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FEASIBILITY STUDY FOR A COUNCIL OF EUROPE CONVENTION ON COUNTERFEIT MEDICINES / PHARMACEUTICAL CRIME

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INTRODUCTION

1. The document at hand is the **Feasibility Study for a Council of Europe Convention on Counterfeit Medicines/Pharmaceutical Crime**[1]**.** The **first part** of the feasibility study addresses the phenomenon of counterfeit medicines, the production and distribution of which should be qualified as pharmaceutical crime (Section 1). A number of initiatives and activities have taken place globally, regionally and nationally to tackle this phenomenon. The first part briefly touches upon the most significant and relevant ones (Section 2). The **second part** of the feasibility study then reflects on two issues: the need for an international legal instrument in tackling *inter alia* the phenomenon of counterfeit medicines (Section 1) and the potential of the Council of Europe in the drawing up of this instrument (Section 2). The **third part** is the core part and highlights relevant points that could be considered in a future legally binding instrument. As it concerns a criminal law treaty in the broad sense, the analysis of possible solutions to the problem and recommendations on the best solution to use – in short: the feasibility study – is geared towards:

- Purpose and scope (Section 1);
- Substantive criminal law (Section 2);
- Prevention (Section 3);
- Investigation, prosecution and procedural law (Section 4);
- International cooperation (Section 5) and
- Monitoring mechanism (Section 6)

The objective of the feasibility study was to determine whether a legal instrument is likely, based on the evidence, to be both necessary and possible and that the outcomes will be capable of tackling the problem on a regional and national basis. The feasibility study will argue that there is an identifiable problem in counterfeit medicines and pharmaceutical crime in general; that it is a remediable problem; and that it can be remedied through legislation.

PART I. THE PHENOMENON OF COUNTERFEIT MEDICINES/ PHARMACEUTICAL CRIME AND THE INITIATIVES AND ACTIVITIES TO TACKLE IT

Section 1. The phenomenon of counterfeit medicines/pharmaceutical crime

2. Counterfeiting is a common problem with several types of internationally traded goods. Counterfeit goods in Europe – whether manufactured here or brought in from other parts of the world – are on the rise, causing risks to consumers' health and well-being, distorting competition, damaging legitimate producers' interests and their brand names, undermining employment and reducing tax income[2]. All counterfeiting is to be deplored. For some goods such as designer clothing, the purchaser is usually aware that the product is not genuine. This is not the case for medicines where all purchasers are vulnerable and are likely to assume that the product is genuine and do not have the ability to decide otherwise. The patient is then at risk. All this makes that medicines cannot be regarded as mere commodities. The consequences of counterfeit medicines are particularly severe (death, disability and injury through a lack of or decreased therapeutic effect or inherent toxicity of the counterfeit) and the same goes for pharmaceutical crime in general.

3. While statistics vary as to the level of counterfeit medicines on the global market, it has been claimed that counterfeit medicines affect 5% to 7% of the global pharmaceutical market[3]. Counterfeit medicines are present in all regions of the world, but developing countries bear the brunt of the problem. An estimated 25% of the medicines consumed in developing countries are believed to be counterfeit. In some countries (e.g. Nigeria) the figure is thought to be as high as 50%[4]. The European Union (EU) maintains that at least 3% of

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[1] The important question as to whether the Council of Europe should draft a Convention on *Counterfeit Medicines*, or rather a Convention on *Pharmaceutical Crime* is analysed thoroughly in the first section of the core part of the feasibility study. See *infra* **18-21.**

[2] For a good report on the impact of counterfeiting of a wide number of products in Europe, see Centre d'études internationales de la propriété industrielle (CEIPI), Impacts de la contrefaçon et de la piraterie en Europe, Rapport final, 9 July 2004. URL: http://ec.europa.eu/justice_home/doc_centre/crime/studies/study_ceipi_counterfeiting_fr.pdf#search=%22%20Impacts%20de%20la%20contrefa%C3%A7on%20et%20de%20la%20piraterie%20en%20Europe%22.

[3] See Council of Europe, Partial Agreement in the Social and Public Health Field, Executive summary of the seminar "Counteract the counterfeiters! Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures", 21-23 September 2005, Strasbourg (Appendix 1.1 Facts and Figures).

[4] Although this is likely to reflect the definitions in place.

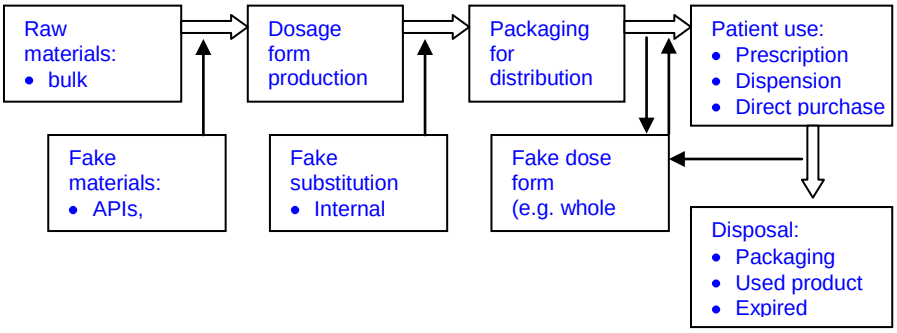
its pharmaceutical market is counterfeited[5]. The Council of Europe *Counterfeit Medicines Survey Report*[6] provides strong evidence that the counterfeit medicines problem is not insignificant in Western Europe and is not likely to go away in the foreseeable future. All European countries are affected whether as manufacturing sites, through transit, or markets.

