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GROUP OF SPECIALISTS ON COUNTERFEIT PHARMACEUTICAL PRODUCTS

(PC-S-CP)

FINAL REPORT

SUMMARY

The Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) was established by the Committee of Ministers under the authority of the European Committee on Crime Problems (CDPC).

Its major task under the terms of reference was to prepare a report, focusing on the key elements, which could be included in a future Council of Europe convention against pharmaceutical crime.

The PC-S-CP adopted its Final Report (hereinafter "the Report") where it:

- took into account the previous work carried out in the field of counterfeiting and in particular counterfeiting of medicines by the World Health Organisation, the European Union and the previous work of the Council of Europe in this area, including Parliamentary Assembly of the Council of Europe;

- stressed that counterfeiting of medical products and related crimes became a growing international problem, threatening public health and undermining the right to life enshrined in Article 2 of the European Convention on the Protection of Human Rights and Fundamental Freedoms;

- agreed that the objective of a future convention should be focused on protecting the public health by introducing to that end new offences and penal sanctions for these offences, without prejudice to the need of protecting intellectual property rights;

- agreed upon the need to prepare a Council of Europe convention against pharmaceutical crime, in particular against counterfeiting of medical products and directly related crimes;

- agreed that a future Council of Europe convention could have a worldwide impact by enabling non-Member States of the Council of Europe to become parties;

- agreed that a future convention should cover medical products, including medicinal products and medical devices and should not include cosmetic products, food and food supplements and biocide products;

- agreed upon a non-exhaustive set of offences to be established by a future convention;

- considered issues relating to jurisdiction, procedural matters relating to international co-operation as well as preventive and administrative measures; and

- agreed upon its proposals as to the possible follow-up mechanism to a future convention.

∗ *The Report has been adopted by the PC-S-CP at its last meeting on 5-7 March 2008 and is "provisional" until the final approval of the Chair of the PC-S-CP.*

I. Introduction

1. The spread of counterfeit goods has become more and more global in recent years and the range of goods subject to infringement has increased significantly. Counterfeiting affects almost any type of medicinal products and medical devices (see paragraphs 27-32 below) for which there is a general consumer demand. Along with the increase of the scale of counterfeiting there is an increasing urgency to raise public awareness as regards its effects not only on the economies of states and on the well-being of their populations, but also on public and individual's health and lives. Counterfeiting is progressively acknowledged as a serious problem by most countries in the World.

2. Specialised international organisations already carried out substantial work to combat counterfeiting, with greater emphasis on the protection of intellectual property rights. However, there is a general recognition that, along with the violation of intellectual property rights, counterfeiting of medicinal products and medical devices puts public health at risk and therefore needs to be addressed as a matter of urgency.

3. Substantial initiatives in the fight against counterfeiting have been taken by the World Health Organisation (WHO). On 18 February 2006, at the Rome International Conference on Combating Counterfeit Medicines, the WHO adopted a declaration stating that "counterfeiting medicines …is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems." So far, however, it has not been possible to elaborate a binding international instrument on this subject within the WHO.

4. In response to the threat by counterfeit pharmaceuticals, the WHO officially launched in November 2006 a global task force IMPACT (the International Medical Products Anti-Counterfeiting Taskforce) involving more than 20 international partners. Its terms of reference cover policy proposals and recommendations on legislation and enforcement, regulatory implementation, communications and innovative technological solutions, including public-private initiatives for the application of new technologies to the detection of counterfeits, and technology transfer to developing countries. The Council of Europe contributes to its work. To ensure the successful expansion of the results of the Council of Europe's work to non-member states, the PC-S-CP stressed the need to follow the work of the WHO IMPACT closely and to take into account the latest developments that took place at the Lisbon Conference on 10-11 December 2007.

5. The European Union has been active in its fight against counterfeiting. Currently, on the basis of a proposal from the European Commission, the Council of the European Union and the European Parliament are examining a set of criminal law measures to supplement civil law and customs action to fight against intellectual property rights violations. The criminal law measures in preparation address issues of intellectual property in general and are not limited to medicinal products and medical devices only.

6. The Council of Europe has also been paying great attention to the issue of counterfeiting. A number of seminars and high level conferences[1] were dedicated to discussing this problem, the threats it poses and possible solutions to it. Throughout these events it was stressed that the Council of Europe should approach the problem of counterfeit pharmaceutical products from a public health perspective and see it as a threat to public health (and safety), thus undermining the right to life enshrined in Article 2 of the European Convention on the Protection of Human Rights and Fundamental Freedoms. To this end the elaboration of an international legal instrument, possibly a convention within the Council of Europe, in co-operation with other relevant international organisations, such as the WHO, was considered advisable.

7. The Survey Report on Counterfeit medicines (also known as the "Harper Report")[2] provided a comprehensive overview of the current situation of counterfeit medicines in the territory of the Council of Europe member states to the Partial Agreement in the Social and Public Health Field and identified existing gaps in legislation and administrative procedures.

