COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 15 November 2007 PC-S-CP (2007) 02 E

GROUP OF SPECIALISTS ON COUNTERFEIT PHARMACEUTICAL PRODUCTS (PC-S-CP)

DRAFT FINAL REPORT

PREFACE

1. The spread of counterfeit goods has become global in recent years and the range of goods subject to infringement has increased significantly. It is often mentioned that Counterfeit Goods make up an estimated 5 to 7% of world trade. However, depending on the region, an actual proportion of counterfeit goods may be much higher[1]. Counterfeiting affects almost any type of goods on which there is a general consumer demand and includes apparel and accessories, media products, food and food supplements, cosmetics and of course medicines and healthcare products.

2. 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 health and indeed, on lives of individuals. Counterfeiting is progressively acknowledged as a serious problem by most countries in the World.

3. Specialised international organisations[2] 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 violating intellectual property rights counterfeiting puts at stake health of individuals, especially in cases where it concerns medicines and other pharmaceutical products.

4. Substantial initiatives in the fight against counterfeiting have been taken by WHO. For several years, it has been aware that help is urgently needed in countries which cannot regulate or monitor pharmaceutical products properly.

5. On 18 February 2006, at the Rome International Conference on Combating Counterfeit Medicines, WHO adopted a declaration which can play a vital part in strengthening global co-operation and in the finding of creative solutions. In particular, this declaration stated that "counterfeiting medicines …is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems." However, it has not been possible to elaborate a binding international instrument on this subject within the WHO up to date.

[1] Nonetheless, these figures cannot be substantiated due to absence of accurate statistical data on this subject and of uniform data collection and evaluation.

[2] The World Trade Organisation (WTO), the World Intellectual Property Organisation (WIPO), Interpol, the World Health Organisation (WHO), the International Chamber of Commerce (ICC) as well as the European Union (EU) European Patent Office (EPO), Europol, Eurojust as well as the European Anti-fraud Office (OLAF).

6. Nevertheless, in November 2006, the WHO officially launched 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, trade, risk 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 is a member of the steering body for IMPACT and contributes to its work programme.

7. The European Union has been active in its fight against counterfeiting[3]. Currently the European Commission is examining the opportunity to provide a set of criminal sanctions to supplement civil law and customs action to fight against intellectual property rights violations.

8. One of the first initiatives of the Council of Europe in this area was a Seminar "The Pharmacist at the crossroads of new health risks: an indispensable partner for their management", which took place in 1999, addressed the risks of counterfeit medicines and possibilities on how to contain them. The seminar conclusions inspired the Resolution ResAP(2001)2 of the Committee of Ministers concerning the pharmacist's role in the framework of health security.

9. As a follow-up to that Resolution 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. The Ad hoc group was entrusted with a comprehensive work programme 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. Ad-hoc Group in its composition and project approach was multisectorial, bringing together officials from Council of Europe member states, European institutions, associations of pharmaceutical industry and trade and international organisations.

10. An important political backing to the work in progress was Recommendation 1673 (2004) "Counterfeiting: problems and solutions" of Parliamentary Assembly of the Council of Europe (PACE). In this political statement PACE noted with concern "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 and reduces tax income."

11. It also 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."

12. Follow-up to this Recommendation gave rise to specific activities at the Council of Europe aiming to combat counterfeiting. First of all one should mention the work carried out by the Committee of Experts on Pharmaceutical Questions on measures to minimise public health risks posed by counterfeit medicines. The results of this work revealed in particular that counterfeit medicines:

    - are reported in an increasing number both within Europe and worldwide;
    - have no specific, harmonised legal definitions, nor legal framework to combat their production;
    - waste governments' healthcare budgets, reduce legal industries' revenues and bypass state tax systems;
    - are produced by counterfeiters who are criminals who are well-financed, equipped with the most recent technology and often belong to organised crime and corruption.

13. When replying to Recommendation 1673 (2004) the Committee of Ministers of the Council of Europe stressed that counterfeit medicines represent a serious threat to public health in all Council of Europe member states, while noting a lack of awareness of the threat that these medicines pose to public health, to health care systems and to the commercial reputation of the private sector.

[3] This paragraph will be followed at the second stage of preparation of this Report by an additional paragraph containing general overview concerning the relevant EU Directives.

14. In 2007 the PACE submitted a Report on the need of the Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods. This Report underlines 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."

15. The PACE Report also concludes that "there is an urgent need for action to raise awareness of the dangers that counterfeiting represents to the individual and collective safety of the public and to shape a coherent European policy for the prevention, deterrence and repression of counterfeiting. It is disturbing that counterfeiting remains a low-risk, high-profit activity as prosecution is cumbersome, sanctions are relatively weak and often difficult to apply, and inter-state co-operation is deficient."

16. It further provides some disturbing figures concerning the increase of the scale of counterfeiting of consumer goods in Europe, based on reported seizures of children's games and toys (1287 cases accounting for 20 million articles in the EU in 2004-2005), foodstuffs[4] (4.4 million items for 2004 and 5.3 million items for 2005 in the EU), electrical equipment (7.5 million items for 2004-2005 in the EU) and medicines (560,598 items for 2005 in the EU).

17. The PACE Report confirms that "the Council of Europe views counterfeit medicines as a special concern constituting a violation of the human right to the highest possible standard of health and, in extreme cases, of the right to life." It also refers to the fact that often counterfeiting is linked to organised crime and, in some instances, contributes to financing terrorist networks.

18. The particularly damaging effect of counterfeit medicines lead to further work on this problem, which aimed to examine its extent and to propose international solutions to it. On 21-23 September 2005 the Council of Europe organised a Seminar titled "Counteract the Counterfeiters - limiting the risks of counterfeit medicines to public health in Europe by adequate measures and mechanisms" with support of the experts of the P-SP-PH/CMED.

19. The participants of this Seminar reached a number of very important conclusions. In particular, they discussed the notion of "pharmaceutical crime/health-care crimes" and agreed that this notion should include, but not be limited to, counterfeit medicines, veterinary medicines and medical devices.

20. In view of the participants, 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.

21. The participants also highlighted the fact that pharmaceutical crimes are aggravated by the wide spread use of the Internet to distribute, buy and sell medicines and health-care products.

22. They took note of the P-SP-PH/CMED Survey Report on Counterfeit medicines (Harper Report), prepared in March 2005 by Dr Jonathan Harper and Mr Betrand Gellie, which inter alia 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.

