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Committee on Social Affairs, Health and Sustainable Development

Minutes

of the Parliamentary Conference on the MEDICRIME Convention held in Paris on 24 November 2015

Opening of the meeting

The conference was opened by **Mr Valeriu Ghiletchi, Chairperson** of the Committee on Social Affairs, Health and Sustainable Development, who welcomed the members of national parliaments, representatives of international organisations, experts and participants.

The Chairperson thanked the representatives of the Directorate General of Human Rights and the Rule of Law (DGI), and the European Directorate for the Quality of Medicines & HealthCare (EDQM) for their excellent co-operation and their generous support in the preparation of the Conference. He also thanked the OECD for kindly providing the meeting room free of charge.

Referring to the Parliamentary Assembly's long-lasting commitment to the fight against counterfeiting, **the Chairperson** stressed that the MEDICRIME Convention was instigated by the Assembly in a recommendation dating back to 2007.[1] The Convention was opened for signature on 28 October 2011, becoming the first legally binding international instrument to criminalise the counterfeiting of medical products and similar dangerous conducts. To date, it had been signed by 24 States including 3 non-member States of the Council of Europe (Guinea, Israel and Morocco) and ratified by 5 only. The recent - fifth - ratification by Guinea meant that the Convention would enter into force on 1 January 2016, which was a very welcome development.

The Chairperson pointed out that the conference aimed at raising the awareness of parliamentarians on the counterfeiting of medical products and similar crimes and their negative impact on public health, as well as stressing the importance of signing and ratifying the MEDICRIME Convention, as a way to combat counterfeiting of medical products. He then briefly introduced the conference programme before leaving the floor to the conference co-organisers' representatives for their opening addresses.

Mr Jan Kleijssen, Director of the Information Society and Action against Crime Directorate, DGI, referred to the recent terrorist attacks in Paris and the threats in Brussels, which had triggered a lot of emotions. In fact, the fight against terrorism, organised crime and counterfeit medicines were linked: some of the proceeds of counterfeiting of medicines were being channelled to the terrorist group known as "Daesh". The Council of Europe's mission was to safeguard human rights, democracy and the rule of law, not the protection of intellectual property rights. At the centre of the Council of Europe's concern in the field of combating MEDICRIME was patient safety. Unfortunately, this type of crime was extremely successful, and, in fact, 25 times more profitable than drug trafficking. It was easy to advertise and supply counterfeit medical products, especially via the internet – which was, in general, a tool for the good (half of mankind was already

* Draft minutes approved and declassified by the Committee on Social Affairs, Health and Sustainable Development at its meeting on 19 April 2016 in Strasbourg.
1 Recommendation 1794 (2007) "The quality of medicines in Europe".

on-line), but also abused by criminal organisations: 62% of all medicines on the Internet were counterfeit, which weakened the public's trust in the system. This was why the Council of Europe's "Budapest" Convention on Cybercrime, together with the effective and powerful criminal law MEDICRIME Convention, were both so important. The MEDICRIME Convention's entry into force on 1 January 2016 would certainly make a difference, but 5 more ratifications were needed for the Convention's Committee of the Parties to be established.

The Chairperson expressed the hope that the day's Conference might lead to further ratifications of the Convention.

Mr François-Xavier Lery, Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting, EDQM, started by welcoming all participants on behalf of Ms Susanne Keitel, the EDQM Director, and thanking the Assembly Secretariat and the colleagues from the Directorate of Information Society and Action against Crime for their joint organisation of the Conference.

Despite being primarily "penal" in nature, one of the key assets of the MEDICRIME Convention was to promote international and cross-sector co-operation (that is between health and law-enforcement and the judiciary). Considering that counterfeiters ignored borders and actually used them to perpetrate their crime, such co-operation was crucial. The phenomenon was affecting both Europe and the whole world, and concerned not only medicines, but also medical devices, as illustrated by the breast implants case manufactured and distributed all over the world by the French company "Poly Implant Prothèse (P.I.P.)". Hence, action was needed at all levels and for all products, including generic ones. The MEDICRIME Convention had been elaborated precisely with this objective in mind, as a powerful legal instrument providing authorities with a tool offering a legal basis for further action at all levels. It was also important to develop a global network of parliamentarians who would ensure that such a legal basis was created.

By gathering parliamentarians from almost 30 countries and several international organisations, the Conference was illustrating the spirit of cross-co-operation and networking within the international community, as well as the strong will to meet the challenge of counterfeiting of medical products and similar crimes.

The Chairperson thanked both speakers. He then drew participants' attention to the Handbook for parliamentarians, which was included in their conference files. The Handbook was designed to serve as a tool for parliamentarians to encourage the signature, ratification and implementation of the MEDICRIME Convention. **The Chairperson** encouraged all parliamentarians to make use of that tool. He then gave the floor to Ms Ilise Feitshans, Executive Director of the Work Health and Survival Project in Switzerland and the USA, to present the Handbook. Ms Feitshans had prepared the Handbook in co-operation with expert consultants, Mr Hugo Bonar, the late Mr Bart Wijnberg, and Professor Asier Urruela Mora, who was also present.