8. An important political backing to the Council of Europe's work against counterfeiting was provided by the Parliamentary Assembly of the Council of Europe (PACE), which adopted a number of Recommendations[3] on this subject. One of the main messages that could be drawn is "the rapidly rising incidence of counterfeit goods in Europe – a phenomenon which places customers' health and well-being at risk, erodes the markets for legitimate producers, damages the reputation of brand names, distorts competition, undermines employment

[1] "The Pharmacist at the crossroads of new health risks: an indispensable partner for their management", Strasbourg, 20-22 October 1999; Seminar "Counteract the Counterfeiters - limiting the risks of counterfeit medicines to public health in Europe by adequate measures and mechanisms", Strasbourg, 21-23 September 2005; International Conference "Europe against Counterfeit Medicines", Moscow, 23-24 October 2006.

[2] Counterfeit Medicines – Survey Report by Jonathan Harper and Bertrand Gellie, Council of Europe Publishing, January 2006.

[3] Recommendation 1673 (2004) "Counterfeiting: problems and solutions"; Recommendation 1793 (2007) on "the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods"; Recommendation 1794 (2007) on "the quality of medicines in Europe".

and reduces tax income." The PACE challenged the image of counterfeiting as a harmless activity and called upon Council of Europe member states "to improve data collection on the linkage between counterfeited goods and injuries or deaths, in particular as regards products such as pharmaceuticals, spare parts, toys, personal care products, household items, foodstuffs, alcoholic drinks and tobacco."

9. In 2007, the PACE submitted a Report on the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods, underlining that "traffic in counterfeit goods is a scourge that is growing to epidemic proportions across the wider Europe in both the range and volume of goods involved. All member states of the Council of Europe are concerned as countries of origin, transit or destination for counterfeit goods." The Assembly highlighted that there is a legal vacuum at international level and that appropriate national authorities are either inexistent or weak and therefore underlined the need to make provision for an international legal instrument establishing specific offences relating to counterfeit medicines so that counterfeiters can be arrested and criminally prosecuted. It welcomed the prospect of elaborating a European convention on the fight against pharmaceutical crime and expressed conviction that a further similar initiative would be necessary to fight all counterfeiting and trafficking in counterfeit goods.

10. At the inter-governmental level, the Committee of Experts on Pharmaceutical Questions "Ad-hoc group on counterfeit medicines" (P-SP-PH/CMED), under the Public Health Committee (CD-P-SP) of the Partial Agreement in the Social and Public Health Field, set up the Ad hoc Group on Counterfeit Medicines in 2003 with the task of focusing on public health protection and possibilities for improved co-operation of member states and other stakeholders as regards counterfeit medicines and other forms of pharmaceutical crime.

11. At its 56th Plenary meeting, the European Committee on Crime Problems (CDPC) agreed on the importance of combating counterfeit pharmaceutical products and stressed that the Council of Europe's work could bring much added value to the initiatives of other international and regional organisations in combating the counterfeiting of medicines and other healthcare products.

12. The CDPC approved the terms of reference of a Group of Specialists on Counterfeit Pharmaceutical Products whose major task was to prepare a report, focusing on the key elements, which could be included in a possible international legally binding instrument to fight crime concerning counterfeit pharmaceutical products focusing in the first place on the criminal law aspects of the problem and on strengthening of international co-operation in preventing this crime.

13. The aim of the present Final Report is to propose major elements for inclusion in a future convention that could be adopted by the Council of Europe to combat the counterfeiting of medicinal products and medical devices and other related crimes that jeopardize public health.

II. Objective of the future legal instrument

14. When discussing the aim of a future convention the PC-S-CP agreed that the notion of "counterfeiting of medicinal products and medical devices" raises at least two major concerns – first and foremost the infringement of public health and the second - violation of intellectual property rights.

15. Bearing in mind the above, the Group considered it necessary, in view of the dual nature of the problem, not to limit a possible instrument to counterfeiting[4] only, but to expand it to all directly related crimes that could infringe public health. The PC-S-CP recognised that a number of such crimes would include intellectual property rights issues, but took the view that the main purpose of the future instrument should be much broader and should focus on penal measures against criminal behaviour involving medicinal products and medical devices and threatening public health.

16. In order to combat the infringement of public health by counterfeit medical products and medical devices the majority of the PC-S-CP concluded that an umbrella notion of "pharmaceutical crime", already referred to in the above-mentioned Report of the PACE, should be introduced, under which relevant offences could be listed. However, there was a strong dissenting opinion from some members of the PC-S-CP as regards the term "pharmaceutical crime" as this term was considered to be vague and misleading, which could be interpreted in many different ways. The Group decided to leave this issue up to the drafters of a future legal instrument.

17. As regards criminalising production of substandard pharmaceutical products, the Group agreed that criminal intent would be necessary for such behaviour to be covered by a future convention.

[4] According to IMS Health, an international consulting and data services company that supplies the pharmaceutical industry with sales data and consulting services, a percentage of medical products not protected by patent rights in the EU member States varies from 67% (Italy) to 96% (Czech Republic). According to the European Generics Association, the market value of generic medical products (which are not protected by intellectual property rights) in some of the European countries varies from 3,7% (Italy) to 50% (Lithuania/Estonia).

III. Why a Council of Europe convention?

18. The PC-S-CP took the view that there are a number of problems, inherent to counterfeiting of pharmaceutical products and medical devices, which necessitate the elaboration of a legally binding international instrument.

