





REGIONAL CONFERENCE

FROM SIGNATURE TO RATIFICATION AND IMPLEMENTATION OF THE COUNCIL OF EUROPE CONVENTION ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH (MEDICRIME CONVENTION)

With the participation of representatives from:
Andorra, Belgium, France, Germany, Republic of Guinea, Ireland, Italy,
Luxembourg, Monaco, Morocco, Portugal, Spain, Switzerland, United Kingdom

PROGRAMME

21-22 November 2013 Madrid Spain

Background and objectives

The Council of Europe has drafted a convention which constitutes, for the first time, an international treaty in the criminal law field on the counterfeiting of medical products and similar crimes involving threats to public health (the MEDICRIME Convention).

Safeguarding public health through penal measures against criminal behaviour, the protection of victims, the promotion of co-operation at national and international levels, and providing preventive measures are the principal aims of the above convention.

The core values of the <u>Council of Europe</u> are the protection of human rights and essential freedoms and the promotion of the rule of law and democracy. The organisation is aiming to identify solutions to the challenges faced by today's society.

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

The counterfeiting of medical products and similar crimes have spread worldwide, no country has been spared.

The Council of Europe has long been concerned about the absence of harmonised international legislation, non-deterrent sanctions in proportion to the harm caused to patients, and the involvement of criminal organisations which operate across borders.

Thanks to its pan-European membership and co-operation with states and regions beyond Europe, the Council of Europe was able to embark on developing an international criminal law treaty focusing on public health and with a truly global impact: mandated by the Committee of Ministers of the Council of Europe and supported by intersecretariat co-operation between the Directorate General of Human Rights and Rule of Law and the Directorate General of Democracy through its European Directorate for the Quality of Medicines & HealthCare (EDQM), the text of the above convention was opened for signature in Moscow (Russian Federation) on 28 October 2011. Spain is the second country to have ratified the MEDICRIME Convention.

Aim of the conference

The aim of this conference is make significant advances in the fight against counterfeit medical products and similar crimes in Europe and worldwide through promoting political support for the practical implementation of the MEDICRIME Convention. The objectives are the following:

- 1. to encourage states to sign and ratify the Convention;
- 2. to raise awareness among members of parliament, law enforcement agencies, NGOs, the media and professionals working in the field;
- 3. to discuss the benefits and challenges in ratifying the Convention;
- 4. to exchange experiences, know-how and networking.

Target audience

The target audience of the conference includes officials responsible for policy-making, representatives of judicial, health and enforcement authorities as well as State Prosecutors, Heads of Police and Customs Agencies, Heads of Medicines Agencies and members of relevant international and European institutions and organisations.

Speakers

Details of the speakers are listed in the appendix to this programme.

Organisation

Venue		San Bernardo Street, N.49, Madrid (Spain)
Registration	Ø	09:15 – 09:45 a.m.
Coffee break	<u></u>	Conference venue
Lunch	101	13h15 (Venue: Parcent Palace, San Bernardo Street, N. 62)
Wine reception	7	13h00 (Venue: San Bernardo Street, N. 49)
Interpretation	6	Simultaneous interpretation (English/French/Spanish) for all sessions
Proceedings		The proceedings will be published
Press conference		10h30 (Room: TBC)
Social event		"A walk around the Madrid of the Habsburgs", organised by Madrid City Hall.

09.15-09h45 ② Arrival and registration of participants

10.00 OPENING SESSION

- > Mr Alberto Ruiz-Gallardón, Minister of Justice of Spain
- > Ms Ana Mato Adrover, Minister of Health, Social Services and Equality of Spain
- > Mr Jan Kleijssen, Director, Information Society and Action against Crime Directorate, Directorate General of Human Rights and Rule of Law (DG I), Council of Europe
- Ms Susanne Keitel, Director, European Directorate for the Quality of medicines & HealthCare (EDQM), Directorate General of Democracy (DG II), Council of Europe
- Mr Ángel Llorente, General Director of International Legal Co-operation and Interfaith Relations, Spanish Ministry of Justice

10.30 a.m. - 11.00 a.m.

Press conference

Coffee break

10.30 g.m. - 11.00 g.m.