23. The participants of the Seminar underlined that according to the Harper Report the danger to the life of people caused by pharmaceutical/health-care crimes was increasing (60 % of the specialists interviewed by Dr Harper indicated that the incidence of counterfeit medicines cases will increase, while only 10 % estimated that counterfeit medicines cases either do not exist or will not increase).

24. Most importantly, the participants agreed that there is a need to develop an international legal instrument, possibly a convention within the Council of Europe, in co-operation with other relevant international instances, such as the WHO, to combat pharmaceutical/health-care crimes.

[4] The WHO has some figures for contaminated medicines and alcohol. It attributes some 200 000 deaths per year to malaria as a result of consuming fake, ineffective, medicines. Thousands of Russians are poisoned and die each year from drinking fake vodka. The state-controlled Shenzhen Evening News has reported that 192,000 people died in China as a result of fake drugs in 2001. Dozens of babies in China are reported to have died after being fed fake milk formula.

25. This event was followed by the International Conference “Europe against Counterfeit Medicines”, which took place in Moscow on 23-24 October 2006 organised under the Russian Federation chairmanship of the Committee of Ministers with experts support of the P-SP-PH/CMED.

26. In their final Declaration (Moscow Declaration) the participants of the Conference emphasised that counterfeit medicines:

    - represent a serious threat to everybody’s health in Council of Europe member states and worldwide, while their production and distribution may constitute a prerequisite of violation of a human right to the maximum feasible degree of physical and mental health and the relevant human rights enshrined in the Universal Declaration of Human Rights and in the European Convention on the Protection of Human Rights and Fundamental Freedoms;

    - have no internationally recognised harmonised legal definition and are not covered by unified international enforcement practice to fight against them…

27. They considered it advisable to develop an international legal instrument (a convention) on the subject that should cover the following issues:

    - legal definitions of key terms in the field of combating the counterfeiting of medicines and their distribution;

    - prevention of counterfeiting of pharmaceuticals inter alia using the measures included in paragraph 9 of the Declaration;

    - a protocol of state actions with regards to identified counterfeit pharmaceuticals and their distribution (confiscation, return to the country of origin and their destruction);

    - recognition that acts of counterfeiting medicines and distribution thereof as well as involvement in such acts are criminal acts and establishment by the participants of the Convention of respective punishments for these crimes, taking due account of their seriousness;

    - co-operation between healthcare authorities and law enforcement agencies of the member states of the Council of Europe;

    - development of mandatory systems of reporting on counterfeit medicines for all the parties to this Convention, inter alia via an intersectional network of Single Points of Contact (SPOCs);

    - the links between such a Convention and other international legal instruments dealing with money laundering and financing of terrorism as well as cyber-crime.

28. Inspired by the Moscow Declaration, as well as by its previous work on this matter, the Parliamentary Assembly of the Council of Europe adopted Recommendations 1793 (2007) on “the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods” and 1794 (2007) on “the quality of medicines in Europe”.

29. In Recommendation 1794 (2007) the PACE stressed that counterfeiting of medicines affects 10% of the world medicines market, and its growth is facilitated by globalisation and the expansion of transborder trade, as well as the ease of use of modern technologies.

30. The PACE further noted that counterfeit medicines are beginning to appear in Europe as a result, in particular, of a lack or the inadequacy of regulations on quality control and distribution. It referred to Moscow Declaration and reiterated the regret of the participants of Moscow Conference that there is no legal instrument on matters relating to crime in the pharmaceutical field.

31. The PACE 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 counterfeiting medicines so that counterfeiters can be arrested and criminally prosecuted.

32. It is now beyond doubt that counterfeiting in general and counterfeit pharmaceutical products in particular have become an increasingly widespread international problem, affecting economies of states and jeopardizing health and, in some cases, lives of individuals. In order to challenge this phenomenon in an efficient manner a concerted international action of states is indispensable.

33. For that action to take place a legal instrument is needed, which would introduce harmonised definitions for pharmaceutical crime and related offences, establish consistent sanctions and other measures to deter this activity and provide for effective tools for international co-operation.

34. "The Council of Europe, given its multidisciplinary approach, its political and legal authority, as well as its pan-European membership, is ideally placed to motivate and mobilise European states to tackle the complex challenge and threat that counterfeiting represents. While a legal instrument with a global reach would undoubtedly be desirable, this would hardly be feasible given the urgency required and the high standards to which the European countries aspire."[5] Such an instrument could be open for accession to all states in the World and could therefore have a global impact.

[5] Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods – Report by the Committee on Economic Affairs and Development of the Parliamentary Assembly of the Council of Europe (Doc. 11227)

S U M M A R Y

INTRODUCTION

35. At its 56th Plenary meeting the European Committee on Crime Problems (CDPC) agreed on the importance of combating counterfeit pharmaceutical products and pharmaceutical crime in general 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.

36. The CDPC approved the terms of reference of the Group of Specialists on Counterfeit Pharmaceutical Products with the major task 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 (the Final Report).

37. The CDPC agreed that the work of the Group should, as a matter of priority, focus on the criminal law aspects of the problem and on strengthening of international co-operation in preventing this crime. Particular attention should be paid to conducts which may jeopardize public health. The possible introduction of corporate liability for crimes relating to counterfeiting of pharmaceutical products was also mentioned.

38. The CDPC agreed in principle that, apart from dealing with counterfeit pharmaceutical products, the Group could examine the possibility of preparing further provisions dealing with a broader range of health care products.

39. The CDPC stressed the need for the Group to take into account existing national legislation of member States in this field as well as other work that is being carried out at an international level, in particular by the European Union and the World Health Organisation.

40. At this meeting, in accordance with the terms of reference of the PC-S-CP, the CDPC appointed Mr Claude DEBRULLE as Chair of the PC-S-CP. Following the nominations from the member States and in accordance with the terms of reference of the PC-S-CP the Secretary General of the Council of Europe appointed as members of the PC-S-CP the following persons:

- Mr Hugo K. BONAR (Ireland)
- M. Jacques FRANQUET (France)
- Mr. Sergey V. GLAGOLEV (Russian Federation)
- Ms Kerstin HJALMARSSON (Sweden)
- M. Hendrick Jan de JONG (Netherlands)
- Ms Popi Nicolaidou KANARI (Cyprus)
- Mr Konstantin KELLER (Germany)
- Ms Ksenija TURKOVIĆ (Croatia)
- Mr Roy VANCAUWENBERGHE (Belgium)
- Mr Fritz ZEDER (Austria)

41. At its first meeting on 6-7 November 2007 the PC-S-CP took into account the complexity of its task and a relatively short time-frame for fulfilling it. The Group agreed to use a written consultation procedure, where appropriate, for preparing and finalising this Report.

