International measures to combat counterfeit medicines and protect public health

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1. Introduction
Threats to patient safety related to the spread of counterfeit medicines have reached global proportions and represent a major public health challenge.

Fake drugs are not equivalent in quality, safety and efficacy to their genuine counterparts; they thus raise serious public health concerns as they can result in therapeutic failures, adverse side effects (like allergic reactions, drug resistance, intoxication) and even death. Both patent-protected and generic medicines, as well as the active substances and excipients of which they are made, have increasingly been targeted by counterfeiters. The situation is likely to worsen as counterfeit...
techniques are becoming more sophisticated (e.g. addition of cheaper substances that mimic genuine drugs in order to bypass standard laboratory, or copying of holograms on drug packaging with increasing accuracy), making fake products hard to identify and more difficult to combat. Actually, the increasing difficulty to detect counterfeit medicines without carrying out costly laboratory tests means that there is a persistent and hidden risk that these products may enter into the legal supply chain and engender potentially disastrous effects on public health.

According to the World Health Organization (WHO), many factors of varying importance contribute to creating an environment in which manufacture of, and trade in, counterfeit medical products can thrive: governments’ unwillingness to recognize the existence or gravity of the problem; inadequate legal framework and penalties; weak administration and coordination, with measures not focused on fighting counterfeiting; ineffective control of manufacturing, import and distribution of medical products; ineffective collaboration among bodies and institutions, such as health authorities, police, customs and the judiciary, involved in regulation, control, investigation and prosecution; ineffective collaboration and exchange of information between public and private sector; insufficient international collaboration and exchange of information.\(^2\)

However, some peculiar characteristics of drug counterfeiting make the phenomenon particularly alarming.

First, the magnitude of the problem and the difficulty to assess its real scale. Counterfeit medicines have been reported to occur worldwide and no country can really consider itself immune from the risk that falsified medicine may reach patients and consumers. The actual extent of the problem varies from country to country and, as said before, depends on a variety of factors: while the incidence is very low (less than 1% of market value) in developed countries,\(^3\) the phenomenon especially affects antiretroviral drugs and medicines to fight life-threatening diseases such as malaria and tuberculosis. See UNODC, *The Illicit Trafficking of Counterfeit Goods and Transnational Organized Crime*, available at <http://www.unodc.org/counterfeit/>.


developing countries (up to 30% of the medicines on sale),\textsuperscript{4} where drug regulatory systems and legislation are absent or ineffective,\textsuperscript{5} smuggling of medicines is rampant, clandestine manufacturing exists, sanctions and enforcement are very weak, and there is high corruption.

Second, the close relationship between drug counterfeiting, organised criminality and new forms of cybercrime. Trade in counterfeit medicines represents a multi-billion euro business for transnational criminal groups, who find it attractive because very high profits are associated with a low risk of interception and prosecution and relatively mild penalties. Moreover, the illicit trafficking of counterfeit pharmaceuticals offers criminals a complementary source of income and a way through which they can launder money and finance other illegal activities. Last but not least, using the Internet to advertise and supply their inherently dangerous products directly to patients and consumers around the world has proven to be a safe and easy \textit{modus operandi} for the criminals involved and has given them a global reach since they have found an emerging marketplace that allows them to take advantage of the almost unlimited possibilities offered by cyberspace.

Third, the globalisation of the pharmaceutical market and the absence of harmonised regulation and control. Increasing international trade of medicinal products, based on global trade arrangements, free trade agreements and deregulation measures, sets a scene which multiplies the opportunities for criminals to place fake medicines on the international market. This occurs in particular when countries do not control export medicines to the same standard as those produced for domestic use, or when medicines are traded through free-trade zones or free ports, where control is lax or absent. As said before, also the circulation of medicines through unregulated channels, especially unauthorised Internet pharmacies (or e-pharmacies), has facilitated the entry of unsafe products into the distribution channels.


\textsuperscript{5} According to the WHO, only about 20\% of its Member States are known to have well developed drug regulation; about 50\% implement drug regulation at varying levels of development and operational capacity and the remaining 30\% either have no drug regulation in place or a very limited capacity that hardly functions.
Faced with the complexity and seriousness of this phenomenon, its rising trend, and the difficulty to uncover and investigate underworld criminal activities, the international community has called for a stronger and more efficient response. This paper will explore some of the most crucial aspects of this problem and the relevant measures of prevention and contrast devised by the leading international organisations involved in the fight against counterfeit drugs. Its aim is to review the state of the art of the relevant legal framework and to highlight ongoing problems and shortcomings in the present international regime.

