## <u>Targeting fake medicins – regional strike on criminal activities :</u> <u>The "MEDICRIME Convention"</u> <u>Episode or overture for the Global Era?</u><sup>1</sup>

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#### Introduction and general comments

Counterfeiting of goods and trademarks as annoying social-economic phenomenon has begun to raise the attention of the countries worldwide to locate and target faking mechanisms for one and exclusive reason: to prevent revenue damages (loss) and increasement of expenditures in the economy in line with the constant wish of achieving – or at least to keep on the borderline – the profit.

The targeted benefit of a so called well-designed and well-outfitted (sometimes typically overvalued) product simply to demonstrate the wealth, capability and ability to achieve it (them) and to display that these symbols are undisputable watermarks of the "self-made-man" career.

No doubt that millions of people really do believe that possessing even fake but branded goods might eliminate the disequality within the social environment .

Naturally, branded goods and counterfeited ones do generate significant issues on markets by all means. No doubts they are eligible to make really harsh distortions in the monetary/economic systems of the state/region not only in whole Europe accounting 47 High Contracting Parties (hereinafter: HCP)<sup>2</sup> but after all the whole World might be in danger when specific goods, pharmaceuticals and their entire environment undergoes a monumental faking mechanism.

A country's budget counts on year by year to produce economic growth, the basic accountig mechanism awaits for the planned, designed revenues (typically the taxes and fares) and the expenditures. One might assume properly that a country always targets to achieve some kind of a balance between the two premisses.

<sup>&</sup>lt;sup>1</sup> The essay was made by the Hungarioan Team for the Competition of Young Judges & prosecutors (THEMIS 2015/EJTN)

<sup>&</sup>lt;sup>2</sup>Council of Europe / Conseil de l'Europe (Strasbourg, France)

It might be a matter of doubt whether there is a strict and direct negative economic impact on the side of revenues by making fake goods in general – more talkative might be the reasoning of that looking at these negative consequences country by country.

However it seems undisputable that the field of *healthcare* has always been one of the most expensive national services worldwide. Moreover that might be manifesting more significance when the ordinary way of merchandising pharmaceuticals actually faces illegal and industrialquantity of fake medicines.

That is why counterfeiting of drugs and medicins are extremely dangerous for the nations and evenly calls for an allied enforcement against the threat.

It has already laid down that:

"..The Council of Europe has long been concerned about the absence of harmonised international legislation, non-deterrent sanctions that were not proportionate to the harm caused to patients, and the involvement of criminal organisations which operate across borders.

Counterfeiting medical products and similar crimes threaten the right to life enshrined in the European Convention on Human Rights and Fundamental Freedoms (ECHR). Incidences of counterfeit medical products and similar crimes undermine public trust in healthcare systems and authorities' surveillance thereof.

*Counterfeiting of medical products and similar crimes have a global spread, no country is spared.* 

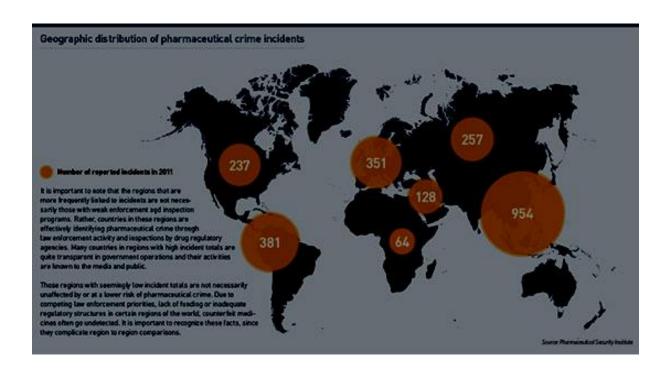
The Council of Europe sees it as a common responsibility for the global community to eradicate this phenomenon, and hence accession to the Medicrime Convention, which will be formally adopted later this year, will be open for all states interested in working with Council of Europe on this important goal.  $"^3$ 

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What are the favourites of medicine counterfeiting ? – this is the first question to be answered in order to locate the targeted field of the fight.