19. First of all, an absence of strict sanctions for counterfeiting of medical products and medical devices at national level – and often the complete absence of penal provisions – make it easy to individuals to produce and distribute counterfeit medicinal products and medical devices without running a meaningful risk of being detected, even less being punished. Partly due to this lacuna, counterfeiting of medical products is often the field of activity for the elements of organised crime. Furthermore, national legislation of States, where it exists, varies considerably[5]. Diversified, dissuasive and proportionate sanctions are indispensable to punish offenders and help prevent such offences effectively.

20. There is no harmonisation or at least approximation in international law of the offences relating to counterfeiting of medicinal products and medical devices. Furthermore, at the time of internationalisation of trafficking of counterfeit medicinal products and medical devices, aggravated by internet trade, which undermines the credibility of legitimately distributed genuine products and makes it impossible to guarantee the quality and efficacy of products supplied, there is no international legal instrument, aiming to combat pharmaceutical crime and defining corresponding offences.

21. The global magnitude of this crime is increasing[6] to an alarming degree, affecting almost all regions and all countries in the World either as countries of origin, transit or final destination of counterfeit medicinal products and medical devices.

22. Furthermore, networks of inter-sectoral co-operation (customs, police, health authorities, judicial authorities) at national level need to be established, as they would be one of the essential components to contribute in an integrated and holistic way to coordination of combating pharmaceutical crime within States and would ensure the efficiency of international co-operation.

23. Bearing in mind that the current work of the EU (see para 5 above), focuses on the respect for intellectual property rights, while the future work of the Council of Europe to combat pharmaceutical crime, will focus on the protection of public health, The PC-S-CP took the view that these two directions would complement one another and would cover all relevant aspects of the problem.

24. In addition to the above, bearing in mind the difficulties experienced by other organisations in developing a legally binding instrument of global application, a Council of Europe convention could provide a set of standards that could then find broader application by inviting non-member states to become parties to such a convention.

25. The above reasons, in the view of the PC-S-CP, lead to the conclusion that time is now ripe for the Council of Europe member states to start negotiating a legally binding instrument to prevent and combat pharmaceutical crime, in particular counterfeiting of medicinal products and medical devices as well as other directly related crimes.

[5] The "Harper Report" demonstrates differences that exist in national legislations concerning criminalising counterfeiting of medical products. A Comparative Study on Concepts of Criminal Legislation, which is currently in preparation by Max Planck Institute for Foreign and International Criminal Law, will provide a more up to date illustration of these differences. Max Planck Institute envisages to carry out a large-scale, in-depth comparative legal study, examining types of counterfeit medical products, ways of counterfeiting, distribution channels, function of the offender and different types of legal consequences of the offence. This study should be available for public by the end of May 2008.

[6] Even though the exact statistics concerning counterfeiting are not available, the following data from the OECD and the WHO is only a little part of information that is available to illustrate the gravity of the global problem of counterfeiting in general and of counterfeit medicines in particular: http://www.oecd.org/dataoecd/13/12/38707619.pdf (OECD) and http://www.who.int/mediacentre/factsheets/fs275/en/index.html (WHO).

IV. Scope of a future convention

26. PC-S-CP agreed that a future convention should cover medicinal products and medical devices for human and veterinary use, but should not cover food, cosmetic products and biocide products. The PC-S-CP then agreed to guide itself by the already existing definitions of relevant products and components.

27. The Group decided to clarify the term "pharmaceutical products" and, taking into account the terminology already in use by the EU and WHO, agreed that using the term "medical products" would be more appropriate. This would include medicinal products (including active pharmaceutical ingredients and excipients) and medical devices (active ingredients, components, software).

28. For the purposes of the present Report as well as a future convention of the Council of Europe medicinal product for human and veterinary use[7] should be:

    a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings (animals); or

    b) Any substance or combination of substances which may be used in or administered to human beings (animals) either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

29. Substance (active pharmaceutical ingredient and excipient) is any matter, irrespective of origin, which may be:

    a) human, e.g. human blood and human blood products, cells, tissues organs;
    b) animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
    c) botanical, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;
    d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

30. Active pharmaceutical ingredient is any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or the function of the body.

31. Excipient means any substance that is not an active pharmaceutical ingredient or a finished medicinal product that is intended to be used for preparing a medicinal product for human or veterinary use.

32. "Medical device"[8] means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

    — diagnosis, prevention, monitoring, treatment or alleviation of disease,
    — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    — investigation, replacement or modification of the anatomy or of a physiological process,
    — control of conception,
    and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

33. The PC-S-CP noted that the application of the legal instrument to the area of medical devices requires careful consideration of the particularities, e.g. in the distribution channels, of these products and recommends involvement of specific experts to address the appropriate terminology when drafting the instrument.

34. As regards clinical investigations, or as they are called in medical field, clinical trials, although the Group recognised the danger of manipulative administration of clinical trial materials and other types of abuse, the

[7] Inspired by Directive 2004/27/EC of the European Parliament and the Council, amending EC-Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC, and Directive 2004/28/EC of the European Parliament and the Council, amending EC-Directive 2001/82/EC on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC)

[8] Inspired by Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices as amended by Directive 2007/47/EC, Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocide products on the market.

majority of specialists were against their inclusion in a future instrument. However, the Chair of the Group was of a different opinion and underlined that a future convention could be a good political opportunity to deal with the violations relating to clinical trials, even when offences relating to them are committed outside the States Parties to a convention.

V. Offences to be established by a future convention

35. For a future convention to be effective, it is necessary to determine which behaviour States Parties should criminalise under such an instrument.

