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 MEDICRIME)
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

Международная конференция высокого уровня

Moscow, Moscou, Москва 26-28 Oct. ктября 2011

SLIDES SESSION I & II

The MEDICRIME Convention: History of its Development

Moscow,
26 october 2011

Fritz Zeder
Ministry of Justice, Austria
Former Chairman of drafting Committee

„что хорошо, то не скоро“

“Rome wasn't built in a day”

… neither was the MEDICRIME Convention

History of the MEDICRIME Convention

- 5 years: 2006 to 2011
- 11 experts
- 3 times 5 months
- 4 phases

History of the MEDICRIME Convention

4 phases:

- The precursors
- The experts
- The officials
- The diplomats

Phase 1: „Precursors“

a. WHO (World Health Organisation)

- moves towards a binding legal instrument combating counterfeit drugs (around 2005)
- but fails!
- Instead: In 2006, establishment of IMPACT (International Medical Products Anti-Counterfeiting Taskforce)

Phase 1: „Precursors“

b. Council of Europe

- 2006 Moscow Conference / Declaration: „Europe against Counterfeit Medicines“
- Parliamentary Assembly: Recommendation 1793 (2007), “Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods”

Phase 1: „Precursors“
b. Council of Europe (cont.)

- 2007, jan.: Feasibility Study of the Institute for International Research on Criminal Policy (IRCP) of the University of Ghent (Prof. Vander Beken et. al.)
- 2007, march: Prioritised Elements for a Council of Europe Convention on the Protection of Public Health against pharmaceutical and healthcare product crime (Hugo Bonar)

Phase 2: „The experts“

- Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP)
  - Mandated by the CDPC (European Committee on Crime Problems)
  - 11 experts nominated (lawyers and pharmaceutical experts) + European Commission
  - Chairman: Claude Debrulle (Belgian Ministry of Justice)

Phase 2: „The experts“ (cont.)

- The “expert group” (PC-S-CP)
  - holds 3 meetings between nov. 2007 and march 2008
  - fulfills its task: a report to the CDPC
- The CDPC gives expanded mandate:
  - Prepare a preliminary draft convention
  - In addition to 11 experts: member states may send representatives

Phase 2: „The experts“ (cont.)

- The “expert group” (PC-S-CP)
  - 4th to 6th meeting (between oct. 2008 and feb. 2009)
  - fulfills its task: a report to the CDPC and a **preliminary draft Convention**

Phase 3: „The officials“

- The CDPC
  - Gives mandate to a formal drafting Committee:
- Ad hoc Committee on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (PC-ISP)

Phase 3: „The officials“ (cont.)

- The “drafting Committee” (PC-ISP)
  - Composed of representatives of all CoE member states: lawyers and pharmaceutical experts
  - Chairman: your speaker
  - only 2 meetings foreseen (june and sept. 2009)

Phase 3: „The officials“ (cont.)

- The “drafting Committee” (PC-ISP)
  - Multidisciplinary approach: dialogue between (penal) lawyers and pharma specialists
  - Solution-oriented spirit
  - capable and engaged secretariat
  - Intense negotiation: evening sessions, written procedure

Phase 3: „The officials“ (cont.)

- The “drafting Committee” (PC-ISP)
  - fulfills its task: a **draft Convention,** by 4th sept 2009, and the Explanatory report
- The CDPC
  - Made some refinement in technical penal law issues
  - Finalised the Convention in nov. 2009

Phase 4: „The diplomats“

- Preparation of the adoption by the Committee of Ministers:
  - Amendments proposed by the Parliamentary Assembly
  - Issue of accession of the EU
  - Issue of Follow-up mechanism
  - Issue of accession of non-CoE-States

Phase 4: „The diplomats“ (cont.)

- Adoption by the Committee of Ministers on 8th dec. 2010
- Open for signature on 28th oct. 2011
- Austria will sign

The MEDICRIME Convention

- 5 years: 2006 to 2011
- 3 times 5 months
- 4 phases

The MEDICRIME Convention - Outlook

- Future 4 phases:
  - More States to sign
  - Implementation
  - Ratification
  - Application in practice

СРАСИБО!

Thank you!