Useful to keep in mind that fighting counterfeiting of medicins should not cover only the item or product itself but the whole pre-industrial, experimental, hardware and software environment as well as the human power capable to take part in, focusing on the region's economy as part of the international entity, influencing it to more or less extent.

<sup>&</sup>lt;sup>3</sup> fragment of <u>http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Default\_en.asp</u> [20.03.2015.]



The method we recommend to examine the structure and the positon of faking medicines in the World it is obvious to scan those regions affected by this illegal activity on the Map<sup>4</sup>:

The measure of the faking activities seems to be in line with the number of inhabitants and the commonly known grade of development. It took only two decades to recover that a new, negatively shadowed pillar of industrial development has been erected Worldwide.

# However the very recognition of the threat generated by the faking activities on medicins has been linked only to the Council of Europe with 47 High Contracting Parties.

It is very useful and energy sparing method to bring together CoE for establishing a Convention on aiming the fight against faking medicins. As for the recent legislative developments one could observe that there has been parallel legislative actions driven by the EU Legislation ( Regulations, Directives, Framework Decisions, Decisions, Joint Actions) and the Conventional umbrella (shield) of the CoE. It is a fact the all 28 Member States of the European Union are being also High Contracting Parties of the Council of Europe at the same time (*dual membership*) therefore the implementation of the Convention into their legal architecture might be purposefully similar.

<sup>&</sup>lt;sup>4</sup>source: www.un.org

Hence we might want to make the statement that *the subject and the form of the Convention is highly eligible for the purpose of the fight against faking medicins*.

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The situation is however not so simple as it has been shown above since there are several relevant aspects to be detemined as terminologies while the targeted issue is also subject to be described as precisely as possible.

That has been apparent for the recent - at least two - decades that faking or counterfeiting medicines assume on one hand the designer/producer/commercial *"troika"* on the other hand the consumer or groups of customers (horizontal approach).

Another question is to be *capable* to describe a region's architecture from the very top of the hierarchy to the bottom of the - typically - criminal organisation (vertical approach).

The two approaches seem to be able uncovering the whole environment of the illegal activity right from all perspectives, and investigators/prosecutors on that ground may establish an almost realtime charter (organogram) of an obvious criminal organisation.

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As for exhausting all criteria it is necessary to be aware of them in order to be able to precisely describe the whole issue.

It is preconditional to establish the main point of interests as starting milestone.

#### 1. Definition

Therefore hereby we recommend to use the World Health Organization's (hereinafter: WHO) terminologies as of global nature :

"....In accordance with Black's Law Dictionary,' the term "counterfeit drug" may be used to describe a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original. In reality, however, a counterfeit drug is defined differently in different countries.

The absence of a universally accepted definition not only makes information exchange between countries very difficult but it also limits the ability to understand the true extent of the problem at global level. In order to address this problem the following definition has been developed by the World Health Organization:

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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."<sup>5</sup>

1. Enhancing factors for counterfeiters to start or to keep on acting

From the apparent lack of political will and commitment by some countries' governments through lack of eligible legislative and coercive measures (inactive jurisprudence including ineligible customs policy, weak penal sanctions too), expensiveness of medicines and even *corruption* and conflict of different interests may play the most significant role in encouraging perpetrators in committing criminal offences in this special field.

As for the latest mentioned factor worth mentioning a special case right these months in China noting a bribery case coming to endpoint: - a Chinese Court imposed almost 500 Million USD on GlaxoSmithKline Pharmaceutical giant<sup>6</sup>. This demonstrates the amounts and values having been at stake in that field.

- 2. The measures to be taken combating fake medicines by the WHO:
- enacting new drug laws or updating existing drug laws for prohibiting counterfeit medicines;
- establishing institutions for the regulation of medicines and clearly setting out in the drug laws, the power, duties and responsibilities of the institution(s);
- training of personnel, including enforcement officers, for national drug control;
- making available necessary financial and other resources;
- ensuring that the drug laws are enforced; and
- fostering international cooperation in the control of pharmaceuticals and entering into bilateral and multilateral agreements with other governments and with international organizations such as WHO, Interpol and the World Customs Organization (WCO).

As seen some of these measures are not of financial nature but more likely picks one's interest on the *willingness* of a community to fight fake medicines.

