

**COUNCIL OF EUROPE MODEL FOR A NETWORK AMONG SINGLE POINTS OF CONTACT TO
COMBAT COUNTERFEITING/FALSIFYING MEDICAL PRODUCTS AND SIMILAR CRIMES**

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Note: more information on terms underlined can be found in the glossary.

1. Introduction¹

- Medical products that have been intentionally manufactured, marketed and distributed outside the scope of the regulatory system of the competent authorities:
 - are **unsafe**, present a **threat to patient health**, the **integrity of healthcare systems and security**;
 - mislead patients as to their contents (identity) or source (manufacture, distribution path);
 - are manufactured and distributed in unlicensed, unregulated and uninspected sites, frequently under unsanitary conditions;
 - there are no assessments of the benefits and risks of those medical products or their ingredients, no ongoing surveillance of their quality and safety;
 - therefore, no product recall and warning will be possible.

(→**Note:** for the purpose of this toolkit, medical products produced, marketed and advertised outside the regulatory control of the competent authorities are referred to as ‘counterfeit/falsified medical products’ **whether or not they originate from criminal** (see Glossary: Pharmaceutical crime) **or otherwise unlawful acts**).

- Combating counterfeit/falsified medical products requires **international cooperation** as producers, distributors, and traders act globally.
- A successful cooperation approach is **two-sided** and comprises:
 - *for cooperation within an individual country:* a network among single points of contact (SPOCs) within the different competent authorities;
 - *for international cooperation* among states, the national SPOCs network is **represented** by a ‘National SPOC’.

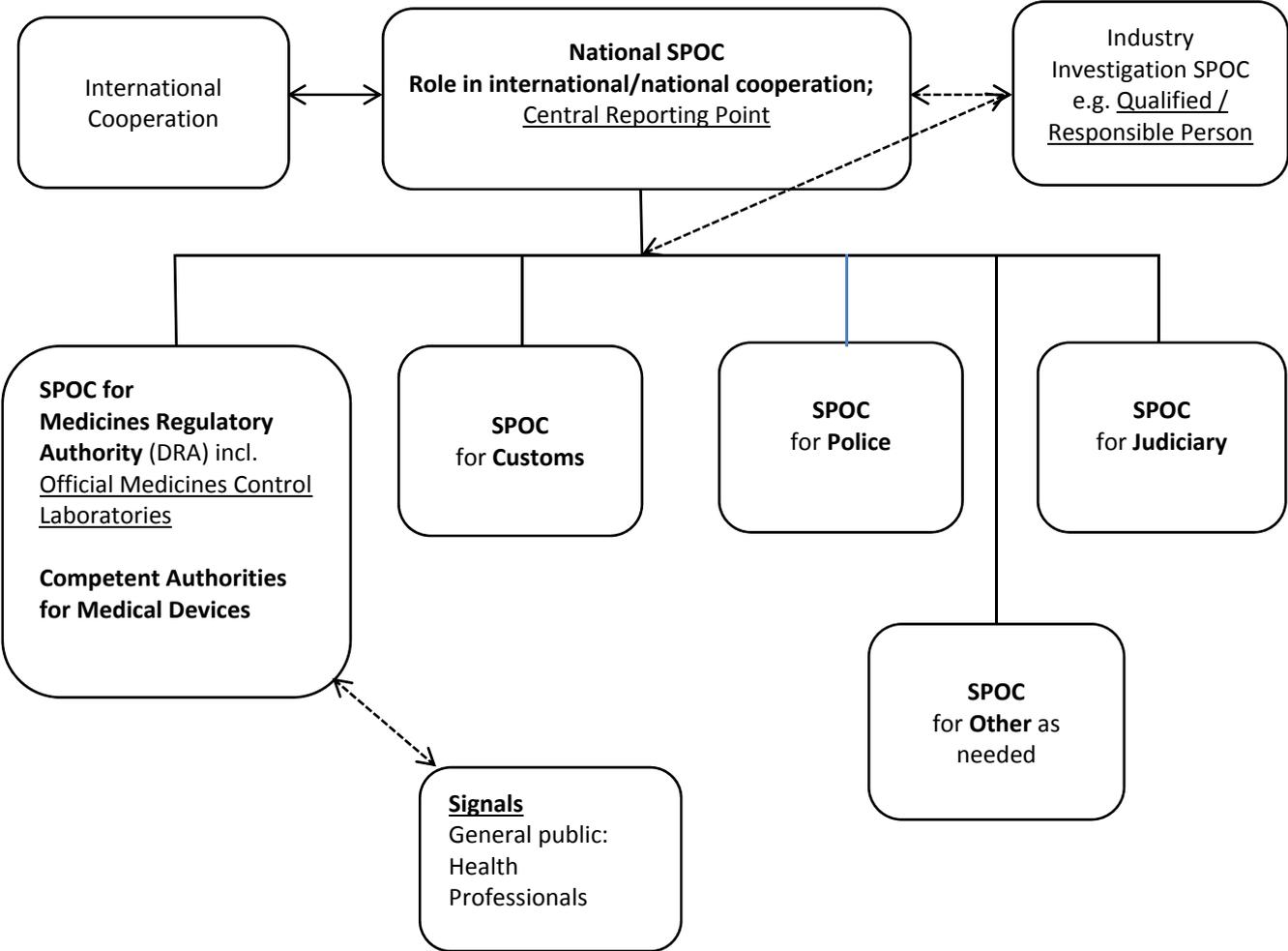
See Chart 1 (next page)