4. The counterfeit problem affects both human and veterinary medicines (patent-protected and non patent-protected – *generics*), as well as medical devices (400,000 different medical devices on the European market). Mention can also be made of blood products, cells and tissues. The problem is present in both the legitimate and the illegitimate or black market.

5. The current phenomenon of counterfeit medicines is due to a wide number of factors that can be summarised as follows[7]: regulatory gaps; incoordination between relevant authorities both nationally and internationally; regulatory body lack of resources; inefficient cooperation between stakeholders; weak administrative structures; weak enforcement and penal sanctions; weak export/transit regulations; disparity in the legal non-availability of certain types of high value medicinal products (unlicensed medicines) between countries; rapid rise in Internet pharmacy trade[8]; weak packaging and printing regulations; increasingly complex distribution chain with transactions involving many intermediaries[9]; high medicinal product prices; recent appearance on the market of so-called "life style and embarrassment" medicinal products; a move of organised crime into medicines counterfeiting associated with increasing sophistication in clandestine manufacture[10]; corruption and conflicts of interest.

6. The increasingly complex distribution chain of transactions involving many intermediaries has to be acknowledged. The production and distribution of medicines is a complex activity consisting of several and rather articulated steps in both space and time. Criminals can infiltrate the legitimate production and distribution chain in different ways. Figure 1 taken from Hopkins, Kontnik and Turnage[11] describes the different points of the production chain at which attacks might occur.

Figure 1: Pharmaceutical production and counterfeit attack flowchart



At distribution level a "business model of counterfeiting" has been put forward[12]. Figure 2 describes how wholesalers and local distributors can introduce counterfeit medicines into the legitimate system, dispensing them to official distributors such as public and private hospitals and clinics, and to individual patients.

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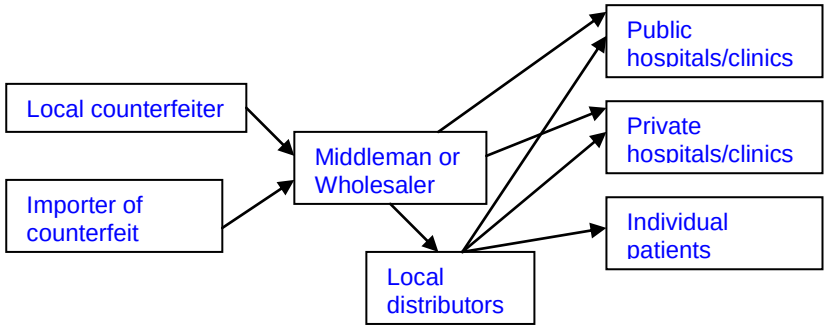
[5] See footnote 3.
[6] J. HARPER and B. GELLIE, *Counterfeit medicines – Survey report*, Council of Europe Publishing, 2006, 242 p. The report was commissioned by the Council of Europe Committee of Experts on pharmaceutical questions and its multisectorial Ad Hoc Committee on counterfeit medicines on the basis of an ongoing project to minimise public health risks posed by counterfeit medicines. It was based on the results of several surveys of Council of Europe Member States (Partial Agreement in the social and public health field) and European pharmaceutical sector stakeholders (manufacturers and wholesalers of medicinal products) conducted by the Ad Hoc Committee in 2003 and 2004 on the subject of legislative and administrative procedures applicable to counterfeit medicines.
[7] *Ibid*.
[8] See *infra* **7.**
[9] See *infra* **6.**
[10] See *infra* **8.**
[11] D. HOPKINS, L. KONTNIK and M. TURNAGE, *Counterfeiting exposed*, John Wiley & Sons Inc., 2003,
[12] World Bank, HNP (Health, Nutrition and Population), *Pharmaceuticals: Counterfeits, Substandard Drugs and Drug Diversion*, March 2005, p. 2. URL: http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief_2_9Mar05.pdf.

Figure 2: Business model of counterfeiting



7. As regards the Internet pharmacy trade, it should be pointed out that the Internet as such is not the problem[13]. Nevertheless, it is an open window to distribution of counterfeit medicines[14], a vehicle through which everything is promoted and subsequently supplied, often illegitimately. Criminals take advantage of the anonymity of the Internet and put the lives of an unsuspecting public at risk[15].

8. A major report produced by an independent consulting group has linked the phenomenon of counterfeit medicines to organised crime[16]. As for the involvement of organised criminal groups in the counterfeiting of medicines, it should be noted that the latter is a very lucrative business due to high demand and low production costs. The absence of deterrent legislation in many countries also encourages counterfeiters. In this sense the current phenomenon is a classic "high profit – low risk" story. In the EU Organised Crime Threat Assessment 2006 commodity counterfeiting is assessed as a rapidly expanding type of crime. It is stated that virtually all goods on sale are counterfeited, and that in addition to the significant economic loss, the serious threat posed to health and safety by *inter alia* counterfeit medicines must be considered[17]. Again proof of the fact that medicines cannot be regarded as mere commodities.

9. In sum, it remains extremely difficult to properly map the phenomenon of counterfeit medicines – and pharmaceutical crime in general. This is largely due to its clandestine nature. Counterfeiters do not advertise their involvement and patients and healthcare professionals most likely will not know until after administration, if they know at all. The difficulties in measuring the scope of the phenomenon are also due to the absence of clear definitions of "counterfeit medicines" and "pharmaceutical crime"[18]. Not only does this absence reinforce the perception that medicines counterfeiting is no different from other types of counterfeiting (a fallacy in terms of public health consequences), it also leads to inconsistencies and non-standardisation of reporting of counterfeit medicines. The absence of clear definitions is amplified by the lack of a European central reference point for collating the instances of counterfeit medicines. The consequence of this is that in Europe – as in the rest of the world – **we still know too little (facts, figures and trends) of the phenomenon of counterfeit medicines – and pharmaceutical crime in general.** The little we *do* know, however, justifies taking strong action.