42. The PC-S-CP also agreed that the Final Report would be prepared on the basis of the document CDPC-BU (2007) 12 "Prioritised elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime", referred to in the terms of reference.

43. The focus of the present Final Report is to consider priorities for inclusion in a possible future convention that may be put in place by the Council of Europe to combat the threat of counterfeit pharmaceutical products for the purpose of protecting the public health[6].

[6] Article 2, European Convention of Human Rights and Fundamental Freedoms, Rome, 4 November 1950, CETS No 5. URL: http://conventions.coe.int/Treaty/en/Treaties/Html/005.htm,

44. In particular, it considers the following features of a possible future convention:

Objective

Scope

Purpose

- Definitions
- Substantive law,
  Prevention, offences, penalties
- Procedural law
  Jurisdiction, investigations, prosecution, reporting, similar law
- International co-operation, mutual Assistance
- Protection of victims
- Monitoring of the implementation

45. A possible legal instrument is likely to achieve wide support and adherence to it if it is brief, uses existing definitions and concepts where appropriate and takes into account the existing provisions and practices in the field of pharmaceutical and healthcare product regulation.

PART 1

Objective of the legal instrument

46. The PC-S-CP agreed that the objective of a possible legal instrument should be to provide procedural and substantive provisions for combating crime against healthcare products, primarily legal measures against counterfeiting of pharmaceutical products.

Scope

47. When discussing the scope of a possible future convention the PC-S-CP agreed that counterfeiting of pharmaceutical products raises at least two major concerns – violation of intellectual property rights and public health risks. Therefore the drafters of the future legal instrument should determine the extent to which infringing intellectual property rights on the one hand and the offences posing a threat to public health on the other hand should be punished.

48. Taking into account the area that is currently covered by the activities of other organisations in Europe, in particular the EU, the Group concluded that in case of the EU the major focus is placed on protecting intellectual property rights, including by introducing criminal measures to that end, which to some extent deal with the question of health and safety for individuals, but only as an aggravating circumstance.

49. In view of the PC-S-CP the approach taken by the EU would cover one part of the problem of counterfeiting, that is the IP rights. Therefore, the Council of Europe instrument should tackle the problem primarily from health protection and criminal law aspects.

50. In light of these discussions and bearing in mind the instructions from the CDPC, the PC-S-CP decided that in its Report it would concentrate on combating counterfeiting of pharmaceutical products by proposing provisions for a binding legal instrument that, as far as the conduct is concerned, would introduce specific offences under the general category of “pharmaceutical crimes”[7], which the States Parties should criminalise.

[7] One of the fundamental tasks of the PC-S-CP would be to propose a definition of “pharmaceutical crime”, if possible.

51. Relating to the products that possible future convention should cover the PC-S-CP acknowledged the difficulty of differentiating between medicinal products and other healthcare products, such as cosmetics and food supplements, which, under certain conditions, may contain active pharmaceutical ingredients. The Group decided that for the clarity of the future instrument as well as for its expediency it should include medicinal products and medical devices for human and veterinary use, as well as clinical trials, but should not cover food supplements and cosmetic products.

52. The Group agreed that much guidance could be obtained from the scope of a legal framework for national legislation on counterfeit medicines, defined by the IMPACT. The advantages of this definition are that it covers medicinal products (both human and veterinary), medical devices, active pharmaceutical ingredients, as well as excipients, which are used in health treatment and self-treatment.

53. As regards borderline products[8], which, in view of the Group are difficult to define, the PC-S-CP agreed that it would not be advisable to include them in the future instrument. In this respect the Group considered that the offence of "mislabelling" should solve practical difficulties when counterfeiting of such products could pose a similar threat to health that is posed by counterfeit pharmaceutical products.

54. To determine the extent of types of crimes involved it is necessary to precisely define the scope of the instrument in terms of how far should it reach in criminalising different conduct. Should it confine itself to penal and control matters relating to illegal activity in respect of the manufacture, trade of healthcare products and reckless professional use or should it consider including products that are legally made and traded, i.e. under authorisation of the State, but which fall far short of legally accepted standards such as to pose a serious risk to human health?

55. The best option seems to be situated at the crossover between the two approaches, that is where there is a deliberate intent to produce a product that is substandard, such as one containing too much, too little or no active or other ingredient that would likely harm the consuming patient and/or the professional.

56. The division may be made in approaching the matter with a view to the type of offence intended. That, in itself, will indicate the level of proof required in evidence to convict the offender. For example, in the Common Law jurisdictions, regulatory offences, such as those in the more expansive category, attract a strict liability approach requiring an act, the actus reus, but no intent, the mens rea, while the offences in a legal instrument now under consideration would require both the intent and the act. It has been considered that such proposed Council of Europe Convention should concern criminal law treaty in a broad sense[9].

57. These issues would have to be considered because not all of the Member States of the Council of Europe have the legal and infrastructural facilities[10] to distinguish between good and bad manufacturing and trade practice and that of criminal intent as regards healthcare products.

Purpose – possible provisions for the Preamble of the future legal instrument

58. The PC-S-CP underscored the need for substantiated arguments in favour of a binding international legal instrument to be exposed in an eloquent and convincing manner at the outset of such instrument. In particular, it considered that the following could be included in such a Preamble:

59. The States Parties to the present Convention,

60. Conscious of the need to criminalise pharmaceutical crimes, comprising of the deliberate and fraudulent production and use and distribution, in its broadest sense, of those pharmaceutical products that are likely to put the patient's health and life at risk;

61. Mindful of the fact that counterfeiting in general infringes the intellectual property rights, erodes the markets for legitimate producers, damages the reputation of brand names, distorts competition, undermines employment and reduces tax income;

[8] The Secretariat would appreciate if examples of "borderline products" could be provided by experts at the stage of written consultation.

[9] Note 4. This approach intended the inclusion of a broad category of activities but did not appear to intend to include regulatory offences. Hence, the broad approach tends to support the intermediate approach mentioned above.