<sup>&</sup>lt;sup>5</sup>source for further too: <http://www.who.int/medicines/services/counterfeit/overview/en/>

<sup>&</sup>lt;sup>6</sup> pls.follow at: <u>http://www.reuters.com/article/2014/09/19/us-gsk-china-idUSKBN0HE0TC20140919</u> [20.03.2015.]

Taking these causes and probable appropriate measures into serious consideration WHO has developed guidelines for the purpose of the combat.

The final aim might be strongly recommended: - to establish a Global Convention on Preventing and Controlling Drug Crimes including faking medicins.

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Keeping in mind the given topic, the negative aspects of counterfeiting drugs and pharmaceuticals hereinafter we do not want to deal with an undoubtedly also very serious consequence of the phenomenon: - the apparent infringement of intellectual property law and related. However the impacts are far not out of sight.

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#### The MEDICRIME Treaty<sup>7</sup> – The Pathfinder

#### **Preliminary observations**

#### Determining the objects of the phenomenon:

It is The Council of Europe which has drawn up the first CoE Convention against counterfeiting medical products and similar crimes involving threats to public health, to establish criminal offences (by HU terms: felonies) obviously *aggreeing to the WHO's experiences and doctrines at CoE level.:* 

- the *manufacturing* of counterfeit medical products.
- *supplying, offering to supply and trafficking* in counterfeit medical products.
- the falsification of documents (package infosheets, manuals, etc.)
- the *unauthorised manufacturing or supplying of medicinal products* and the marketing of *medical devices* that do not comply with conformity requirements.

<sup>&</sup>lt;sup>7</sup>, Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health" – Moscow, 28.10.2011. at: <a href="http://conventions.coe.int/Treaty/en/Treaties/Html/211.htm">http://conventions.coe.int/Treaty/en/Treaties/Html/211.htm</a>

The Convention also lays down a framework for national and international co-operation between the competent health, police and customs authorities at both national and international level, measures for crime prevention by also involving the private sector, and the effective prosecution of crime and the protection of victims and witnesses.

Furthermore, it provides for the establishment of a committee to follow up the implementation of the Convention by the signatory states.<sup>8</sup>

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A Treaty usually as rich in essential directives as its Preamble is able to summarise the character and central topics of the issue subject to rule :

"The member States of the Council of Europe and the other signatories to this Convention,

Considering that the aim of the Council of Europe is to achieve a *greater unity between its members;* 

Noting that the counterfeiting of medical products and similar crimes by their very nature *seriously endanger public health;* 

Recalling the Action Plan adopted at the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), which recommends the development of measures to strengthen *the security of European (in 47 States) citizens*;

Bearing in mind the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly on 10 December 1948, the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5), the European Social Charter (1961, ETS No. 35), the Convention on the Elaboration of a European Pharmacopoeia (1964, ETS No. 50) and its Protocol (1989, ETS No. 134), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, ETS No. 164) and the Additional Protocols thereto (1998, ETS No. 168, 2002, ETS No.186, 2005, CETS No. 195, 2008, CETS No. 203) and the Convention on Cybercrime (2001, ETS No. 185);

Also bearing in mind the other relevant work of the Council of Europe, particularly the decisions of the Committee of Ministers and work of the Parliamentary Assembly, notably

<sup>&</sup>lt;sup>8</sup> pls.see: <http://www.edqm.eu/en/the-medicrime-convention-1470.html>

Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security, the replies adopted by the Committee of Ministers on 6 April 2005 and on 26 September 2007, concerning respectively, Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions" and 1794 (2007) on the "Quality of medicines in Europe", as well as relevant programmes conducted by the Council of Europe;

Having due regard to other relevant international legal instruments and programmes, conducted notably by the World Health Organisation, in particular the work of the group IMPACT, and by the European Union, as well as in the forum of the G8;

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health, by introducing notably new offences and penal sanctions relative to these offences;

Considering that the purpose of this Convention is to prevent and combat threats to public health, giving effect to the provisions of the Convention concerning substantive criminal law should be carried out taking into account its purpose and the principle of proportionality;

Considering that this Convention does not seek to address issues concerning intellectual property rights;