Presentation of the Handbook for parliamentarians

Ms Ilise L. Feitshans, Executive Director of the Work Health and Survival Project, Switzerland and the USA

Ms Feitshans presented the handbook as a crystallisation of an instrument to spread information and also to promote the ratification of the Convention. She explained how new technology amplified the risk of counterfeit medicines for human and veterinary use. Highlighting the scope of the problem, she provided data and figures taken from the handbook to illustrate why counterfeit medicines were a major threat to global health. The MEDICRIME Convention marked the first time that international criminal law had been agreed by several countries in this field, allowing for legislation and accountability to take into consideration that health is a human right that has to be protected.

Ms Feitshans pointed out the importance of international collaboration between experts, which allowed for harmonising of laws and enforcement opportunities, providing oversight mechanisms and transparency and accountability to fight organised crime.

Referring to the ratification of the Convention, she commented that the members of the Council of Europe were a role model for others but that the MEDICRIME Convention was also open to non-member States and that they should also be encouraged to ratify the Convention in order to ensure its wide and systematic application.

Ms Feitshans concluded with the words of the President of PACE calling for ratifications without further delay because “health and life cannot wait”.

[The experts’ Powerpoint presentation is available on the PACE Extranet.]

Victims’ testimony

Ms Christiane Etévé-Mousset and Ms Catherine Petit, Association for the defence of women with P.I.P. prosthesis, France

The Chairperson introduced the next two speakers, Ms Christiane Etévé-Mousset and Ms Catherine Petit, who were both victims of counterfeiting and both from the Association for the defence of women with P.I.P. prosthesis in France. He thanked them for having accepted to share their experience.

Ms Etévé-Mousset and **Ms Petit** are victims of counterfeiting and members of the French association for the defence of women with PIP implants (manufactured by Poly Implant Prothèse). They provided testimony on this case still to be finally determined by the courts concerning which little information is available.

Ms Etévé-Mousset and **Ms Petit** started their presentation by giving a brief account of their breast cancer stories which had involved the rupture of their implants, with all the resulting negative health consequences. Then, they summarised the facts of the P.I.P.+ case, including the criminal cases started against Mr Jean-Claude Mas, the company’s owner, whose company had knowingly sold implants filled with industrial-grade silicon.

Ms Petit, followed by **Ms Etévé-Mousset,** told their own personal stories. **Ms Petit** then took the floor again to describe in a few words the PIP implants scandal, a fraud case that is both very simple and very complex because of its social and judicial ramifications. She provided information on the checks carried out and the convictions pronounced against the founder of the company PIP.

Ms Petit went on to describe the actual composition of the PIP industrial gel and the effects of this gel on the health of victims.

Ms Etévé-Mousset then explained why these victims were engaged in a general combat for the establishment of a health policy that included the prevention of fraud and counterfeiting, by bringing the provisions for regulating prostheses into line with those applicable to medicines, as well as reinforcing supervision in that field by truly independent bodies.

Referring more specifically to the PIP case, **Ms Etévé-Mousset** called for an observatory to be set up to monitor the long-term effects of prostheses, conduct research regarding inflammation and early and late malfunctions due to PIP implants and undertake effective research into siliconomas.

With regard to justice, she called for reparation of the physical, psychological and social harm suffered by the victims, for an effort to expedite the judicial proceedings in the forthcoming two trials and for the introduction of a possibility of bringing class actions, including in the medical sphere.

Ms Etévé-Mousset concluded by pointing out that the trial itself was shocking. Such a health policy could not be envisaged without being aware of personal situations and stories in addition to the statistical data.

[The witnesses Powerpoint presentations are available on the PACE Extranet.]

Health damage caused by counterfeiting of medical products and similar crimes in Europe

Ms Sabine Walser, Consumer Health Protection and Anti-Counterfeiting

Ms Sabine Walser gave the presentation on behalf of **Mr. Bastiaan Venhuis,** Senior Scientific Officer of the National Institute for Public Health and Environment (RIVM), from the Netherlands, because he could not be present due to health issues. **Ms Walser** focused on the health problems caused by counterfeiting of medical products.

First, **Ms Walser** presented the state of play in Europe. On the one hand, there was occasional contamination of the official supply chain because expensive but life-saving products were the target of organised crime. On the other hand, there was a booming illegal supply chain as capacity-enhancing medicines were used by sportsmen and -women. **Ms Walser** pointed out that in the UK, there had been 15 falsified medicines' incidents between 2005 and 2011 and only seven of them had been seized before medicines had reached patients. Also, in 2014 the Italian Agency of medicines announced that there were some 2,000 illegal operations with more than 10,000 units of life-saving products which had entered the European Economic Area. **Ms Walser** explained that some of these products were very attractive to users because of their high accessibility and the convenience of payment and delivery. These products could provoke different health problems like cardiovascular or liver damage. There were challenges in proving the damage that was caused by the falsified products due to the fact that victims did not have the means to report the crimes.

