THE COUNCIL OF EUROPE CONVENTION ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH
(MEDICRIME CONVENTION)
COUNTERING THE SPREAD OF COUNTERFEIT MEDICAL PRODUCTS

International High-Level Conference

CONVENTION DU CONSEIL DE L'EUROPE SUR LA CONTREFAÇON DES PRODUITS MÉDICAUX ET LES INFRACTIONS SIMILAIRES MENAÇANT LA SANTÉ PUBLIQUE
(CONVENTION MÉDICRIME)
CONTRER LA PROPAGATION DES PRODUITS MEDICAUX CONTREFAITS

Conférence internationale à haut-niveau

ПРОГРАММА

КОНВЕНЦИЯ СОВЕТА ЕВРОПЫ ПО ФАЛЬСИФИКАЦИИ МЕДИЦИНСКОЙ ПРОДУКЦИИ И СХОДНЫМ ПРЕСТУПЛЕНИЯМ, УГРОЖАЮЩИМ ЗДОРОВЬЮ НАСЕЛЕНИЯ
(КОНВЕНЦИЯ МЕДИКРИМ)
ПРОТИВОДЕЙСТВИЕ ФАЛЬСИФИКАЦИИ МЕДИЦИНСКОЙ ПРОДУКЦИИ

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SESSION I
INTRODUCTION TO THE MEDICRIME CONVENTION

The MEDICRIME Convention in the political context

Mr Bernard MARQUET, Rapporteur, Social, Health and Family Affairs Committee,
Parliamentary Assembly of the Council of Europe

Président,
Madame la Ministre,
Directeur Général,
Mesdames et Messieurs les participants,

(A. Introduction)
Je suis honoré d'être invité à intervenir devant vous à cette occasion en tant que rapporteur de l'Assemblée parlementaire du Conseil de l'Europe, porte-parole des citoyens de 47 Etats membres par l'intermédiaire de leurs représentants démocratiquement élus.

Cette conférence, dédiée à la convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique, dite convention MÉDICRIME, est une contribution significative à la protection des droits humains, et en particulier au droit à la santé des européens. Je profite de cette occasion pour remercier les autorités de la Fédération de Russie pour avoir organisé cette conférence afin d'ouvrir la Convention à la signature.

Nous sommes tous conscients du bien précieux que représente une bonne santé mais nous l'oublions et le sous-estimons trop souvent. Nous n'apprécions notre santé et n'y attachons de l'importance que lorsqu'elle est fragile ou menacée, voire lorsque nous l'avons perdue. Nous demandons alors à nos gouvernements de faire tout leur possible pour la protéger.

La convention MÉDICRIME est une réponse forte de nos gouvernements européens aux peurs des citoyens. C'est un instrument destiné à accroître leur confiance dans les professionnels et les systèmes de santé.

Les citoyens européens ne doivent pas se faire d'illusions quant à l'urgence du problème. Ces dernières années, les médicaments contrefaits supposés traiter de graves maladies comme le cancer, la cardiopathie ou les troubles mentaux, ont pénétré la chaîne d'approvisionnement légale en Europe et sont parvenus jusqu'aux patients.

Cette convention érige en infraction punissable la contrefaçon et en fait, par conséquent, une activité beaucoup plus risquée.

En établissant cette convention, les gouvernements et les parlements tiennent à réaffirmer leur engagement à coopérer à la détection des produits médicaux contrefaits, factices ou marqués d'une fausse étiquette, aux enquêtes sur ce phénomène et à l'enraiement de son développement exponentiel.

Nous, les parlementaires, nous engageons à prendre toutes les mesures nécessaires pour assurer l'accès à des produits médicaux de qualité. Nous allons travailler pour renforcer la lutte contre les produits médicaux contrefaits et les infractions similaires en Europe et dans le monde, en instaurant le soutien politique nécessaire à la mise en œuvre de la Convention, et encourager la coopération internationale.

Nous nous engageons aussi à aider les autorités compétentes qui s'occupent de déceler les produits médicaux contrefaits et de lutter contre ce phénomène en établissant des mécanismes appropriés permettant une coopération internationale et un échange d'informations entre elles.

(B. Médicaments contrefaits proposés sur internet et stratégies générales de protection de la santé et d'insertion sociale)

N'oublions pas qu'aujourd'hui, c'est l'individu dissimulé derrière un site web qui est la cible. Le problème de la vente de médicaments contrefaits sur internet prend des proportions spectaculaires. Les contrefacteurs sont devenus des groupes plus organisés ; ils ont formé des réseaux professionnels et adopté des méthodes de commercialisation et des techniques publicitaires perfectionnées.

L'émergence des technologies du Web 2.0, comme les blogs et les réseaux sociaux, ont fait du Web un espace publicitaire très attrayant et puissant. L'anonymat d'internet et son énorme capacité de communication représentent des facteurs de risque supplémentaires s'agissant de la prolifération des médicaments.

Il faut donc appliquer le principe de précaution et prendre toutes les mesures qui s'imposent pour protéger la sécurité des patients et des consommateurs face à l'expansion de ce phénomène.

A cet égard, j'ai relevé avec satisfaction que le recours à la distribution à grande échelle, y compris par l'intermédiaire des systèmes informatiques, pour fournir des produits médicaux contrefaits était considéré comme une circonstance aggravante aux termes de la convention MÉDICRIME.

Toutefois, dans le cadre des stratégies de santé, il convient de s'interroger sur les raisons qui poussent les patients à se procurer des médicaments auprès de sources non réglementées. Il peut s'agir du faible coût, de l'accessibilité, de la commodité, du caractère honteux attribué à certaines pathologies, comme les maladies mentales et sexuelles, ou de la méconnaissance du danger.

L'anonymat relatif oriente les gens vers des conseils et des produits qu'ils hésiteraient à demander à leur prestataire de santé ou à leur pharmacien.

La pauvreté est aussi un facteur aggravant qui pousse les patients vers des produits médicaux moins chers.

Les dispositions de droit pénal doivent aller de pair avec des politiques de protection de la santé et d'insertion sociale de grande ampleur. Les décideurs doivent donc tenir compte de ces facteurs et veiller à ce que le coût de l'amélioration des mesures de sécurité ne soit pas à la charge exclusive des patients, ce qui contribuerait à accroître les inégalités en matière de santé.

(C. L'Assemblée encourage fortement la coordination, la synergie et la solidarité internationales)

Votre présence ici aujourd'hui et l'engagement d'un si grand nombre d'Etats sont un signe positif, porteur d'espoir…

Je voudrais souligner la plus-value qu'apporte le Conseil de l'Europe à cette Convention grâce à la synergie des actions entreprises par ses différentes entités telles que la Direction

Européenne de la Qualité du Médicament & Soins de Santé (DEQM), la Direction générale des droits de l'Homme et des affaires juridiques, le Comité des Ministres et l'Assemblée parlementaire. Notre bonne volonté seule ne permettra certes pas d'éliminer des pratiques contraires à l'éthique et à la loi mais elle peut, par ses effets, ramener leur incidence à un niveau plus gérable.

La convention MÉDICRIME présente une feuille de route claire pour continuer de progresser vers cet objectif et l'Assemblée parlementaire s'emploiera activement à promouvoir sa signature et sa ratification par le plus grand nombre possible de pays. Cependant, l'amélioration du cadre réglementaire n'est qu'un des éléments de la stratégie.

La volonté politique est nécessaire pour intégrer la convention MÉDICRIME dans le droit national, faire appliquer les lois et établir un système efficace et coordonné de mécanismes de contrôle et de traçabilité permettant d'identifier les produits et de les rappeler en toute sécurité. La police et les douanes devraient disposer d'un nombre accru d'instruments pour arrêter les contrefacteurs et les poursuivre en justice.

