DANISH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION 2012

Conference under the Danish Presidency of the Council of the European Union

PROGRAMME

COMBATTING FALSIFIED MEDICAL PRODUCTS AND SIMILAR CRIMES THROUGH LEGAL INSTRUMENTS AND PRACTICAL MEASURES

Copenhagen (Denmark)
16 May 2012

Hotel Scandic Copenhagen
Vester Soegade 6
1601 Copenhagen, Denmark

Sundhedsstyrelsen
Danish Health and Medicines Authority

edqm
European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Background and objectives

Falsifying of medical products and similar crimes have reached truly global dimensions. Criminal groups bypass regulatory requirements and systems which are set up to safeguard the quality and safety of medical products. Their illegal activities threaten people's lives and well-being and disrupt the integrity of national healthcare systems.

The Council of Europe, a pan-European international organisation with 47 member states, has long been working to combat and prevent the counterfeiting of medical products and similar crimes.

The Council of Europe's Committee of Ministers adopted in December 2010 the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention[1]) and opened it for signature by states in October 2011: it is the first binding international legal instrument criminalising the counterfeiting of medical products and similar crimes involving threats to public health. To date, 15 states have signed the MEDICRIME Convention[2]. This includes Denmark, host of this conference, which signed it on 12 January 2012.

The MEDICRIME Convention focuses first and foremost on the protection of public health by criminalising "false representation of medical products as regards identity and/or source" with criminal intent and similarly dangerous crimes[3]. It does not regulate legal production or distribution of medical products, but targets criminal behaviour involving medical products including medicinal products for human and veterinary use and medical devices and study medication. It does not interfere with other legal instruments which offer recourse to IPR claims.

In 2011, EU Directive 2011/62 amending EU Directive 2001/83 on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products[4], entered into force in the 27 EU member states. This EU Directive provides for strengthened requirements for medicinal products for human use such as control and inspections, record-keeping for wholesale distributors, on-line sale to the public, and introduces an obligation to put an authenticity feature on the outer packaging.

The Council of Europe MEDICRIME Convention has genuine weight as a criminal law instrument and, at the same time, perfectly complements the above EU Directive on falsified medicines. The definitions and concepts detailed within the Convention are compatible with all legal systems and apply to all medical products used for the diagnosis, treatment or prevention of disease in humans and animals, including medicinal products and medical devices and the ingredients, parts and materials of which they are formed.

Denmark hosts this conference during its Presidency of the Council of the European Union (EU) over the first half of 2012. The conference is organised within the framework of the 2012 spring meeting of the Heads of EU Medicines Agencies Working Group Enforcement Officers (HMA WGEO) in Copenhagen. The HMA WGEO is mandated to promote human and animal health through ensuring adherence to the regulations of the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing of information. The HMA WGEO facilitates the cooperation between members' agencies, co-ordination and exchange of information with a focus on the agencies' regulatory competencies. It comprises members from drug enforcement and specialised police agencies from EU and European Economic Area (EEA) member states. The HMA WGEO significantly enhances the ultimate goal of drug regulatory authorities (DRA), *i.e*. to protect public health in co-operation with other national agencies, international organisations and relevant stakeholders.

This conference is jointly organised between the Danish Health and Medicines Authority and the Council of Europe's Directorate for the Quality of Medicines & HealthCare (EDQM), Directorate General of Democracy.

It is essential for states, public and private stakeholders to take concerted action. Such action can only be effective and sustainable if it is based on specific, internationally harmonised legislation and practical cooperation.

It is time to unite against medicines falsifications and similar crimes!

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[1] http://www.conventions.coe.int/?pg=/Treaty/projets/Projets_en.asp

[2] http://www.conventions.coe.int/Treaty/Commun/ListeTraites.asp?CM=8&CL=ENG

[3] Similar crimes: The intentional manufacture, storage, supply (offer), the placement on the market of medical products without authorisation and/or non-compliant with conformity requirements" are criminalised to take account of the danger and spread of similar crimes. An example of such criminal conduct is offering products claiming to be effective against cancer but which have never been authorised by a competent authority.

[4] Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

The aim of the conference is to:

- facilitate co-operation and networking between enforcement officers within health authorities and police authorities in all countries in Europe;
- emphasise the importance of co-operation and networking against falsified medical products and similar crimes between government bodies including through single points of contacts (SPOCs) both at the national and international levels;
- promote awareness concerning the challenges facing DRAs and other government bodies as regards falsified medical products and similar crimes;
- create awareness of the Council of Europe MEDICRIME Convention, the importance of signing and ratifying it and facilitate the signature and ratification process through sharing of experiences.

International experts, including the delegations of the Council of Europe European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and of its subordinate Committee of Experts on Minimising Risks posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED), will contribute their expertise in the field to the programme and share best practices.