2. A Complex and Multifaceted Phenomenon Raising Complex Legal Issues
Counterfeiting of pharmaceuticals is a complex and multifaceted phenomenon involving a variety of aspects that would each deserve thorough attention.

Among the many legal issues that arise in this context, three can be sorted out as the most critical: the absence of a standard definition of counterfeit medicines, the lack of regulation of e-pharmacies at global level, and the lack of criminalisation of pharmaceutical offences in most jurisdictions, coupled with the need for enhanced inter-State cooperation in repressive activities.

a. The definition of counterfeit medicines
Counterfeit medicines are defined differently in different countries and regions of the world and there is still no standard definition at both the national and the international levels.⁶

A comparative study directed by the WHO shows that States either have no legal definition of “counterfeit medicine” in their legislation or use this term exclusively to describe intellectual property/trademark violations.⁷ Also at the international level, the terms used by international organisations (counterfeit/falsified/fraudulent) are sometimes intended to be interchangeable, to designate the same problem or some of its partly overlapping elements, while in other circumstances they are only

partially coincident, either pointing to the element of intellectual property rights (IPR) violations or to the criminal element of intentional fraud.

The absence of a universally accepted definition makes information exchange between countries very difficult, limits the ability to understand the true extent of the problem at global level, and hinders the development of global strategies of contrast. In order to address this problem, the WHO Secretariat elaborated the following definition in 1992 together with the International Federation of Pharmaceutical Manufacturers and Associations: “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.” According to this definition, the meaning associated with “counterfeit medicines" incorporates various cases ranging from adulteration of the product with respect to its components (inactive and ineffective preparations containing no active ingredients; medicines containing wrong dosages of active ingredients, or different active ingredients, or contaminated or harmful toxic substances instead of the required active ingredients) to the tampering of its packaging and labelling (including products being initially genuine, that is to say products containing the correct quantities of active ingredients, but whose packaging has been modified in order to declare a higher level of active ingredients, a later expiration date, the wrong name of manufacturer and/or country of manufacture).

In consideration of this variety of meanings, the WHO has started adopting the term “SSFFC medicines” – where the acronym stands for substandard/spurious/falsely-labelled/falsified/counterfeit – which reflects the different aspects of drug counterfeiting and also the various terms employed in different regions of the world. For example, the term “spurious” is employed in South Asia for products falsely labelled or intended to deceive, while “falsified” is more used in European terminology.

It should also be noted that this acronym includes “substandard medicines”, albeit their posing a different problem. In fact, they are pharmaceutical products that
fail to meet either their quality standards and specifications, or both. They may arise due to the application of poor manufacturing practices or due to the storage and distribution of the product under improper conditions leading to deterioration of its good quality. These medicines can themselves be considered as SFFC when a legitimate manufacturer gets involved in a criminal activity and produces a substandard product intentionally or deliberately.

The difficulty to reach a consensus on this topic was recently illustrated by the decision of the World Health Assembly, adopted in May 2012, to establish that the newly adopted Member State Mechanism on SSFFC medical products would employ the term “SSFFC medical products” “until a definition has been endorsed by the governing bodies of WHO” and to entrust it with the task of “further develop[ing] definitions of ‘substandard/spurious/falsely-labelled/falsified/counterfeit medical products’ that focus on the protection of public health”.

As anticipated above, the problem is wider than the WHO context, since other international organisations have made different choices. For example, the European Union employs the term “falsified” to mean a false representation of the identity (including its packaging and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients), source (including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder), or history (including the records and documents relating to the distribution channels used) of a medical product, while excluding unintentional quality defects and IPR infringements. The Council of Europe employs the term “counterfeit” to mean a false representation as regards identity and/or source and declares that

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9 45th WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2010. The Expert Committee made it clear that “each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing.”

10 See infra paragraph 3.a.


focus is on public health threats. The United Nations Office on Drugs and Crime employs the term “fraudulent” as equivalent to “falsified”, to stress the intentional fraud element with the exclusion of intellectual property issues.