Notre succès se mesurera à l'aune de l'impact qu'aura la convention ; or, nous dépendons de vous pour garantir une application effective de la législation sur les médicaments contrefaits : administration sanitaire, instances judiciaires, autorités d'exécution, chefs des services médicaux et pharmaceutiques, responsables des agences du médicament, procureurs, responsables de la police et des douanes.

Je fait appel aux gouvernements des Etats qui vont signer la convention pour mettre toutes les ressources nécessaires à la disposition de l'organe de suivi de la convention MÉDICRIME pour lui permettre de superviser pleinement la mise en œuvre de la convention une fois qu'elle sera en vigueur.

Je souhaiterais aussi voir les futurs Etats parties de la convention apporter un soutien aux activités complémentaires nécessaires menées par le Conseil de l'Europe pour mettre en œuvre concrètement la convention, que ce soit des échanges de bonnes pratiques ou de recherches supplémentaires dans ce domaine.

Pour la mise en œuvre de la convention MÉDICRIME, il faudra des données fiables, un observatoire pourrait être établi sous les auspices du Conseil de l'Europe, éventuellement en coopération avec l'Union européenne, et l'Organisation mondiale de la santé pour rassembler des données sur les affaires de produits frauduleux qui présentent un danger pour la santé publique. Cette mesure faciliterait la décision sur la nécessité d'un protocole additionnel à la convention MÉDICRIME pour en élargir la portée à tous les produits dangereux.

Nous avons également besoin d'un cadre européen et international solide regroupant le Conseil de l'Europe, l'Union européenne et l'Organisation mondiale de la santé. La concurrence n'est pas de mise dans cette entreprise; seul doit prévaloir le besoin pressant d'instaurer une coopération et une solidarité internationales plus étroites pour bénéficier de la contribution de toutes les parties prenantes.

Notre entreprise ne sera pas couronnée de succès si nous agissons isolément.

La convention sera pleinement efficace lorsqu'elle sera ratifiée par d'autres pays en Europe et au-delà. Nous devons sensibiliser les pays du monde entier, en commençant par un noyau d'Etats qui se doteront de systèmes fiables pour empêcher les médicaments contrefaits de pénétrer la chaîne d'approvisionnement.

L'Assemblée parlementaire est extrêmement satisfaite de tout ce qui a été réalisé jusqu'ici et souhaite vivement soutenir les futurs développements en vue de limiter les risques que font courir aux patients les produits médicaux contrefaits.

Je vous remercie beaucoup de votre participation et de votre engagement.

SESSION I
INTRODUCTION TO THE MEDICRIME CONVENTION

The MEDICRIME Convention: history of its development, significance, and relation to other international instruments

Mr Hugo BONAR, Irish Medicines Board

Counterfeiting and similar crimes of medical products is a global challenge requiring a global solution. That solution had not been addressed by the Criminal Law until the adoption of the MEDICRIME Convention in December 2010. It is recognised that more than punitive measures are needed. Improving cooperation at all levels and implementing quality standards and awareness raising initiatives to prevent these crimes involving a threat to public health are also necessary ingredients in this challenge. These are all components of the MEDICRIME Convention.

This presentation reviews why the MEDICRIME Convention is unique. It is the only dedicated criminal law international legal instrument focused on the protection of public health as its primary aim against the threat of counterfeit medical products and similar crimes. As a Council of Europe convention it potentially is open to other countries around the world making it a potential global solution. The presentation discusses other initiatives in this field and why we should pay attention to them. As the illegal trade in in both illegal and authentic medical products is an international one it is necessary for all parties to cooperate to the fullest extent regardless of how well or poorly that their anti-counterfeiting laws and systems are developed. The criminals will exploit the weakest links to circumvent the strongest of laws.

The presentation reviews briefly four high level initiatives and mentions three enforcement led initiatives. The MEDICRIME Convention can support these activities. For the foreseeable future the MEDICRIME Convention is unique in that it will remain the only international initiative of its kind.

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

General principles of co-operation in the judicial field supported by the Council of Europe

Mr Jesper HJORTENBERG, European Committee on Crime Problems (CDPC)

Introduction (general)

Background - Conventions

International judicial cooperation in criminal matters in Europe without the Council of Europe is unthinkable. Many years have passed since the first steps on the road to judicial cooperation were taken in Strasbourg, but what is still impressive – in my view – is the visionary approach the Council of Europe took more than half a century ago.

Back in 1957 and 1959 the need for extradition and mutual legal assistance was – I imagine - quite limited, compared to what we have later experienced. States were in contact with each other, but the big flow of persons, goods and services across borders had not begun. As a simple reflection of that, crime linked in some way to more than one state was known, but not an everyday reality for police, judges or prosecutors. There were not many real opportunities to commit cross-border crime back then.

Nevertheless, the Council of Europe negotiated and opened for ratification the so called "mother conventions" on extradition and mutual legal assistance concluding this work in 1957 and 1959.

These Conventions and their additional protocols are still the pillars of judicial cooperation in criminal matters in Europe.

Many things have changed since then, but the quality of the principles laid down in the texts of the conventions has never been questioned. We still base judicial cooperation on these principles. This is not only a statement for an occasion like this high-level conference, or something I have to say representing the CDPC, which is the steering Committee responsible for the conventions. It is a proven fact from practice around the member states where the conventions are used to get valuable information and to ensure that justice is done.

It is today a simple fact that complex criminal cases could hardly ever be successfully investigated or prosecuted without the possibility to get judicial assistance from other states. We all know that the world has become relatively small. Freedom of movement is now well established, as part of what you could call modern society. But when this freedom is abused by criminals, we need ways to handle criminal cases where we cannot rely only on information available in the state, where the case is conducted, and where the presence of the suspect in that state is not a given thing.

With the help of the Council of Europe Conventions, states and their judicial authorities are able to get the assistance they need.

Principles

The whole idea and the very basic principle of the Conventions is that we base cooperation on mutual obligations and reciprocity. Today, one state is the requesting state and tomorrow it may be the requested state in the same or another case. The existence of rules of cooperation makes the situation in specific cases foreseeable for all the state parties to the Conventions. Law enforcement in the involved states can base its casework on these possibilities. Impunity for criminals is at the same time made difficult. Escaping or dividing your activities between different states should not bring criminals outside the reach of justice.

Mutual legal assistance in accordance with the 1959 Convention and its Protocols should be afforded promptly and should include the widest measure of mutual assistance as stated in article 1. Also the 1957 Convention on Extradition opens up for quite extensive possibilities of arrest and transfer from one state to the other of persons suspected or convicted in criminal cases.

The Conventions contain a lot of detailed rules and it is not my intention to go through all these rules, many of which limit the general principles that vide measures of assistance shall be afforded. One could say that it is almost a basic principle that states have been reluctant to accept any request for assistance. There are limits to how far a state can go. State sovereignty was relevant when the Conventions were drafted and still is. Justice issues are core issues, also in modern states. It is thus no surprise that there have been many matters to discuss over the years, but as the Protocols to the Conventions show, there is a movement towards fewer restrictions in the area of judicial cooperation.

A typical theme for discussion has been double criminality – meaning basically that assistance may only be afforded when the crime in the requesting state, which the request to assistance refers to, is also considered a crime in the requested state. Common substantial criminal law provisions as foreseen for instance in the MEDICRIME Convention could therefore be a very good idea. If you look back over the years themes such as ordre public, political offences, fiscal offences and the need to apply domestic procedures when handling requests, are classical discussion points. But again, a movement towards fewer restrictions can be observed, although not all states move at the same time and there is still quite a way to go. The more states share common legal structures and legal principles, the easier it is to cooperate. Something which also lies behind the MEDICRIME Convention.