- Networking within states and at the international level through SPOCs will enable states to protect public health and prevent health damage of patients and users, through:
 - enhancing the capacity to identify sources of counterfeit/falsified medical products;
 - managing and preventing risks posed by counterfeit/falsified medical products;
 - strengthening the capacity to combat and prevent counterfeit/falsified medical products at international level (e.g. regional joint investigations).

Public health protection should be a priority.

¹ To assist policymakers, regulatory and enforcement authorities and industry representatives in preventing and combating counterfeit/falsified medical products, the Council of Europe developed this Single Points of Contact System (SPOC) Model endorsed by WHO IMPACT, Work stream ‘Enforcement’ chaired by PFIPC and Interpol; the model was tabled by PFIPC.

Chart 1



2. National Network among Single Points of Contact of the competent health, medicines/device regulatory, customs, police, and judicial authorities within a state.

Goals

- Information collection, reporting exchange and analysis;
- Operational management of a signal of counterfeit/falsified medical products within individual area of responsibility of the competent authority;
- Collaboration-assistance in prevention/management of risks and unlawful actions;
- Collaboration-assistance in investigation; **optional**: coordination of investigation through the operational SPOC;
- Up-to-date lists of SPOCs for national/international cooperation.

Structure

- Single Points of Contact (SPOCs) may be individuals or units;
- Specific nomination/designation of officials for cooperation within a SPOC unit or as a SPOC;
- Formal or informal cooperation agreements between authorities and other stakeholders (such as healthcare professionals, industry; **optional**: Qualified/Responsible Person/Industry investigation SPOC within a company performing the duties of a SPOC for the purpose of liaison and cooperation with authorities in the counterfeit/falsified medical product investigation);
- Regular and ad hoc meetings;
- Electronic, secured data management (databases).

If the SPOC is a single person, arrangements must be made to ensure a 24/7/365 effective communication link is made available for the other SPOCs.

Function

The national network develops procedures and implements:

- Receiving signals, data collection ('Reporting'): information will be collected using an appropriate *Rapid Alert Form*²;
- Handling signals: see Chart 2, page 7;
- (Periodic) analysis: data/signals, reports, results of preventive/enforcement actions;
- Training³;
- Awareness programs;
- Establishing and updating SPOCs lists (for national/international cooperation).

The **medicines/device regulatory authority SPOC** is responsible for the public health risk assessment of suspected/verified cases and follow-up to this assessment.

Skills

Appropriate familiarity with relevant legislation in the field of counterfeit/falsified medical products and professional experience in enforcement.