In such a context, clarity on definitions seems ever more essential to devise appropriate strategies aimed at preventing and responding to public health hazards caused by counterfeit drugs. In this respect, it is crucial to aptly distinguish between public health concerns and trademark concerns, so that the global health issues raised by this phenomenon are not clouded by prevailing considerations of economic or other nature. It follows that in order to avoid conflation of trade or intellectual property problems and public health needs, it is compelling to adopt a standardised definition of “counterfeit medicines” and to focus both on the distinction of cases of IPR violations (technically “counterfeits”) from other cases (“falsified” medicines) and on the regimes applicable to branded and generic medicines. These issues should be addressed from both the domestic and international law perspectives. Such an approach would greatly help national law-makers in adopting anti-counterfeiting legislation targeted at public health protection and based on a clear distinction between IPR violations, falsified medicines, unintentional violations of quality/safety requirements, and legitimate generics.

b. The regulation of e-pharmacies

Due to the global spread of e-commerce, online pharmacies have appeared with increasing frequency and nowadays the Internet plays a significant role in the worldwide diffusion of counterfeit medical products. In recent years counterfeiters have been exploiting the web as an important unregulated channel to offer counterfeit medicines both at the wholesale and at the retail level, often creating an independent distribution process which directly targets distributors and final users.

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13 See Article 4 of MEDICRIME Convention, cited infra note 40. Paragraph 38 of the Explanatory report to the Convention states that “Though the terms ‘counterfeit’ and ‘counterfeiting’ are also used in a more narrow sense in the field of protection of intellectual property rights, the ad hoc committee decided to use these terms for the purposes of this Convention in the sense in which they are widely understood and used, i.e. corresponding to ‘false’ and ‘manufacturing a false product and passing it off as genuine’.”

14 See preamble to Resolution 20/6, cited infra note 19.
As said before, the illegal sale of counterfeit and falsified medicines to the public via unauthorised e-pharmacies represents one of the major public health hazards. In fact, according to the WHO, in over 50% of cases, medicines purchased over the Internet have been found to be counterfeit.\footnote{WHO, Medicines: spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines, Fact sheet Nº 275, May 2012.}

Various types of illegal online pharmacies exist, basically including rogue and fake e-pharmacies. Rogue e-pharmacies are those that do not adhere to accepted standards of medicine and/or pharmacy practice, including standards of safety, and those that engage in fraudulent and deceptive business practices. On the other side, through fake e-pharmacies cyber criminals do not really sell medicines, but only use them as baits to defraud online buyers, as in the case of identity theft and credit card cloning. Both types of deceptive e-pharmacies – rogue and fake ones – are often efficiently promoted by spam messages.

The major problem is that people who are attracted by the easy availability of cheaper, stigmatised or unauthorized treatments are largely unaware of the dangers of purchasing drugs from these pharmacies. It would be very important, building on statistical data or through direct surveys, to identify the categories of patients and consumers most exposed to falsified medicines (e.g. lower and disadvantaged classes, poorly educated people, people suffering from diseases considered as taboos, like problems affecting the psychological or sexual sphere), to assess which are the major driving motives pushing people to prefer purchase from e-pharmacies (e.g. anonymity, cheap prices, the need for specific drugs such as antidepressants, anorectics, illegal doping substances), and evaluate economic-related factors (e.g. people seek medicines that are sold more cheaply because paying for medicines can consume a significant proportion of individual or family income or people live in poor or developing areas where supplies of medicines at regular health facilities do not meet demand). Lacking a global regulation of e-pharmacies, this comprehensive socio-economic approach would be fundamental for better understanding the overall complexity of the phenomenon and for the preparation of targeted awareness-raising, information and prevention campaigns, especially directed to the most vulnerable groups of patients.
and consumers. In such a way, prevention initiatives would partially respond to the challenges posed by the increasing recourse to this unregulated and dangerous channel of distribution.

c. Criminalisation and international cooperation

As said before, trade in counterfeit medicines attracts organised criminal groups who create complex distribution channels characterised by a high level of organisation, an equally high degree of specialisation, labour exploitation, corruption, and the ability to use any possibility provided by technology. Moreover, the reason for the strong growth of this type of crime is the relatively low risk of detection and prosecution compared with the potential high financial gains (trafficking in fake pharmaceuticals is in fact estimated to be even more profitable and less risky than trafficking in narcotic drugs).