Other points, which have often been discussed over the years, are related to procedures. It is more and more accepted that judicial authorities should be able to communicate directly with each other. It is, from a practical point of view, by far the easiest way to gain good results in specific cases. This issue is also linked to the important problem: Speed.

To get assistance from another state takes very often time – sometimes a lot of time. The conventions do operate with certain time limits or statements related to the need for promptness, but I believe this is still an issue, that is a daily problem for many practitioners.

Cases are very different, so fixed time limits may be problematic. Many problems are linked to the functioning of national systems. Lengthy procedures, appeals and much more along these lines.

The problem is also linked to communication. It is my experience that most prosecutors or judges in requested states should pay more attention to informing the requesting party about what is happening in the case, they have received. The following questions are typically relevant to the requesting state:

Was the request received?

What will happen next?

Are there any legal problems?

Does the requested state need clarifications?

What is the time frame for execution of the request?

Will there be appeal possibilities?

I am, anyhow, not very pessimistic about judicial cooperation. My experience - and also the most recent at EUROJUST - is that it is generally possible to get the assistance that the authorities are looking for. Many practical issues are to be solved in each case, but generally the Council of Europe Conventions work quite well.

The Conventions and Protocols are well known all over Europe. Not every child knows them, but judicial authorities do in general, and the principles are quite easy to apply and also adjustable to developments. Possible improvements are constantly considered by the PC-OC Committee of the Council of Europe - a work that has resulted in several additional protocols already. The work of the PC-OC is closely followed by the CDPC, which I am representing here today.

I mentioned practical issues a minute ago. Practical issues are in the hands of practitioners – police, prosecutors, judges. It is therefore worthwhile thinking of what we can do for practitioners and this is also considered by the Council of Europe. At the same time networks are developed around Europe and also in other parts of the world, making the people doing "hands on work" get together and facilitating daily business. EUROJUST, where I work on a daily basis, is also representing this trend, in that case within the European Union. EUROJUST is in no way a very closed "club". Via agreements and contact points EUROJUST is also open to the rest of the world. I find these trends in judicial cooperation positive and worth enhancing.

The MEDICRIME Convention and cooperation

Being this a conference on the MEDICRIME Convention, I will also say a few words about the provisions in that Convention on international cooperation in criminal matters. The provisions can be found in article 21

"Article 21 – International co-operation in criminal matters
1 The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.
2 The Parties shall co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention.
3 If a Party that makes extradition or mutual legal assistance in criminal matters conditional on the existence of a treaty receives a request for extradition or legal assistance in criminal matters from a Party with which it has no such a treaty, it may, acting in full compliance with its obligations under international law and subject to the conditions provided for by the law of

the requested Party, consider this Convention as the legal basis for extradition or mutual legal assistance in respect of the offences established in accordance with this Convention."

This article sets out the general principles that should govern international cooperation in criminal matters related to the scope of the MEDICRIME Convention.

Paragraph 1 obliges Parties to co-operate, on the basis of relevant international and national law, to the widest extent possible for the purpose of investigations or proceedings of crimes established under the Convention, including for the purpose of carrying out seizure and confiscation measures. In this context, particular reference is made to the European Convention on Extradition (CETS No. 24), the European Convention on Mutual Assistance in Criminal Matters (CETS No. 30), the European Convention on the Transfer of Sentenced Persons (CETS No. 112), the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (CETS No. 141) and the Council of Europe Convention Laundering, Search, Seizure and Confiscation of the proceeds from Crime and on the Financing of Terrorism (CETS No.198). Hereby I have also highlighted some of the other relevant conventions in the area. The method used in article 21 is quite usual for the Council of Europe in this field. New Conventions make reference to existing Conventions but do not repeat provisions that can be found elsewhere.

In the same way as for paragraph 1, paragraph 2 obliges Parties to co-operate, to the widest extent possible and on the basis of relevant international, regional and bilateral legal instruments, on extradition and mutual legal assistance in criminal matters concerning the offences established by the Convention.

Paragraph 3 is also important and adds further value in the context of the MEDICRIME Convention.

It 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, which serves no purpose between Council of Europe member states because of the existence of the European Conventions on Extradition and Mutual Legal Assistance in Criminal Matters, dating from 1957 and 1959 respectively, and the Protocols to them, is of interest because of the possibility provided to third states to sign the Convention (Article 28). The requested Party will act on such a request in accordance with the relevant provisions of its domestic law which may provide for conditions or grounds for refusal. Any action taken shall be in full compliance with its obligations under international law, including obligations under international human rights instruments.

Concluding remarks

This brings me to the end of my intervention. I started by commenting the visionary approach taken more half a century ago when drafting and concluding the "mother conventions" on mutual legal assistance and on extradition. You can take the usefulness of these Conventions for more than 50 years as a good sign.

Well prepared and highly relevant Conventions will have a long life. The MEDICRIME Convention is another and more recent example of work well done. It means that there are very good possibilities of a long and prosperous life for this Convention as well, to the benefit of public health and the citizens of the states that will sign and ratify the Convention.

Thank you for your attention.

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

Support by the EDQM for prevention and follow-up measures included in the MEDICRIME Convention

Mr Domenico DI GIORGIO, Chairman, European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

The cooperation between the points of contact in the interested administrations, at a national and international level, is one of the key points to consider in the strategies against illegal medicines.

Council of Europe Committees of Experts foster this process through the development of ad hoc tools (training sessions, publications, databases...) aimed at reaching the full establishment of an efficient network between all stakeholders, allowing a timely and secure exchange of data on suspect cases.

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

Added value of the MEDICRIME Convention

Mr Gerald HEDDELL, Medicines and Healthcare products Regulatory Authority (MHRA), United Kingdom

The Council of Europe MEDICRIME convention on the counterfeiting of medical products and similar crimes involving threats to public health has been published and will be open for signature on 28 October 2011. The convention is designed to address counterfeit medical products through penal sanctions, preventative measures, the protection of the rights of victims and promotion of international co-operation on counterfeiting and similar crimes.

The focus of the convention is specifically on the protection of public health and does not cover infringements of intellectual property rights. This convention is designed to encourage member states to ensure that they have adequate legislation in place to combat the threat of counterfeit medical products and is part of a series of Council of Europe initiatives targeted at this issue.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been directly involved with the Council of Europe with regards to the issue of counterfeit medicines since 2004, helping organise the 'Combat the Counterfeiter' Seminar in Strasbourg in 2005 where the concept of a convention was first tabled. Since then, the MHRA and other UK officials have participated in the negotiations towards the development of this convention and see it as an extremely useful tool both for countries developing a response to this issue and those that have been dealing with the problem but have inadequate legislation in place in all necessary areas to tackle counterfeit medical products.

The presentation will highlight the key areas that the Council of Europe MEDICRIME Convention covers, providing examples of counterfeit medicine cases in the UK where the MHRA has benefitted from legislation/arrangements in the key areas or may benefit from improved procedures in the future:

- The manufacturing of counterfeit medical products
- The supply, offering and trafficking of counterfeit medical products
- The falsification of documents
- Investigation and prosecution
- Sanctions - penal and administrative
- Co-operation amongst authorities - national and international
- Preventative measures

The UK plans to sign the Council of Europe MEDICRIME Convention in the near future once necessary national approval processes are complete.

