

the increasingly private healthcare sector – at least if eHealth producers focus more on the ‘average’ patient when producing eHealth products than on the patient with special needs. For example, current eHealth devices often require computer skills that many older people do not have, such as appointment booking online, medical records online, virtual doctor’s appointments/meetings, apps or activity wristbands. In addition, people with different impairments (visual, hearing, physical, cognitive and language) risk being excluded if the market is not forced to create alternative options for people who are not part of the larger (and thus more profitable) ‘average’ population. Thus, demographic changes demand increased efforts to integrate the ability to deal with diversity in eHealth systems from the very start. Current legislative tools in Sweden for pushing developments in that direction seem rather weak.

Paradoxically, although many areas raise potentially thorny legal problems, eHealth is still a relatively unregulated field. The legal system is not adapting very speedily to the rapid changes being experienced in healthcare. This is especially noticeable from a privacy point of view. Healthcare is one of the most sensitive and information-intensive sectors in society, and there is a significant need for a legal safety net that is adapted for the supply of personal health information at different levels and fast information transfer between different eHealth providers. For example, eHealth tools and techniques need to be designed so that products and services can provide acceptable levels of privacy. The new EU data protection regulation is a good example of the current need for safeguarding integrity and privacy issues. Given that eHealth deals to a large extent with the collection and sharing of patient data, it is important to examine how data protection and privacy laws affect healthcare practices. Some parts of eHealth – such as electronic health records and healthcare “big data” – expand the possibility of collecting, analysing and displaying registry data. During recent years, Swedish and European public authorities and entities have developed public platforms and infrastructures that provide access to large amounts of healthcare information, including data from clinical trials and patient information. In addition, other actors such as pharmaceutical companies, healthcare providers, laboratories and insurance companies have accumulated years of health data in medical databases and have digitized their patient records. Thus, there is a tremendous potential for research and quality assessment based on this vast amount of healthcare information that has been

compiled as a result of eHealth. At the same time, unresolved integrity and privacy issues remain. One such issue is the collection and use of patient data from older persons with cognitive impairments, who do not have the capacity to consent to the use of their data.

There are good reasons to argue for proactive strengthening of legal protection in the area of e-services. The EU data protection regulation reflects this need for stronger legislative awareness and proactive legislation efforts; assertive legislative initiatives are needed to ensure that the state can fulfil its obligations and guarantee citizens’ right to healthcare as well as to integrity and privacy. However, the need for increased government control through national standards in healthcare must be balanced with the need for local variations and requirements. This is a delicate and difficult task for future legislation-making, yet it seems crucial for a successful outcome.

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## Falsified Medicines and Global Public Health: The European Response



**Stefania Negri**

Jean Monnet Chair in European Health,  
Environmental and Food Safety Law

The falsification of medicinal products is a major threat to public health worldwide and has rapidly become a global criminal phenomenon.

Falsified medicines raise serious concerns about patient safety, because they are not equivalent in quality, safety and efficacy to their genuine counterparts. As such, they can result in therapeutic failures, adverse side effects (including allergic reactions, drug resistance, intoxication) and even death.

Fake drugs also pose a serious security issue because the link between drug falsification and organized crime, including cybercrime, is well established. Trade in falsified and counterfeit medicines represents a multi-billion euro business for transnational

criminal groups, who are attracted by high profits associated with a low risk of interception and relatively mild penalties. Moreover, the illegal market of pharmaceutical products offers a significant additional way through which criminal groups can launder money and finance other illegal activities.

International organisations and pharmaceutical companies report that this phenomenon is on the rise around the globe, but the magnitude of the problem and its real scale are difficult to assess. The globalisation of the pharmaceutical market and the absence of harmonised regulations and controls have played a crucial role in facilitating the circulation of falsified drugs. Increasing international trade of medicinal products sets a scene which multiplies the opportunities for counterfeiters to place fake medicines on the international market. Also the circulation of medicines through unregulated channels, especially unauthorised Internet pharmacies, has facilitated the entry of unsafe products into the distribution channels. Moreover, counterfeiting techniques have become ever more sophisticated, making it harder to identify fake products and more difficult to combat the risk that they may enter into the legal supply chain.

Confronted with such a complex and multifaceted phenomenon and its rising trend globally, the international community has called for a stronger and more coordinated response. Several international players have become actively involved in combating falsified drugs, including the major pharmaceutical companies operating at a global level and key international organizations such as the World Health Organization, which launched in 2006 the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), the United Nations (through its Office on Drugs and Crime), the World Intellectual Property Organization, and Interpol's Pharmaceutical Crime Unit. Each of these organizations has offered over time an important contribution through normative, operational and law enforcement activities, as well as technical support to Member States.