As with other forms of crime, criminal groups use to their advantage gaps in legal and regulatory frameworks, weaknesses in capacity and the lack of resources of regulatory, enforcement and criminal justice officials, as well as difficulties in international cooperation. There is accordingly an urgent need to take decisive repressive and preventive measures at both the national and international levels in order to protect the lives of individual patients and consumers and public health in general.

The first problem to address is the fact that, although fake medicinal products are always illegal, many countries lack an appropriate deterrent legislation or have never enacted a special legislation outlawing counterfeiting or the unauthorised manufacturing and supply of medicinal products, or the placing on the market of medical devices that are not in compliance with conformity requirements. In some jurisdictions, where these practices are considered as crimes, it occurs that penalties are too mild as compared to the severity of the action. To make things worst, the absence, until recently (that is to say until the adoption of the MEDI-CRIME Convention\(^\text{16}\)), of a dedicated international legal instrument establishing these activities as criminal offences (specifically aggravated when realised within an organized crime context), and providing the basis for efficient international co-operation to combat them, has facilitated the cross-border operation of criminals in this field.

\(^{16}\text{See infra paragraph 3.c.}\)
It is indeed the transnational dimension of the problem that calls for an intense international cooperation between police and judicial authorities, with special focus on investigation and prosecution of the activities carried out by criminal organisations in the field of manufacturing, distributing and selling counterfeit and falsified medicines, including distribution via the Internet. At present, two legal instruments are relevant for cooperation purposes at the European and global levels. The first is the Framework decision on the European arrest warrant, which establishes at article 2.2 that a number of offences – including participation in a criminal organisation, fraud, counterfeiting and piracy of products, computer-related crime – may give rise to surrender pursuant to a European arrest warrant without verification of the double criminality of the act, provided that they are punishable in the issuing Member State by a custodial sentence or a detention order for a maximum period of at least three years.\(^{17}\) The second is the Palermo Convention against transnational organized crime,\(^{18}\) the main international instrument in the fight against organised criminality of global reach. As highlighted by the UN Commission on Crime Prevention and Criminal Justice and by the Economic and Social Council, the Convention could be of great utility in re-enforcing international cooperation in the fight against trafficking in falsified medicines through its provisions on mutual legal assistance, extradition and the seizing, freezing and forfeiture of the instrumentalities and proceeds of crime.\(^{19}\)

Finally, given the peculiar role that the Internet plays in pharmaceutical crimes, a third treaty should be applied as a complementary tool to the other relevant conventions, namely the Council of Europe Cybercrime Convention.\(^{20}\)


\(^{19}\) CCPCJ, Resolution 20/6, Countering fraudulent medicines, in particular their trafficking, of 15 April 2011; ECOSOC, Resolution 2012/19, Strengthening international cooperation in combating transnational organized crime in all its forms and manifestations, of 26 July 2012.

3. The International Legal Framework and the Measures Adopted at Global and European Level

Several important international players are currently active in combating counterfeit medical products and similar crimes, namely the WHO, who leads the global efforts in this field, the World Intellectual Property Organization, the European Union, the Council of Europe, and the United Nations, especially through the UN Interregional Crime and Justice Research Institute and UN Office on Drugs and Crime. Although each of these organisations has offered an important contribution through operative and normative activities, this paragraph will focus on the initiatives taken by the WHO, the European Union and the Council of Europe aimed at protecting public health rather than countering IPR violations.

a. The global action taken by the WHO

The WHO started addressing the threat posed by counterfeit medical products in some resolutions adopted by its Assembly in the Eighties and Nineties. These resolutions requested the Director-General to initiate programmes for the prevention and detection of the export, import and smuggling of falsely-labelled, counterfeited or substandard pharmaceutical preparations and to support Member States in their efforts to combat the manufacture, trade and use of counterfeit medical products. In response to such requests, the Secretariat organised international consultations, intensified collaboration with Member States and other organisations, and issued guidelines for the development of measures of contrast.

In light of the further developments and changes occurred in counterfeiting practices, in 2006 the WHO launched the first global initiative, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a partnership comprised of all the major players in the fight against fake medicines, including drug and regulatory authorities, inter-

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21 See at <http://counterfeiting.unicri.it/>.
24 WHO, Resolutions WHA41.16 of 13 May 1988 and WHA47.13 of 12 May 1994 on the rational use of drugs, and resolution WHA52.19 of 24 May 1999 on the revised drug strategy.
national organisations, non-governmental organisations, enforcement agencies, pharmaceutical manufacturers associations, health professionals and patients’ groups.