Ms Walser underlined the importance of the MEDICRIME Convention which aimed to tackle medical product crimes and protect patients from being exposed to hazardous products. The role of the MEDICRIME Convention was the criminalisation of production and distribution outside the legal chain, crime prevention ensured by awareness-raising campaigns and the protection of the patients.

In conclusion, **Ms Walser** underlined that unsafe products deprived patients of the right to life and health and denied them the right to accessible and effective medicines. The MEDICRIME convention was a legal tool which could close existing legal gaps, giving victims a certain status but most importantly it could make possible the identification, treatment and prevention of health damage, caused by medical product crimes in Europe.

[The experts' Powerpoint presentation is available on the PACE Extranet.]

Discussion

Ms Kalmari stressed that the counterfeiting of medicines was an international problem. Many people were buying medicines on the internet and it was not always possible to find the "owner" of the website selling the counterfeit products. She wondered whether stringent marketing rules for the internet would solve the problem, and if so, whether such rules could really be implemented or would create too much bureaucracy for legal companies.

Mr Kiral wondered why the ratification of the MEDICRIME Convention was taking so much time. If one could answer this question honestly, the issue could be dealt with more efficiently.

Ms Vokshi also wondered why the number of ratifications was so low, and why her country (Albania) had neither signed nor ratified the Convention when there were so many fake medicines circulating there. Citing several examples, she underlined the importance of spreading awareness on how counterfeit medicines were harming the health of so many people.

Referring to the P.I.P. case where controls had failed significantly, **Mr Parmelin** asked what would be the best way to control the manufacturing chain in order to prevent such cases from happening again.

Mr Babloyan announced that Armenia was going to activate the process of ratification soon, although it was difficult for ex-Soviet countries, in particular, to put the necessary monitoring procedures into place.

In reply to the questions, **the Chairperson** said that one of the main reasons for the limited number of signatures and ratifications of the MEDICRIME Convention was the lack of awareness about the problem of counterfeiting. The Handbook aimed precisely at reversing this tendency by raising parliamentarians' awareness on the issue. It was up to parliamentarians to feel concerned about the problem of counterfeiting

and push for the ratification of the Convention, which was the international benchmark in this field. Countries also needed to assess the implications of a possible ratification and if necessary, modify their criminal laws to put them in conformity with the Convention.

Ms Feitshans made it clear that although the MEDICRIME Convention served a good purpose, behind the scenes there would always exist those who had an interest in allowing the counterfeiting to continue and who would come up with excuses for not ratifying this important tool. The only solution would be to implement an "internal system of thinking" on why this convention mattered, and to bring some individual attention to the national laws. This process required expertise in the legislative field, as well as working hand-in-hand with public health professionals.

The issue of the Internet was always problematic. In **Ms Feitshans'** view it would not be prudent to legislate the Internet for the purpose of preventing medicrimes. The main challenge would rather consist in improving quality of information and quality of control.

Replying to another question, **Ms Feitshans** noticed that in some situations an abundance of regulations was justified, if they functioned to serve a purpose. It would be important to make a thoughtful use of such bureaucracy by creating an infrastructure that would accomplish the purpose of implementing the regulations and encouraging a meaningful ratification of the Convention.

Mr Kleijssen referred to the existing confusion: in the minds of many, the issue of counterfeiting of medicines concerned intellectual property rights only. A lot of policy-makers were not even aware of the fact that the present debate was focused on the rights to life and to health.

Mr Kleijssen gave an example of work which was conducted by the Council of Europe in order to promote the ratification of treaties – awareness-raising seminars, conferences and training for law enforcement officials, among others. He gave a positive example of the Cybercrime Convention – activities related to the Convention were now carried out in 125 countries worldwide. Nevertheless, it had taken a couple of years to achieve such remarkable progress.

Mr Lery mentioned the case of a medicine which had been withdrawn from the territory of the European Union due to the lack of certainty about its efficiency; however, it remained on sale in some other countries.

Mr Lery stressed the necessity to acknowledge the lack of mutual recognition among the authorities in such cases, and as a result, to put in place some specific regulations which would allow one country to make decisions based on information provided by another country.

Mr Lery mentioned that the MEDICRIME Convention was a penal convention and there was a clear need to implement other parallel regulations: control, inspections, testing laboratories, surveillance of internet websites. The MEDICRIME Convention was a key element of this holistic approach, but not the only one.

Counterfeit medical products: an ever-growing phenomenon in transnational organised crime

Mr Carlos María Romeo Casabona, Professor in Criminal Law, Director of the Inter-University Chair in Law and the Human Genome, University of Deusto and University of the Basque Country, Spain

Mr Casabona, expressed the lack of consciousness of the importance and urgency of the ratification of the MEDICRIME convention. Counterfeiting of medicines had become a new opportunity for organised transnational crime, most of the time underestimated by the authorities.