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

Added value of the MEDICRIME Convention

Mr Cosimo PICCINNO, Italian Carabinieri for Public Health Safety

Analysis results confirmed that the pharmaceutical crime is a transnational phenomenon developed in different countries with different legal systems. This is a barrier, sometimes insuperable, for police forces and enforcement agencies.

The signature of the MEDICRIME Convention is a relevant signal for the Council of Europe countries that will have the possibility to facilitating the approval of new laws to fight against counterfeiting of medical products and similar crimes.

The experience of a specialized police force in this sector revealed that more often international investigations cannot be carried out effectively across the countries involved because in some circumstances the pharmaceutical crime was not considered a criminal crime thus international police communication channels cannot be followed.

Another added value of the MEDICRIME Convention is the possibility to embrace a larger number of countries than the EU Member States. Many extra EU Member States are afflicted by pharmaceutical crimes and still don't have appropriate legislative measures to tackle this phenomenon.

Finally, a proposal to facilitate the activity of the enforcement authorities: the creation of a MEDICRIME network of experts. Each Council of Europe Member State should identify a contact person/agency that will be able to give information about the pharmaceutical legislation in his country and periodically inform about the state of the art about the signature of the MEDICRIME Convention and future legislative developments

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

International co-operation initiatives

Why should international organisations co-operate? Why should capitals do their homework?

Mr Bart WIJNBERG, Expert, Netherlands

I will briefly outline that the Council of Europe, WHO, OECD, Interpol, ICU, the EU and a number of other international organizations as well as NGOs and the private sector have contributed or are contributing to an international anti-counterfeiting web or network. If each organization seeks its strength, and from this position of strength seeks cooperation, this will strengthen the public health goal of protecting citizens – patients and others.

BUT, the work starts in capitals. The parties involved, in particular the Ministries should do their homework first and coordinate among many parties involved in combating counterfeiting.

My talk will include some remarks on the use of some terms used and the political ramifications of terminology.

One message will be that the MEDICRIME Convention is intended and has potential to inspire parties to cooperate.

SESSION II
CO-OPERATION BETWEEN STATES UNDER THE MEDICRIME CONVENTION

International co-operation in the official quality control of medicines

The co-operation within the European Network of Official Medicines Control Laboratories (OMCL Network)

Ms Popi KANARI, State Control Laboratory, Cyprus

Counterfeiting is a multi –billion industries that poses a major threat not only to patients who are more vulnerable but to the general public. The Council of Europe has drawn up the first International MEDICRIME Convention to criminalise the manufacturing of counterfeit medical products, supplying, offering to supply and trafficking, the falsification of documents, the unauthorised manufacturing or supplying of medical devices that do not comply with conformity requirements. The MEDICRIME Convention is a legal instrument that can not only protect human lives but also the rights of the victims and it is open for adoption to members as well as non members of the Council of Europe. The implementation is based on 3 pillars that target on strengthening: existing and promoting new legislative and administrative procedures and measures, co-operation and collaboration at a National level and International level between Health Authorities, Customs, Police and Judiciary system as well as between Authorities and Industry, expertise and means in the identification for detection for prevention. OMCLs play a key role in certain articles in The MEDICRIME Convention namely- Articles 17, 18, 22 and 25.

The OMCLs have a great capacity to support Law Enforcement, Drug Regulatory Authorities and Customs as they have a plethora of data collected over the years on original and generic drugs –less on APIs, as well as on counterfeit products and therefore can describe and identify obvious differences to the genuine/authorised product –active ingredient, colour, physical characteristics, related substances, can link with analytical and technical expertise one counterfeit with another, can link a counterfeit product with API /Raw materials if available and can even link a counterfeit product with illegal/unauthorised manufacturing premise if there is sufficient data.

However, OMCLs need to enhance further their capacity to support even more the implementation of the Convention at a technical level. They should use existing intelligence to tailor specific sampling schemes targeted for the identification of counterfeit drugs, cover the whole distribution chain (including internet pharmacies) with the collaboration of the Drug Authorities, have more information on traceability (if known) of a product should be given to OMCLs by Regulatory Authority, apply more techniques for labelling and packaging. They should also look more into APIs and their impurities (profile as tracer, residual solvents), excipients (IR, NIR) coating-Specific surveillance programmes on APIs, keep a good data bank for all these details for comparisons (if possible use software available in the trade and have easier access to reference standards not provided by EP e.g. anabolics.
At the same time EDQM can further enhance the role of OMCLs in the area of counterfeits by strengthening data on APIs involving more OMCLs (collaborative studies) and also give OMCLs access to impurity profiles of Authorised APIs, provide a forum for information exchange, raise awareness to the Strengthen data on APIs, involving more OMCLs (collaborative studies), give OMCLs access to impurity profiles of Authorised APIs, provide a forum for information exchange, raise awareness to the public with the support of the OMCL network, provide training opportunities to OMCLs and to other stake holders with the

collaboration with OMCLs, provide awareness to the public , provide training opportunities to OMCLs and to other stake holders with the collaboration with OMCLs.

The way forward for the implementation of the MEDICRIME Convention is, apart from the political will, for EDQM in collaboration with OMCLs and Regulatory Drug Authorities to optimize the use of existing networks and infrastructures at both national level and a European/International level to facilitate further the implementation of the Convention.

It is important also to set up a risk management procedure/system for suspected counterfeit products and adverse drug reaction (ADR) reporting and pharmacovigilence system. Within the Network, centres of technical expertise (in specific techniques i.e. NMR) in counterfeit drugs can be set up to provide either training or assistance or data if needed- thus saving resources.

OMCLs could also collaborate more with Academia for specific techniques.

It is essential however that a minimum expertise in the identification /analysis of counterfeit products should exist in all OMCL s so that in a crisis case (e.g. Paracetamol case involving children) a country can respond and take measures immediately.

By exchanging knowledge and skills and streamlining the expertise within the OMCL Network a better informed risk analysis is achieved, limited resources are utilized to address counterfeiting by avoiding duplication, more coordinated and multi-disciplinary (Customs, Police, Justice) investigations are put forward, and from such results more counterfeiting groups are dismantled /disrupted Protecting Public Health –protecting possible victims from counterfeit medical products.

SESSION III
NETWORKING - A KEY TO FIGHTING COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES & THE SUCCESSFUL IMPLEMENTATION OF THE MEDICRIME CONVENTION

A network of points of contact to support the fight against counterfeit medical products and similar crimes

Multisectorial co-operation based on the Council of Europe model of a network of single points of contact (SPOCs)

Mr Roy VANCAUWENBERGHE, Belgian Federal Agency for Medicines and Health Protection

There is no "one bullet" strategy for fighting counterfeiting of medical products and similar crimes. The only choice is a multidisciplinary and multisectorial approach for detection, communication, investigation and prosecution. The main stakeholders are the drug regulatory authorities (DRA), police, customs, justice and industry. The lack of communication, information exchange and joint operational action between them gives the lead to the criminals and is a waste of time and resources.

The most important part of the anti medical products' counterfeiting and similar crimes' strategy is the improvement or strengthening of collaboration between DRA, police, customs and justice at national and international levels. The different stakeholders have their own competences, expertise and jurisdiction which create the framework for cooperation and information exchange. The secrecy of investigation may not hamper the safeguarding of public health and a proper balance between the interests of law enforcement and respect for fundamental human rights is needed.

The DRA should be informed whenever medicinal products are involved and the assistance by the relevant commercial and industrial sectors to the competent authorities regarding risk management is needed, as these sectors have vast product expertise which is very valuable for networking and the decision-making process.