SESSION 1 OBJECTIVES AND BENEFITS OF THE MEDICRIME CONVENTION

Chair: Mr Lorenzo Salazar,
Chair of the Council of Europe's Committee of Crime Problems (CDPC), Italy

11.00	Origin, purpose and objectives of the MEDICRIME Convention Mr Hans-Holger Herrnfeld, Federal Ministry of Justice, Berlin, Criminal Law Department, Germany
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11.15	The work of the PACE in the MEDICRIME Convention
	Mr Jim Dobbin, Vice-chairperson of the Sub-Committee on Public Health,
	Parliamentary Assembly of the Council of Europe
11.30	The role of the European Court of Human Rights
	Ms Ksenija Turkovic, Judge at the European Court of Human Rights on respect of
	Croatia
11.45	Spanish strategy against counterfeiting of medical products 2012-15
	Ms Belén Crespo Sánchez-Eznarriaga, Director, Spanish Agency of Medicines and
	Medical Devices (AEMPS)
12.00	Discussion

SESSION 2 PROTECTING THE VICTIMS OF COUNTERFEITING MEDICAL PRODUCTS

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

12.15	The protection of the victims of counterfeiting medical products	
	Ms Luisa Vidal, Judge, Spain	
12.30	A customs approach to combat trafficking in counterfeiting of medicines	
	Ms Junko Yamamoto, Technical Attaché, World Customs Organisation	
12.45	Industry's role in protecting the public from counterfeit & illicit medicines	
	Mr Ashley How, Director EMEA, Pharmaceutical Security Institute, PSI	
13.00	Discussion	

SESSION 3 ROUND TABLE

Chair: Mr Oscar Alarcón Jiménez Co-Secretary of Council of Europe's Committee of Crime Problems (CDPC)

State of play of the signature/ratification of the MEDICRIME Convention

The following delegations will take the floor: Andorra, Belgium, France, Germany, Republic of Guinea, Ireland, Italy, Luxembourg, Monaco, Morocco, Portugal, Spain, Switzerland, United Kingdom.

These delegations are requested to make a statement indicating the state of play of the MEDICRIME Convention in their country

16.15 p.m. - 16.30



SESSION 4 TACKLING A TRANSBORDER CRIME

Chair: Mr Hugo Bonar,
Enforcement Manager, Irish Medicines Board (IMB), Ireland

16.30	The Swiss experience in tackling the counterfeiting of medical products
	Mr Matthias Stacchetti, Head of the Criminal Division, Swissmedic, Swiss agency for
	the authorisation and supervision of therapeutic products
16.45	Facing challenges in the combat against counterfeiting medical products
	Ms Popi Nikolaidou-Kanari, Director, State General Laboratory of Cyprus
17.00	Prosecution of the counterfeiting of medical products: practical perspective Mr Manuel Casanova, Lieutenant, Head of the consumer and environmental Department, Operational central unit, Guardia Civil (Spain) Mr Juan José Castro García, National Police Inspector, Chief of Group 2 of the
	Consume, Environment and Doping Section at the Central Brigade of Investigation in Specialised Crime
17.30	Operation PANGEA: how to combat counterfeit and illicit medicines? Ms Cecilia Fant, Specialized officer, Medical product counterfeiting and Pharmaceutical Crime Sub-Directorate, INTERPOL
17.45	Discussion

End of Day 1

18.00 p.m. – 20.00 p.m. Social Event (organised by Madrid City Hall)

09.15-09h45 ② Arrival and registration of participants

SESSION 5

COMBATING FALSIFIED MEDICINES THROUGH CRIMINAL LAW: THE CRIMINAL OFFENCE AND PROSECUTION OF THE PERPETRATORS

Chair: Mr Carlo Chiaromonte, Head of the Criminal Law Division, Council of Europe

09.45	Measures for prevention contained in the MEDICRIME Convention (Substantive law) Mr Carlos María Romeo Casabona, Professor in Criminal Law, UPV-EHU and Director of the Inter-University Chair in Law and the Human Genome, University of Deusto and University of the Basque Country
10.00	Combating falsified medicines through criminal law: the criminal offence and
	prosecution of the perpetrators
	Ms Rosa Calvo, Prosecutor, Spain
10.15	Criminal offences through Internet: the case of the MEDICRIME Convention
	Ms Pilar Nicolás Jiménez, Public Law Department, Faculty of Law, University of the
	Basque Country
10.30	Consideration of the MEDICRIME Convention and relevance to medicines and
	devices sectors
	Mr Lincoln Tsang, Chair of biological/biotechnology committee and vice-Chair of
	nomenclature committee, British Pharmacopoeia Commission
10.45	Discussion

11.00 a.m. - 11.30 a.m.



SESSION 6

ASSOCIATING STATES AND REINFORCING INTERNATIONAL COOPERATION

Chair: Ms Suzanne Keitel, Director, European Directorate for the Quality of Medicine & HealthCare, Council of Europe

11.30	International co-operation: Ibero-American meetings with competent authorities in
	medicines
	Ms Belén Escribano Romero, Head of the Inspection and Control Department,
	Ministry of Health, Spain
11.45	The example of the Official Medicines Control Laboratories (OMCL) Network
11.45	The example of the Official Medicines Control Laboratories (OMCL) Network Ms Silvia Muñoz Botella, European Directorate for the Quality of medicines &
11.45	