International High Level Conference

Significance of Medicrime Convention

How does it relate to other initiatives

Moscow, 26 October 2011

Hugo K. Bonar

IRISH MEDICINES BOARD

Introduction

- Significance of Medicrime – no comparable instrument
- Why consider options
- What are the options to Medicrime
- What is the future for Medicrime

IRISH MEDICINES BOARD

Significance of Medicrime Convention

- Only dedicated international legal instrument
  - Addresses Public Health through criminal law
  - Counterfeit and similar crimes
- Wide scope
  - Medicines, API, Excipients,
  - Medical Devices Accessories, parts & materials
- Made for today, ready for today
  - Addresses current challenges
  - Ready for Signing and implementation
- Potential implementation beyond Europe
- Safeguards Public Health

IRISH MEDICINES BOARD

Why consider the options

- Global criminal activity addressed by
  - Different cultural approaches
  - Different understanding of the challenges
  - Different priorities
- Medical Product Counterfeiting may not be a crime
- Definition of a counterfeit may be different
- The Challenges may be similar but with a different focus
  - Quality products V Affordable products
- Criminals understand our difference and capitalise on them
- We recognise our differences, but fail to agree
- Consider the options to consider cooperation

Options: Other initiatives

- IMPACT
  - International Medical Product Anti-Counterfeiting Task Force
- SSFFC Committee
  - Substandard/Spurious/Falsely labelled/falsified/counterfeit
  - Medicines, vaccines, in-vitro diagnostics
- Falsified Medicines Directive, 2011/62/EU
  - Medicinal Products
- UNDOC –
  - UNDOC strategy against Trafficking in fraudulent medicines identification of priorities and Partners

Medicrime Convention – can support enforcement led initiatives

- Interpol
  - Resolution for better cooperation with regulatory authorities
- PFIPC
  - Permanent Forum on International Pharmaceutical Crime
  - Work Groups on Training, Communications, Information exchange, and Counterfeit investigations
  - Operation Pangea
- HMA WGEO
  - Heads of Medicines Agencies Working Group of Enforcement Officers
  - Work Stream Groups on Distribution, Internet Threats, Counterfeit, API threats, Training and Education

The future for Medicrime?

- Potential –
  - Open to 47 Member States for immediate signature on 28 Oct 2011
  - Open to non-member states
  - Adaption by other regions to suit culture
  - Adaption by the UN for an alternative global approach
- Medicrime may be the only viable option
  - 2011-2020
- Viable only if implemented and now

IRISH MEDICINES BOARD

Contact

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Enforcement Manager
Irish Medicines Board
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Ph: +353 1 6343436, +353 86 8271032 (m)
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Website: www.imb.ie

IRISH MEDICINES BOARD

Presentation

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

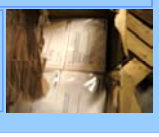
Domenico Di Giorgio
Italian Medicines Agency | AIFA
Director of Counterfeit Prevention Unit

October 2011
Moscow Conference

DANGEROUS, ILLEGAL PRODUCTS ARRIVING TO OUR MARKET

Fake natural products containing APIs like sildenafil and tadalafil: imported as "natural products", sold in non pharmaceutical shops

Small parcels shipped through postal services to private address: tenth of packages for local illegal distribution networks (e.g. sex shops, gyms).



INTERNATIONAL REGULATION

Currently: IPR Infringement, Illegal Importation, GMPs…

EU Directive 2011/62 of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

CoE MEDICRIME Convention
Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

CD-P-PH
TERMS OF REFERENCE

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

"...iv. minimise public health risks posed by counterfeit medical products and similar through multisectorial prevention and risk management strategies and the support to the elaboration, implementation and follow-up of relevant national legislation and international legal instruments including the development of and training on best practices, the maintenance and development of a specific multisectorial expertise in this field, in co-operation with other relevant Council of Europe bodies, in particular the European Committee on Crime Problems (CDPC);

v. contribute to the multisectorial and multidisciplinary follow-up mechanism ensured by the Committee of the Parties to the MEDICRIME Convention;".

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

CMED
TERMS OF REFERENCE

Committee of experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CMED)

"as provided for in the future MEDICRIME Convention, and expanded in the MEDICRIME Explanatory Memorandum, make available scientific expertise to the Committee of the Parties to the Council of Europe MEDICRIME Convention as regards its specific functions such as the facilitation of information exchange on significant legal, policy or technological developments in relation to the application of the provisions of the Convention;..."

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

CD-P-PH, CMED AND THE MEDICRIME CONVENTION

- Multisectorial monitoring mechanism to ensure the effective implementation of the Convention
- Involvment of expert subordinate bodies (CMED)
- Development of practical tools (eg. Training and investigative schemes, publications)
- **Fostering intersectorial cooperation**

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

SUPPORTING THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

Active promotion of the knowledge and use of the MEDICRIME Convention through practical measures and concrete support for national and international legislation, in particular as regards the prevention and cooperation articles, should be a priority of the Committee CD-P-PH and its Committee of Experts CD-P-PH/CMED in line with its terms of reference.