36. The Group took into account the conclusion of the WHO IMPACT Lisbon Conference (10-11 December 2007) that counterfeiting of medical products is a serious crime per se regardless of evidence of harm actually caused. The PC-S-CP agreed that in order to facilitate defining of different behaviour that needs to be criminalised the use of the definition of a counterfeit medical product, endorsed by the Lisbon Conference of the WHO IMPACT on 10-11 December 2007, should be considered by the drafters of a convention.

37. When defining the behaviour to be criminalised the Group agreed not to aim at criminalising quality defects or non-compliance with Good Manufacturing Practice/Good Distribution Practice by licensed producers of legitimate, authorized medical products, unless criminal intent is present (see also para 17 above).

38. With the above in mind and taking into consideration the objective of a future convention the PC-S-CP agreed that a non-exhaustive list of offences, from the area of pharmaceutical crime, could be proposed for the consideration of the drafters of a future convention, stating that each member state shall be required to adopt such measures as may be necessary to establish as criminal offences under domestic law the following conduct, committed intentionally:

- Manufacture, packaging, distribution, supplying or offering for supply, storing, keeping for supply (storing only, for the purpose for someone to distribute it afterwards), placing on the market or putting into service (refer to medical devices, the EU term, is the same as selling it, putting into service is using it), promotion (including advertising), illicit trafficking, importation, exportation, of a counterfeit medical product;

- Mislabelling with respect to identity, history and or source of a medicinal product;

- Mislabelling with respect to components and/or properties of a medical device;
- Adulteration of authentic medical product;

- Diversion of a medical product, which should be understood as the intentional unauthorized movement of these products from their intended supply chain, to an unapproved destination[9];

- Professional use of a counterfeit, adulterated, diverted or tampered medical product and medical device, including in clinical trials;

- Procurement of a counterfeit, diverted, adulterated or tampered medical product;

- Possession of a counterfeit medical product with the purpose of committing any of the offences listed above[10];

- Manufacturing and/or possession of counterfeit and/or fake packaging, notwithstanding that the product, whether authentic or not, does not accompany such packaging, with the purpose of committing any of the offences listed above;

- Tampering with a medical product.

39. A future convention should also cover aiding or abetting, inducing as well as attempting or conspiring to the commission of the offences established above.

[9] Diversion could undermine the delivery of needed medical products to regions where these products are needed and hence undermine access to medicines. Quality of medicines is also endangered due to the infringement of integrity in the distribution chain, caused by diversion, which creates a risk of mixing different medicines. Diversion could also lead to furnishing clandestine distribution networks with the authentic products with no regulatory control whatsoever.

[10] The aim of the convention should not be criminalising mere purchasing or possession of a counterfeit medical product for personal use and in good faith.

40. For the purposes of this Report, a medical product is counterfeit when there is a false representation in relation to its identity (name, composition, strength, or any other element that may influence the judgement of health professionals, patients or consumers about the identity of the product), history (different stages of distribution) or source (manufacturer, country of manufacturing, country of origin, marketing authorisation holder, or any other element that may influence the judgement of health professionals, patients or consumers about the source of the product). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

41. Adulteration, which may target an active pharmaceutical ingredient and/or product and excipient of a pharmaceutical and/or medicinal product as well as components and/or software of a medical device, should be understood as a misrepresentation of the composition of the medical product, including false representation on its documentation and/or labels of qualitative and quantitative composition.

42. Tampering means an illegal intervention with a foreign substance or component in a genuine medical product, carried out by an actor who interjects himself into the production and/or distribution system aiming at undermining the integrity of a medical product. It almost exceptionally targets genuine products and impedes the access to genuine and effective medical product by undermining the reputation of the authorised manufacturer and/or the public credibility of the medical product in question.

43. Diversion mostly targets genuine products and has the potential to render them less efficient useless or even harmful (by ignoring the storing conditions and/or expiry date) and/or to use them as a cover for distributing counterfeit medical products to their original destination (by delivering the addressee a counterfeit product instead of the one ordered).

44. In the view of the PC-S-CP offences should also include trafficking in counterfeit medical products. Some specialists suggested considering the inclusion into a future convention of a provision similar to the one in the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, along the following lines: illicit trafficking in medical products means doing or being involved, whether in his/her state of nationality or elsewhere, in any of the following: transportation, transfer, harbouring of a counterfeit medical product without authorisation and without ownership.

45. Cybercrime Convention and its Additional Protocol could be relevant when defining specific offences as some of the aspects covered by its articles would indeed be appropriate for counterfeit medical products. For example, intentional access to the computer system in order to acquire medical products without right, misuse of devices, computer related forgery as well as attempt, aiding or abetting should not be overlooked when preparing the future legal instrument.

46. Extensive discussion took place as regards the threshold that should be applied to criminalise pharmaceutical crime related to medical products and medical devices and other related offences. Majority of the Group were of the opinion that the mere fact of having committed a behaviour proscribed in a future convention would be sufficient to constitute a crime, without necessarily causing actual harm or risk of harm. However, different stages of aggravating circumstances could be envisaged, in accordance with the traditional approach of criminal law.

47. The PC-S-CP agreed that ultimately it would be up to the drafters of a convention to determine liability in respect of each specific offence established in a future convention, which could vary from negligence to intent of damaging public health.