The support of the multi-sectorial audience to implement activities complementing and facilitating the appropriate implementation of the Council of Europe MEDICRIME Convention and the EU Directive on falsified medicines will be laid down in conclusions to be adopted by the participants at the end of the conference.

Target audience

The target audience of the conference includes officials at senior operative level including health (e.g. inspectorates and law enforcement units) and police authorities from the 47 Council of Europe member states including the 27 member states of the European Union, observer states, and observers to the Commission of the European Pharmacopoeia from states not members of the Council of Europe.

Participants need to be fluent in English. No interpretation into other languages will be provided**.**

Speakers

The complete list of speakers will be appended to the final programme.

Working methods

High importance will be attached to interactive sessions. The session chair will moderate the presentations and the key messages conveyed by the individual speakers. He/she will involve the audience and the speakers in the discussions at the end of the session.

Organisation

Venue		Hotel Scandic Copenhagen Vester Soegade 6, 1601 Copenhagen, Denmark Tel.: +45 33 14 35 35, Fax: +45 33 32 12 23, e-mail: copenhagen@scandichotels.com
Registration		Conference registration desk: 08:30 – 09:30 a.m.
Coffee break		"Grand Ball/Amalienborg" meeting room: foyer
Lunch		Hotel restaurant
Proceedings		The proceedings will be published in English after the conference
Press conference		"Christian" meeting room: 10:00 – 10:30 a.m.

The Danish Health and Medicines Authority offers the lunch and coffee breaks.

16 May 2012	Room: Grand Ball/Amalienborg	
	Welcome address and opening	
Chairperson:	Ms Jytte LYNGVIG, Danish Health and Medicines Authority, Denmark	
09:00 – 09:15 a.m.	The importance of the Council of Europe MEDICRIME Convention and the EU Directive on falsified medicines	Ms Astrid KRAGH, Minister for Health, Denmark
	Keynote address	
09:15 – 09:30 a.m.	Combatting falsified and illegal medicines – challenges and counter-strategies	Mr Gerald W. HEDDELL, Medicines and Healthcare products Regulatory Authority (MHRA), United Kingdom
SESSION I Recent international legislation concerning falsified medical products and similar crimes		
Chairperson:	Ms Jytte LYNGVIG	
09:30 – 09:45 a.m.	The Council of Europe MEDICRIME Convention: aims and scope	Mr Kristian BARTHOLIN, Council of Europe
09:45 – 10:00 a.m.	EU Directive on falsified medicines	Mr Fabio D'ATRI, European Commission
10:00 – 10:30 a.m.	**Coffee break**	
SESSION II Co-operation and networking –an indispensable prerequisite for tackling falsified medical products and similar crimes		
Chairpersons:	Mr Hugo BONAR, Irish Medicines Board, and Ms Ruth MOSIMANN, Swissmedic, Switzerland	
10:30 – 11.15 a.m.	Challenges for **health authorities** as regards **drug enforcement** and **networking** at both the national and international levels	Mr Nimo AHMED, Medicines and Healthcare products Regulatory Authority (MHRA), United Kingdom Ms Anita FILIPOVIĆ SUČIĆ, HALMED, Croatia Mr Yurii POGREBNIAK/ Mr. Sergii DUBOVYTSKYI, State Administration of Ukraine on Medicinal Products
11:15 – 11:30 a.m.	**Discussion**	
Chairperson:	Mr Domenico DI GIORGIO, AIFA, Italy and Chairman of the European Committee on Pharmaceuticals and Pharmaceutical Care (Council of Europe)	
11:30 a.m. – 12:15 noon	Internet: communication and enforcement strategies	Ms Monika JOHANSSON, Medical Products Agency, Sweden Mr Laurent RUFF, O.C.L.A.E.S.P., France Mr Ashley HOW, PSI
12:15 – 12:30 noon	**Discussion**	
12:30 noon – 2:00 p.m.	Lunch break	

16 May 2012	Room: Grand Ball/ Amalienborg	
SESSION III Signing and ratifying the Council of Europe MEDICRIME Convention: added value?		
Chairperson:	Mr Jesper HJORTENBERG, Office of the Director of Public Prosecution, Denmark; Vice-Chairman of the European Committee on Crime Problems (Council of Europe)	
02:00 – 02:45 p.m.	Experiences made during the preparation of signature in individual states signatories: - benefits expected from signing the Convention, - issues raised and solutions identified - next practical steps towards ratification	Mr Mickey ARIELI, Ministry of Health, Israel Mr Einar MAGNÚSSON, Ministry of Welfare, Iceland Ms Ruth MOSIMANN Mr Helder MOTA FILIPE, INFARMED, Portugal Mr Alexey TEREKHOV, Roszdravnadzor, Russian Federation Mr Henrik Helmer STEEN, State Prosecutor's Office, Denmark
02:45 – 03:30 p.m.	**Discussion**	
03:30 – 04:00 p.m.	**Coffee break**	
SESSION IV The way forward		
Chairpersons:	Ms Jytte LYNGVIG & Ms Susanne KEITEL, EDQM (Council of Europe)	
04:00 – 04:15 p.m.	Designing a strategic approach to support the effective implementation of the Council of Europe MEDICRIME Convention and the EU Directive on falsified medicines	Mr Hugo BONAR, Mr Jesper HJORTENBERG Mr Bart WIJNBERG, Expert
04:15 - 04:30 p.m.	**Adoption of the conference conclusions**	
04:30 p.m.	**Closing**	