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

SUPPORTING THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

1. Safe access to good quality medical products for human and veterinary use.

2. Prevention and prosecution of counterfeiting of medical products and similar crimes.

3. Support to regulatory systems and procedures, drug enforcement, and public empowerment (awareness raising) for an effective implementation of MEDICRIME Convention.

4. Enforcement of the MEDICRIME Convention by using auxiliary model approaches.

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

AN EXAMPLE OF SUPPORT: PUBLICATIONS

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

NEXT CHALLENGE: THE INTERNET ISSUE

SUPPORT BY THE EDQM (COUNCIL OF EUROPE) FOR PREVENTION AND FOLLOW-UP MEASURES INCLUDED IN THE CONVENTION

THANK YOU

Domenico Di Giorgio
Italian Medicines Agency | AIFA
Director of Counterfeit Prevention Unit

October 2011
Moscow Conference

Safeguarding public health

Added Value of the Medicrime Convention

Moscow 26-28 October 2011

Gerald Heddell - Director Inspections, Enforcement & Standards Division
Medicines and Healthcare products Regulatory Agency

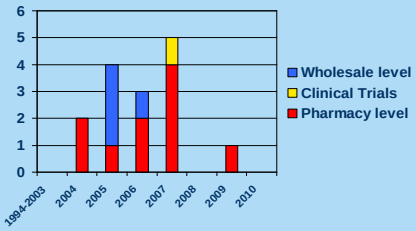
Outline

- **MHRA and the Council of Europe**
- **Counterfeit Medicine Situation - UK**
- **Medicrime Convention and Added Value**
- **Conclusion**
- **Questions/Discussion**

MHRA and the Council of Europe

- **2004** – MHRA has been involved from the outset of this initiative, providing participants on the Committee of Experts on Minimising the Risks posed by Counterfeiting of Medical Products and Similar Crimes
- **2005** – MHRA on Organising Committee that arranged the 'Combating the Counterfeiter' Conference in Strasbourg, ran a Training workshop, provided speakers and helped fund event
- **2006** – MHRA provided a panel chair and speakers for the CoE International Conference on Counterfeit Medicines in Moscow
- **2006-2011** – MHRA chaired Training Committee of Expert Group, helping organise and deliver training to 120 regulatory and law enforcement delegates
- **2008-2010** – MHRA representatives participated in the Convention drafting working group
- **2011** – MHRA present here to help launch the Medicrime Convention!
- **2012** – during the UK's role as Chair of the Council of Europe Committee of Ministers, MHRA will host a 2-day training package in London for regulators, Police and Customs
- **2012 – UK plans to sign Convention once necessary national approval processes are complete**

Counterfeit Situation - UK licensed supply chain



Wholesale - Anti- cholesterol, Anti- inflammatory, Anti-platelet, Alopecia, Erectile Dysfunction.

Pharmacy - Anti-cholesterol, Anti-platelet, Anti-psychotic, Erectile dysfunction, Prostate cancer, Appetite suppressants, Chronic asthma.

Clinical Trial - Anti - platelet

Medicrime Convention and Added Value

Key Areas:

- Manufacturing of counterfeit medical products
- Supply, offering and trafficking of counterfeit medical products
- Falsification of documents
- Investigation and Prosecution
- Sanctions – penal and administrative
- Cooperation amongst authorities – national and international
- Preventative measures

Medicrime Convention and Added Value

Key Areas:

- Manufacturing of counterfeit medical products

Good Manufacturing Practice?

London 2004

Good Manufacturing Practice?

London 2010

- Investigations resulted in prison sentences ranging from 3 to 5½ years and a £1.5m confiscation order
- Offences included Misuse of Drugs Act, Trade Marks Act and Proceeds of Crime Act
- **Medicrime Convention provides support for effective sanctions for the offence for Counterfeiting Medical Products**

Medicrime Convention and Added Value

Key Areas:

- Manufacturing of counterfeit medical products
- Supply, offering and trafficking of counterfeit medical products
- Falsification of documents
- Investigation and Prosecution
- Sanctions – penal and administrative
- Cooperation amongst authorities – national and international

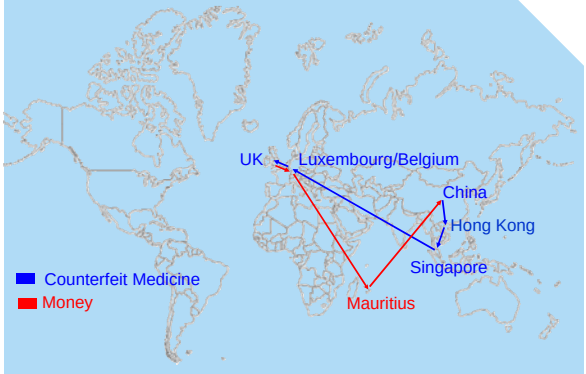
2007 UK Counterfeit Case

- Most serious known case of Counterfeit Medicines penetrating the UK Supply Chain
- 72,000 packs of counterfeit medicine (Over 2 million doses) penetrated the UK supply chain between December 2006 and May 2007 (Retail value 2007 £4.7m)
- Medicines were for the treatment of Psychosis, Prostate Cancer and Heart Disease
- Seven batches of three medicines were subject of a class 1 recall from the market in May and June 2007