Counterfeiting of medicines posed a growing risk to public health in Europe and beyond, with the root cause being misuse of information and new technologies in illegal products. He summarised how penalties had been focused on the economic impact and not on the public health consequences.

Mr Casabona revealed how these medical products might get onto the legal distribution chain and how they had been sold "legally", usually involving several different parties during the process to sell them. The Convention could be used as an instrument to fight the illegal internet sales, through international co-operation. He gave the example of 20 million medicines which had been intercepted by Interpol in recent years.

Commenting on the necessity of introducing the Convention into national criminal law, he emphasised that international co-operation was an instrument to reach the goal of protecting public health as well as the victims.

Mr Casabona highlighted the four main crimes: adulteration, trafficking, falsified documentation, and harming public health with counterfeit medicines and medical products. The MEDICRIME Convention was an independent but complementary instrument in relation to the EU Directive, which went further than the Directive by including both veterinary medicines and specific criminal law provisions.

He concluded by urging parliamentarians to put this matter on their national agendas.

[The experts' Powerpoint presentation is available on the PACE Extranet.]

The added value of the MEDICRIME Convention for public health

Mr Bernard Marquet, former member of the Parliamentary Assembly of the Council of Europe (PACE), PACE rapporteur on "Quality of Medicines in Europe", Monaco.

Mr Marquet began his presentation by pointing out that the counterfeiting of medical products had adverse effects on public health and public safety, which made it vital that the MEDICRIME Convention be ratified.

As a dental surgeon, the rapporteur considered that victims deserved greater protection, as they faced a range of problems, such as the difficulty of proving the damage suffered and the emotional and financial impacts. He stressed the importance of complying with the prevention principle, adding that recalls of medicines were uncommon and incomplete. Furthermore, the pharmacovigilance system could not detect the effects of fake medicines.

The Parliamentary Assembly's Recommendation 1794 (2007) had consequently called on the Committee of Ministers of the Council of Europe to draw up the MEDICRIME Convention. **Mr Marquet** listed its key aspects: the implementation of patient protection mechanisms by member states, the preparation of an effective legal instrument, the organisation of information campaigns and the promotion of intersectoral co-operation.

With regard to its implementation, the Convention made it a criminal offence to manufacture and/or supply counterfeit products, established co-operation between the various authorities, created a victim status and proposed deterrent penalties. Noting that the Convention would come into effect on 1 January 2016, **Mr Marquet** stressed that Guinea was becoming a model for humanity by enabling it to enter into force. At the same time, in Europe this lucrative and dangerous market was still being under-estimated, and there were inconsistencies between the different pieces of legislation and the deterrent effects of the penalties.

In response to certain misunderstandings, **Mr Marquet** said there was no link between the MEDICRIME Convention and intellectual property law, and the Convention therefore concerned neither marketing authorisations nor prohibitions. The rapporteur assured the participants that the Council of Europe had the capacity to implement an instrument intended to be applied world-wide, drawing attention to the example of the European Convention on Human Rights, which was global in scope. He maintained that the aim of the Convention was not to criminalise honest producers.

Concluding his remarks, **Mr Marquet** said the report set out the benefits of the MEDICRIME Convention, which was an instrument that could be adapted to the way each state operated, while facilitating the harmonisation of legislation and the provision of public information. He called on the participants to focus on public health and urge governments to act.

[The experts' Powerpoint presentation is available on the PACE Extranet.]

Examples of good practices in fighting the counterfeiting of medical products and similar crimes

Mr Domenico Di Giorgio, Director of the Office for Product Quality and Counterfeiting, Italian Medicines Agency (AIFA), Italy.

Mr Domenico Di Giorgio defined counterfeiting as the misrepresentation of medical products with intent. He started his presentation by listing counterfeiting activities and the targeted products, providing examples of counterfeit medical devices.

The expert discussed whether counterfeiting represented a pressing issue in Europe. He provided examples of some illegal production sites and "middlemen" which had been identified in Europe. Additionally, thefts of medicines had seen a big increase in Italy after 2011.

Mr Di Giorgio presented good practices to fight medical product crimes, such as securing legal production and distribution chains of medical products, information, sensitisation and awareness-raising, as well as crime prosecution and prevention. He emphasised that no individual state, nor region, nor organisation, nor sector alone could control international medical product crimes. He referred to the Herceptin case: warehouses storing illegal medicines had been discovered, but only a few actors had been charged. Usually thefts were investigated at a local level, and only « low-level criminals » could be brought to justice. He pointed out that the Medicrime Convention promoted co-operation in investigation both at national (art. 17) and international (art. 21) levels.

Mr Di Giorgio concluded with the fact that good practices, *ad hoc* co-operation alone, were not sufficient to fight medical product crimes. He indicated that *ad hoc* networking without a legal basis was not sustainable. Fighting counterfeiting and similar crimes involving medicines for human or veterinary use, active ingredients or excipients and medical devices, required specific, harmonised legislation (criminalisation, crime prevention, co-operation) across the world. The expert underlined that the EU Falsified Medicines Directive (2011/62/EU) had regulatory purposes, whereas the MEDICRIME Convention had a criminal focus. In addition, the latter Convention covered health products beyond medicinal products for human use and criminal offences, and included provisions for serious policing powers.The MEDICRIME Convention and the EU Directive were not interchangeable, but rather complementary.