[13] See also Council of Europe, Partial Agreement in the Social and Public Health Field, *Selling and advertising of medicines on the internet,* Prepared by the Committee of Experts on Pharmaceutical Questions, Strasbourg, 13 November 2002. URL: http://www.coe.int/t/e/social_cohesion/soc-sp/Sale%20internet.pdf. This study aims to provide an overview on the state of e-commerce and electronic advertising of medicinal products in the member states of the Partial Agreement.
[14] Not to mention adulterated and tampered medicines. See also *infra* **21.**
[15] Commission warns about fake drugs on the internet, IP/06/375, Brussels, 27 March 2006.
[16] See G. SATCHWELL, *A Sick Business. Counterfeit medicines and organised crime*, The Stockholm Network, 2004. URL: http://www.efpia.org/2_indust/sickbusiness.pdf.
[17] EUROPOL, EU Organised Crime Threat Assessment (OCTA) 2006, p. 9.
[18] See *infra* **18-21.**

Section 2. Initiatives and activities to tackle the phenomenon of counterfeit medicines / pharmaceutical crime

10. A number of initiatives and activities have taken place globally, regionally and nationally to tackle the phenomenon of counterfeit medicines and pharmaceutical crime in general – the latter however only to a smaller extent. The *Pre-Report to the Feasibility Study on a Council of Europe Legal Instrument*[19] presents a global view thereof, with a particular focus on those initiatives and activities that impact on the European Region[20]. Making reference to the listing of initiatives and activities in the *Pre-Report* facilitates the reflection on two issues in the second part of the feasibility study: 1) the need for a legal instrument in tackling the phenomenon of counterfeit medicines/pharmaceutical crime and 2) the potential of the Council of Europe in the drawing up of this instrument. The *Pre-report* has demonstrated that, overall, there are two very different, yet complementary ways to approach the phenomenon of counterfeit medicines – and pharmaceutical crime in general: 1) as a violation of intellectual property rights (IPR) and wider economic interests, and 2) as a public health problem.

PART II. AN INTERNATIONAL LEGAL INSTRUMENT ON COUNTERFEIT MEDICINES / PHARMACEUTICAL CRIME

Section 1. The need for an international legal instrument

11. Despite all efforts that have been made to address the problem, an international legal framework covering counterfeit medicines is still lacking at present. Hence the clear need for an international legal instrument, the justifications of which are manifold[21]. 1) The potential threat to life and public health remains. Counterfeit medicines also undermine the confidence of patients and healthcare professionals in the healthcare system, not to mention the burden they impose on healthcare budgets. 2) Counterfeiting knows no boundaries or jurisdictions. Based on mounting evidence, national measures alone appear to be insufficient to address the international nature and scope of the phenomenon of counterfeit medicines. 3) At present Europe lacks a central reference point for collating all relevant data, as provided by the competent authorities and the pharmaceutical industry on the basis of clear definitions of “counterfeit medicines” and “pharmaceutical crime”. 4) Counterfeit medicines and pharmaceutical crime in general generate “high profit”, with only a “low risk” of apprehension. Moreover, several cases indicate links with organised crime.

12. The need for a strong international instrument has already been acknowledged by the participants to the Seminar “Counteract the counterfeiters! Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures” (Strasbourg, 21-23 September 2005). The issue whether this instrument *should* be a Council of Europe Convention was left aside. The Seminar Conclusions simply stated that “This instrument *could* be a Council of Europe Convention”[22]. At the International Conference “Europe against Counterfeit Medicines” (Moscow, 23-24 October 2006) the need for a strong international instrument was reiterated. The Moscow Declaration expresses the conviction of the participants that “an international legal instrument – Convention (…) – *should* be developed without delay under the aegis of the Council of Europe and adopted”[23]. The potential of the Council of Europe in the drawing up of this instrument is further reflected upon in the next section, considering both intrinsic and added value.

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[19] Council of Europe, European Committee on Crime Problems (CDPC), *Pre-Report to the Feasibility Study on a Council of Europe Legal Instrument* (By Hugo K. Bonar, Scientific Expert), Strasbourg, 9 June 2006.

[20] Some of the most significant and relevant ones discussed are: Council of Europe (CoE), European Union (EU), World Health Organisation (WHO), World Intellectual Property Organisation (WIPO), Organisation for Economic Cooperation and Development (OECD), European Patent Office (EPO) and the Permanent Forum on International Pharmaceutical Crime (PFIPC).

[21] See Council of Europe, 55th Plenary Session of the CDPC, Strasbourg, 3-7 April 2006 – agenda item 7.4 Counterfeiting (Notes on the presentation Mr. Johan Sabbe). See also Council of Europe, 51st session of the PC-OC, Strasbourg, 1-3 March 2006 – agenda item 6.3 Counterfeiting (Notes on the presentation Mr Hugo Bonar).

[22] See footnote 3.

[23] International Conference, Europe against Counterfeit Medicines, Moscow, Russian Federation, 23-24 October 2006, Moscow Declaration (§ 6).

