- **international cooperation** among states, the national SPOCs network is represented by a “National” SPOC”.

Public health protection should be a priority

Benefits of networking among SPOCs...

Council of Europe Model: SPOCs network for national and international cooperation



Council of Europe activities/experiences with SPOCs networking approach (1)

Comprehensive and integrated approach

Committee of Experts on minimising public health risks posed by counterfeiting of medical products and similar crimes

- Support for the development of specific **legislation**
- Multisectorial **cooperation and intelligence building** → SPOCs

Council of Europe activities/experiences with SPOCs networking approach (2)

- **Public Health protection:** awareness, risk communication, identification of health damage in patients
- **Sharing of best practices-** EDQM supported training platform: since 2007 200 health-police-customs officials from 45 states (in- and outside Europe) trained
- Network of training participants

Council of Europe activities/experiences with SPOCs networking approach (3)

Committee of Experts on minimising public health risks posed by counterfeiting of medical products and similar crimes

- Development Council of Europe model 2004-2005
- «National and International Co-operation: a model for network and SPOCs»: adopted June 2007
- Adopted by Heads of Medicines Agencies' Working Group of Enforcement Officers (HMA-WGEO), September 2007

Council of Europe activities/experiences with SPOCs networking approach (4)

Committee of Experts on minimising public health risks posed by counterfeiting of medical products and similar crimes

- Endorsed by Permanent Forum on International Pharmaceutical Crime (PFIPC) and tabled at WHO IMPACT Meeting in December 2007 endorsing the model for international use
- Inspired articles 17 and 22 of the Council of Europe MEDICRIME Convention

EDQM- Risk management & prevention of medical products crimes (4) Training....

Results: 2007 – on going **500** officials trained (Europe & other regions)

Beginners /induction course (Council of Europe member states)

Multidisciplinary cooperation (SPOCs) training : Europe, Asean Pacific Economic Area (APEC) and Africa (in cooperation with Project REPT/EC: Jordan, Morocco, Ghana, Senegal and Cameroon

2016-2017: new advanced training module for European officials in preparation

Conclusions (1)

- Everyday new victims of counterfeit/falsified medical products – *no time to loose*
- **All competent authorities** should benefit from networking through SPOCs within their states and across borders
- Networking across borders is only effective if based on common concepts, understanding and working methods: **Council of Europe model; harmonised approach in APEC economies**

Conclusions (2)

- Council of Europe MEDICRIME Convention supports **measures and legal concepts in criminal law and administrative cooperation** (globally useful, enhancing impact of other international criminal law convention and cost-efficient)
- Council of Europe welcomes global international cooperation
- ***Criminals do network – let's do better!***

Thank you for your attention!

For more information:

www.coe.int

www.edqm.eu