[The experts' Powerpoint presentation is available on the PACE Extranet.]

International co-operation in counterfeiting cases

Ms María Poza Cisneros, Senior Judge, Deputy to the National Member for Spain, EUROJUST

Ms María Poza Cisneros raised awareness on the importance of international co-operation in counterfeiting cases and explained the need to promote good practices through the ratification of the MEDICRIME Convention. She referred to counterfeiting as being a cross-border crime, usually with supply chains in several countries, including internet sales and links to other crime types.

Ms Poza Cisneros pointed out the importance of international co-operation in matters related to extradition, double criminality, minimum penalties, mutual legal assistance, conflicts of jurisdiction, and harmonisation of domestic law. She appreciated the role of Eurojust that had accomplished international operations, mentioning the case of Vigorali, a fake lifestyle drug that had been sold on-line, from India to the United Kingdom and then had been distributed to several other countries. She explained the complexity of this multinational operation that involved financial engineering, illegal supply chains, and had resulted in consequences for victims, international proxy servers, etc. **Ms Poza Cisneros** pointed out how an international legal framework had been helpful during the investigation and the results of the operation.

Discussion

Mr Marquet underlined that in contrast to the European Union, which had opted for soft law measures to tackle the problem of counterfeiting of medicines, the Council of Europe had decided to draw up a legally binding instrument addressing all relevant aspects of the issues in a comprehensive manner. The MEDICRIME Convention had also introduced a paradigm shift whereby the counterfeiting of medicines was no longer considered from the perspective of intellectual property (IP) but from that of public health. These were probably the reasons why the ratification process was taking so much time. Indeed, countries not only had to adapt their legislation to the Convention and ensure co-operation between different authorities (including justice, finance, health, police and customs), but also had to change the latters' mind-set which was formatted to address the issue from an IP rights perspective.

Mr Jónasson expressed his appreciation for the organisation of such an enlightening conference and the stimulating discussions being held. Iceland had signed the MEDICRIME Convention while he was the Minister of Interior, a fact of which he was very proud. **Mr Jónasson** pointed out that the Convention did not address IP issues, but referred to "similar crimes", an expression which had to be clarified. Referring to compulsory licencing of patented drugs in countries like China and India, he wondered whether the billions of dollars lost because of counterfeiting - mentioned in expert presentations - related also to the lost profits of the pharmaceutical industry in these countries. Taking up the case presented by Mr Di Giorgio (i.e. theft of expensive medicines from Italian hospitals), he wondered whether the exorbitant prices of medicines imposed by the pharmaceutical industry were not a stimulating factor for counterfeiting. Finally, reacting to the morning's discussion on whether the internet could be regulated or not, he said that criminal offences committed on or via internet had to be addressed, just like any other crime.

Mr Bah stressed that the signature and ratification of the MEDICRIME Convention was a public health emergency of international dimensions. On the African continent, the problem was going beyond the countries' capacity to deal with it. He took the opportunity to thank the organisers of the conference.

Mr Babloyan affirmed that the basic human right to health should be a priority for everyone. He underlined the importance of proper storage and transportation of medical products, referring to the fact that in some cases, undue handling and distribution lead to the deterioration of rightly-produced medicines of appropriate quality. He suggested that wrongful distribution and storage should be criminalised.

Mr Mathieu stressed the importance of the issue and congratulated Mr Marquet on his high-quality work in this field. He drew the attention of the participants to two opposing notions – public health and liberty, particularly liberty on the internet and liberty of intellectual property. The expert was surprised that so few countries had ratified the Convention and he wondered what could be the responsibility of those Council of Europe member States, who failed to ratify this important legal instrument, before those people who risked losing their health as a result of consuming counterfeit medicines.

Replying to the question on the economic relevance of the crime, **Mr Di Giorgio** indicated that the counterfeiting of medicines was particularly attractive for criminals due to their high price. Criminals sold expensive products at low prices through the Internet, thus attracting more and more consumers and deriving considerable profits.

The expert made it clear that sharing good practices was paramount in order to fight the crimes that were menacing public health.

Without ratifying the MEDICRIME Convention, authorities were not only unable to catch the so-called "big fish", but they could not go after "middlemen", for instance pharmacists, who purchased medical products at less than half the market price from unauthorised operators. In such cases, countries were left with no choice but to apply the administrative rules of the pharmaceutical code in Europe, including insufficient fines and administrative sanctions.

In response to **Mr Jónasson's** question about similar crimes, **Ms Poza Cisneros** answered that similar crimes were related to threats to public health and not the defence of IP rights. In order to detect internet crimes she pointed out that all tools needed to be in place.

Ms Feitshans replied that the Internet was complex and warned to be careful, balancing freedom with the dangers.