[10] Note 4

62. Stressing that counterfeiting of pharmaceutical products, which constitutes a particular pharmaceutical crime, represents a serious risk to the health of individuals and safety of Member States, threatening the right to life enshrined in Article 2 of the European Convention on Human Rights and Fundamental Freedoms (ECHR);

63. Recognising that pharmaceutical crime is a dynamic activity, including the illegal production, deliberate and fraudulent adulteration, tampering, trafficking and distribution of pharmaceutical products, committed with disrespect to laws and/or borders of States;

64. Realising that Member States have a responsibility both to their populations and to other Member States to strive for the promotion and observance of the obligations to defeat counterfeiting of medicines and other pharmaceutical products, as well as other pharmaceutical crimes;

65. Declaring that effective action to prevent and combat pharmaceutical crimes, especially counterfeiting of pharmaceutical products, requires a comprehensive international approach that includes criminalising this conduct and protecting its victims;

66. Despite a variety of national and regional instruments containing practical measures to combat counterfeiting, alarmed by the absence of a binding international legal instrument addressing the matter of counterfeit pharmaceutical products for the protection of public health and safety;

67. Confident of the fact that in the absence of such an instrument, health and lives of persons vulnerable to or because of their illness are exposed to additional risks posed by counterfeit pharmaceutical products;

68. Convinced, therefore, of the need to bring about an international legal instrument, providing for specific offences for such conduct and appropriate sanctions, prescribing common enforcement powers among Member States, introducing mandatory reporting of counterfeiting, trafficking, adulteration and tampering of medicines and other pharmaceutical products, the exchange of information between States, creating an obligation to control active pharmaceutical ingredients and the manufacturing equipment and waste and rejected materials, and to establish a supervisory facility to ensure that the legal instrument is effective;

69. Have agreed as follows:…

PART 2

Definitions

70. The PC-S-CP agreed that for the success of the future legal instrument, requiring to cover such a technical issue as counterfeit pharmaceutical products clear definitions should be included in such an instrument.

71. Agreement among many sources will be needed in order that workable and effective definitions are developed. The Group agreed that it would be preferable to adopt definitions that are already in use, where they exist and are appropriate. Some, however, either do not exist, or where they do are not standardised or sufficiently up to date to take account of modern developments. For the moment it is probably sufficient to highlight the ingredients of the important ones. The drafting group, which will work on the text of the future legal instrument, will have to agree upon a range of more specific definitions.

72. In their preliminary comments on this subject the experts referred to definitions that already exist in other organisations (in particular the EU and WHO) and have received relatively wide acceptance. The Group agreed that the following definitions should be usefully considered when preparing the legal instrument:

73. Medicinal product for Human use (EU definition)[11]

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

[11] The same definition, with corresponding terms, is applicable to medicinal product for veterinary use. More guidance concerning other definitions from the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (page 12).

b) Any substance or combination of substances which may be used in or administered to human beings 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.

74. Active pharmaceutical ingredient (ICH[12] definition)

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug 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.

75. Medical Device (EU definition)

Any instrument, apparatus, appliance, material or other article, wheter used alone or in combination, including the software 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 or compensation for an injury or handicap
-investigation, replacement or modification of the anatomy or of a physiological process
-control of contraception, 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 functions by such means.

76. Counterfeit medicine (WHO definition of 1992)

A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

77. The above definition was used as a working definition by the P-SP-PH/CMED[13]. This is the most globally accepted definition in use. It is a comprehensive definition, but it may now be time to review it. A number of definitions exist for counterfeit medicines. Some members of the Group highlighted the advantages of simple and descriptive definitions, which could follow the rapid development in this area, without the need to being regularly updated.

78. The essential elements of a counterfeit pharmaceutical product that should be covered are the following:

1. Deliberate and fraudulent mislabelling with respect to its identity and or source;
2. Deliberate and fraudulent mislabelling as to active pharmaceutical ingredient and/or levels of such contained in the product, or mislabelled to show an active pharmaceutical ingredient where no active pharmaceutical ingredient is contained therein[14];
3. Deliberate and fraudulent mislabelling as to the presence of an active pharmaceutical ingredient that is not disclosed on the labelling;
4. Deliberate and fraudulent mislabelling with respect to the packager where this is different to the authorised packager under prevailing legislation in the State concerned;
5. Deliberate and fraudulent manufacture and/or procession, and/or packaging, and/or promoting, and/or transporting, and/or supplying (including keeping for supply) any healthcare product without entitlement by law to perform such functions;
6. Deliberate and fraudulent supplying of a medicine with fake packaging;
7. Possession of fake packaging in respects of a healthcare product, notwithstanding that the product, whether genuine or not, does not accompany such packaging[15].

[12] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

[13] World Health Organisation, Counterfeit medicines, Fact Sheet No. 275, Revised February 2006, URL:http/www.who.int/mediacentre/factsheets/fs275/en. Definition at Appendix 1.

[14] This provision should permit the classification as a counterfeit of a genuinely branded product which is manufactured by or with the permission of the brand holder and where it deviated from recognised standards. This seems to fit, to an extent, with the provision of the *Art 8,Arzneimitteigesetz 2004– (German Pharmaceutical Act)*

[15] An example of this is the Stop Counterfeiting in Manufactured Goods Act, 2006, which amends Title 18 US Code, Section 2320 (Trafficking in Counterfeit Goods or Services – enacted 25 June 1948). This includes packaging without the manufactured goods.

79. However, according to some members of the Group, the WHO definition contains concepts that need further clarification.

80. Also some experts considered it advisable, when defining terms within the scope of the future legal instrument, to avoid using the phrase “as determined in national legislation” as widely varying differences at the national level would not contribute to harmonised application of the provisions of this instrument. “As defined by national legislation” should be a compromise of last resort, acceptable only after exhaustion of other more uniform solutions.

81. The PC-S-CP decided to take into account the revision that is currently undertaken by the European Pharmacopoeia concerning definition for substances for pharmaceutical use, which covers both active and "inactive" ingredients. The Group stressed the fact that some manufacturers produce ingredients that are not used exclusively for pharmaceutical purposes and therefore are not always covered by general pharmaceutical regulation scheme.

82. The experts agreed that if the active ingredient is counterfeit then the finished pharmaceutical product should also be considered counterfeit.

83. The Group also considered that clinical trials and quality control, where performed improperly and with fraudulent intent, should be covered by the offences defined in the future legal instrument. The same should hold true for unauthorised clinical trials. In relation to this specific issue useful guidance could be obtained from the Convention on Human Rights and Biomedicine and its Additional Protocols and from the EU Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

84. The PC-S-CP also discussed possible penalisation of providing devices that are or could be used in counterfeiting. Some members acknowledged that it would be difficult to control access to such devices and others considered that such criminal provisions would be overly simplified and too far-reaching.