CLOSING SESSION

12.30	Mr Fernado Román García, State Secretary of Justice, Spain
	Ms Pilar Farjas Abadía, Secretary General of Health and Consumer Affairs, Ministry
	of Health Social Services and Equality of Spain
	Mr Carlo Chiaromonte, Head of Criminal Law Division, Council of Europe
	Mr Ángel Llorente, General Director of International Legal Co-operation and
	Interfaith Relations, Spanish Ministry of Justice

12.50 End of the conference

13.00 p.m. - 13.30 p.m. TReception offered by the Ministry of Justice of Spain

APPENDIX

Chairs / Speakers

Mr Oscar Alarcón Jiménez, Secretary of the MEDICRIME Conference, Co-Secretary of the Committee of Crime Problems (CDPC), Council of Europe

Mr Hugo Bonar, Enforcement Manager, Irish Medicines Board (IMB), Ireland

Ms Rosa Calvo, Prosecutor, Spain

Mr Manuel Casanova, Lieutenant, Head of the consumer and environmental Department, Operational central unit, Guardia Civil, Spain

Mr Juan José Castro García, National Police Inspector, Chief of Group 2 of the Consume, Environment and Doping Section at the Central Brigade of Investigation in Specialised Crime

Mr Carlo Chiaromonte, Head of the Criminal Law Division, Council of Europe

Ms Belén Crespo Sánchez-Eznarriaga, Director, Spanish Agency of Medicines and Medical Devices (AEMPS)

Mr Jim Dobbin, Vice-chairperson of the Sub-Committee on Public Health, Parliamentary Assembly of the Council of Europe

Ms Belén Escribano Romero, Head of the Inspection and Control Department, Ministry of Health, Spain

Ms Cecilia Fant, Specialized officer, Medical product counterfeiting and Pharmaceutical Crime Sub-Directorate, INTERPOL

Ms Pilar Farjas Abadía, Secretary General of Health and Consumer Affairs, Ministry of Health Social Services and Equality of Spain

Mr Hans-Holger Herrnfeld, Federal Ministry of Justice, Berlin, Criminal Law Department, Germany

Mr Ashley How, Director EMEA, Pharmaceutical Security Institute, PSI

Ms Susanne Keitel, Director, European Directorate for the Quality of medicines & HealthCare (EDQM), Directorate General of Democracy (DG II), Council of Europe

Mr Jan Kleijssen, Director, Information Society and Action against Crime Directorate, Directorate General of Human Rights and Rule of Law (DG I), Council of Europe

Mr Ángel Llorente, General Director of International Legal Co-operation and Interfaith Relations, Spanish Ministry of Justice

Ms Ana Mato Adrover, Minister of Health, Social Services and Equality, Spain

Ms Silvia Muñoz Botella, European Directorate for the Quality of medicines & HealthCare (EDQM), Council of Europe

Ms Pilar Nicolás Jiménez, Public Law Department, Faculty of Law, University of the Basque Country, Spain

Ms Popi Nikolaidou-Kanari, Director, State General Laboratory, Cyprus

Mr Fernado Román García, State Secretary of Justice, Spain

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

Mr Alberto Ruiz-Gallardón, Minister of Justice, Spain

Mr Lorenzo Salazar, Chair of the European Committee of Crime Problems (CDPC), Council of Europe

Mr Matthias Stacchetti, Head of the Criminal Division, Swissmedic, Swiss agency for the authorisation and supervision of therapeutic products, Switzerland

Mr Lincoln Tsang, Chair of biological/biotechnology committee and vice-Chair of nomenclature committee, British Pharmacopoeia Commission, United Kingdom

Ms Ksenija Turkovic, Judge, European Court of Human Rights

Ms Luisa Vidal, Judge, Spain

Ms Junko Yamamoto, Technical Attaché, World Customs Organisation

Organising Committee:

1. Council of Europe:

- Information Society and Action against Crime Directorate, Directorate General Human Rights and Rule of Law, Criminal Law Division, DG I:
 - o Mr Carlo Chiaromonte, Head of the Criminal Law Division
 - Mr Oscar Alarcón Jiménez, Secretary of the Regional MEDICRIME Conference, Co-Secretary of the European Committee of Crime Problems (CDPC)
- EDQM, Directorate General Democracy, DG II

2. Ministry of Justice of Spain:

- Ms Ana María Andrés Ballesteros, Deputy DG for Justice Affairs in the European Union and International Organizations
- Ms Inmaculada Aguado-Muñoz Ramírez, Advisor and Head of the Support Unit at the General Directorate of International Legal Cooperation and Interfaith Relations
- Mr Javier Gómez de Agüero López, Advisor at the Secretary of State of Justice Cabinet
- Ms Pilar Vilaplana García, Legal Advisor at the General Directorate of International Legal Cooperation and Interfaith Relations
- Ms Silvia Negro Alousque, Head of Service at the General Directorate of International Legal Cooperation and Interfaith Relations
- 3. Cultural programme: with the collaboration of the City Hall of Madrid