However, despite the global reach of the phenomenon and the commitment of these institutions in finding suitable solutions, only at the European level has a solid legal response been provided by the European Union and the Council of Europe. In recent years, these organizations have succeeded in creating an integrated legal framework aimed at achieving a certain degree of harmonisation of the rules applying to the manufacture and trade of falsified medicines.

The first important achievement was the adoption by the EU Council and the European Parliament of the Falsified Medicine Directive (Directive 2011/62/UE of 8 June 2011), which took effect 2 January, 2013. The Directive is particularly important because it represents the first EU legislative measure 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. To this end, the Directive has imposed tougher rules with new harmonised, pan-European measures, including an obligatory authenticity feature on the outer packaging of the medicines; stricter controls and inspections of producers of active pharmaceutical ingredients; strengthened record-keeping requirements for wholesale distributors; and, most interestingly, the first common regulation of e-pharmacies. In this latter respect, the Directive has introduced a common logo, recognisable throughout the Union, to be clearly displayed on every page of the website of legally-operating online pharmacies and retailers. According to this system, the logo can be trusted only if a purchaser, after clicking it, is redirected to the entry of that pharmacy on the list of legally operating online pharmacies and retailers registered on the national authority web-page. The Directive also requires Member States to lay down rules on effective, proportionate and dissuasive penalties applicable to infringements of the national provisions adopted pursuant to the Directive concerning the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as the sale of falsified medicinal products at a distance to the public by means of information society services.

The second major achievement was the adoption, on 28 October 2011, of the Council of Europe MEDICRIME Convention, the first international treaty against falsified medical products with a clear focus on the protection of public health. This Convention, in force as of 1 January 2016, represents a significant milestone in the fight against the falsification of medicines through European criminal law and harmonised criminal legislation at pan-European level.

The core provisions of the Convention impose on States Parties the obligation to criminalise a number of offences that amount to pharmaceutical crimes: the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories; the intentional supplying and offering to supply falsified products, including the acts of trafficking, brokering, procuring, selling or offering

for free, promoting also through advertising, keeping in stock, importing and exporting such products, their active substances, excipients, parts, materials and accessories; the intentional falsification of documents; the intentional unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements. For these crimes the Parties are required to lay down effective, proportionate and dissuasive sanctions, such as prison sentences that may give rise to extradition in case of individual liability, and criminal, administrative, civil or monetary sanctions in case of corporate liability of legal entities.

Both European instruments are particularly noteworthy since they provide an interesting model of prevention and repression which could be usefully exported to other regional settings, or even applied as a global pattern of legal regulation.

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## WAML President's Report



**Thomas T. Noguchi,**  
President of WAML

About four months from now, we will have the Baku Congress. We look forward to seeing you in Baku, Azerbaijan. The first scientific Session begins July 11 and the Congress ends on July 13, 2017. Registration opens July 10, in the afternoon.

Since we are now an annual Congress, we have established an educational congress in a part of the world where we were not able to schedule in the past. The WAML has never been in this region. The Republic of Azerbaijan is located north of Iran, east of Armenia, south of Russia, and to the east is the Caspian Sea. Baku is a very modern capital city and its surrounding regions hold many magnificent historical sites. We will be taking a Post- Congress tour and highly recommend early planning for the Congress as well as reserving tours of such a wonderful country. The Republic of Azerbaijan has maintained peace and

secularism, with many regions showing rapid progress and harmonious support.

Program Chair is our Treasurer, Prof. Dr. Vugar Mammadov who is well established as an expert in forensic medicine as well as medical law. This WAML World Congress is the 50<sup>th</sup> Anniversary Meeting since the WAML started the first World Congress in Ghent, Belgium in 1967. We are expecting the participation of many scholars and experts in Medical Law and Ethics as well as Legal Medicine from Russia and surrounding countries.

The EC has established a regular monthly meeting on the first Saturday of each month; thus far we have discussed many current topics, such as the Los Angeles Congress, preparation of the Baku Congress, WAML Finance and operational funds, and statutes (bylaws). Through excellent management, Denise McNally was able to work with the Millennium Biltmore Hotel so that the hotel completely waived the penalty charge for the LA Congress. Our deep appreciation goes out to Denise for her great work.

We'd like to increase communication with our members. Please do not hesitate to contact us directly or through Denise, so we may hear your concerns. We continually strive to improve our service to the membership.

I look forward to welcome you in Baku July 10-13 of this year.

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## WAML Secretary General's Report



**Ken J. Berger**  
MD, JD  
WAML Secretary General

The World Association for Medical law and its members are leaders in health law, legal medicine, medical ethics and forensic medicine.