85. As regards the definition of offences in the future legal instrument there was a general agreement within the Group that the notion of pharmaceutical crime should be introduced, which should include first of all counterfeiting of pharmaceutical products, and should also cover other related offences (mislabelling, adulteration, trafficking, tampering etc.) Pharmaceutical crime is a crime committed in relation to any pharmaceutical product, whether in the developmental or finished stage, that has the potential to harm the public or individual health.

86. The Group stressed that any form of pharmaceutical crime should be considered a punishable offence under the future legal instrument, regardless whether it caused actual harm.

87. As regards criminalising of substandard pharmaceutical product focus should be placed on the presence of criminal intent, even where the product in question is produced by the marketing authorisation holder with intent to pass it off as the genuine product authorised for the market. While it is a genuinely produced product by the legitimate producer, it is not the same product as is authorised and as it claims to be. This approach may be a necessary development in this sphere to protect public health where other legislation protects the proprietary right holder. In this case it would aim at protecting the public from the proprietary rights holder’s criminal intent. Any other failure to respect quality standards would fall outside the ambit of the future legal instrument.

Other Healthcare Products[16]

88. Non-medicine healthcare products which:

1. Were not made with the authorisation of the intellectual property rights owner where such rights are protected by law, and/or
2. Have been deliberately and fraudulently mislabelled as to source and identity, and
3. Bear on the label or container or on the product itself or on accompanying literature, the trademark, trade name or other identifying mark, imprint or device or any likeness thereof, without authorisation of the registered owner of such trademark, trade name or other identifying mark, imprint or device,
4. With the intention of passing it off as the genuine product.

[16] As we did not discuss this particular point during the first meeting the Secretariat would appreciate further clarification on this term.

Pharmaceutical Crime

89. Along with counterfeiting, which is a major offence that could be included under the heading of "pharmaceutical crime" other offences need to be defined (see also para… of this Report). The best way would probably be to adopt definitions for the purpose of the future legal instrument.

90. It is the legal area that is normally defined, such as Cybercrime[17], Environmental Crime, or Economic Crime[18]. However, the offences relating to these areas of law are provided for in various statutes. Pharmaceutical Crime is a relatively new concept, while offences or provision for them in subordinate legislation, and significant level of penalties on conviction already exist in many jurisdictions under specific statutes[19] enacted to cover some of these issues, but certainly not the most serious ones involving criminal intent, such as counterfeiting.

91. The ingredients of this definition will be general but must include any infringement of any criminal activity affecting pharmaceutical products. This would include legislation that regulates or prohibits activities in relation to the manufacture, procurement, distribution, trafficking, advertisement, packaging, adulteration, tampering, counterfeiting or handling of any healthcare product or active ingredient or component or part in the preparation or manufacture of a healthcare product contrary to such regulations or prohibitions. It may also include criminal violations of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Clinical Practice (GCP)[20].

92. The future instrument could also include, but should not be limited to, the following offences:

Trafficking in pharmaceutical products:

93. "Trafficking in pharmaceutical products" means doing or being involved, whether in his/her state of nationality or elsewhere, in any of the following[21]:

(a) Supplying or offering to supply a pharmaceutical product, produced, supplied or offered in contravention with the future legal instrument,
(b) Transporting or storing a pharmaceutical product, controlled in contravention with the future legal instrument,
(c) Importing or exporting a pharmaceutical product Fin contravention with the future legal instrument,
(d)
(e) Handling of any pharmaceutical product or active pharmaceutical ingredient or component of a part in the preparation or manufacture of a healthcare product in contravention with the future legal instrument,
(f) Assisting or inducing the commission outside a Member State of an offence punishable under the future legal instrument and/or a corresponding national law,
(g) Aiding, abetting, counselling or procuring the commission of any of the offences mentioned in (a) to (e) above or attempting or conspiring to commit any such offence or inciting another person to do so,
(h) And (a), (b) and (d) must be transported through a Transit State without being placed on the market of that Transit State.

94. The above activities are excluded where they are authorised by the MS in which they go through these processes or activities.

Adulteration

95. It will have to be considered whether other healthcare products may be adulterated in the same sense as medicines. Adulteration may include an active pharmaceutical ingredient/starting material:

[17] Council of Europe Convention on Cybercrime, Budapest, 23 November 2001, CETS – No.185. http://conventions.coe.int/Treaty/EN/Treaties/Html/185.htm.
[18] E.g. Black's Law Dictionary, Eighth Edition, Thompson West, 2004, p.399
[19] e.g. Irish Medicines Board Act 1995, Section 32, No 28 of 1995. http://acts.oireachtas.ie/zza29y1995.1.html
[20] T. Vander Beken, Feasibility Study for a Council of Europe Convention on Counterfeit Medicines/Pharmaceutical Crime, Institute for International Research on Criminal Policy, Ghent University, 2006.
[21] This tends to correlate to the provisions of Articles 1 and 3, United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. http://www.incb.org/incb/en/index.html

(a) that it does not represent as being included, or is represented at levels that it does not contain on its documentation and on the labelling in the finished dosage product[22],
(b) At levels not represented as being included, or is represented at levels that it does not contain on its documentation in the bulk form, where so supplied.

Tampering[23]

96. Tampering of a pharmaceutical product may include the following:

(a) Manufacturing or supplying or placing on the market or putting into service and knowing that some or all of the healthcare products or any other healthcare product are or have been subject to actual or potential tampering, or
(b) Some or all of those healthcare products have been subject to actual or potential tampering and the person is reckless as to that fact.

97. The above it may also contain additionally

(c) The person fails within 24 hours after becoming aware of, or becoming aware of a substantial risk, or actual or potential tampering to notify the MS in which he is situated
(d) The person receives information or a demand in relation to (a) or (b) above and fails to take action within 24 hours after becoming aware of, or becoming aware of a substantial risk, or actual or potential tampering to notify the MS in which he is situated.

Professional use/clinical trial (to be explained by the experts)

PART 3

Substantive Law

Prevention

98. The PC-S-CP considered that, without prejudice to the deterring effect of criminal penalties for offences relating to counterfeiting of pharmaceutical products, States should also avail themselves of preventive measures with a view to contributing to further suppression of this activity.

99. In this respect States should be encouraged to draw up list of good practices and 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.