Based on the principles enshrined in the Declaration of Rome of 18 February 2006, the Taskforce aims to coordinate action across and between countries in order to halt the production, movement and commerce – both between traders and with consumers – of counterfeit medical products around the globe. It has identified five areas where action is needed in order to combat counterfeit medical products effectively: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology, and communication.

Accordingly, IMPACT has developed the “Principles and elements for national legislation against counterfeit medical products”, covering administrative, civil and criminal aspects, which aim to assist Member States in establishing, complementing or updating national and regional legislation or regulation regarding counterfeit medical products. It has also developed recommendations for strengthening WHO’s Good Distribution Practices, and has submitted them for consideration and appropriate action to WHO’s Expert Committee on Specifications for Pharmaceutical Preparations. IMPACT has also drawn up a communication strategy for creating awareness of the risks created by counterfeit medical products in the supply systems, supporting policy objectives and increasing commitment of those who can influence change. Model materials have been prepared to create awareness among, and foster cooperation of, health professionals.

In 2010 the World Health Assembly asked WHO to convene a time-limited and results oriented intergovernmental working group (the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products) which examined, from a public health perspective, WHO’s role in measures to ensure the availability of quality, safe, efficacious and affordable medical products.

26 Available at <http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf>. The principles were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007.
and WHO’s role in the prevention and control of medical products of compromised quality, safety and efficacy such as SSFFC medical products, excluding trade and intellectual property considerations.

In 2012 the World Health Assembly discussed the outcome of the Working Group meetings and adopted a resolution creating a new Member State Mechanism on SSFFC medical products. The main objectives of the Mechanism include: to identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SSFFC medical products in order to strengthen national and regional capacities; to exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels; to strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries; to collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products; to facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective; to promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products; to further develop definitions of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” that focus on the protection of public health.

IMPACT and the Mechanism on SSFFC medical products confirm WHO’s leading role as global actor in the fight against drug counterfeiting, especially through legal and technical assistance to States and coordination of efforts. Nonetheless, the Organisation’s lack of binding


29 While the Member States Mechanism will be reviewed in 2017, reports of both the Mechanism and the Working Group are regularly transmitted for examination by the World Health Assembly and the Executive Board, the latest being the report submitted by the Secretary-General during the May 2015 session. See Doc. A68/33, 20 March 2015, available at <http://apps.who.int/gb/e/e_wha68.html>.

regulatory and enforcement powers in this field represents a remarkable limit to the efficacy of its action.

b. The legislative measures adopted by the European Union

Directive 2011/62/UE is particularly relevant because it amends Directive 2001/83/EC in order to institute a Union-wide code on medicines for human use aimed at preventing the introduction of falsified medicinal products into the chain of legal procurement, by making the distribution circuit more secure, particularly on the Internet. It introduces the first definition of “falsified medicines” in EU law and clearly distinguishes between illegal falsified medicinal products and licit medicine containing unintentional defects of quality attributable to errors of manufacturing or distribution. The definition provided by the Directive is released from intellectual property issues in order to focus on public health hazards.

To protect and improve public health, the Directive introduces tougher rules with new harmonised, pan-European measures, to ensure that medicines are safe and that the trade in medicines is rigorously controlled. To this end, the new measures include an obligatory authenticity feature on the outer packaging of the medicines; a common, EU-wide logo to identify legal online pharmacies; stricter controls and inspections of producers of active pharmaceutical ingredients comply with good manufacturing practice; and strengthened record-keeping requirements for wholesale distributors.

The Directive also addresses the issue of quality and safety of medicines introduced into the Union and that of active substances. On the one hand, it places on Member States the obligation to take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are not intended to be placed on the market of the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified. On the other, it places an obligation on Member States to take appropriate measures to ensure that manufacturers of active substances on their territory comply with good manufacturing practices and that active substances are imported if, inter alia, the active substances are accompanied by a written confirmation from the competent authority of the exporting third country which confirms that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union.

The most interesting provisions of this Directive concern the regulation of e-pharmacies. The Directive introduces a “common logo” for websites of legally-operating online pharmacies/retailers. This logo has
to be clearly displayed on every page of the website offering the medicinal products and must be recognisable throughout the Union, while enabling the identification of the Member State where the online pharmacy/retailer is established.