VI. Nature of Sanctions

48. Each Member State should be required to make the commission of an offence established in this instrument liable to criminal sanctions that should be commensurate with the gravity of the offence and the level of guilt and should take into account any relevant aggravating circumstances (actual bodily harm or death, repeat offending, offence committed by organised crime group, offence committed through the use of violence or under arms etc.). In any case, applicable sanctions should be effective, proportionate and dissuasive, including deprivation of liberty, where appropriate and could give rise to extradition.

49. In the view of the PC-S-CP, States Parties to a future convention should have at their disposal a range of measures, allowing withdrawal of the products resulted from pharmaceutical crime from criminals. It includes confiscation of objects, regardless the quantity, of the instrumentalities and proceeds from this crime, or confiscation of property of the corresponding value. These measures are envisaged by Article 3 of the

Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime, but they do not cover the offences that a future convention would envisage.

50. At the same time, bearing in mind the specificity of offences related to pharmaceutical crime, the States Parties of a future convention should envisage a broad range of sanctions to be applied, taking into account specific details of each offence. Such sanctions could include destruction of medical products endangering public health, total or partial, temporary or definitive closure of an establishment that was used to commit the offence in question, permanent or temporary ban on exercising commercial or entrepreneurial activities, placing under judicial control, legal dissolution etc. The Group agreed that suspension and annulment of diplomas and/or licenses for professional/entrepreneurial activity should apply as additional sanction in cases of offences committed by pharmaceutical industry (including licensed manufacturers, brokers, sellers etc.) or healthcare professionals. In addition, the States Parties could establish black lists of offenders belonging to this sphere.

51. The PC-S-CP believed that, although currently it is up to the States to determine the type of responsibility applied to legal persons for criminal offences, time is now ripe to include criminal responsibility of legal persons in the future legal instrument, due to the gravity of offences within pharmaceutical crime. To that end provision should be made to prosecute the legal person by itself or, where appropriate, in addition to an individual representing that legal person, with a view to applying effective, proportionate and dissuasive penal sanctions.

VII. Jurisdiction

Determining jurisdiction of State(s) Party(ies)

52. When discussing the matter of establishing jurisdiction over a specific offence, the PC-S-CP noted that national law could be sufficient when an offence and its consequences take place on the territory of that state, provided the behaviour in question is criminalised under national law. However, it is often ineffective in combating counterfeiting of medical products outside the state borders.

53. The PC-S-CP considered that the provisions, aimed at determining jurisdiction of Parties[11] which already exist in a number of Council of Europe's treaties on international co-operation, could be a good source of inspiration for drafters of a future convention.

54. Along with the above provisions concerning jurisdiction should ensure that future Parties use their powers to prosecute and sentence offenders at least for offences committed wholly or partly on their territory. In so doing, the drafters could consider the possibility of waiving the dual criminality requirement so as to make sure that the perpetrators may be prosecuted even though the offence was not a crime in the state where it was committed. for the most serious offences inter alia by comparing them with those offences for which normally the dual criminality is not required in existing international instruments.

55. It was clarified that, as a matter of principle, criminal law can be applied and implemented only by the state which enacted that law. However, application of foreign administrative law could merit further examination. In certain cases definition of a crime might derive from administrative law of another State. In such cases thought should be given to determining to what extent the other state's administrative law should apply.

56. Apart from the criteria applicable in the relevant Council of Europe treaties for determining jurisdiction additional, victim-related criteria, could apply, where appropriate (habitual residence, nationality, location of the victim at the time of suffering damage; territory where the damage, occurred etc.).

57. For most serious offences, the drafters of a future convention might explore possibilities for establishing jurisdiction that would go beyond the territoriality principle of applying criminal law (as it is the case in the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse).

58. A possibility for the State to prosecute an offence when it refuses extradition of the person for that offence could also be considered. A situation where the victims of a particular offence are in a country other than where the offence was committed but no Party is willing to exercise jurisdiction over it should also be dealt with.

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[11] For example, Para 1 of Article 22 of the Cybercrime Convention states that Each Party shall adopt such legislative and other measures as may be necessary to establish jurisdiction over any offence established in accordance with Articles 2 through 11 of this Convention, when the offence is committed:

a) in its territory; or
b) on board a ship flying the flag of that Party; or
c) on board an aircraft registered under the laws of that Party; or
d) by one of its nationals, if the offence is punishable under criminal law where it was committed or if the offence is committed outside the territorial jurisdiction of any State.

59. It has to be noted that solving conflicts of jurisdiction between states is a complex and sometimes politically sensitive issue, which has not been successfully achieved through legal texts so far. With this in mind, the PC-S-CP agreed to stress the importance for States Parties to a future convention to facilitate resolving such conflicts by becoming parties to the European Convention on the Transfer of Proceedings in Criminal Matters (CETS No.073), if they have not already done so.

VIII. Exchange of information, procedure and international co-operation

Exchange of information

60. In order to effectively prevent and combat pharmaceutical crime exchange of information and co-ordination of efforts at national and international level are essential.

61. The Parties to a future convention should ensure a coordinated preventive and repressive action at the national level to combat pharmaceutical crime, in particular counterfeiting of medical products. To this end the Parties should usefully designate a responsible authority in charge of such coordination, which would unite representatives of healthcare regulatory bodies, police, customs, as well as representatives of the commercial and industrial sectors.