2007 UK Counterfeit Case

- MHRA seized 1.3m doses before reaching pharmacies
- Further 7000 packs recovered following recalls
- 25,000 packs (700,000 doses) reached pharmacies and patients
- Products contained between 50% - 80% of Active pharmaceutical ingredient together with unknown impurities
- No known fatalities or adverse reactions
- Counterfeits indistinguishable from genuine through visual identification alone

2007 UK Counterfeit Case – Global nature



2007 UK Counterfeit Case

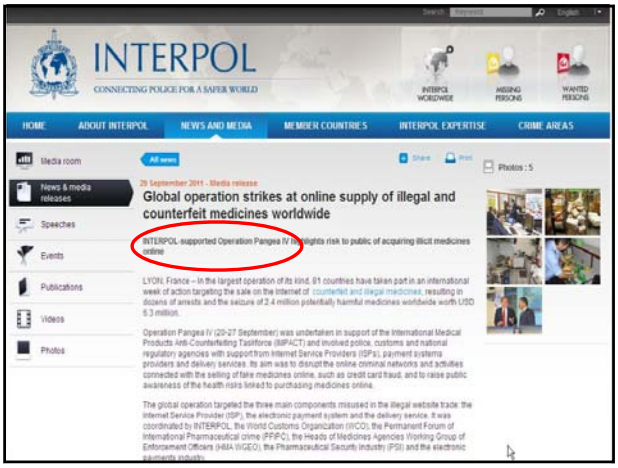


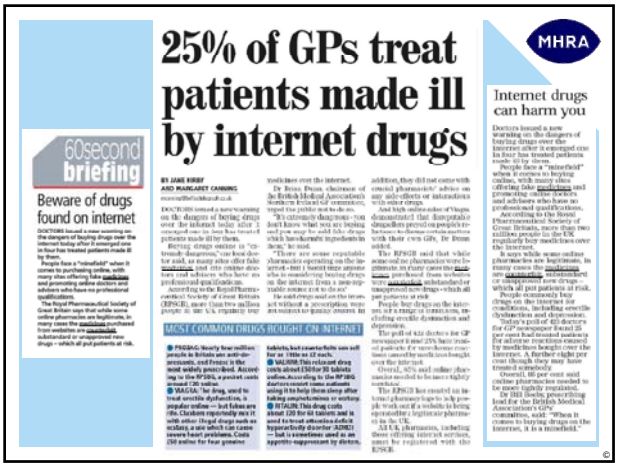

2007 UK Counterfeit Case - Scale

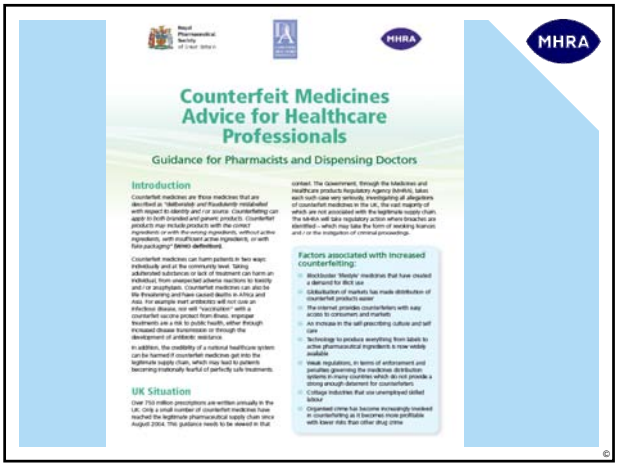
- 3 ½ year investigation
- 13 countries involved, evidence obtained through mutual legal treaties – **not all countries co-operated**
- 17,000 pages of evidence, 4000 evidence exhibits
- 40 computers and phones forensically examined, **falsified documents uncovered**
- 93 witnesses gave evidence at trial from 6 countries
- 205 witnesses made written statements
- Resulted in prison sentence of 8 years
- Primary offences were Conspiracy to Defraud and Trade Marks Act
- **Co-operation amongst authorities nationally and international was critical**
- **Medicrime Convention may help to speed this process up, make it more efficient and reach out to more countries**