100. Preventive measures should include, in particular:

- appropriate educational measures, starting from school;
- provision of regular information, targeting broader general public;
- professional training for medical professionals, representatives of law enforcement and other relevant authorities;
- detection of counterfeit material, including active pharmaceutical ingredients through targeted action;
- regulating outside contact, coding system, easily identifiable signs, tamer proof, product markers that are easy to detect[24]; and
- pharmaceutical analysis, including forensic analysis, which should be carried out when justified by the risk faced due to its costly character.

[22] This is a common usage and meaning of the term drug adulteration. See Black's Law Dictionary, Eighth Edition, Thompson West, 2004, p.535 –"a drug that does not have the strength, quality, or purity represented or expected.
[23] The Secretariat would appreciate if a definition is provided for "tampering".
[24] The Secretariat would appreciate if this bullet point is explained by the experts.

101. As a supplementary measure for preventing the spread of counterfeit pharmaceutical products beyond the frontiers the states could introduce mandatory licensing of internet sellers of such products.

102. Preventive measures could also cover licensing and controlling brokers and controlling packaging material, including labels. Any excessive materials should be destroyed by the manufacturer. Control of equipment, though difficult to achieve, should be carried out and there should be an obligation to destroy used equipment, ideally, by the manufacturers.

103. Administrative measures to prevent counterfeiting and distribution of counterfeit medicines should be further developed outside a possible convention. 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.

104. 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.

105. The PC-S-CP agreed that violation of some of the administrative procedures could trigger criminal responsibility.

Offences and Penalties

106. Each member state will be required to adopt such measures as may be necessary to establish as criminal offences under domestic law the following conduct, when committed domestically or internationally:

    1. Production, manufacture, packaging, distribution, fraudulent diversion, adulteration, tampering, offering for supply, keeping for supply, placing on the market or putting into service, promotion, trafficking, importation, exportation, procurement of the manufacture and supply in contravention of this instrument[25];
    2. Deliberate and fraudulent professional use of pharmaceutical product, that has the potential to harm the health of the end user;
    3. Deliberate procurement of a counterfeit, fraudulently diverted, adulterated or tampered healthcare product;
    4. Deliberate procurement of a counterfeit, fraudulently diverted, adulterated or tampered starting material or active pharmaceutical ingredient or reckless as to whether it was counterfeit for the purpose of any of the activities in 1. above;
    5. Possession in relation to 2 and 3. above.
    6. In relation to tampering, the person fails within 24 hours after becoming aware of, or becoming aware of a substantial risk, or actual or potential tampering to notify the member state in which he is situate, or
    7. The person receives information or a demand in relation actual or intended tampering and fails to take action within 24 hours after becoming aware of, or becoming aware of a substantial risk, or actual or potential tampering to notify the MS in which he is situate[26].

107. Knowledge, intent, purpose or recklessness as to the fact, required as an element of an offence set out above may be inferred from objective factual circumstances. No such specific offence specifically in relation to healthcare products exists in Europe at present apart from Germany. (In Germany it is not specifically counterfeit, but worded to include it[27]).

108. Each Member State will be required to make the commission of an offence established in this instrument liable to sanctions (laying down a minimum term of imprisonment) that should be commensurate with the gravity of the offence 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.).

[25] Note 23 above, Article 3 a) 1)
[26] Support for this type of provision is found in the Therapeutic Goods Act, 1989, Australia. URL:http/www.austlii.edu.au/au/legis/cth/consol_act/tgal1989191/s42e.html
[27] See Appendix 1 for English translation. Note: the translation may vary from the original German text.

109. It would be crucial to include the criminal responsibility of legal persons in the future legal instrument. To that end provision should be made to prosecute the legal person by itself or, where appropriate, in addition to an individual[28]. There may be a requirement to ensure that the proceeds of the crimes are confiscated. This may require provisions to also ensure the tracing and freezing of assets associated with this.

110. Cybercrime Convention could be relevant when defining specific offences as some of the aspects covered by its articles would indeed be appropriate for pharmaceutical crimes. For example, intentional access to the computer system in order to acquire pharmaceutical 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.

111. Procedural aspects: Several accompanying demands on the Member State are required to have procedures to ensure that the 1) offence is investigated and 2) the offender is present in Court and is prosecuted.

PART 4

Procedural Law

Harmonisation of Enforcement Powers

112. Most Drug Regulatory Authorities/Medicines Competent Authorities use powers that were conceived to effect regulatory inspections rather than criminal investigations. Police services have powers focused on criminal investigation but do not have powers in respect of medicines and other healthcare products in many countries. Therefore, there exists a lacuna in the enforcement powers and in the standardisation of such powers where they exist. Such harmonisation will be necessary in order to provide for the common enforcement powers, transmission of information, evidence and working cooperation among member states.

113. The powers required are included in the paragraphs below. These powers include the passage of information between specific persons in Member States, provision of similar powers for search and seizure of product and documentation, judicial orders for forfeiture of assets and destruction of product and equipment and mandatory reporting.

114. Pharmaceutical crimes and other related offences are increasingly committed by the use of information technology. Such crimes are international in nature. The communications are often outside of the investigating jurisdictions. Even when they are within the jurisdiction they are often successfully concealed from investigators. When investigators identify such communications and stored data it is necessary to preserve it in order to obtain the necessary evidence to complete the investigation. It is also necessary to identify and obtain information that is on connected servers, whether inside or outside the jurisdiction. The power to obtain production orders for search and seizure of stored computer data is necessary to the investigation.

115. Therefore, it would be relevant if, when drafting the future legal instrument, for some of the provisions of the Cybercrime Convention to be taken into account, in particular as regards such aspects as expedited preservation of stored computer data, expedited preservation and partial disclosure of traffic data, authorisation to issue production order, search and seizure of stored computer data etc.

Resources

116. The Member States may be required to ensure that they provide for the adequate resources of appropriate enforcement facilities, which includes providing legislation that provides adequate powers to each of the public authorities charged with this enforcement.

[28] For example, Para 1 of Article 26 of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse states that each Party shall take the necessary legislative or other measures to ensure that a legal person can be held liable for an offence established in accordance with this Convention, committed for its benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within the legal person, based on:

a) power of representation of the legal person;
b) an authority to take decisions on behalf of the legal person;
c) an authority to exercise control within the legal person.