62. If basic principles of national jurisdiction allow, each State Party should take necessary measures to enable controlled delivery and other special investigative techniques such as electronic and other forms of surveillance as well as infiltration operations by competent authorities on their territory with the view to effectively combat organised crime.

63. The Group recommended that measures are taken to put an end to the use of the services implicated in remote sales of counterfeit, tampered, adulterated or diverted medical products. These measures should notably include the following:

- A coordinated action to prevent and repress the use of these services for the purpose of illicit trafficking;

- Elaboration and implementation by the law-enforcement authorities of investigative and control techniques, enabling the discovery of counterfeits in parcels destined for remote sales.

64. Mechanisms facilitating the transfer of non-evidential material in support of cross-border investigation of counterfeiting of medical products and other related crimes are indispensable to successfully combat these crimes at international level.

65. According to the PC-S-CP one of the difficulties with international co-operation in preventing and (Kanari) combating pharmaceutical crime, including counterfeiting of medical products, is the timely manner of transmitting data that is important for detection and investigation. This should not be confused with the transmission of evidence, which is more necessary for and mostly takes place through international letters rogatory.

66. Provisions are required to allow the transmission of information to each other in different jurisdictions in connection with a criminal investigation involving counterfeit medical products. This should ideally be provided for through the requirement of member states to establish such specific appointees, to be known as Single Points of Contact (SPOCs – see the Appendix to this Report)[12].

[12] In June 2007 the Council of Europe Ad hoc Group on Counterfeit Medicines adopted a Model for a Network of Single Points of Contact (SPOCs). This model establishes a network of entities responsible for the management of notifications of medical products suspect of being counterfeit or of other pharmaceutical crimes. The entities involved comprise drug regulatory authorities including the official medicines control laboratories, customs, police and justice authorities.
The SPOCs model was endorsed at the IMPACT General Meeting (Lisbon, 12-13 December 2007), which indicated that some review of the language was still required and was being done by IMPACT's Enforcement working group (for more information please see the Summary Report of the IMPACT General Meeting http://www.who.int/impact/events/IMPACTGeneralMeeting2007report.pdf).

International Co-operation

67. Already existing mechanisms for international co-operation should be used to the greatest extent possible, especially as regards the existing Council of Europe instruments on international co-operation in criminal matters[13]. The future instrument should make sure that there is an implementation mechanism available to guarantee immediate action when needed, such as, for example, cross-border joint operations among health, regulatory, police, customs and other relevant authorities. To this end the States parties should be able to conclude bilateral or multilateral treaties allowing establishing joint investigation teams.

68. The PC-S-CP also took note that the European Commission had proposed, in the above-mentioned criminal law measures (see para 5), a possibility for the rights holders, where they have enough technical knowledge, to provide assistance to joint investigation teams.

69. Some specialists suggested that Official Medicines Control Laboratories (OMCL) could contribute to the operation of such an international co-operation network by making it obligatory to inform all other members of the network of any discovery of a counterfeit pharmaceutical product. Bearing in mind the existing EU Rapid Alert system and the desirability to avoid any parallel reporting system, it was recommended to have a centralised reporting network for quality defects as well as for counterfeit medical products.

Procedural matters

70. Taking into account the gravity of pharmaceutical crime it could be relevant to make it possible for criminal proceedings to be initiated by public prosecutors or other relevant state bodies, as the major goal of combating pharmaceutical crime is protecting public health.

71. Considering that pharmaceutical crime operates in an economic environment very often with the objective to lead to financial profit or material advantage, the PC-S-CP underlined the importance of financial investigations by prosecuting authorities. In particular, it is necessary to update the necessary material elements of proof of economic and financial character at the different stages of counterfeiting of medicines. These stages may vary from providing the starting materials through production cycles all the way until placing on the market. It is particularly important for cases where different stages take place in different states. Furthermore, financial investigations could, on the one hand, contribute to establish the financial source of illegal activity and on the other hand to establishing the culpability of the others, identify co-offenders and "beneficiaries" of the offence.

72. Bearing in mind the specificity of offences related to pharmaceutical crime the States Parties should enable the pharmaceutical specialists and, if necessary, the rights holders concerned or their representatives, as well as any other experts could bring in their contribution to investigations. The Group thinks that this close co-operation, with respect to the rule of law, is necessary not only to facilitate the operation of justice and investigative authorities, but also to timely intervene in the identification, seizure and confiscation of products, with the potential of endangering public health, as well as the indispensable elements of proof.

IX. Prevention, administrative measures, protection of victims

Preventive measures

73. The PC-S-CP considered that, without prejudice to the deterring effect of penal sanctions for offences relating to counterfeiting of medical products, states should also avail themselves of preventive measures with a view to contributing to further suppression of this activity.

74. In this respect States should be encouraged to draw up list implement and enforce of good practices guidelines, especially good manufacturing practice, good distribution practice and good pharmacy practice guidelines or other appropriate standards and to exchange their positive experience in preventive measures. A strategy for increasing public awareness about counterfeit pharmaceutical products and about avoiding becoming their victims should be developed.

75. Other preventive measures should include, in particular:

- appropriate educational measures, starting from school;

- provision of regular information, targeting broader general public;

[13] Council of Europe Conventions on Extradition, on Mutual Assistance in Criminal Matters, on Supervision of Conditionally Sentenced or Conditionally Released Offenders, on the International Validity of Criminal Judgments, on the Transfer of Proceedings in Criminal Matters, on the Transfer of Sentenced Persons, and on the Laundering, Search, Seizure and Confiscation of the Proceeds of Crime.