Different jurisdiction, expertise, know-how, possession of information and the absence of a harmonised and common approach in investigations and information-sharing at national level can only be streamlined by organising a platform where all stakeholders meet each other. A national network of liaison officers connecting their different authorities is a condition sine qua non to fight counterfeit medical products and similar crimes. The (Single) Point of Contact needs not necessarily to be an individual person but may also be an entity such as a group or a department within an agency. The network should function as an operational tool and, if necessary, provide information to investigators, collect and centralise all information (database) and disseminate to the network partners on a need to know basis. This is the common denominator for networking and cooperation. The added value of networking and cooperation for politicians and the different authorities is advice on how to adjust their policies and strategic choices and making important savings in terms of time and resources.

Since different countries have different approaches to counterfeit medical products and related crimes no unique structure of a network can be imposed. Most of the countries have one or another way of collaboration between DRA, customs and police.

The MEDICRIME Convention draws the lines of a collaboration framework consisting mainly of networking and information exchange within the limits of domestic law. It does not in any way oblige Parties to introduce new bodies tasked with co-ordination and information exchange in the field of counterfeiting of medical products and similar crimes.

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Multisectorial assistance programmes in the fight against counterfeit medical products and similar crimes based on the example of Portuguese-speaking countries

Mr Helder MOTA FILIPE, Portuguese National Authority of medicines and Health Products, I.P. (INFARMED)

Portugal has a long standing cooperation with Portuguese speaking countries namely African Portuguese speaking countries.

The phenomenon of counterfeited medical products is one of the biggest problems these countries face in the access to medicines. INFARMED works closely with these countries in many areas providing regulatory and scientific support and has for some years has also provided technical assistance in the area of counterfeited medicines through several actions and initiatives hoping to help in the development of the necessary infrastructures to tackle this problem effectively. Benefitting from long relationships, we set out to support the setting up of a SPOCs network between these countries. Although this objective is not yet completely achieved steady steps have been given and lessons learnt in search of the successful attainment of these objective.

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES OF INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Protecting the legal medical product and its production and distribution chain – prevention, risk management & co-operation with authorities

The contribution of the international pharmaceutical industry to fight against counterfeit medical products and similar crimes

Mr Ashley HOW, Director Europe, Pharmaceutical Security Institute (PSI)

Industry has a key role to play in combating counterfeit medical products and similar crimes. Industry knows its own products, its product and packaging security features and how those products should be made. It employs expert technical and scientific operations to identify and analyse counterfeit versions of its medical products and investigative operations to identify and track down those international criminals responsible for the manufacture and distribution of those counterfeit products. It then provides evidence of those crimes and the criminals responsible to the relevant authorities and supports the ensuing prosecutions by providing expert evidence. In order to tackle the problem there is a need to understand the true scale and nature of the problem and to help achieve that the research-based pharmaceutical industry created the Pharmaceutical Security Institute, PSI.

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES FOR INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Initiatives aimed at strengthening the integrity of the legal production and distribution chain

The EDQM tracing service project (eTACT) and its support for the objectives of the MEDICRIME Convention

Ms Susanne KEITEL
Director of the European Directorate for the Quality of Medicines & HealthCare

The Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM) have developed a comprehensive anti-counterfeiting strategy which includes a number of activities, e.g. the adoption of the MEDICRIME Convention on counterfeiting of medical products and similar crimes involving threats to public health and the training of customs, police and health officers. As part of this anticounterfeiting strategy, a new EDQM project called eTACT aims to develop a traceability and mass-serialisation system that can be used by authorities and stakeholders (i.e., manufacturers, suppliers, distributors, healthcare professionals, patients) across the global pharmaceutical supply chain. Giving patients the option of verifying the authenticity of their medication is a unique feature of EDQM's project which will significantly contribute to strengthening the public's confidence in the legal supply chain.

The eTACT system will rely on a central EDQM repository, supported by decentralised repositories among the manufacturers or with national bodies in an information-sharing model. Existing national systems will remain in place. The flexibility of this approach is a prerequisite for dealing with the key challenge of interoperability and for preparing for the complex implementation of future European requirements for traceability of medicinal products as defined by the recently adopted European Union Falsified Medicines Directive 2011/62 and its future delegated acts.

By providing business stakeholders and regulators with a flexible pan-European system, the EDQM eTACT project allows for a harmonised, standardised, and centralised securitisation of the legitimate pharmaceutical supply chain, whatever the distribution route. The system extends to the legitimate Internet sales of medicines promoted in some European countries for economic reasons. Public governance of such a system is vital to ensure effective and proper project development in coordination with regulatory authorities and to prevent the misuse of data (e.g., commercial data, information to patients on product).

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES FOR INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Protecting the patient and the consumer - practical co-operation on the international level

Trade in counterfeit medical products via the internet

Mr Stephen McMAHON, International Alliance of Patients' Organizations (IAPO)

No one State, Institution, government or non-government organisation has the capacity to counter illegal counterfeiters of medicinal medications and devices on their own. Good Law is good because it is enforced and has the support and trust of the wider societies.

In my presentation I want to explain that the first steps by Patients from all around the world have been taken and that they are not only talking to each other but are sharing best practices thereby accelerating improvements in quality healthcare.

The counter measures to take out counterfeiters of medicines and devices are many, but it is at the patients' laptop all around the world that we can work together and inform them of the dangers, and play a small yet important part to protect the lives of many, and basic societal infra-structure.

We must also be prepared that the distribution of counterfeit medicines in times of pandemic fears can be motivated by other extreme agendas that may not be motivated by fiscal profit.

In the final analysis "Reform and change in our health care systems should not be preceded by funerals and injury to patients"

This is why the Signing of the MEDICRIME convention is a major milestone to protect vulnerable patients

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES FOR INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Protecting the patient and the consumer - practical co-operation on the international level

Multisectorial co-operation as regards the fight against the trade in counterfeit medical products and similar crimes via the internet

Mrs Lynda SCAMMEL, Medicines and Healthcare products Regulatory Authority (MHRA), United Kingdom

Operation Pangea is an international initiative which has been running for 5 years and targets illegal activity involving medicines being offered for sale on the Internet.

This is the largest enforcement operation tackling Internet sales of pharmaceuticals and includes INTERPOL, IMPACT, the World Customs Organisation (WCO), the Permanent Forum on International Pharmaceutical Crime (PFIPC) and the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO).

Operation Pangea IV ran between 20 – 27 September and 81 countries (a record number!) across the world joined forces to take action against this illegal and dangerous activity.

The results are very encouraging.
Approx 8,000 packages were seized containing nearly 2.5 million doses valued at approximately £5 million (of which UK seizures were 1.2 million doses)
Approx 13,500 websites taken down (of which 12,800 were by the UK with Metropolitan Police Central eCrime Unit)
606 internet adverts removed from auctions sites and social media websites.

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES FOR INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Protecting the patient and the consumer - practical co-operation on the international level

Control of postal shipments as a key component of the effective fight against counterfeit medical products and similar crimes

Mr Ashley HOW, Director Europe, Pharmaceutical Security Institute (PSI)

The counterfeiter and/or the distributor operating at the first point of distribution will not be successful unless he/they can successfully distribute the products. The Internet is the preferred market place for a high percentage of such counterfeit medical products and similar crimes and the post/parcel systems are exploited and utilised as the supply chains. If the criminals can ensure that significant quantities of their illegal products are delivered into the market place to others that will distribute them to the customers then they will have achieved success. In the E.U., for example, if the efforts of customs at the border can be thwarted then the products can be in free circulation. In both instances the post and parcels systems are being used. Therefore, for the authorities to achieve success to combat this problem there needs to be greater focus on the issue, increased resources to tackle the problem and better coordination between countries.