Section 2. The potential of the Council of Europe

13. The **intrinsic values** of the Council of Europe are *inter alia* the following. 1) Comprehensive membership: a Council of Europe Convention could cover (at least) 46 Member States, with fairly high standard of legal and healthcare systems, thus providing the opportunity to draft a high-quality text, both from the legal and the health point of view. 2) Rapidity: the Council of Europe is able to produce conventions in a relatively short time (e.g. 1 to 2 years). 3) Multidisciplinary approach: at the Council of Europe, the legal and the health sectors could usefully cooperate in the drawing up of the instrument. 4) Human – thus patient – rights based approach: a Council of Europe Convention would protect Article 2 (Right to life) of the European Convention on Human Rights[24] by placing a positive obligation on each Party.

14. As mentioned earlier, other international institutions are also active in the area of counterfeit medicines. However, their approach and/or working methods are different from those of the Council of Europe. The latter even has **added value** over global (WHO) and other regional (EU) initiatives. The WHO and the Council of Europe share the public health approach. Nevertheless, the WHO has abandoned the initial idea of having an international framework convention. Instead an International Medical Products Anti-Counterfeiting Taskforce (IMPACT)[25] was launched, as an immediate response to the need for urgent internationally coordinated action to combat counterfeit medicines. The European Commission approaches counterfeiting primarily as a violation of intellectual property rights. Medicines are covered by IPR legislation[26], but not specifically targeted.

15. A Council of Europe Convention could provide a ready-made basis for a WHO convention on a global scale. It could also provide the ready-made legislation for the EU in the field of public health. This is not to say that Council of Europe action is one-way traffic. On the contrary, a Council of Europe Convention would also benefit from drawing upon the WHO and EU *acquis*.

PART III. POINTS TO CONSIDER IN A COUNCIL OF EUROPE CONVENTION ON COUNTERFEIT MEDICINES / PHARMACEUTICAL CRIME

16. Judging from the second part of the feasibility study, there is indeed a need for a legal instrument. Moreover, the Council of Europe – with its European-wide legal and public health mandate based on the protection of human rights – can be seen as the most appropriate and best-equipped institution to draw up this instrument. This leaves the third part of this feasibility study with the question of the possible content of such an instrument. This part will highlight relevant points that could be considered in a future Council of Europe Convention on Counterfeit Medicines/Pharmaceutical Crime. As the future Council of Europe Convention concerns a **criminal law treaty in the broad sense**, the sections below cover: 1) Purpose and scope; 2) Substantive criminal law; 3) Prevention; 4) Investigation, prosecution and procedural law , 5) International cooperation and 6) Monitoring mechanism.

Section 1. Purpose and scope

17. Ultimately, a Council of Europe Convention on Counterfeit Medicines/Pharmaceutical crime will be instrumental to protect the right to life (Article 2 European Convention on Human Rights) and the right to protection of health (Art. 11 revised European Social Charter[27]). This **purpose statement** could be in the very first Article of the future Convention, as well as in the Preamble to the Convention.

18. As for the scope of the future Convention, overall, two approaches are possible: a **minimalist approach** leading to a Council of Europe Convention on *Counterfeit Medicines* and a **maximalist approach** ending in a Council of Europe Convention on *Pharmaceutical Crime*. Within each approach there is again more than one option. There is general agreement that counterfeiting of medicines comes under pharmaceutical crime,

[24] Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 November 1950, CETS – No 5.
[25] IMPACT is a voluntary grouping of governments, organisations, institutions, agencies and associations from developing and developed countries working towards the common goal of fighting counterfeit medical products. Its establishment had been proposed by WHO and was endorsed by 160 participants at an international conference in Rome in February 2006. The Rome Conference issued a set of principles, calling for WHO to lead the establishment of IMPACT and set the conceptual framework for IMPACT's work.
[26] The recent legislative steps adopted at EU level to increase the protection of intellectual property rights include: Regulation (EC) n° 1383/2003 on customs action, Directive 2004/48/EC on the enforcement of intellectual property rights and the July 2005 Proposals for a Directive and a Framework Decision on criminal measures.
[27] European Social Charter (revised), Strasbourg, 3 May 1996, CETS – No 163.

which broadly speaking covers any criminal activity affecting pharmaceuticals. However, there appears to be less agreement about definitions of both "counterfeit medicines" and "pharmaceutical crime".

19. The WHO has developed following definition of **counterfeit medicines**: "they are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients"[28]. Despite the consensus this working definition represents, the definitions used in practice would differ enough to create problems[29]. Moreover, this definition – already dating from 1992 – has been perceived as too restrictive. Indeed, not only are medicines counterfeited, but also veterinary products, medical devices and other healthcare products. The future Council of Europe Convention could cater with modern developments in counterfeiting by covering healthcare products in general, i.e. medicines (both human and veterinary), medical devices and perhaps even cosmetics and nutrition supplements. Although the protection of public health would justify this *sensu lato* approach, it may not be achievable. The legal instrument also has to remain workable. It may, therefore, not be a recommended approach to include cosmetics and nutrition supplements insofar they fall outside the accepted definition of medicines[30].