On 24 June 2014 the Commission adopted the Implementing Regulation No. 699/2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity. According to the Regulation, the verification of the authenticity of the common logo is done via a hyperlink between the website of the person authorised or entitled to supply medicinal products at a distance and the website hosting the national list. These hyperlinks must be fixed and reciprocal, permanent and secured. The logo can be trusted only if a purchaser, after clicking, is redirected to the entry of that pharmacy on the list of legally operating on-line pharmacies and retailers registered in that Member State on the national authority web-page.

The introduction of this common logo is an important preventive measure to guarantee that patients and consumers only buy from legally operating pharmacies or retailers and hence to guarantee the safety of the products. It provides an interesting model which could be usefully “exported” and applied as a global pattern of e-pharmacies regulation.

c. The Council of Europe MEDICRIME Convention

Moving to the Council of Europe, it has to be noted that the Organisation has long been involved in finding adequate answers to the serious problems posed by the counterfeiting of medical products and other threats to public health, in particular through the work of the European Directorate for the Quality of Medicines and Healthcare, but
also through decisions and recommendations of both the Committee of Ministers and the Parliamentary Assembly.\textsuperscript{39}

In 2007 the Committee of Ministers decided to set up a Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) to be entrusted with the task of drafting an \textit{ad hoc} international legal instrument. Following the adoption of a draft Convention by the PC-S-CP, negotiations were launched in the \textit{ad hoc} Committee on Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (PC-ISP) with the participation of all member states and observers of the Council of Europe. The PC-ISP made a series of amendments to the draft Convention prepared by the PC-S-CP, notably with regard to the provisions on substantive criminal law, and at its last meeting adopted a draft text, which was finalised by the European Committee on Crime Problems (CDPC) and finally adopted by the Committee of Ministers on 8 December 2010.

The Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention),\textsuperscript{40} is the first international treaty against counterfeit medical products. The focus of the Convention is on the protection of public health, while the protection of IPR does not fall within its scope.


\textsuperscript{40} Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention), CETS No. 211, Moscow, 28 October 2011 (not yet in force). As of May 2015, it has been signed by 19 countries and ratified only by four: Ukraine, Spain, Hungary, Moldova. On 5 January 2015 the Council of Ministers of France authorised the ratification of the Convention and on 13 February 2015 the Council of Ministers of Belgium approved a draft legislation assenting to the Convention. It is open for signature also by the European Union and the non-member States which have participated in its elaboration or enjoy observer status with the Council of Europe.
The Convention adopts a very broad definition of counterfeit and of medical products, covering medicines for both human and veterinary use, active substances, excipients, medical devices with their components and accessories, and medication used in clinical trials, irrespective of their status under intellectual property law, which means that generic medical products are also included under the scope of the Convention.\(^{41}\)

The MEDICRIME Convention imposes on States Parties the obligation to criminalise the following offences, when committed intentionally: the manufacturing of counterfeit medical products; supplying, offering to supply and trafficking in counterfeit medical products (which also covers the acts of procuring, selling or offering for free as well as brokering and promoting including through advertising these products); the falsification of documents; similar crimes threatening public health, such as the unauthorised manufacturing or supplying of medicinal products (for example sprawling black market for medicinal products for hormonal treatment produced both legally and without authorisation as means of doping for sports persons and others) and the placing on the market of medical devices which do not comply with conformity requirements. This obligation aims to allow gaps to be filled in domestic law in cases where criminal and administrative liability for the manufacturing, distributing and selling of such products is not covered by national legislation.

The substantive criminal law provisions of the Convention respond to the need to criminalise such offences as considered to be inherently dangerous to public health; those provisions are applicable also in cases where only a potential threat to public health has been detected, and no actual physical or psychological damages to victims have materialised.

The Convention also contains a very important provision on corporate liability, which aims to make commercial companies, associations and similar legal entities (“legal persons”) liable for the pharmaceutical crimes performed on their behalf and for their benefit by anyone in a leading position acting within their powers, as well as for the offences committed by any employee or agent of the entity whenever anyone in

\(^{41}\) In this respect, see the critical comments made by Roger Bate, Amir Attaran, “A counterfeit drug treaty: great idea, wrong implementation”, *The Lancet*, vol. 376, October 30, 2010, pp. 1446-1448.
a leading position has failed to supervise, i.e. has not taken appropriate and reasonable steps to prevent employees or agents from engaging in criminal activities on the entity’s behalf.