Medicrime Convention and Added Value

- Manufacturing of counterfeit medical products
- Supply, offering and trafficking of counterfeit medical products
- Falsification of documents
- Investigation and Prosecution
- Sanctions – penal and administrative
- Cooperation amongst authorities – national and international
- Preventative measures


INTERPOL
CONNECTING POLICE FOR A SAFER WORLD
HOME
ABOUT INTERPOL
NEWS AND MEDIA
MEMBER COUNTRIES
INTERPOL EXPERTISE
CRIME AREAS
Media room
News & media releases
Speeches
Events
Publications
Videos
Photos
Global operation strikes at online supply of illegal and counterfeit medicines worldwide
INTERPOL-supported Operation Pangea IV highlights risk to public of acquiring illicit medicines online
LYON, France – In the largest operation of its kind, 81 countries have taken part in an international week of action targeting the sale on the internet of counterfeit and illegal medicines, resulting in dozens of arrests and the seizure of 2.4 million potentially harmful medicines worldwide worth USD 6.3 million.
Operation Pangea IV (20-27 September) was undertaken in support of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and involved police, customs and national regulatory agencies with support from Internet Service Providers (ISPs), payment systems providers and delivery services. Its aim was to disrupt the online criminal networks and activities connected with the selling of fake medicines online, such as credit card fraud, and to raise public awareness of the health risks linked to purchasing medicines online.
The global operation targeted the three main components misused in the illegal website trade: the Internet Service Provider (ISP), the electronic payment system and the delivery service. It was coordinated by INTERPOL, the World Customs Organization (WCO), the Permanent Forum of International Pharmaceutical crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO), the Pharmaceutical Security Industry (PSI) and the electronic payments industry.


25% of GPs treat patients made ill by internet drugs
60second briefing
Beware of drugs found on internet
MHRA
Internet drugs can harm you
MOST COMMON DRUGS BOUGHT ON INTERNET


MHRA
Counterfeit Medicines
Advice for Healthcare Professionals
Guidance for Pharmacists and Dispensing Doctors
Introduction
Factors associated with increased counterfeiting:
UK Situation

Conclusion

MHRA

- No product supply chain is impenetrable
- Council of Europe Medicrime Convention is the first international treaty of its kind
- Provides tools for legislative changes with appropriate penal sanctions
- Promotes legal gateways for international cooperation
- **Safeguarding public health is at the core of the Convention**
- **Convention aims to help prevent a catastrophic major incident that causes serious physical harm or fatalities**

Questions/Discussion?

Safeguarding public health

Thank you

All Enforcement enquiries and potential referrals to:

MHRA Case Referrals Centre
casereferrals@mhra.gsi.gov.uk or tel +44 (0)20 3080 6330

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gerald.heddell@mhra.gsi.gov.uk

LA VALEUR AJOUTEE DE “MEDICRIME”

La pensée d’une force de Police (carabiniers) spécialisée dans la sauvegarde de la santé

Bâle 2010

CONCLUSIONS

ARMONISATION DES LOIS

COLLABORATION INTERINSTITUTIONELLE

CARABINIER NAS

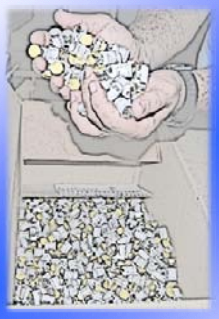
POLICE SPECIALISEE

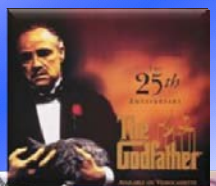

1962
2011
CARABINIERI
NAS
1000
Officiers / Sous officiers
au service du
Ministère de la Santé


TECHNIQUES
INVESTIGATRICES


ENQUETES ET MODALITES OPERATIONELLES
LA STAMPA
Maxi operazione anti doping
13 arresti e oltre 100 indagati
INVESTIGATRICES
(POLICE JUDICIAIRE)
PAS SEULEMENT
D'INSPECTION -BUREAUCRATIQUE
(INSPECTEUR DE SANTE)