20. *Quid* **pharmaceutical crime** in general? Although the term "pharmaceutical crime" has been in use since at least 1998 (establishment of the Permanent Forum on International Pharmaceutical Crime, PFIPC), there is no common understanding of its meaning and what it includes. Broadly speaking, pharmaceutical crime covers any criminal activity affecting pharmaceuticals[31]. The idea of inserting in the future Council of Europe Convention a definition of a term as cloudy as pharmaceutical crime should be approached with care. An elegant alternative could be the simple enumeration, under the heading of pharmaceutical crime, of the separate criminal activities, excluding the mere irregularities. A parallel can be drawn with the Council of Europe Convention on Cybercrime[32]. Cybercrime – a crime area, not a crime as such – is left undefined. Instead, 9 criminal offences, grouped in 4 different categories, are listed. **Counterfeiting** would obviously be included. **Adulteration and tampering of medicines** and – again following a *sensu lato* approach – medical devices could be added to the list. The protection of public health is to benefit from this, as counterfeited, adulterated and tampered medicines create similar health risks. Within these limits[33], a Council of Europe Convention on Pharmaceutical Crime (maximalist approach) would then be preferable to a legal instrument dealing merely with counterfeit medicines (minimalist approach).

21. Tampering and adulteration involve the criminal manipulation of medicines and medical devices by an unauthorised party. These activities usually are carried out by subjects such as pharmacists, who may dilute packaged pharmaceuticals to increase profits, or other individuals who wish to hit innocent final consumers (patients)[34]. Tampering is any unauthorised change of *appearance* of a product. Typical examples of tampering include any unauthorised breaking of seals, any change applied to the packing materials including the removal or addition of stickers, marks or other features. Adulteration is any unauthorised change of the *quality* of a product, including the addition of unauthorised or unlabelled substances.

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[28] World Health Organisation, *Counterfeit medicines*, Fact sheet N° 275, Revised February 2006. URL: http://www.who.int/mediacentre/factsheets/fs275/en.

[29] World Health Organisation, Health Technology and Pharmaceuticals, *Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation*, 27 January 2006 (original draft by Michelle Forzley, revised by WHO). URL: http://www.who.int/medicines/events/FINALBACKPAPER.pdf.

[30] Cfr. 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, OJ L 311, 28.11.2001, p. 67 (Directive as last amended by Directive 2004/27/EC, OJ L 136, 30.4.2004, p. 34). Article 1 contains the definition of a "Medicinal product" for human use.

[31] Examples of pharmaceutical crime: crimes involving narcotics and psychotropics, veterinary related problems, crimes involving borderline products and unlicensed medicines, doping (human and veterinary), counterfeiting and IPR related problems, gifts and inducements, forgery, publicity, theft, falsifying clinical trials, crime involving traditional Chinese medicines, Internet, diversion, licensing, import, export, transit – crimes, crimes involving mail order/courier, criminal violation of Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Clinical Practices (GCP), Good Veterinary Practices (GVP).

[32] Convention on Cybercrime, Budapest, 23 November 2001, CETS – No 185.

[33] Also outside the scope of what is being considered here are the areas of human health crimes, which are usually torts (civil law) and sometimes offences against persons (criminal law).

[34] ABNH, *Pharmaceutical counterfeiting, tampering and diversion. The threat to world health and the quest for solutions*, December 2002, p. 1. URL: http://www.abnh.com/security/Pharm_whitePaper_WEBSITE.pdf.

Section 2. Substantive criminal law

22. Harmonising **substantive criminal law** regarding counterfeiting/pharmaceutical crime will prevent criminals from "shopping" to find countries where they face no consequences for their behaviour.

23. In both the minimalist approach (counterfeit medicines) and the maximalist approach (pharmaceutical crime) proper **incriminations** for counterfeit medicines – or healthcare products in the *sensu lato* option – need to be established. In the maximalist approach (pharmaceutical crime) incriminations also need to be established for adulteration and tampering of medicines and medical devices. Incriminations imply that each Party is to adopt such legislative and other measures as may be necessary to establish certain acts as criminal offences under national law.

24. Specified criminal offences could include: manufacturing, storing, advertising[35], offering for supply[36], supplying[37], importing, exporting and trafficking counterfeit medicines (material element or *actus reus*). The standard mental element or *mens rea* proposed for these offences is intent. However, in a given case it may be difficult to demonstrate that something was done intentionally. It is therefore worthwhile to consider negligence as well[38], for all but the manufacturing of counterfeit medicines. To do so in the latter case would be a *contradictio in terminis*, deceit and the intention to deceive being essential to any counterfeit operation. The concept of negligence requires a violation of the required ordinary diligence often laid down in legal, administrative or technical rules, or rules generally acknowledged in the specific professions concerned.

25. Both the counterfeit-part and the medicines-part of counterfeit medicines would then have to be defined taking into account what was said about the scope in Section 1[39]. The WHO definition could still serve as starting point. Inspiration can also be sought in definitions that have already been established around the world (e.g. Australia, Germany, Nigeria, Pakistan, Philippines, United States)[40]. The Australian counterfeit definition is interesting as it is the most elaborate of all. Under Australian law, therapeutic goods are counterfeit if the label or presentation of the goods; any document or record relating to the goods or their manufacture; any advertisement for the goods, contain a false representation of a following matter: the identity or name of the goods; the formulation, composition or design specification of the goods or of any ingredient or component of them; the presence or absence of any ingredient or component of the goods; the strength or size of the goods (other than the size of any pack in which the goods are contained); the strength or size of any ingredient or component of the goods; the sponsor, source, manufacturer or place of manufacture of the goods (Therapeutic Goods Act 1989 – SECT 42E)[41]. The German definition, which is provided by way of a prohibition, could also be built upon. Germany is in fact one of the very few European countries to have appropriate legislation and related experience. Under German law it is prohibited to produce or put into circulation pharmaceutical preparations that are considerably reduced in their quality due to deviation from recognised pharmaceutical standards, or are falsely labelled regarding identity or origin, or have a misleading or deceiving denomination, statement or design. A deception is present when: a therapeutic effectiveness or effects are attributed to a pharmaceutical preparation, which it does not have; the impression is incorrectly given that a success in another way may be expected with certainty or that no detrimental effects will arise following appropriate or long-term use of the pharmaceutical preparation; with the aim of deception about the pharmaceutical preparation's quality, denominations, statements or labels are used which are significant for the assessment of the pharmaceutical preparation (German Pharmaceutical Act, *Arzneimittelgesetz (AMG)* – Article 8).