Taking into account the need to prepare a comprehensive international instrument which is centred on the aspects linked to prevention, protection of victims and criminal law in combating all forms of counterfeiting of medical products and similar crimes involving threats to public health, and which sets up a specific follow-up mechanism;

Recognising that, to efficiently combat the global threat posed by the counterfeiting of medical products and similar crimes, close international co-operation between Council of Europe member States and non-member States alike should be encouraged,. ....<sup>"9</sup>

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It is quite clear that the Preamble diligently defines the basic features of the targeted object and displays the main stations in the negotiative process in Global and European (i.e.: the 47 HCP of the Council of Europe) term as well.

<sup>&</sup>lt;sup>9</sup> pls.find at: <http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm>

Focusing on the prerequisits the following Articles mainly stipulate and regulate some very important terms and descriptions for the purpose of crossborder applicability in the first Chapter such as:

#### "Article 1 – Object and purpose

1 The purpose of this Convention is to prevent and combat threats to public health by:

a providing for the criminalisation of certain acts;

b protecting the rights of victims of the offences established under this Convention;

c promoting national and international co-operation.

2 In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

#### Article 2 – Principle of non-discrimination

The implementation of the provisions of this Convention by the Parties, in particular the enjoyment of measures to protect the rights of victims, shall be secured without discrimination on any ground such as sex, race, colour, language, age, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

#### Article 3 – Scope

This Convention concerns medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

#### Article 4 – Definitions

For the purposes of this Convention:

a the term "medical product" shall mean medicinal products and medical devices;

b the term "medicinal product" shall mean medicines for human and *veterinary* (!) use, which may be:

i any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;

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

iii an investigational medicinal product;

c the term "active substance" shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product;

d the term "excipient" shall mean any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product;

e the term "medical device" shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

i diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii investigation, replacement or modification of the anatomy or of a physiological process;

iv control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

f the term "accessory" shall mean an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device;

g the terms "parts" and "materials" shall mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof;

h the term "document" shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof;

i the term "manufacturing" shall mean:

i as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

ii as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

iii as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state;

j **the term "counterfeit"** shall mean a false representation as regards identity and/or source;

k **the term "victim"** shall mean any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8."

For us prosecutors and judges what else should be more likely interesting than the Chapter II. wherein the Treaty rules the very Substantive Criminal Law standards to be applied by the High Contracting Parties (*with regard to the quantitative limits of the essay: enlisting only*).

Hereby we give the essential explanations by our own with the intention to simplify but on the basis of the Convention:

Article 5 – Manufacturing of counterfeits

The widest methods, tools and institutions used in order to achieve the product itself

Article 6 – Supplying, offering to supply, and trafficking in counterfeits

By ads on the Internet<sup>10</sup> or solely spreading charming informations about the product falsified

Article 7 – Falsification of documents

",Scripta manent" – needless to say that a manual or a factsheet might transfer the sense of being insured by the manufacturer

Article 8 – Similar crimes involving threats to public health

Depending on the legacy of the national substantive law criteria

Article 9 – Aiding or abetting and attempt

General dogmatic terms

Article 10 – Jurisdiction

Paying curious regard on the avoidance of the collision of jurisdictions between the EU Member States<sup>11</sup>

Article 11 – Corporate liability

Must be given on National ground

Article 12 – Sanctions and measures

Effective, proportionate mostly pecuniar sentences even at non-criminised level

<sup>&</sup>lt;sup>10</sup> the Internet is widely mentioned to be the carrier of the vicious activities borderless and uncensorized – here comes the issue of covert investigations and gathering covert data

<sup>&</sup>lt;sup>11</sup> pls.see: 2009/948/JHA Framework Decision

#### Article 13 – Aggravating circumstances

Death, dagame, break of confidence by the abuse, criminal organisation,

recidivism

Also bearing in mind that Substantive Law regulations might only be applied within exactly assigned rules of Criminal Procedure, the Treaty dedicates a whole Chapter for ruling that as well as for the measures to be taken by the Contracting Parties in the field of *cooperation between them on the ground of mutual trust and confidence, appointed contact persons of data exchange* – giving the autonomy to the States to apply their own procedural rules concerning gathering secret informations and data too (intelligence questions).