Jurisdiction

117. When discussing the matter of jurisdictions the PC-S-CP noted that national jurisdictions are powerless to combat counterfeiting of pharmaceutical products due to its increasing international character. Therefore, the future legal instrument needs provisions regulating the issue of jurisdiction, which should have double purpose: 1) to ensure that Parties use their powers to prosecute and sentence offenders at least for offences committed wholly or partly on their territory; 2) to facilitate the settlement of conflicts of jurisdiction between Parties by requiring them to cooperate in deciding which of them will prosecute the alleged offender, when an offence is within the jurisdiction of more than one Party. A situation where the particular offence has international consequences, but no Party is willing to exercise jurisdiction over it should also be dealt with.

118. The provision on jurisdiction would then have to lay down a list of criteria to give some guidance. The traditional criteria of the European Convention on the Transfer of Proceedings in Criminal Matters could be complemented by additional, victim-related criteria, where appropriate (habitual residence, nationality, origin of the victim; territory where the damage occurred etc.).

119. The PC-S-CP took into account the fact that a number of Council of Europe's treaties on international co-operation already contained provisions, which proved to be effective in determining jurisdiction of Parties in case there is a conflict of jurisdictions[29].

120. In Group's view one of the fundamental issues is that of dual criminality[30]. The drafters of the future instrument would need to determine if the dual criminality principle should be one of the requirements to prosecute the offender or should it do away with this requirement. Determining this would be facilitated by assessing the seriousness of counterfeiting of pharmaceutical products in comparison with those offences for which normally the dual criminality principle is waived in international instruments[31].

121. In relation to powers of competent authorities the Group had a discussion concerning the law that the Party would be entitled to apply in case it exercises jurisdiction over an offence that was subject to dispute of jurisdictions. Some members of the Group questioned the possibility for the competent authority of such a Party also to apply the law of the other country where the offence has been committed.

122. It was clarified that as a matter of principle criminal law can be applied and implemented only by the state which enacted that law. Implementation of other countries laws is not an option in criminal cases. The application of foreign administrative law would however be a different question and could merit further examination.

Transmission of information among designated enforcement parties.

123. Provisions are required to positively provide for the transmission of information to each other in different jurisdictions in connection with a criminal investigation involving pharmaceutical and healthcare product crimes. 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)[32].

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[29] 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.

[30] The dual criminality principle means that both the country requesting extradition and the country that should arrest and return the alleged criminal recognize that what he or she is alleged to have done, is a crime under national legislation.

[31] Such crimes include, but are not limited to, participation in an organised crime, terrorism, trafficking in human beings, sexual exploitation of children and child pornography, trafficking in arms, ammunition and explosives, corruption, money laundering etc.

[32] A model SPOC procedure has been developed within the Council of Europe Ad Hoc Group on Counterfeit Medicines. Document P-SP-PH-CMED/RD6.1/8 (2006), Guidance on the management of counterfeits – Cooperation structures and model procedure (submitted by Dr. Tobias Gosdschan, January 2006).

124. This facility would need to be a working operational power rather than a mutual assistance facility, which is a very formal procedure, which enables the transmission of data by judicial means. The latter will be the mode of transmission of the ultimate evidence for legal proceedings where required in another jurisdiction.

Exchange and compilation of information

125. To ensure the efficiency of information transmission/reception mechanism it is important to identify competent authorities that should receive information not only concerning criminal but administrative procedures as well. In all cases single points of contact would be very useful and could be encouraged by the future legal instrument.

126. There is currently no legal basis for the routine passing of information within a multi-sectoral network. Intelligence sharing between healthcare product regulatory agencies, police, Customs and with designated trade and industry representatives is a modern requirement to defeat counterfeiters. Police and Customs do have such facilities within their own spheres[33]. However, there does not exist one Single Point of Contact (SPOC) through which all such information can be channelled on an informal basis. Each country will have a Mutual Legal Assistance programme and supporting legislation whereby evidence may be transferred through judicial routes. However, here it is the establishing of SPOCs and the transfer of non-evidential material in support of cross-border investigation of pharmaceutical and other healthcare product crimes in the jurisdiction of the Member states.

127. A provision is required within the legal instrument to provide for international co-operation in respect of criminal law enforcement procedures in connection with pharmaceutical crime, including the counterfeiting of pharmaceutical and other healthcare products.

128. A provision is required to create an obligation on Member States SPOCs to provide assistance to a requesting Member State where it relates to a specific issue under investigation of pharmaceutical crime in another Member State.

Provisions on International Cooperation

129. According to the PC-S-CP one of the difficulties with the international co-operation is a timely manner of transmitting data that is important for investigation and eventually for substantiating the charge. In order for the future legal instrument to function effectively it must mandate transmission of such information in a legally regulated manner. It is a very important tool in successful investigation. At the same time it should not be confused with the transmission of evidence, which is more necessary for and mostly takes place through courts.

130. Already existing mechanisms for international co-operation should be used. The future instrument should make sure that there is an implementation mechanism available to guarantee immediate action when needed, as it is the case in the convention on the protection of children against sexual exploitation and sexual abuse.

131. The Group agreed that in practical terms the future legal instrument should facilitate cross-border joint operations among health, regulatory, police, customs and other relevant authorities. The future instrument should also enable states to make use of relevant Council of Europe instruments on international co-operation in criminal matters.

132. Currently, there are is significant number of legal instruments provided by the Council of Europe in this area of the criminal law to point to the linkages required to be made by the future legal instrument in on combating counterfeiting of pharmaceutical products.

[33] Interpol, Europol, World Customs Organisation

133. These include Council of Europe conventions on extradition[34], mutual assistance in criminal matters[35], supervision of conditionally sentenced or conditionally released offenders[36], the international validity of criminal judgments[37], the transfer of proceedings in criminal matters[38], the transfer of sentenced persons[39], and the laundering, search, seizure and confiscation of the proceeds of crime[40]. In some of these instruments offences justifying possibility of extradition are already established and standards are set.

134. In view of the fact that the future legal instrument will introduce new offences the PC-S-CP considered that it would be appropriate for States Parties to adopt legislative and other measures necessary to furnish their competent authorities with powers and procedures for the purpose of specific criminal investigations or proceedings in respect of these offences[41], including co-operation with competent authorities of other Parties.

135. Official Medical Control Laboratories could bring their contribution to the operation of such international co-operation network by making it obligatory to inform all other members of the network or a discovery of a counterfeit pharmaceutical product. The PC-S-CP also took note that the European Commission is considering a possibility for the rights holders, where they have enough technical knowledge, to provide assistance to joint investigation teams.