² Rapid Alert Form – could be added as supplement, if desired

³ Training – elements could be added as supplement, if desired

3. International cooperation among the 'National SPOCs' (one per individual state)

Goals

In the case of counterfeit/falsified medical products moving across multiple borders/countries, **international cooperation** between the National SPOCs (one for each state) will ensure effective communication and provide a basis for collaboration in operative action at both national and international levels. It will also facilitate protecting patients promptly and timely from counterfeit/falsified medical products.

Structure

One 'National SPOC' of each individual state for international cooperation.

Optional: regular meetings

Function

Operates as contact point for an individual state within the **international cooperation** among the **National SPOCs** of individual states.

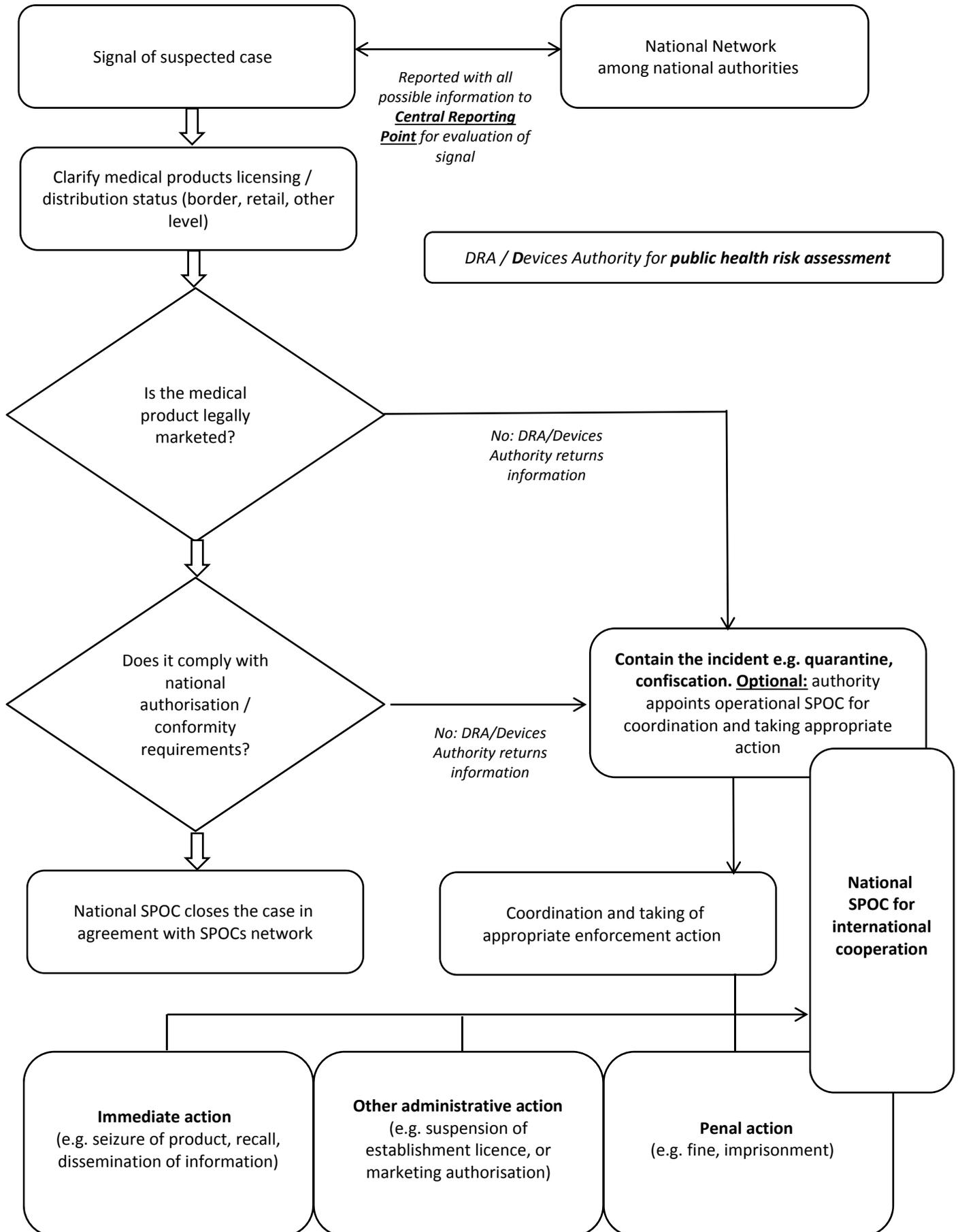
The National SPOC represents the SPOCs within the **health, medicines/device regulatory, customs, police, and judicial authorities** of an individual state.