26. With regard to the adulteration and tampering of medicines and medical devices, criminal offences will also need to be formulated, rephrasing into substantive criminal law what was said in Section 1[42].

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[35] Including via the Internet. See also *supra* **7.**
[36] *Id.*
[37] *Id.*
[38] This is for example also the case in the Convention on the Protection of the Environment through Criminal Law, Strasbourg, 4 November 1998, CETS – No 172, Article 3 – Negligent offences.
[39] See *supra* **18-21.**
[40] See J. HARPER and B. GELLIE, *o.c*, 16.2 (USA, Philippines); World Health Organisation, Health Technology and Pharmaceuticals, *Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation*, 27 January 2006 (by Michelle Forzley), p. 12-13 (Nigeria, Pakistan, USA, Philippines) ; Concept Paper on the requirements of an international legal instrument or cooperation agreement on pharmaceutical crime, May 2006 (by Dietrich Schnädelbach), Annex 1 (USA, Germany, Nigeria, Australia).
[41] URL: http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s42e.html.
[42] See *supra* **21.**

27. The future Convention will need to make sure that **attempting, aiding or abetting** the commission of any of the offences established in accordance with the Convention are equally treated as criminal offences.

28. Furthermore**,** the future Convention will need to ensure that legal persons can be held liable for any of these offences, committed for their benefit by any natural person. Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative and is without prejudice to the criminal liability of the natural persons who have committed the offence. Article 12 of the Convention on Cybercrime is a good example of such a **"corporate liability"** provision.

29. Apart from incriminations, the future Convention also needs to cover **sanctions.** Each Party should adopt such legislative and other measures as may be necessary to ensure that the criminal offences established in accordance with the Convention are punishable by "effective, proportionate and dissuasive" sanctions. Apart from deprivation of liberty (for natural persons) and fines and confiscation of objects, instruments and products stemming from offences or of goods whose value correspond to those products (for natural and legal persons) the Convention could also provide for following sanctions to be made available by each Party: destruction of the goods; total or partial closure, on a permanent or temporary basis, of the establishment used primarily to commit the offence; a permanent or temporary ban on engaging in commercial activities; placing under judicial supervision; judicial winding-up; a ban on access to public assistance or subsidies; publication of judicial decisions[43]. What "effective, proportionate and dissuasive" would then imply in terms of the **level of sanctions** is difficult to state at this point. There are hardly any precedents, as proper incriminations are currently lacking in most of the 46 Council of Europe Member States. The protection of public health should in any case function as the standard in establishing sentences and fines for the offences. In this respect following circumstance is to be regarded as aggravating: the result in *significant* damage to health. Committing the offences within the framework of a criminal organisation could also be regarded as an aggravating circumstance.

Section 3. Prevention

30. The future Convention will need to call upon Parties to take appropriate measures in the fields of research, information, raising the awareness of the public (patients and healthcare professionals) and the pharmaceutical industry, with a view to **preventing counterfeit medicines/pharmaceutical crime** and the negative effects on public health. The raising of public awareness is of paramount importance with regard to the dangerous practices associated with the Internet pharmacy trade[44]. In preventing medicines and medical devices from being counterfeited, adulterated or tampered, Parties to the future Convention could also be required to encourage the adoption of practical solutions involving new technologies which enable the authentication of medicines (techno-prevention). In the same preventive sense parties could be urged to move forward in the field of control of active ingredients, packaging material and manufacturing equipment.

Section 4. Investigation, prosecution and procedural law

31. Without proper **enforcement**, any effort to harmonise substantive criminal law[45] is ineffectual. The investigation and prosecution of the criminal offences established in accordance with the future Convention will be for the Parties' police, customs and drug regulatory authorities, as well as for their judicial authorities. A Parties' obligation worth considering is the set-up of specialised units within the aforementioned authorities. A provision that could also be inserted is the obligation for Parties to provide legislation that gives adequate powers to each of the public authorities charged with enforcement. Ideally these enforcement powers (e.g. powers of entry, search and seizure under judicial warrant; judicial powers to order forfeiture and destruction of counterfeited, adulterated and tampered medicines and medical devices) would then have to undergo harmonisation as well. International cooperation is to benefit from this.