How to overcome obstacles in the ratification process

Mr Sidiki Cissé, Vice-President of the Health Committee of the National Assembly of Guinea.

Mr Sidiki Cissé, Vice-President of the Health Committee of the National Assembly of Guinea, described the process of ratifying the MEDICRIME Convention in his country. The context in which the Convention had been adopted in Guinea had been very problematic. The Convention had come at a timely moment to respond to the needs that had emerged.

Mr Cissé described the nine stages in the process of ratifying the MEDICRIME Convention in Guinea. During that process, he had noted an interest among the highest national authorities, especially the country's President, who took the issue of combating the illegal trade in medical products very seriously.

The MEDICRIME Convention had been ratified by the Republic of Guinea, the fifth country to do so, in 2015 and had entered into force in January 2016.

Mr Cissé described the players involved in the ratification process and went on to talk about the difficulties encountered at that time, especially owing to the Ebola epidemic in 2014, to which the country had devoted all its attention and energy over a period of many long months. Lastly, he mentioned the opportunities afforded to Guinea to prepare for its accession to the MEDICRIME Convention.

Mr Cissé concluded by pointing out that the accession and ratification process had been slow in Guinea in spite of the political will expressed by the head of state and the commitment of the professionals concerned. He recommended that the Council of Europe provide assistance for both professionals and the authorities of the Health and Foreign Ministries, which had a vital role in the process, and organise international meetings

with the participation of representatives of countries wishing to accede to the Convention or potentially intending to do so.

Ms Claude Chirac, Vice-President of the Chirac Foundation, France

Ms Claude Chirac, Vice President of the Chirac Foundation, began by congratulating Guinea on ratifying the Medicrime Convention. She hoped France would speed up the ratification process.

She described the Foundation, which had been set up by Jacques Chirac in 2008 to continue his work for future generations in support of peace, cross-cultural dialogue and equal access for everyone to global public goods, including access to quality health services and care. The problem of "fake medicines" was, she said, a scourge condemned as from the 1980s by President Chirac, who had urged political leaders to take action against this trade and its tragic consequences for the poorest of the poor. Since the 2009 Cotonou Appeal, the Foundation had taken part in a large number of international conferences that had promoted the Medicrime Convention (Montreux in 2010, Ouagadougou in 2011, Niamey in 2013, Geneva in 2014 and Dakar in 2014 and 2015).

Ms Chirac drew attention to a number of key statistics. 10% of medicines sold in the world, and 60 to 80% in Central Africa, were fake. 200,000 people died every year because of fake anti-malarial drugs. Such trafficking was extremely profitable with little risk for those involved in it.

Since 2011, the Foundation had endeavoured to enlist the support of political leaders and instil a sense of responsibility in them, with a view to securing the signature and ratification of the Medicrime Convention, the first international legal instrument criminalising the production and distribution of counterfeit medicines. The Foundation pushed for the adoption of laws and public health measures. She called for innovative funding methods (such as the tax on airline tickets allocated to combating the three major global pandemics: malaria, tuberculosis and AIDS).

The Foundation raised awareness within the populations most affected, especially in Africa. It had conducted a major campaign in Africa on the theme "Street medicine kills".

Mr Marc Gentilini, General Delegate of the Chirac Foundation for Access to Quality Medicines and Health Care, said this serious health issue was more than a scandal; it was a crime to which the Medicrime Convention provided a response. An appeal had been made to the French Academy of Medicine. It was necessary to consider the African countries which were the most affected and where there was a great deal of corruption, with fake medicines accounting for more than 60% of the market. Asia and South America were also afflicted by the scourge. 60% of veterinary drugs were counterfeit. The WHO had significantly failed in its duty here, by allocating only two officials to deal with fake medicines. **Mr Gentilini** was convinced of the need to increase public awareness and condemn abuses on the internet. It was also necessary to educate health professionals, including by incorporating sessions on fake medicines into their training curricula. Given the urgency of the situation and the lack of awareness, it was essential to urge politicians to act. At the same time, the cost of medicines must be reduced, and health and welfare cover permitting access to quality health services and care must be put in place.

Discussion

Mr Stéphane Le Masson (Agence En Phase) asked why there were so few French parliamentarians present at the meeting. He wondered about the possible ways to sensitise French authorities, including parliamentarians and the government. He wondered what role pharmacists and doctors could play in preventing counterfeit crimes.

Ms Chirac noted that parliamentarians from all countries had many urgent matters to deal with, and she extended particular thanks to the representatives of Guinea for their participation. She explained that some countries, like France, did not understand the importance of the issue of counterfeit medicines. However, now, thanks to the internet, many countries were more aware of the problem. She highlighted the role of the Council of Europe in launching this Convention. She indicated that new generations were more conscious about the danger that false medicines posed for public health.

Professor Gentilini answered that the working groups of the French National Academies of Medicine, Pharmacy and Veterinary would provide their vision on the subject on 8 December 2015.

Mr Luc Besançon, added that the real issue is how do we convince the different Governments, and he pointed out that the answer could be to explain how investments in non-counterfeited medicines give health outcomes.