The detailed regulation was highlighted-likely taken by the Convention due to the nature of the targeted phenomena which obviously encounters the fact that this criminal activity is almost exclusively linked to serious crossborder criminality, especially leading to the financing of terrorism and establishing / participating in criminal organisations.

The following Chapters' scope covers the fine-tuned ruling for the protection of victims, their legal standing in the procedures. These are extremely sensitive questions nowadays not only CoE - but EU-wide too:

- must be well informed,
- supported
- put in the widest safety (family and environment too)

A Treaty's effectiveness is always being monitored by the fast implementation into the Contracting Parties' Legal Architecture.

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Tracking the informations we can see talkative numbers and the tendency of the real willingness from the Parties to transpose the Treaty's regulations into the legal practice as fast as possible:

### Council of Euro Convention on the counterfeiting of medical products and similar crimes involving threats to public healtl CETS No.: 211

Special conditions of opening for signature

Opening for signature	Entry into force
Place: Moscow Date : 28/10/2011	Conditions: 5 Ratifications including at least
	3 member States of the Council of Europe
	Date : //

Status as of: 18/11/2014

Member States of the Council of Europe

	Signature	Ratification	Entry into force	Notes	R.	D.	A.	Т.	C.	0.
Albania										
Andorra										
Armenia	20/9/2012									
Austria	28/10/2011									
Azerbaijan										
Belgium	24/7/2012									
Bosnia and Herzegovina										
Bulgaria										
Croatia										
Cyprus	28/10/2011									
Czech Republic										
Denmark	12/1/2012									
Estonia										
Finland	28/10/2011									
France	28/10/2011									
Georgia										
Germany	28/10/2011									

Greece							
Hungary	26/9/2013	13/12/2013	13/12/2013 12	x			
Iceland	28/10/2011						
Ireland							
Italy	28/10/2011						
Latvia							
Liechtenstein	4/11/2011						
Lithuania							
Luxembourg	22/12/2011						
Malta							
Moldova	20/9/2012	14/8/2014					
Monaco							
Montenegro							
Netherlands							
Norway							
Poland							
Portugal	28/10/2011						
Romania							
Russia	28/10/2011						
San Marino							
Serbia							
Slovakia							
Slovenia							
Spain	8/10/2012	5/8/2013			Х		
Sweden							

<sup>&</sup>lt;sup>12</sup> implemented *a priori*; setting the comformity by the Act No.100 from 2012. (entry into force: 01.07.2013) on the New Penal Code of Hungary in form of establishing a new legal fact of criminal offence Art. 186. : "Faking Medical Product". Demonstrates that HU has always been ready to stand by the requirements of the Rule of Law & Law and Order (as usual and in comformity with the Copenhagen Criteria)

Switzerland	28/10/2011					
The former Yugoslav Republic of Macedonia						
Turkey	29/6/2012					
Ukraine	28/10/2011	20/8/2012				
United Kingdom						

Non-members of the Council of Europe

	Signature	Ratification	Entry into force	Notes	R.	D.	A.	т.	C.	0.
Belarus										
Canada										
Guinea	10/10/2012									
Holy See										
Israel	28/10/2011									
Japan										
Mexico										
Morocco	13/12/2012									
United States of America										

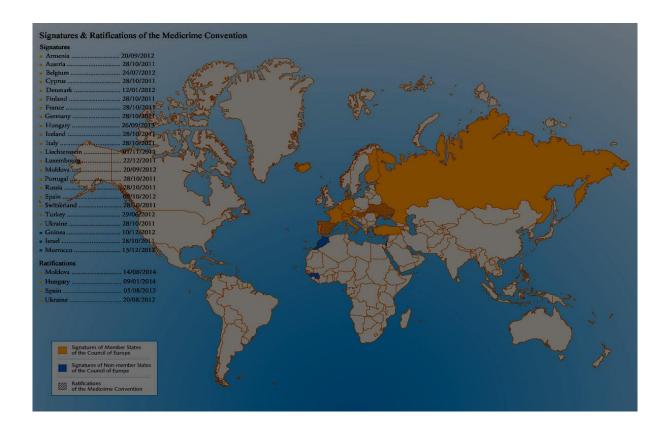
## International Organisations

	Signature	Ratification	Entry into force	Notes	R.	D.	A.	т.	C.	0.
European Union										

Total number of signatures not followed by ratifications:					
Total number of ratifications/accessions: (Moldova, Hungary, Spain, Ukraine)	4				