- professional training for medical professionals, representatives of law enforcement and other relevant authorities;

- introduction of appropriate track-and-trace technology;

- detection of counterfeit material, including active pharmaceutical ingredients through targeted action;

- regulating improvements in labelling and packaging including unique coding system, easily identifiable signs, tamper proof, product markers that are easy to detect; and

- pharmaceutical analysis, including forensic analysis, which should be carried out when justified by the risk faced due to its costly character.

76. The Group agreed that not all of the above measures could find their place in a future convention due to complexity of their harmonious implementation, but considered it very important to draw the attention of the drafters to them, as these measures could be applied by states on a case-by-case basis at the national level.

77. The PC-S-CP suggested that all professional activities within the distribution chain from manufacturing to supply of medical products to the patient / heath professional should be supervised by the state. This should include notification to the authority and appropriate licences/authorisations granted by the state authority. Similar activities carried out via remote sales should be subject to the same principles. In particular, the Group was of the opinion that mandatory licensing of internet sellers of medical products could further assist in preventing the spread of counterfeit medical products.

78. In addition to official good practices guidelines strengthening of self-control mechanisms, such as elaboration of codes of conduct to international enterprises by the private sector, with the participation and supervision of the State, could also stimulate monitoring of the all parties concerned by the States themselves.

79. The Group also considered that any excessive materials, used at any stage of producing a medical product, should be destroyed by the manufacturer or otherwise made unavailable for use. Controlled disposal of equipment and accessories, though difficult to achieve, should be carried out and there should be an obligation to ensure controlled disposal of materials, equipment and accessories, ideally, by the manufacturer, taking all measures to avoid abuse of these materials and equipment.

Administrative measures

80. Administrative measures to prevent counterfeiting and distribution of counterfeit medical products should be further developed outside a future convention.

81. These measures could include the request of clarity in documentation to promote traceability of products, especially active pharmaceutical ingredients, application of good pharmaceutical practice, good distribution practices, including purchasing from someone with the manufacturing license, encourage e-pharmacy measures and regulating internet supply and e-pharmacy of healthcare products within the European Region.

82. To this end it is important to bear in mind Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine, adopted by the Committee of Ministers of the Council of Europe on 5 September 2007.

83. In addition, states parties of a future convention should undertake to inform each other on instances of counterfeit medical products, as well as the potential victims (industry and public). A provision could also be included requiring States Parties to ensure that their industry, trade and health care professionals also report such instances to competent authorities of that state.

Protection of victims

84. Regardless the fact that the focus of the future legal instrument is to deter counterfeiting of pharmaceutical products and punish offenders involved the issue of protection of victims of pharmaceutical crimes should be duly reflected in such an instrument.

85. To the very least, the drafters should bear in mind the principles laid down in Recommendation Rec(2006)8 of the Committee of Ministers to member states on assistance to crime victims, in particular the availability of measures to alleviate the negative effects of crime and assistance to victims in all aspects of their rehabilitation, provision of medical care, material support and psychological health services as well as social care and counselling, access to information of relevance to their case and necessary for the protection of their interests and the exercise of their rights as well as right to effective access to remedies should be followed.

86. As already indicated in the Declaration adopted by the participants of the International Conference "Europe against Counterfeit Medicines" (Moscow, 23-24 October 2006), the PC-S-CP agreed that the compensation of patients for damages resulting from counterfeit medication, as well as other civil remedies for victims could be included in a future convention.

X. Monitoring mechanism for a future convention

87. The PC-S-CP acknowledged that the effective implementation of the future legal instrument, which would be dealing with the topic that will require systematic interaction between States Parties, could not be possible without the effective multidisciplinary monitoring mechanism, which would allow States Parties to regularly consult each other in relation to practical difficulties and enable them to propose solutions to these difficulties.

88. The PC-S-CP stressed that it is up to the drafting committee to decide the specific monitoring mechanism for a future legal instrument. It agreed however that it would be extremely important that the follow-up mechanism proposed be as dynamic as the phenomenon of counterfeit pharmaceutical products, as potent as necessary to ensure the application of consistent standards and as clear-cut as needed to encourage the widest possible acceptance of the future legal instrument. The Group also agreed that the possibility of on-site visits, followed by specific country reports, could be usefully considered in implementation of a future convention.

89. The Group took note of the three monitoring mechanisms established under different conventions of the Council of Europe:

- a specific monitoring committee, with the power of carrying out State Party visits and prepare assessment reports and specific recommendations to the State Party concerned;

- a convention committee, enabling States Parties to consult each other periodically with a view to facilitating the effective implementation of the legal instrument, including the identification of any problems and proposing solutions to them;

- a general monitoring through reviewing the provisions of the legal instrument by a responsible steering committee at the Council of Europe, such as the European Committee on Crime Problems (CDPC) and the Committee of Experts on the operation of European conventions in the penal field (PC-OC).

90. The PC-S-CP noted that any monitoring mechanism could be supported by States Parties through a) integrating of the principles of the future instrument into national legislation and b) contributing to the preparation of conclusions of any future monitoring body. The Group took the view that the final decision will depend on the scope and the content of a future instrument.