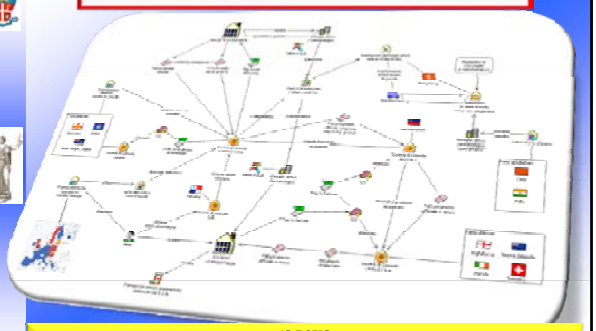
CRIME PHARMACEUTIQUE





INTERET CRIMINEL CROISSANT

TRIANGULATION



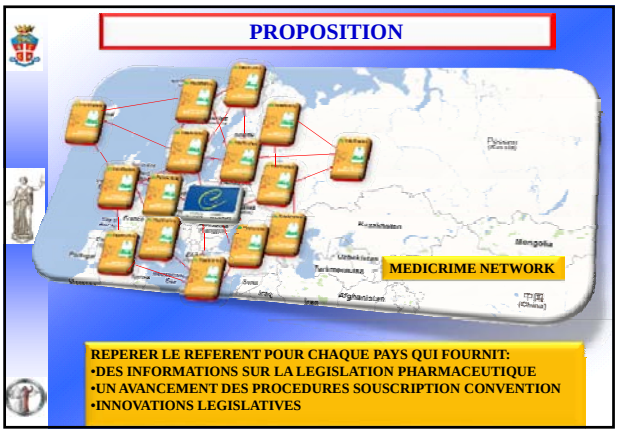
13 PAYS
CHINE-INDE-HONG-KONG-BELIZE-ILES VIERGES-PANAMA-NOUVELLE ZELANDE LIECHTESTEIN-ALLEMAGN-ANGLETERRE-IRLANDE-SUISSE-ITALIE

TRIANGULATION


SIGNATURE “MEDICRIME”
NO
STOP


LE PLUS GRAND NOMBRE DES PAYS IMPLIQUES


ENQUETE ANABOLIC
Федеральная служба Российской Федерации
по контролю за оборотом наркотиков
Federal Drug Control Service
of the Russian Federation
+
CARABINIER
NAS
АПТЕКА


PROPOSITION
MEDICRIME NETWORK
REPERER LE REFERENT POUR CHAQUE PAYS QUI FOURNIT:
•DES INFORMATIONS SUR LA LEGISLATION PHARMACEUTIQUE
•UN AVANCEMENT DES PROCEDURES SOUSCRIPTION CONVENTION
•INNOVATIONS LEGISLATIVES


MERCI DE VOTRE ATTENTION

Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes Moscow, Russia, October 26-28, 2011

Multi-regional Cooperation in the Fight to Stop Counterfeit/Falsified Medicines and Similar Crimes via the Internet

Presented by:
Jeffrey Gren, Director, Office of Health and Consumer Goods, U.S. Department of Commerce

Presentation Outline

1. The Global Counterfeit/Falsified Medicines Problem and Growth of Internet Crime
2. APEC Anti-counterfeit Medicine Initiatives
3. Combating Counterfeit Medicines Internet Crime
4. Summary and Conclusions

2

Introduction – The Global Counterfeit Medicines Problem

- Factors leading to this increase in falsified/counterfeit medicines include:
  - Increase in criminal activity and level of sophistication
  - High profit level (even higher than for narcotics)
  - Internet provides a marketing vehicle for counterfeiters to distribute counterfeit medicines
  - Lack of penalties, enforcement, and coordination in prosecution in many overseas markets have created conditions for counterfeiting to grow

3

Introduction – The Global Counterfeit Medicines Problem (cont'd)

- Globalization of the pharmaceutical industry has contributed to the ready supply of APIs to counterfeiters, as manufacturing of APIs and finished dosage form medicines shifts from developed to lesser developed countries
- Counterfeiting impacts all aspects of the pharmaceutical industry – patented drugs, generic drugs and OTC medications
- Globalization of the pharmaceutical industry has also contributed to the growth of substandard medicines

4

Introduction – The Global Counterfeit Medicines Problem (cont'd)

- Lack of vigilant oversight can lead to supply chain vulnerability
- Supply chain vulnerability, in turn can lead to entry of counterfeit drugs into legitimate distribution channels
- Lack of effective API regulations and the growth of counterfeit or adulterated APIs are significant global problems

5

APEC-Funded Anti-counterfeit Medicines - Past Activities

- Under the APEC Life Science Innovation Forum (LSIF) there is an anti-counterfeit/falsified medicines initiative
- The spread of anti-counterfeit/falsified medicines is a significant problem facing APEC economies and through joint cooperation by APEC economies we hope we can make a significant impact on this global problem
- We also hope to include non-APEC economies and WHO in this APEC Initiative since stopping the spread of counterfeit medicines requires global cooperation

6

APEC Funded Anti-counterfeit Medicines Past Activities (cont'd)

- During 2008 and 2009 APEC LSIF organized three Asia anti-counterfeit medical product seminars – January 2008 and March 2008 in Singapore and a February 2009 seminar in Mexico City
- Attendance during three seminars (over 300) included regulators, customs, law enforcement and judicial officials, as well as industry representatives
- Findings of the APEC Anti-counterfeit medical product seminars were presented to APEC Ministers and an APEC Anti-counterfeit Medicines Action Plan was developed
- We are very pleased that the APEC Anti-counterfeit Medicines Action Plan has been endorsed by the APEC LSIF Planning Group during September 2010