#### Notes:

a: Accession - s: Signature without reservation as to ratification - su: Succession - r: Signature "ad referendum". R.: Reservations - D.: Declarations - A.: Authorities - T.: Territorial Application - C.: Communication - O.: Objection.<sup>13</sup>



One must take into account that at least five HCPs of the CoE must ratify the Convention in order to take a mandatory effect (*erga omnes*).

As for the preliminary implementation of The Convention into the Hungarian national legal architecture we recommend to see all below:

The New Penal Code of Hungary was announced by the Act No.100 from 2012.

<sup>&</sup>lt;sup>13</sup><http://www.conventions.coe.int/Treaty/Commun/print/ChercheSig.asp?NT=211&CM=8&DF=20/0 9/2014&CL=ENG>

To bring legal facts (*crimen de lege lata*) in comformity with the Convention the next disposition was created:

#### " Falsification of Health Care Products

Section 186

(1) Any person who:

a) falsifies health care products or produces falsified health care products;

*b)* supplies, offers, places on the market or deals with false or falsified health care products, or health care products which have not been authorized in Hungary;

*c)* imports or exports, or transports in transit through the territory of Hungary false or falsified health care products, or acquires and/or possesses such in unreasonable quantities;

*d*) acquires and/or possesses health care products which have not been authorized in Hungary in unreasonable quantities, or imports or exports, or transports in transit through the territory of Hungary such products;

*e)* uses an original document related to health care products for commercial purposes for reasons other than for which such document was intended;

is guilty of a felony punishable by imprisonment not exceeding three years.

(2) The penalty in the cases provided for in Paragraphs *a*) and *b*) of Subsection (1) shall be:

*a)* imprisonment between **one to five years** if the criminal offense results in permanent disability or serious health impairment;

b) imprisonment between two to eight years if the criminal offense results in death.

(3) Any person who commits the criminal offense defined in Subsection (1):

a) as a healthcare employee;

b) as an employee of an authorized manufacturer, wholesaler or public supplier; or

c) in criminal association with accomplices;

is punishable by imprisonment between **one to five** years.

(4) The penalty under Subsection (3) shall be imposed if false or falsified health care products, or health care products which have not been authorized in Hungary are widely distributed to users.

(5) For the purposes of this Section:

*a)* 'health care product' shall mean medicinal products, veterinary medicinal products, medical devices, in vitro diagnostic medical devices, and investigational medicinal products;

*b)* 'unreasonable quantity' shall mean any quantity that goes beyond what is considered to serve the personal needs of a specific person;

c) 'health care product not authorized in Hungary' shall *inter alia* mean medical devices placed on the market without a conformity evaluation test, and any product in which active ingredients are used in violation of the statutory provisions on the composition of a given product. Authorized health care product shall *inter alia* cover any medicinal product which does not have a marketing authorization in Hungary, in connection with which the conduct defined in Paragraph *b*) or *d*) of Subsection (1) is carried out, where this is subject to authorization or notification in accordance with the relevant legislation.

III.

#### Summary and recommendation:

The MEDICRIME Treaty is an exceptionally good example of reacting by the community of civilised nations on new phenoma appearing as novice in the list of issues to be solved.

Regarding the purposefully determined apparent common will of CoE to establish new institutions in the fight against counterfeiting of drugs and medicins, the MEDICRIME Convention seems to be an eligible tool for achieving that.

European Nations must sign and ratify the Convention in the name of cooperation in criminal matters in line with EU's similar, complementary instruments<sup>14</sup> finally to come together in the fight against counterfeiting mechanisms leading to financing terrorism through organised crime.

Budapest, 20.03.2015.

The Hungarian Team

<sup>&</sup>lt;sup>14</sup> freezing, confiscation, EAW, EEW, EIO etc.