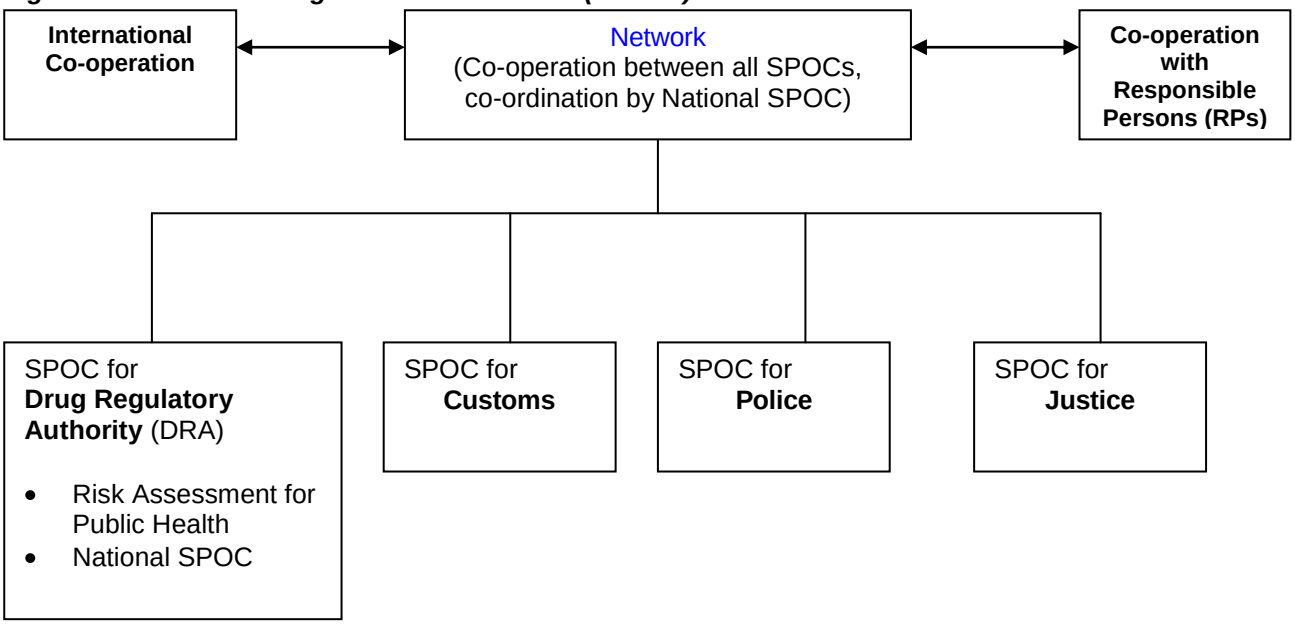
32. Pharmaceutical crime is *par excellence* international crime, i.e. without boundaries or jurisdictions. The future Convention therefore cannot do without a provision on **jurisdiction**. Its purpose is twofold: 1) To ensure that Parties use their powers to prosecute and sentence offenders (at least) for offences committed wholly or partially 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

[43] Cfr. Article 4 Council Directive Proposal on criminal measures aimed at ensuring the enforcement of intellectual property rights. COMMISSION OF THE EUROPEAN COMMUNITIES, COM (2005)276 final, Brussels, 12 July 2005, Proposal for a European Parliament and Council Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights.
[44] See also *supra* **7.**
[45] See *supra* **22-29.**

offence is within the jurisdiction of more than one Party. 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[46] could easily be complemented by more victim-related criteria (ordinary residence, nationality, origin victim; territory where the health damage occurred)[47]. Prosecutors must take into account the interests of victims (patients) and whether they would be prejudiced if any prosecution were to take place in one jurisdiction rather than another. Such consideration would include the possibility of victims claiming compensation. As part of their discussions to resolve these cases prosecutors should explore all the possibilities provided by current international conventions and instruments, for example to transfer proceedings and to centralise the prosecution in one Party.

33. The aforementioned specialised units within Parties' police, customs, drug regulatory and judicial authorities[48] could then be designated Single Points of Contact (SPOCs) within a pharmaceutical crime network, operating at both the national and the international level. This **Network of Single Points of Contacts (SPOCs)** is yet to be established and is to be given its legal basis in the future Convention. For the further implementation a complementary legal instrument under the aegis of the Council of Europe (preferably a Resolution) would be more appropriate. A model cooperation structure has already been developed and seems to be well-supported[49]. Although originally designed for counterfeit medicines, the scope could easily be extended to other forms of pharmaceutical crime. Figure 3 illustrates the model Network of Single Points of Contact (SPOCs)[50].

Figure 3: Network of Single Points of Contact (SPOCs)



34. In its national component the SPOC Network is to contribute to a better coordination and cooperation between the Parties' different sectorial authorities and between these authorities and the pharmaceutical sector stakeholders. The latter (manufacturers, wholesalers, distributors) would all have Responsible Persons (RPs), which are contacts at privates comparable to the contacts within the authorities. To allow the **national SPOC Network** to play its key-role in information, the future Convention will have to provide for

[46] See Article 8 in particular. European Convention on the Transfer of Proceedings in Criminal Matters, Strasbourg, 15 May 1972, CETS – No. 073.
[47] See T. VANDER BEKEN, G. VERMEULEN, S. STEVERLYNCK and S. THOMAES, *Finding the best place for prosecution. European study on jurisdiction criteria*, Antwerp-Apeldoorn, Maklu, 2002, 91 p.; T. VANDER BEKEN, G. VERMEULEN and O. LAGODNY, "Kriterien für die jeweils 'beste' Strafgewalt in Europa. Zur Lösung von Strafgewaltskonflikten jenseits eines transnationalen Ne-bis-in-idem", *Neue Zeitschrift für Strafrecht*, 2002, 624-628. See also COMMISSION OF THE EUROPEAN COMMUNITIES, COM (2005) 696 final, Brussels, 23 December 2005, Green Paper On Conflicts of Jurisdiction and the Principle of *ne bis in idem* in Criminal Proceedings (presented by the Commission).
[48] See *supra* **31.**
[49] See Doc. 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). Cfr. International Conference "Europe against Counterfeit Medicines", Moscow, 23-24 October 2006
[50] *Ibid.*

mandatory reporting of instances of pharmaceutical crime. It should be noted, however, that the future Convention can only impose obligations on Parties – thus States. For the pharmaceutical industry to report, the Convention can merely oblige Parties to take all appropriate measures to at least encourage the industry to report to the competent national authorities. For the competent authorities to report within and between themselves, the future Convention can only facilitate by making it an obligation to establish legislation to permit the exchange of information.