7

Proposed APEC LSIF Anti-counterfeit Action Plan Components:

- Strong cooperation among APEC economies is critical
- Cooperation within each APEC economy between regulators, customs, law enforcement, judicial and industry is also critical
- APEC economies should work together to collect data on counterfeit medicines
- APEC economies should coordinate on legislation and penalties for prosecuting drug counterfeiters

8

Proposed APEC LSIF Anti-counterfeit Action Plan (cont'd)

- Many falsified/counterfeit medicines enter APEC economies through Internet sales. Better internet prevention and education strategies are needed
- Detection technologies to identify unsafe drugs are extremely important
- Cooperation on the global shipment of ingredients used in the production of counterfeit medicines is also needed
- APEC cooperation on counterfeit medicines public awareness is important for patients, health professions, regulators, custom officials and law enforcement officials

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Proposed APEC LSIF Anti-counterfeit Possible Future Activities

- The first activity of the Action Plan was completed several weeks ago in Beijing – a September 27-28 Drug Safety and Detection Technology Workshop
- During this workshop APEC economies shared best practices and developed the first draft of a guidance document on how to use detection technologies as part of a larger strategy to ensure that counterfeit/falsified medicines are removed from the drug supply chain

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Proposed APEC LSIF Anti-counterfeit – Possible Future Activities (cont'd)

- In cooperation with other APEC economies the U.S. plans to develop an additional APEC anti-counterfeit /falsified medicines projects to take place during 2012 and beyond implementing the APEC LSIF Action Plan
- One proposal being considered is a workshop to take place during 2012 with a focus on public awareness and the development of a Single Point of Contact System for counterfeit/falsified medicines investigations
- Future workshops being considered include:
  - Internet Medicines Crime
  - Good Distribution Practices for Medicines
  - API Regulatory Practices and Counterfeit/Falsified APIs

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Combating Counterfeit Medicines –Internet Crime - The Problem

- One of the negative consequences of the growth of the Internet is that the Internet has become a significant method for the sale and distribution of counterfeit medicines
- While twenty years ago most counterfeit medicines did not contain medicinal ingredients (i.e. ground up dry wall and highway paint) currently a large percent of counterfeit medicines contain APIs or excepients
- What is scary is the counterfeiters are often using real pharmaceutical ingredients since they are seeking repeat business. Of course all counterfeit are unsafe and may not have the correct ingredients
- In developed markets, such as the United States and Europe, the majority of counterfeit medicines are distributed through the Internet
- Several studies have documented that the vast majority of medicines distributed through the Internet are counterfeit

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Combating Counterfeit Medicines – Internet Crime - The Problem

- APIs are being sold on Internet sites promoting medicinal uses
- Major pharmaceutical company security units track the production of APIs used is commonly counterfeited drugs, and they find significant amounts being produced in countries, such as China, that are in many cases sold through Internet websites
- Distribution of APIs though the internet has become a much larger global problem in the past decade since the global production of APIs have been shifting to China and India and many experts predict that in the next 10 - 15 years 80 % of all APIs will be made in China and India
- We are also finding more evidence of counterfeit and

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Combating Internet Crime – Possible Solutions

- Public awareness of the dangers of counterfeit medicines. For example, a Korean study highlighted that erectile dysfunction drugs purchased on-line can have significant health risk
- Enforcement and shutting down of websites selling APIs. For example, the China Ministry of Public Security has shut down numerous Chinese websites selling APIs with medicinal claims for APIs not registered with the China State Food and Drug Administration (SFDA)
- Public Health Warnings – For example, USFDA issued a public health warning about a fake version of antiviral Tamiflu being sold on-line causing harmful reactions
- Increased law enforcement efforts focused on

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Combating Internet Crime – Possible Solutions

- Cooperation within countries to monitor and shut down Internet sites selling counterfeit medicines. For example, in the United States, the USFDA, US Immigration and Boarder Enforcement and US Customs and Boarder Protection and other law enforcement agencies have participated in a number of law enforcement actions focused on counterfeit medicines and Internet sites
- Multi-lateral Cooperation is also critical. For example "Operation Pengea IV" was a worldwide "week of action" September 20-27 targeting on-line sales of counterfeit and illegal medicines resulting in 2.4 million units seized, 55 arrests around the world, closure of over 13,000 websites and significant Public

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Combating Counterfeit Medicines - Internet Crime –Possible Solutions