Mandatory Reporting of Instances

136. A requirement to ensure that Member States are compelled to report instances of pharmaceutical and healthcare crime needs to be included. A further provision should also be made requiring Member States to insert in their law a requirement for industry and trade to also report such instances to them. It should be ensured that such a reporting requirement lays down clear provisions as to who has to then what to whom and when. No legal provision to report a suspect[42], or in most cases an actual counterfeit medicine or healthcare product currently exists in Member State's legislation, apart from possibly Germany[43]. The regulatory requirement in Germany is to report a quality defect that triggers the reporting of the counterfeit. This is a simple mechanism that currently works in all EU Member States (note of the Secretiariat – PIC/S Scheme for non-EU member States) and perhaps in other Council of Europe Member States with regard to quality defective products in general. The Council Of Europe (Ad Hoc Group on Counterfeit Medicines) proposed an amendment to the European Medicines Agency (EMEA) Rapid Alert System (RAS) to take account of reporting of counterfeit medicines. On the request of EMEA to provide recommendations on the RAS amendment proposal the European Union Medicines Enforcement Officers Group (EMEO) made recommendations on the revised document. However, that is not mandatory and may not be used in all Council of Europe Member States. It is not submitted by industry. It will generally apply to authorised medicines rather than unauthorised/black market medicines. There needs to be a mandatory requirement that industry, trade and health care professions will report a suspected or actual counterfeit medicine or healthcare product and that MSs have an obligation to report any such instance that comes to their attention.

[34] European Convention on Extradition, Paris, 13 December 1957, CETS –No.024. Additional Protocol, Strasbourg, 17 March 1978, CETS – No.099. Second Protocol, Strasbourg, 8 November 2001, CETS – No. 182

[35] European Convention on Mutual Assistance in Criminal Matters, Strasbourg, 20 March 1959, CETS – No. 030.

[36] European Convention on the Supervision of Conditionally Sentenced or Conditionally Released Offenders, Strasbourg, 30 November 1964, CETS- No.051.

[37] European Convention on the International Validity of Criminal Judgements, The Hague, 15 May 1972, CETS – No.070.

[38] European Convention on the Transfer of Proceedings in Criminal Matters, The Hague, 15 MAY 1972, CETS- No.073.

[39] Convention on the Transfer of Sentenced Persons, Strasbourg, 21 March 1983, CETS – No.112. Additional Protocol, Strasbourg, 18 December 1997, CETS – No. 167

[40] Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime, Strasbourg, 8 November 1990, CETS – No. 141.

[41] Further guidance on this matter can be obtained from Article 14 of the Cybercrime Convention (CETS No.185).

[42] The Rules Governing Medicinal Products in the European Union, Vol. 4, EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Chapter 8, Date of Revision December 2005, date of coming into operation 01 February 2006. URL: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-4/pdfs-en/2005_12_gmp_part1_chap8.pdf. This provides that a manufacturer is required to report a suspected counterfeit medicinal product. The guideline in itself is intended to support the regulatory standards of manufacturing and not specifically intended as a mandatory legal instrument to criminalise non-reporting. The text is "8.8. The competent authorities should be informed if a manufacturer is considering action following possible faulty manufacture, product deterioration, detection of a counterfeit or any other serious quality problems with a product."

[43] *Art 8,Arzneimitteigesetz 2004– German Pharmaceutical Act)*

PART 5

Additional obligations

137. Additional obligations on Member States should be included, to assist in the prevention of such crimes under consideration, through the following:

- To control active pharmaceutical ingredients (APIs), packaging material, manufacturing equipment (to include the destruction, handling of waste and rejected materials) is required in order to provide a mandatory system of prevention of such items returning to the marketplace in the furtherance of criminal activity.

- Control of APIs as currently they lack regulatory control. They are often imported and supplied through brokers who themselves are not regulated. APIs are sourced in Asia and sold in and through Europe to other global regions. There is a requirement to ensure that APIs are genuine products and produced by the declared manufacturer.

- A provision is provided for the recording and/or licensing of brokers of APIs, to provide for the full record keeping of the pedigree of APIs, and offences where it does not occur.

- Packaging materials be controlled. Currently, they can be easily scanned and copied. Packaging materials should be strictly controlled both from a custody viewpoint and use, from printing to the end use. This may be done by use of various technological solutions, either individually, such as RFID or in combinations, such as 2D bar-coding and mass serialisation. Such technology usage should not be the concern of a legal instrument as it is fast moving, expensive to impose a particular burden on industry and controversial as to which technology solution to use. This should be left to industry. However, Member States should be required to actively encourage industry to use the up to date solutions to protect the integrity of their product and therefore the public safety. All packaging not used, destroyed or damaged must be accounted for. This should form part of a mandatory regime and provide an offence where there is a breach.

- Manufacturing equipment be strictly controlled both in its supply and disposal after its use. An offence is required for manufacturing or supplying any manufacturing equipment where it is known or reasonable believed to be put to use for the purpose of a pharmaceutical and healthcare product crime, particularly in counterfeiting or reckless as to the purpose it is to be supplied for. This applies equally in respect of equipment in the medicines and other healthcare products areas. Control records should be maintained as to the pedigree of such equipment from beginning to end of life. Clearly, this can only apply to tools, dyes and other equipment specifically made for the healthcare production industry. For other equipment, disposal records should be maintained.

- The accounting for and certified disposal of all rejected and waste medicines and healthcare products be mandatory by all suppliers down to retail level.

Protection of Victims

138. 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.

139. 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.

Monitoring mechanism

140. 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 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.

141. 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).

142. The Group, at its first meeting, did not indicate any particular preference to either one of the above ways for monitoring the 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.

143. The PC-S-CP also 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) allowing systematic publication of conclusions of any future monitoring body. The work carried out by the Official Medical Control Laboratories could contribute to technical aspects of such a task.

144. Elaboration of guidelines to international enterprises by the private sector, with the participation of the State and introduction in national legislation of a requirement to public denouncement of pharmaceutical and other relevant enterprises, which in view of the States Parties do not respect the guidelines on good practices could also stimulate monitoring of the pharmaceutical industry by the States themselves.

Expressions of Desire

145. The legal instrument should provide for:

- The expression of a strong desire in the instrument to encourage Member States to engage in a Public Awareness campaign to alert the public, healthcare professionals and industry to the dangers of pharmaceutical and healthcare product crimes, with particular reference to the supply by Mail Order, particularly by Internet suppliers.

- The expression of a strong desire in the instrument to encourage Member States to engage in the development of a common approach to regulating Internet supply and e-pharmacy of healthcare products within the European Region.