APPENDIX

Chairs / Speakers

Welcome
Ms Astrid KRAGH, Minister for Health, Denmark,

Keynote speech
Mr Gerald W. HEDDELL, Director Inspection, Enforcement and Standards Division (I&E/S), Deputy Chief Executive Officer, Medicines and Healthcare products Regulatory Authority (MHRA), United Kingdom

Closing
Dr Jytte LYNGVIG, Director, Danish Health and Medicines Authority, Denmark
Dr Susanne KEITEL, Director, EDQM, Council of Europe

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Mr Nimo AHMED, Group Manager (Acting), Enforcement Group, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Mr Mickey ARIELI, Director Pharmaceutical Crime Unit, Ministry of Health, Israel

Dr Kristian BARTHOLIN, Administrative Officer, DGI/Action against Crime Department, Council of Europe

Mr Hugo BONAR, Enforcement Manager, Irish Medicines Board

Mr Fabio D'ATRI, Health Systems and Products, Directorate General Health and Consumers, European Commission

Dr Domenico DI GIORGIO, Ph. D., Director of Counterfeit Prevention Unit, Agenzia Italiana del Farmaco (AIFA), Italy; Chairman European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (Council of Europe)

Mr. Sergii DUBOVYTSKYI, Director of Department for State Quality Control, State Administration of Ukraine on Medicinal Products

Ms Anita FILIPOVIĆ SUČIĆ, Head of Regulatory Affairs Department, Croatian Agency for Medicinal Products and Medical Devices

Mr Ashley HOW, European Director, Pharmaceutical Security Institute

Mr Jesper HJORTENBERG, Deputy Director, Office of the Director of Public Prosecution, Denmark; Vice-Chairman European Committee on Crime Problems (CDPC) (Council of Europe)

Ms Monika JOHANSSON, Manager, Chemical Analyses, OMCL, Medical Products Agency, Sweden

Dr. Susanne KEITEL, Director, DGII/ European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

Dr Jytte LYNGVIG, Director, Danish Health and Medicines Authority, Denmark

Mr Einar MAGNÚSSON, Director of Pharmaceutical Affairs, Ministry of Welfare, Iceland

Ms Ruth MOSIMANN, Head of Control Illegal Medicines, Swiss Agency for Therapeutic Products (Swissmedic), Switzerland; Vice-Chairperson of the Committee of Experts on Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED), Council of Europe

Professor Helder MOTA FILIPE, Vice-President of the Executive Board, Infarmed, Portugal

Mr Yurii POGREBNIAK, Informational-Analytical Division, State Administration of Ukraine on Medicinal Products, Ukraine

Capitaine Laurent RUFF, Office Central de Lutte contre les Atteintes à l'Environnement Et à la Santé Publique (O.C.L.A.E.S.P.), France

Mr Henrik Helmer STEEN, Deputy State Prosecutor, State Prosecutor's Office, Denmark

Dr Alexey TEREKHOV, Adviser of the Head of Roszdravnadzor (Federal Service on Surveillance in Healthcare and Social Development)

Mr Bart WIJNBERG, Expert

Joint organising team

Danish Health and Medicines Authority: Mr Kim HELLEBERG-MADSEN, Head of Department; Ms Maria HØY, Presidency Co-ordinator, Ms Matilde KYST-BEHRENS, Lawyer

HMA WGEO Secretariat: Mr Nimo AHMED, Group Manager (Acting), Enforcement Group, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Council of Europe
DG II/ EDQM:
Department of Biological Standardisation: Dr Karl-Heinz BUCHHEIT, Deputy Head, Dr Sabine WALSER, Administrative Officer, liaison of joint organising team - programme; Ms Lydie KELLER, Assistant; **Public Relations & Documentation Division**: Ms Caroline LE TARNEC, Head of Division, Ms Fiona GILCHRIST, Deputy Head; Mrs Beatrice BARTH CLANDILLON, Assistant.

DGI/Action against Crime Department: Dr Kristian BARTHOLIN, Administrative Officer

Council of Europe European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH, Steering body): Dr Domenico DI GIORGIO, Chairman; Committee of Experts on Minimising Public Health Risks posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED): Ms Ruth MOSIMANN, Vice-Chairperson;

Mr Bart WIJNBERG, Expert