SESSION IV
MEDICRIME CONVENTION: PERSPECTIVES FOR INDUSTRY, DISTRIBUTION AND HEALTH PROFESSIONALS

Protecting the patient and the consumer - practical co-operation on the international level

Modern approaches to risk communication in combating counterfeit medical products and similar crimes: public campaigns and information about incidences

Mr Domenico DI GIORGIO, Director of Italian Anti-Counterfeiting Unit, AIFA

Risk communication is an essential element of the strategies and activities used to counteract the risks posed by the counterfeiting of medical products and similar crimes.
The two basic risk-communication approaches, "proactive" (awareness-raising/ preventive) and "reactive" (incident-related) communication, should be appropriately managed, through a science-based approach (both in healthcare and communication issues), in order to empower all stakeholders, including consumers and patients, to actively contribute their share to contain risks for their health, without generating anxiety or panic.

BIOGRAPHICAL NOTES

Mr Andreas Balsiger Betts is Head of Legal Affairs and Member of the Management Board of Swissmedic, the Swiss Agency for Therapeutic Products. He is a lawyer by profession and did his studies at the University of Bern. It is also in Bern, where he passed his bar exam. After graduation he worked as a research associate at the Department for Public Law from 1985 to 1987. From 1988 to 1995 he was an Examining magistrate and District Court judge in the Canton of Bern. In 1995 he joined the Legal Department of the Swiss Federal Administration of Finance as Head of a Legal Division and in 1997 he became General Counsel of the City of Bern. He left this post in 2003 to join Swissmedic, where he built up the Legal Services and placed special emphasis on creating a Penal Division.

Mr Hugo K. Bonar, B.A., LL.B, TEP
Hugo Bonar is the Enforcement Manager, Irish Medicines Board (IMB). He holds degrees in Public Sector Management from the Institute of Public Administration, Dublin, and in Laws from Trinity College, Dublin. He established the enforcement facility in the IMB in 2000 when he joined the Board. He previously served as an Army Officer in the Irish Defence Forces. He is a qualified lawyer (Ireland and New York). He was an expert member of the drafting and negotiating committees for the MEDICRIME Convention development at the Council of Europe. He was the moderator for the Council of Europe's workshop 'Medicines on the Internet' at the Internet Governance Forum, 2009. He is the past Chair of HMA WGEO; currently a member of the Management Committee of PFIPC and of the Management Committee of the International Internet Week of Action (Operation Pangea).

1/2 Dr. Domenico Di Giorgio, Agenzia Italiana del Farmaco (AIFA)
is Director of the Counterfeit Prevention Unit for the Italian Medicines Agency (AIFA). He holds a PhD (1994) in biochemistry and a BSc (1990) in Chemistry from the University of Rome (La Sapienza). From 1996 he was senior GMP inspector for Ministry of Health and AIFA and since 2003 he started working on anti-counterfeiting: currently, he is responsible for coordinating the national anti-counterfeiting activities as coordinator of the national task-force IMPACT Italia and of the "Pharmaceuticals and Cosmetics" working group at the National Anti-Counterfeiting Council.
He is the editor of the books "Counterfeit medicines: facts and case studies" (Council of Europe, EDQM, 2009), the IMPACT Handbook (IMPACT, AIFA, 2011), "Counterfeit medicines" (Council of Europe, EDQM, AIFA, 2011), "Counterfeit medicines: risk communication" (Council of Europe, EDQM, AIFA, 2011), and of the related booklet series aimed at the training of the investigators. He is Chairman of the EDQM, Council of Europe "Committee of experts on minimising public health risks posed by counterfeiting of medical products and related crimes" and "European Committee on Pharmaceuticals and Pharmaceutical Care": coordinator and member of the organising committee of the AIFA-WHO international conference "Combating Counterfeit Drugs" (Rome, 2006);
2/2 Dr. Domenico Di Giorgio
Italian member and Acting Executive Secretariat responsible for IMPACT-WHO; Consultant of the Italian Senate (e-pharmacies and counterfeit medicines).

Mr Jeffrey L. Gren, office of health and consumer goods, U.S. department of commerce. Mr Jeffrey L. Gren is Director of the Office of Health and Consumer Goods (OHCG) within the U.S. Department of Commerce. OHCG's mission is to

help U.S. health and consumer goods firms to compete in world markets by fostering export opportunities, providing support for trade negotiations, performing industry analysis, working with foreign governments to reduce regulatory and other trade barriers, and developing industry-led joint government/industry initiatives. Examples of major accomplishments as Director of OHCG include leading global activities to stop the spread of counterfeit medicines, serving in a leadership role in the U.S. - China Pharmaceuticals and Medical Devices Subgroup and organizing numerous health regulatory training programs for regulators and firms from countries with developing revised regulatory regimes, such as China, Russia, Ukraine, Asia and Latin America. Mr. Gren has been with the U.S. Department of Commerce since 1976 and has held several past positions as well. Mr. Gren has a Masters of Arts in Economics from North-eastern University, Boston, Massachusetts in 1972, and a Bachelor of Science in Business Administration from North-eastern University in 1971. In 2007, 2003, 1999, and 1997 Mr. Gren received the International Trade Administration Bronze Awards, and in 2010, 2009, 2000 and 1996 he received the Department of Commerce Silver Awards.

Mrs Josée Hansen, Pharm. D
She is chief inspector for pharmaceutical affairs and medical technology at the Dutch Health Care Inspectorate.
She was Dutch delegate at various Council of Europe expert committees on pharmaceutical questions, counterfeit medicines and medication safety. Currently she is head of Dutch Pharmacopoeia Authority and leads the Dutch delegation in the European Pharmacopoeia Commission.
From 2007-2010 Mrs. Hansen was project leader at WHO in Geneva of the Priority Medical Devices project which resulted in the report "Medical devices, managing the mismatch", published in September 2010.

1/2 Mr Gerald W. Heddell, Director of Inspection, Enforcement & Standards Medicines & Healthcare products Regulatory Agency
Gerald Heddell joined the MHRA as Director of the Inspection, Enforcement & Standards Division on 4 January 2005. Gerald is a microbiologist who is a Chartered Biologist and a member of the Society of Biology and the Royal Society of Chemistry. Since leaving the U.K. National Health Service in 1978, he has worked in a succession of progressively senior roles in manufacturing and quality assurance in the pharmaceutical industry. Gerald has experience in most aspects of pharmaceutical manufacture and control. This has included microbiological development, analytical laboratory management, quality assurance, business development, director of a large

2/2 Mr Gerald W. Heddell
Sterile manufacturing facility and, most recently, European Quality and Compliance Director for GlaxoSmithKline. In his current position with the MHRA, Gerald's responsibilities focus on the quality of medicines in the U.K. and include a comprehensive surveillance, inspection and enforcement programme, the licensing of pharmaceutical manufacturers and wholesalers, defective medicines reporting, unlicensed imports, borderline products, medicines testing and the British Pharmacopoeia.

Mr Jesper Hjortenberg was appointed National Member for Denmark at EUROJUST on 01 September 2010. He has been a prosecutor since 1988 and has worked at the Office of the Danish Director of Public Prosecutions for many years. From 2002 to 2007, he was Head of the International Division of the DPP's Office,

and since 2007 served as Deputy Director with responsibility for casework and international matters.
He prosecuted a large number of cases before the Danish Supreme Court from 1996 to 2010. Mr Hjortenberg participated in negotiations for the EU 2000 Convention on mutual legal assistance and the 2002 EUROJUST Decision as part of the Danish delegation at the meetings in Brussels, and has been Danish member of the Council of Europe Steering Committee on Crime Problems (CDPC) for more than ten years.
He is currently a member of the CDPC Bureau.