Section 5. International cooperation

35. In its international component the SPOC Network consists of the Parties' National SPOCs. It has been rightly recommended that the SPOCs of the drug regulatory authorities should also act as National SPOCs[51]. The future Convention would provide the **International SPOC Network** with a legal basis for the exchange of information. A legal basis for the routine passing of information within a multisectorial network is currently lacking. Each Party does have a mutual assistance programme and supporting legislation whereby evidence may be transferred through judicial routes[52]. Police and customs also have facilities within their own spheres. What does not exist, however, is one SPOC through which non-evidential information can be channelled on informal basis. The feeding of the National SPOCs will be crucial to the success of the International SPOC Network. As stated above, the future Convention can only facilitate by making it an obligation to establish legislation to permit the exchange of information. It should also be kept in mind that for police and judicial authorities, providing information where this would compromise ongoing investigations cannot be taken for granted.

34. The SPOC Network is ideal to house a **rapid alert system**. Care is needed to distinguish between quality defect rapid alerts, of which there are many for non-criminal reasons and those necessary for highlighting and notifying pharmaceutical crime issues, notably counterfeit medicines. The Rapid Alert System (RAS) on quality defects of authorised medicines, currently used jointly by the Pharmaceutical Inspection Convention/ Pharmaceutical Cooperation Scheme (PIC/S) and by the European Medicines Agency (EMEA), could also be used for transmitting alerts on counterfeit medicines. Experience has shown that it is difficult to use the existing alert form. It was therefore proposed to complement the existing Rapid Alert System with a new form, set-up specifically for the exchange of information on counterfeit medicines[53]. Depending on further developments in this area, an amended RAS could be given a place in the future Convention.

36. Qualifying as a criminal law treaty in the broad sense, the future Convention cannot but contain provisions on **international cooperation in criminal matters**[54]. In the context of the feasibility study it is sufficient to make reference to the Council of Europe *acquis* in this area – which is outstanding and in which drafters will be able to find inspiration. The future Convention should in any case impose a general obligation on the Parties to afford each other all possible co-operation within the limits of the (bi- and multilateral) agreements to which they have acceded and their national law. The reference made to instruments on cooperation can be formulated in a general way. It includes of course the Council of Europe Conventions on extradition[55], mutual assistance in criminal matters[56], the supervision of conditionally sentenced or conditionally released offenders[57], the international validity of criminal judgements[58], the transfer of proceedings in criminal matters[59], the transfer of sentenced persons[60], the laundering, search, seizure and confiscation of the proceeds of crime[61].

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[51] *Ibid.*
[52] See also *infra* **36.**
[53] The Committee of Experts on Pharmaceutical Questions' ad hoc Group on Counterfeit Medicines developed such a new form in 2004, which was further optimised at the EU Medicines Enforcement Officer (EMEO). See http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/pharma_and_medicine/Specific_projects.asp#TopOfPage.
[54] Regardless of the fact that e.g. the 2005 Convention on Action against Trafficking Against Human Beings does not contain specific provisions. See Council of Europe Convention on Action against Trafficking Against Human Beings, Warsaw, 16 May 2005, CETS – No 197, Chapter VI – International co-operation and co-operation with civil society.
[55] European Convention on Extradition, Paris, 13 December 1957, CETS – No 024. Additional Protocol, Strasbourg, 15 October 1975, CETS – No 086. Second Additional Protocol, 17 March 1978, CETS – No 098.
[56] European Convention on Mutual Assistance in Criminal Matters, Strasbourg, 20 March 1959, CETS – No 030. Additional Protocol, Strasbourg, 17 March 1978, CETS – No 099. Second Additional Protocol, Strasbourg, 8 November 2001, CETS – No 182.
[57] European Convention on the Supervision of Conditionally Sentenced or Conditionally Released Offenders, Strasbourg, 30 November 1964, CETS – No 051.
[58] European Convention on the International Validity of Criminal Judgements, The Hague, 28 May 1970, CETS – No 070.
[59] European Convention on the Transfer of Proceedings in Criminal Matters, The Hague, 15 May 1972, CETS – No 073.

Section 6. Monitoring mechanism

38. A final point to consider is the issue of the monitoring of the implementation of the future Council of Europe Convention. Providing for a **monitoring mechanism** in the Convention would prevent it from falling into disuse, or worse, from never being used at all. The Convention would clearly benefit from a monitoring mechanism *à la* GRECO (Group of States against corruption)[62] or GRETA (Group of experts on action against trafficking in human beings)[63]. A yet to be established committee of experts (e.g. GREPHAC – Group of experts on Pharmaceutical Crime) could perform this delicate, yet indispensable task. The Council of Europe Secretariat could also play its role.

[60] Convention on the Transfer of Sentenced Persons, Strasbourg, 21 March 1983, CETS – 112. Additional Protocol, Strasbourg, 18 December 1997, CETS – No 167.
[61] Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime, Strasbourg, 8 November 1990, CETS – No 141.
[62] GRECO evaluates through a dynamic process of peer pressure, the compliance with undertakings contained in the legal instruments of the Council of Europe to fighting against corruption. See URL: http://www.coe.int/t/dg1/Greco/Default_en.asp.
[63] See Council of Europe Convention on Action against Trafficking Against Human Beings, Warsaw, 16 May 2005, CETS – No 197, Chapter VII – Monitoring mechanism.