States are also required to lay down sanctions which are “effective, proportionate and dissuasive”, such as prison sentences that can give rise to extradition, in case of individual liability, and criminal, administrative, civil or monetary sanctions, in case of corporate liability, including other measures like exclusion from entitlement to public benefits or aid, temporary or permanent disqualification from the practice of commercial activities, placing under judicial supervision, or a judicial winding-up order. The Convention also provides for the seizure, confiscation and destruction of medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences or to facilitate their commission; moreover, it envisages that proceeds of the offences, or property whose value corresponds to such proceeds, may be seized or confiscated.

The Convention also designs a legal framework for national and international co-operation across the different sectors of the public administration involved in combating pharmaceutical crimes, namely the competent health, police and customs authorities on both the national and international levels, as well as measures for crime prevention, the effective prosecution of crime through measures of cooperation in investigation and prosecution, and the protection of victims and witnesses.

Last but not least, it provides for the establishment of a monitoring mechanism based on a multisectoral and multidisciplinary approach, centred on the work of a Committee of the Parties, responsible for follow-up tasks related to the implementation of the Convention, including the identification of any problems and the effects of any declarations made under the Convention; playing a general advisory

42 Article 21, paragraph 3, of the Convention authorises a Party that makes mutual assistance in criminal matters or extradition conditional on the existence of a treaty to consider the Convention as the legal basis for judicial co-operation with a Party with which it has not concluded such a treaty. This provision is of particular interest because of the possibility provided to third States to sign the Convention. The Parties must in any case act in accordance with the relevant provisions of their domestic law which may provide for conditions or grounds for refusal, as well as with their obligations under international law, including international human rights law.
role exercised also by making specific recommendations to the Parties; serving as a clearing house and facilitating the exchange of information on significant legal, policy or technological developments in relation to the application of the provisions of the Convention.

Overall, and despite the criticism addressed to its wording, the Convention represents an important step forward in the criminalisation and repression of pharmaceutical crimes and could somehow meet the need for a global convention until the WHO takes a similar initiative.

4. Conclusions: The Need for Enhanced Coordination of Efforts and Synergies between Existing Legal Instruments

Counterfeit medicines are now endemic in the global drug supply chain and, as said before, constitute a serious challenge for shared global health security and patient safety.

It is now generally acknowledged that combating drug counterfeiting requires efforts to act simultaneously on legislation, enforcement, technology and communication strategies. This means that, to develop successful measures of contrast, this phenomenon should be addressed through a multisectoral, multidisciplinary and collaborative approach, based on the cooperation of all relevant stakeholders, including lawyers, scientists, health and drug authorities, customs, police, health professionals, pharmacists, the pharmaceutical industry, professional and consumers associations, international organisations as well as their agencies and dedicated programs.

As suggested by the WHO, priority action at State level should include strengthening national legislation in order to criminalise counterfeiting of medicines, strengthening regulatory systems and controls, improving collaboration among governmental entities (such as health, police, customs, local administrative units, judiciary); developing a communication strategy to ensure that health professionals, the general public and the media are aware of the dangers associated with counterfeit medi-

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43 See supra note 41.
cines. Moreover, national, regional and international strategies aimed at combating counterfeit medicines should be based on: a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement; b) intersectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools; c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public; d) development of technical competence and skills in all required areas; e) appropriate mechanisms for ensuring vigilance and input from health-care professionals and the public.45

At international level, the World Health Organization, the European Union and the Council of Europe are playing a key role in adopting anti-falsification initiatives and providing technical and normative support to Member States. However their actions should be coordinated and integrated in order to develop synergies and avoid duplication of efforts and resources. At the European level, while awaiting the entry into force of the MEDICRIME Convention, synergies seem to be particularly desirable through complementary application of ad hoc legislation – like Directive 2011/62/UE – and other relevant binding instruments such as the Framework Decision on the European Arrest Warrant and the Cybercrime Convention. At the more general level, given the absence of a global convention (to be negotiated under the auspices of WHO or jointly of WHO and the UN Office on Drugs and Crime46), the synergic application of the Palermo Convention and the rules of international criminal law47 could represent the basis for worldwide prosecution and repression of pharmaceutical crimes seriously endangering public health.

47 In the sense that pharmaceutical crimes could be considered crimes against humanity, see Attaran, Bate, and Kendall, supra note 44.