Mr. Ashley How is the Europe, Middle East & Africa Director, for the Pharmaceutical Security Institute, PSI, a position he has held since 4th May 2004. He is based in the UK. Ashley works closely with the Institute's twenty six members to ensure the integrity of pharmaceuticals and, most importantly, to protect public health. His core functions are to support the efforts of the PSI Members, law enforcement agencies and drug regulatory authorities to combat counterfeit medicines, to liaise with national and international organisations in the field of counterfeit medicines, to gather information and intelligence on all aspects of illegal medicines and to provide training and awareness raising in relation to pharmaceutical crime. Ashley represents the Institute at numerous international meetings, conferences and seminars. Prior to this appointment Ashley served 30 years with the Metropolitan Police in London, England, 28 years of which were spent as a detective. Much of his detective career was spent working on operational units based at Scotland Yard investigating serious and organised crime both in London and the UK as well as on an international level where it impacted upon the UK. His last position was with the UK's National Hi-Tech Crime Unit and his role there included representation of the UK as a hi-tech crime expert at INTERPOL, G8 and other international fora.

1/2 Mrs Popi Kanari, BSc, Ph.D.
Dr Popi Kanari is the Director of State General Laboratory in Nicosia, Cyprus which is a Department of Ministry of Health. She holds a PhD (1974-1977) in Chemistry from the University of London and a BSc (1971-1974) in Chemistry from the same University. From 1977 till 1980 she was employed in higher education. In 1980 joined the State General Laboratory and since 1990 she worked as an Analyst - Grade I, in Pharmaceuticals and in Forensic Chemistry and Toxicology Labs.
2/2 Mrs Popi Kanari
In 1990 she was promoted Senior Analyst (part of the Management team). She was Head of: Section B, namely: (a) Forensic Chemistry (Narcotics) and Toxicology Lab., (b) Pharmaceuticals (Veterinary and Human) and Cosmetics Lab. and Food Supplement, (c) Veterinary Drug Residues Lab., and (d) All labs accredited by ISO 17025. She has served as head of National Anti-Doping Committee for 6 years and is a member in National and International Boards and Committees, Member of the expert Committee on Counterfeit Pharmaceutical products of the Council of Europe 2007-2010, Expert of Council of Europe on Counterfeit Drugs – Drafted the Convention on Counterfeit Medicines, Member of the Advisory Forum of EFSA etc. She is the author more than 100 scientific papers in international or national scientific journals and conference proceedings.

Mrs Susanne Keitel is a licensed pharmacist with a Ph.D. in pharmaceutical technology. Her work experience includes 10 years in pharmaceutical development in industry, with five years as Department Head of "Pharmaceutical Development/Oral Dosage Forms" at the former Schering AG, Berlin. From 1997 to 2005, she held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs

and Medical Devices (BfArM), Germany. She additionally served as Acting Head of the Division European Procedures from November 2003.
From July 2005 to October 2007, Susanne Keitel was Head of EU, International Affairs at BfArM. During her time with BfArM, she represented the agency in a number of EU committees. She was actively involved in the International Conference on Harmonization (ICH), where she represented the E.U. as topic leader and rapporteur. On a national level, she was, from 2001 to 2007, Chair of the German Pharmacopoeia and the German Homeopathic Pharmacopoeia. Since October 2007, Susanne Keitel is Director of the European Directorate for the Quality of Medicine & HealthCare (EDQM) of the Council of Europe in Strasbourg.
She also lectures in the postgraduate course "Master of Drug Regulatory Affairs" at Bonn University, where she is responsible for the module on the quality dossier. In 2009, Dr. Keitel was elected as corresponding Foreign Member at the French Académie Nationale de Pharmacie.

Mr Bernard Marquet
Né le 13 juillet 1955, marié, trois enfants. Docteur en chirurgie dentaire. Membre de l'Assemblée Parlementaire du Conseil de l'Europe depuis 2005
Rapporteur de La qualité des médicaments en Europe qui a demandé la Convention MEDICRIME, et rapporteur du Projet de convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique.
Président de la Commission de l'Environnement et du Cadre de Vie du Conseil National de Monaco
Vice-président de la Commission des questions sociales, de la santé et de la famille du Conseil de l'Europe.

Mr Stephen McMahon, Ireland, IAPO, Treasurer and Board Member. He formally worked in the Oil Industry for 30 years. He co-founded the Irish Patients' Association (IPA) and is currently its executive Chairman, the IPA is based in Dublin and is a voice for patients in Ireland. The Irish Patients Association listens and learns from the many experiences of patients, their families and carers and helps resolve their issues and bring problems to the fore. The ultimate goal of the Association is a world class, patient centred health care system that is built on trust. The IPA is working alongside many healthcare organisations and educational centres in Ireland, ensuring that the patient remains at the very centre of healthcare. Patient safety is a key to that goal. Mr McMahon commissioned Dublin City University to produce a briefing document to raise the seriousness of counterfeit medicines for the then Minister responsible for medication in 2005. He advised the Irish Department of Trade in preparing its successful submission for the E.C. Security FP call for 2010 which provided FP7 funding for innovations to tackle counterfeit medicines. He has organised multi stakeholder meetings in Ireland to combat counterfeiters. He has briefed other patient groups with an interest in this area of patient protection.

Mrs Ruth Mosimann is Head of the unit Control of Illegal Medicines, at Swissmedic, the Swiss Drug Regulatory Agency. She holds a diploma of pharmacy by the University of Berne (1991). Prior to joining Swissmedic, Ruth worked for pharmaceutical industry. She worked in development divisions for the international companies Schering-Plough, Novartis and CSL Behring. Ruth had either managerial or project management jobs, but always in the field of clinical supplies which involved

packaging and international logistics of products in development. In May 2006 she was hired by Swissmedic as a scientific officer responsible for counterfeits and illegal trade within Switzerland. One year later, a new unit for market monitoring of illegal medicines was created and Ruth was promoted to head this unit. Her unit is active in enforcement against illegal trade, imports of medicinal products, counterfeits and in pharmaceutical expertise in penal cases. Since 2008, she is Vice-Chair of the Council of Europe Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes.

1/2 Prof. Helder Mota-Filipe, National Authority of Medicines and Health Products (INFARMED I.P.), Portugal
is Vice-President of the Executive Board of INFARMED, I.P., National Authority of Medicines and Health Products, since 2005. He was in charge of the Inspection, Licencing and OMCL sectors (2005-2010). He is currently responsible for the human medicines and medical devices sectors. He is currently the chairman of the INFARMED's taskforce on counterfeited medicines. He is Associate Professor of Pharmacology and Therapeutics at the Faculty of Pharmacy of the University of Lisbon. He is also Principal Investigator in Pharmacology and Translational Research Unit at the iMED (Institute for Medicines) from University of Lisbon. He holds a PhD (1996) in Pharmacology and a PharmD (1990) from the Faculty of Pharmacy of the University of Lisbon. He is extensively involved in the development of research programs, such as Immunopharmacology and pharmacological modulation in ischemia-reperfusion and shock.
2/2 Prof. Helder Mota-Filipe
He is a member of several Scientific Societies. He has been Member of the National Research Ethics Committee (2004) and EMA expert in Human Medicines Safety (2003). He has been member of CHMP (EMA) since June 2011.