Conclusions by Mr Valeriu Ghiletchi, Chairperson of the Committee on Social Affairs, Health and Sustainable Development

The Chairperson thanked the speakers, the co-organisers, the Secretariat and the interpreters, as well as all the participants for their contribution to the success of the Conference. He stressed that the launch of the Handbook for parliamentarians would only be truly successful if parliamentarians made use of it. He therefore invited them to do so. He also asked participants to take home the following three messages:

1. Counterfeiting of medical products was not a victimless crime. It was a public health problem which affected the health and lives of millions of Europeans, and many more people worldwide;
2. The Council of Europe MEDICRIME Convention was a game-changer. It was the first binding international legal instrument which combined a criminal law with a public health approach and facilitated international co-operation, and also included prevention and victim-assistance measures;
3. For the MEDICRIME Convention to work effectively, more signatures and ratifications of the Convention were needed. The goal should be to rival the reach of the Cybercrime Convention, which had become truly global.

The Chairperson closed the conference by inviting all parliamentarians to follow the urgent advice of the Assembly President to “ratify this important convention without delay, as health and life cannot wait.”

Committee on Social Affairs, Health and Sustainable Development
Commission des questions sociales, de la santé et du développement durable

List of presence

Parliamentary Conference on the MEDICRIME Convention

REPRESENTATIVES OF NATIONAL PARLIAMENTS

Name	Country	Function
Ms Albana VOKSHI	Albania	Chairperson of the Committee on Health and Social Affairs
Mr Ara BABLOYAN	Armenia	Chairperson of the Standing Committee on Health Care, Maternity and Childhood
Mr Rostislav VYZULA	Czech Republic	Chairperson of the Health Committee
Mr Claude MALHURET	France	Rapporteur on the MEDICRIME Convention, Senate
Mr Konstantinos BARKAS	Greece	Vice-Chairperson of the Standing Committee on Social Affairs
Ms Alma MONKAUSKAITE	Lithuania	Member of the Committee on Health Affairs
Mr Sveinung STENSLAND	Norway	Member of the Standing Committee on Health and Care Issues
Mr Florian-Dorel BODOG	Romania	Secretary of the Committee on Public Health, Senate
Mr Predrag MIJATOVIĆ	Serbia	Member of the Health and Family Committee
Mr Guy PARMELIN	Switzerland	Chairperson of the Committee on Social Security and Public Health
Mr Mehmet İlker ÇİTİL	Turkey	Member of the National Assembly

PARTNERS FOR DEMOCRACY

Mr Mohamed Faisal ABU-SHAHLA	Palestine	Head of Social Affairs, Health and Education Committee

OTHER COUNTRIES

Mr Valentin MILOSHEVSKY	Belarus	Deputy Chairperson of the Standing Committee on Health, Physical Culture, Family and Youth Policy, House of Representatives
Mr Sidiki CISSÉ	Guinea	Vice-Chairperson of the Health Committee

MEMBERS OF THE COMMITTEE ON SOCIAL AFFAIRS, HEALTH AND SUSTAINABLE DEVELOPMENT

Ms Sílvia Eloïsa BONET	Andorra	Member
Ms Naira KARAPETYAN	Armenia	Member
Ms Petra DE SUTTER	Belgium	Member
Ms Milica MARKOVIĆ	Bosnia and Herzegovina	Member
Ms Gabriela PECKOVÁ	Czech Republic	Member
Mr Jaak MADISON	Estonia	Member
Ms Anne KALMARI	Finland	Member
Mr Ögmundur JÓNASSON	Iceland	Member
Mr Valeriu GHILETCHI	Republic of Moldova	Chairperson
Mr Jean-Charles ALLAVENA	Monaco	2nd Vice-Chairperson
Mr Ben-Oni ARDELEAN	Romania	Member
Ms Ana MATO	Spain	Member
Mr André BUGNON	Switzerland	Member
Ms Liliane MAURY PASQUIER	Switzerland	Chairperson of the Sub-Committee on Public Health
Mr Luc RECORDON	Switzerland	Member
Mr Serhii KIRAL	Ukraine	Member
Mr Oleksii GONCHARENKO	Ukraine	Member

SECRETARIAT OF DELEGATION OR OF POLITICAL GROUP

Name	Country/Group
Ms Sevda VALJEVCIC	Bosnia and Herzegovina
Ms Veronika KRUPOVÁ	Czech Republic
Ms Sofia VERGI	Greece
Mr Bashar SULAIMAN	Palestine
Ms Francesca ARBOGAST	Socialist Group

INTERNATIONAL ORGANISATIONS

Name	Organisation	Function
Mr Giorgio SINCOVICH	Europol	Senior Intellectual Property Crime Expert
Ms Agnes COUFFINHAL	OECD	Senior Economist, Health Division
Ms Allison COLBERT	OECD	Consultant, Health Division
Mr Philippe VORREUX	World Customs Organization	Manager of the Intellectual Property Rights, Health and Safety Programme
Mr Michael DEATS	World Health Organization	Head of surveillance and Rapid Alert System for Substandard/Spurious/Falsely labelled/ Falsified/Counterfeit (SSFFC) Medical Products