The national SPOC is responsible for transmitting and receiving requests for information and/or cooperation as regards fighting counterfeiting/falsification of medical products.

Skills

(See item 2: Appropriate familiarity with relevant legislation in the field of counterfeit/falsified medical products and professional experience in enforcement).

Chart 2



GLOSSARY

Central Reporting Point: The National SPOC should act as a point where all information on *medical products produced, marketed and advertised outside the regulatory control of the competent authorities whether or not they originate from criminal or otherwise unlawful acts* is centralised and information is disseminated to network partners (for the purpose of this toolkit: such medical products are referred to as ‘counterfeit/falsified medical products’). Information/signals from stakeholders (such as industry, health professionals and patients) should be channeled through appropriate, fast and effective channels to the National SPOC.

Medical Product: For the purpose of this model, medical products are understood as medicinal products for human and veterinary use, active substances, excipients, medical devices, parts, materials and accessories of medical devices.

National SPOC: Operates as one contact point within the **international cooperation** between ‘**National SPOCS**’ of individual states. The National SPOC represents the SPOCs within the competent authorities of a state; the national SPOC is responsible for transmitting and receiving requests for information and/or cooperation as regards fighting counterfeiting/falsifying medical products.

Network: Formal or informal collaboration between SPOCs at national and international level, as appropriate.

Networking: Activities between network members consisting of operational management and information exchange in relation to counterfeiting/falsifying medical products.

Official Medicines Control Laboratories: National medicines control laboratories/reference laboratories. They may be organised in an international network, are important partners and should be involved for their competencies in analytical verification, a pre-requisite for public health risk assessment.

Operational SPOC: The SPOC identified and appointed by the national authorities to coordinate and lead the investigation. SPOCs may agree on which agency will lead, but that is very different to who actually leads the investigation. For example, a police SPOC may have responsibility for the action happening, but the investigation may be by a different unit specialised in a particular field, e.g. serious crime where organised crime groups are involved. **The decision should be left to the national authorities to decide for themselves how investigations are done.**

Pharmaceutical crime: criminal behaviour of people involved in producing, marketing and advertising outside the regulatory control of the competent authorities medicinal products.

Preventive action: Key preventive measures are namely the introduction, at national level, of quality and safety requirements of medical products on the one hand, and measures ensuring the safe distribution of such products on the other. States should lay down in their domestic law, the appropriate quality and safety requirements as well as the measures ensuring safe distribution. As one example of the latter, the introduction of adequate track and trace systems could be mentioned. As further preventive measures, training may be provided to health care professionals, providers, police, customs and relevant regulatory authorities and awareness-raising campaigns for the general public with the involvement of relevant non-governmental organisations and the media; to supervise all professional activities within the distribution chain of medical products, as well as to develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

Qualified/Responsible Person (QP/RP) / Industry investigation SPOC: Company person who will perform the duties of SPOC for the purpose of liaison and cooperation with the authorities in the counterfeit/falsified medical product investigation. In the regulatory system, it may be more appropriate to focus on the QP/RP. Otherwise, or for investigation, an 'Industry SPOC for investigations' (e.g. an individual in a company for the corporate security element of industry) may be useful.

Signal: Any appearance of a problem with medical products that can be considered or related to counterfeiting/falsifying.

Single Point of Contact (SPOC) within the competent authorities of a state:

- 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) or,
- Accessible unit, entity, service or person responsible for receiving information and data and for exchanging information, prevention and combating of counterfeit/falsified medical products, management of suspect verified cases within the responsibility of its own competent authority.