Brigadier General Cosimo Piccinno was born in Naples on June 24, 1950.
He is married and has two daughters and two granddaughters.
He joined the Carabinieri Force in 1973. During the first four years of his career, he was stationed in the Puglia and Veneto Regions.
From 1977 to 1990, he was Commander of the Carabinieri Companies in Campania Region. During the next three years, he was Senior Officer at the Carabinieri General Headquarters dealing with subversion and organized crime.
In 1993, he attended a special course at the Military War School.
From 1993 to 1998, he was in Sicily as Commander of the Carabinieri in Palermo before taking over the Territorial Provincial Unit in the same city. Recalled to the Carabinieri General Headquarters in Rome, he directed the Organization Office for five years. In the rank of Colonel, he was the Provincial Commander of Carabinieri in Milan followed by the position of Commander of the Training Department in the Officers' School in Rome.
He was also Chief of Staff of the Interregional Command "Ogaden" in Naples with responsibility for five Regions of the south of Italy.
On October 1, 2008, Brigadier General Piccinno assumed command over the Carabinieri for Public Health Safety. In this position, he was awarded the Gold Medal of Merit of Public Health for his excellent work.
Since 2008 he attended several international and national conferences as speaker on pharmaceutical crimes and related risks.

Mr Hugh Pullen, Associate Director European Government Affairs, Eli Lilly and Company, he covers anti-counterfeiting issues and external trade policy for Eli Lilly

and Company, based in Brussels. Mr Pullen is vice-chair of the Anti-Counterfeiting Working Group of the European Federation of Pharmaceutical Industries and Associations (EFPIA). He has taken a leading role in representing the innovative pharmaceutical industry's position on recent E.U. legislation including the Falsified Medicines Directive. A graduate in political science, Mr Pullen was formerly Head of APCO Worldwide's European trade practice, based in Brussels. Previously, he worked in the European Commission's Directorate-General for External Trade and, prior to that, in the UK's Foreign and Commonwealth Office.

1/2 Mr Christian Tournié
Mr Christian Tournié is a Seconded National Expert within Unit Against Organised Crime of the DG Home Affairs at the European Commission. He is a French Senior Officer of the Gendarmerie Nationale. Seconded to the European Commission since June 2006, he is in charge of policy and criminal law aiming fake pharmaceutical products and counterfeit goods linked to serious and organised crime. He has been dealing with fake goods since 1988.

2/2 Mr Christian Tournié
He has actively collaborated at European and international levels on the falsified medical products and on crimes threatening public health, notably related with the Medicrime Convention field (2006 – 2011). He is also involved within European bodies on measures to improve the effectiveness of financial investigations as a means of fighting organised crime and the proceeds of crime. He headed some multi-disciplinary European working groups (1999 – 2006) and led a number of international criminal investigations (1988 – 1997).
He was deputy head of the "Europol and Organised Crime" Section of the French Gendarmerie Directorate-General and was seconded to Europol (2004 – 2006). He headed the department of the Gendarmerie's Criminal investigation Academy for serious and organised crime, economic crime, and cyber crime 1999 – 2004).
For many years, Mr Christian Tournié has initiated and led European training projects for law enforcement officers, magistrates and experts, in cooperation with the private sector as well. He is involved in various Universities as a lecturer and in charge of programs related to Justice and Home Affairs. He is graduated in law and has a Master's degree in finance.

Mr Roy Vancauwenberghe is a senior inspector, member of the Federal Agency for Medicines and Health Products (FAMHP) in Belgium.
Before joining the FAMHP he was a Belgian government agent working in development aid in Central Africa from 1978 till 1990. He was responsible in Rwanda for a small plant (50 FTE) manufacturing sterile and non-sterile medicines covering the Rwandese government needs in essential medicines.
After leaving Rwanda in 1990 he became an inspector at the Pharmaceutical Inspectorate in Belgium first at the secretariat for Marketing Authorizations and since 1993 as field inspector involved in inspecting veterinary depots and assisting in fighting illegal use of medicines (hormones) in stock breeding.
He was nominated liaison officer for the Pharmaceutical Inspectorate with the Belgian National Hormone Cell after the assassination of Veterinary Surgeon Karel Van Noppen in 1995. Since 2004 he is fully occupied with pharmaceutical Crime and was involved in numerous field investigations on illegal use of hormonal products in stock breeding and doping in sports, diversion and counterfeit medicines collaborating with police and customs. He is now head of the Special Investigation Unit of the FAMHP.
He assisted in starting up the PFIPC (Permanent Forum on International Pharmaceutical Crime) in 2000 and the EMEO (European Medicines Enforcement

officers) in 2004 which changed name into the HMA-WGEO (Head of Medicines Agencies – Working Group of Enforcement Officers). For both the EMEO and HMA-WGEO he was / is the Vice-president.
He is also member of the actual CD-P-PH/CMED - EDQM (Committee of Experts on minimizing Public Health Risks posed by counterfeiting of Medical Products and Related Crimes) being the former Ad Hoc Group on Counterfeit Medicines (P-SP-PH/CMED) of the Council of Europe since the starting up in 2004.
As a member of the PC-S-CP (Group of Specialists on Counterfeit Pharmaceutical Products) he worked with 11 other experts on a Council of Europe Convention on Counterfeiting of medical products and similar crimes involving threats to public health.

Mr Bastian Venhuis, National Institute for Public Health and the Environment (RIVM) - the Netherlands.
Mr Bastiaan Venhuis is attached to the Dutch National Institute of Public Health and the Environment (RIVM) as a senior scientist. Bastiaan holds a PhD in Drug Design & Discovery and MSc's in Synthetic Organic Chemistry and Teaching. Bastiaan previously worked in clinical research and medicinal chemistry.
In his current capacity Bastiaan is responsible for assessing the health risks posed by falsified medical products. Earlier this year Bastiaan was commissioned by the Dutch Health Ministry to develop methodology for detecting actual health damage caused by falsified medical products. Together with EDQM this project was scaled up to 8 European countries. His main other activities are direction laboratory analyses of suspect samples, data mining, and trend watching. Bastiaan represents RIVM at various international anti-counterfeiting fora.

Dr Bart Wijnberg has been working till his retirement in May 2010 in the Ministry of Health in the Netherlands. He has a legal (University of Amsterdam, Sorbonne, Paris) and a social sciences (Université de Montréal) background. His work experience has been in bioethics (national and international legislation – OECD, UNESCO, Council of Europe), quality of care (legislation), and research policy for pharmaceuticals and medical devices. His work has included lobbying and brokering: bridging people, institutions and disciplines with the aim of fostering public health. Recent activities at the Ministry of Health have included serving as Dutch delegate at the Council of Europe's negotiations for the MEDICRIME Convention and as delegate at WHO activities in the field of substandard/spurious/falsely-labelled/falsified/counterfeit medical products. He has also been involved with EU directives and OECD activities in this field, and with ACTA (Anti-Counterfeit Trade Agreement). He has been delegate to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG, as one of its vice-chairs),

Mr Fritz Zeder, Hon.-Prof., Dr. Jur., D.E.A. Paris II, is head of unit in the criminal legislation directorate at the Austrian Federal Ministry of Justice in Vienna; he has been working in this department since 1991.
The competences of his unit comprise criminal law aspects of drugs law, pharmaceutical law, food law, anti-doping law and law on media, and also juvenile justice, money laundering, penal responsibility of legal persons and international co-operation in criminal matters. He has vast experience in negotiating international criminal law instruments, within the E.U., but also within the Council of Europe and other fora.

He is also professor at the University of Vienna on criminal law (special field: European criminal law) and publishes regularly on different items (again especially on European criminal law).
In 2009, he was the chairman of the Council of Europe Committee which elaborated the MEDICRIME Convention; before, he was also member of the Council of Europe experts' group which prepared a first draft for this Convention.