APPENDIX I

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

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

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[14] the participants called for the establishment of a network of Single Points of Contact for

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

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[15], 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

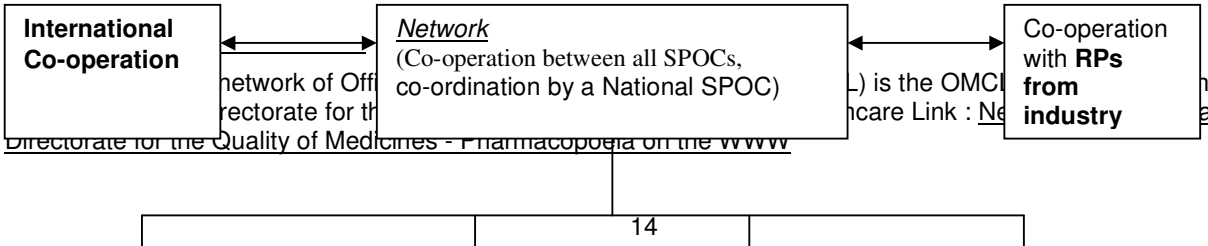
Single Point of Contact (SPOC): an entity responsible for the operational management of a signal in their own area of responsibility and the exchange of information

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
- 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[16] 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.

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.

[16] 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 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[17] for reporting pharmaceutical crime to other National SPOCs.

[17] 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

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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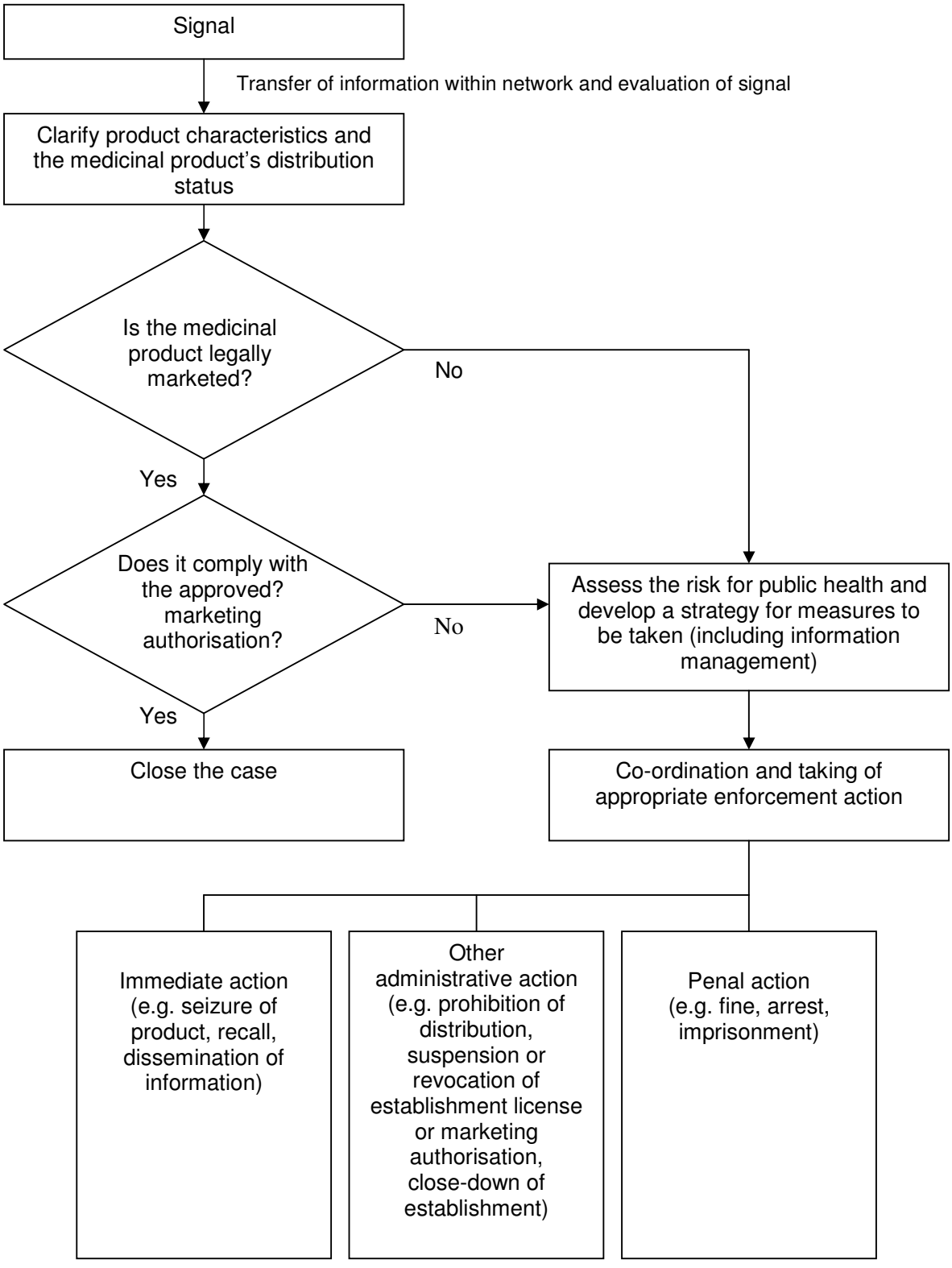
Attachment


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)