OTHER ORGANISATIONS

Mr Thierry MATHIEU	Conference of International Non-Governmental Organisations	Vice-Chairperson of the Committee on Democracy, Social Cohesion and Global Challenges
Mr Luc BESANÇON	International Pharmaceutical Federation	General Secretary and Chief Executive Officer
Ms Diane DE LAUBADERE	National Institute of Advanced Studies in Security and Justice, France	Officer, Chief Editor, *Revue DéfIS*
Ms Angélique LE MAZOU	National Institute of Advanced Studies in Security and Justice, France	Officer, Deputy Chief Editor, *Revue DéfIS*

EXPERTS / SPEAKERS

Name	Function
Ms Claude CHIRAC	Vice-President of the Chirac Foundation, France
Mr Domenico DI GIORGIO	Director of the Office for Product Quality and Counterfeiting, Italian Medicines Agency (AIFA), Italy
Ms Christiane ETÉVÉ-MOUSSET	Association for the Defence of Women with P.I.P. prosthesis, France
Ms Ilise L. FEITSHANS	Executive Director of the Work Health and Survival Project, Switzerland and the USA
Mr Bernard MARQUET	Former member of the Parliamentary Assembly of the Council of Europe (PACE), PACE rapporteur on "Quality of Medicines in Europe", Monaco
Ms Catherine PETIT	Association for the Defence of Women with P.I.P. prosthesis, France
Ms María POZA CISNEROS	Senior Judge, Deputy to the National Member for Spain, EUROJUST
Mr Carlos María ROMEO CASABONA	Professor in Criminal Law, Director of the Inter-University Chair in Law and the Human Genome, University of Deusto and University of the Basque Country, Spain

MEMBERS OF THE EUROPEAN COMMITTEE ON PHARMACEUTICALS AND PHARMACEUTICAL CARE (CD-P-PH)

Ms Hanne BAK PEDERSEN	Programme Manager, Health Technologies and Pharmaceuticals, Division of Health Systems and Public Health, WHO Regional Office for Europe, Denmark
Mr Emanuele CESTA	Administrative / Legal Officer, Product and Counterfeiting Office, AIFA, Italy
Mr Aboubacar Sidiki DIAKITÉ	Health Inspector, Ministry of Public Health and Hygiene, Guinea
Mr Einar MAGNÚSSON	Director of Pharmaceutical Affairs, Department of Economic Analysis, Ministry of Welfare, Iceland
Ms Olivia NEMETH	Legal Officer, Directorate General of Health, Ministry of Social Affairs and Health, France
Mr Jozef SLANY	Director of Division of Pharmacy, Ministry of Health, Slovak Republic
Mr Mkrtich SHAKARYAN	Head of Inspection Department, Scientific Centre of Drugs and Medical Technology Expertise, Ministry of Health, Armenia
Mr Pavle ZELIC	International Cooperation and Public Relations Manager, Medicines and Medical Devices Agency, Serbia

OTHERS

Mr Thierno BAH	President of the Observatory of Drugs, Guinea
Mr Marc GENTILINI	General Delegate to Access to Quality Healthcare, Chirac Foundation, France
Mr Marc-Antoine JASSON	Policy Officer, Chirac Foundation, France
Ms Dragana POKRAJAC	Interpreter of the National Assembly of Serbia
Ms Marie-Agnès ROURE	Deputy Administrator, Committee on Foreign Affairs, Defence and Armed Forces, Senate, France
Mr Christian TOURNIÉ	*Lieutenant-colonel*, Deputy for European Affairs and International Cooperation, *Office Central pour les Atteintes à l'Environnement et à la Santé Publique* (OCLAESP), France
Mr Asier URRUELA	Professor of Criminal Law, University of Zaragoza, Spain

SECRETARIAT OF THE COUNCIL OF EUROPE

Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly

Ms Tanja KLEINSORGE..... Head of the Secretariat of the Committee
Ms Ayşegül ELVERİŞ..... Co-Secretary to the Committee
Mr Raul MALLAINA GARCIA ..... Co-Secretary to the Committee
Ms Jannick DEVAUX ..... Project Manager
Ms Fatima NOUICER ..... Assistant
Ms Alina BELIAEVA..... Assistant

European Directorate for the Quality of Medicines & HealthCare (EDQM)

Mr François-Xavier LERY..... Head of Section for Pharmaceutical Care,
..... Consumer Health Protection and Anti-Counterfeiting
Ms Sabine WALSER ..... Administrative Officer, Secretary to the CD-P-PH
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Mr Oscar ALARCON JIMENEZ..... Co-Secretary to the European Committee on Crime Problems (CDPC)

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Mr Francesc FERRER..... Media Officer

The Directorate of Communications

Ms Estelle STEINER..... Media Officer