- Public and Private Sector Cooperation. For example, in the U.S. the Intellectual Property Enforcement Coordinator (IPEC) announced significant private sector coordination in the form of 11 major Internet commerce companies planning to establish a non-profit organization referred to as the Center for Safe Internet Pharmacies (CSIP); and support of Verified Internet Pharmacy Practice Sites (VIPPS)
- Private Sector Initiatives. For example, the National Association of Boards of Pharmacy (NABP) announced progress in effort to fight rogue Internet drug outlets. During 2010 three major Internet search engines agreed to limit their advertising to Internet pharmacies in the U.S. that are associated with

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Combating Counterfeit Medicines - Internet Crime –Possible Solutions

- Other notable examples of private sector initiatives are the Partnership for Safe Medicines (PSM) and the Pharmaceutical Security Institute (PSI)
- PSM issues a weekly update and a Safe Medicines Alert and offers partnerships with specific countries such as India, China and Thailand
- PSI maintains the “Counterfeiting Incident System” which is a unique incident-based reporting mechanism inaugurated in 2002 which includes pharmaceutical crime reports from open sources such as press releases, academic journals, media articles, or government warnings, as well as member company reports
- Another notable public private partnership is the US Pharmacopeia Quality of Medicines Program (PQM) (a USAID

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Summary and Conclusion

- During my presentation I covered the following:
  - The global counterfeit/falsified medicine problem and the growth of internet crime
  - APEC/Anti-counterfeit/Falsified Medicine Activities
  - Activities to combat Internet medicines crime
  - Counterfeit/falsified medicines is a significant growing global problem and I am hopeful that the programs and cooperative activities I outlined during my presentation will make an impact to stop the spread of counterfeit medicines

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INTERNATIONAL HIGH-LEVEL CONFERENCE
"MEDICRIME CONVENTION"

26-28 October 2011, Moscow

The Co operation within the OMCL NETWORK

Dr Popi Kanari,
Director
State General Laboratory
Ministry of Health, Cyprus

Objectives of the Presentation

To show:

- The imperative need for the adoption and implementation of the Convention on Combating Counterfeit of Medical Products and Similar Crimes
- The important role of OMCL s and their integrated action with all stakeholders at a national and international level
- The immense benefit in the protection of public health

An Imperative Need for Adoption and Implementation

- Traditionally the problem of counterfeit pharmaceuticals was limited to developing nations in Asia and Africa .Nowadays counterfeiting is rapidly becoming a world wide concern and it is gaining momentum
- The increase in global trade and the growth of internet sale coupled with weak regulatory and enforcement structures in a number of countries has exacerbated the problem

A public health threat

- Defraud consumers
- Lead to loss of confidence in the entire health system and affect its the credibility
- Can cause great harm such as
  - Allergies and fatalities
  - Heavy metal and chemical poisoning
  - Promote drug resistance strains to disease
- Not limited to brand name prescription and lifestyle drugs

Counterfeit drugs –a threat to patient health – can cause even deaths

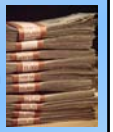
- Counterfeit meningitis vaccines caused deaths in 1995
- Pregnant women injected with counterfeit iron for anaemia
- Children who took paracetamol syrup with diethylene glycol (children died in Haiti 1965) (in Bangladesh 1990) (in 2006 in Panama)
- Heparin case with OSCS -2007

Very few cases are reported because :

- In Almost all cases the diagnosis preceding the administration of counterfeits has not been made by a professional so it is very difficult to identify contra-indications resulting from patient's state of health or interactions with concomitant treatments

Reasons for Increase in Counterfeiting

- A high profit activity
- Remains a low risk activity
- Sanctions are now relatively weak and often difficult to apply
- Inter-state co-operation is deficient
- Cross-border vigilance is deficient
- Taxation systems are bypassed
- Weak administrative structures
- Counterfeiters know that there is still a legal vacuum and legal uncertainties



Counterfeiting: a significant part of the shadow economy and shadow trade

- Likely involvement in other types of crime
- Potential for significant financial gain and funding of organized crime
- Potential links to terrorism
- Countries can for example be used as transit areas or brokers without realising it

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A challenge for all: preventing and combating threats to public health through a legal instrument - a Convention

- The Council of Europe has drawn up the first International MEDICRIME Convention to criminilise
  - ❑ The manufacturing of counterfeit medical products
  - ❑ Supplying ,offering to supply and trafficking in counterfeit medical products
  - ❑ The falsification of documents
  - ❑ The unauthorised manufacturing or supplying of medical products

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MEDICRIME CONVENTION

A Convention, with signatory parties for its implementation which provides a Legal Instrument, which so far was non existent, to protect public health ALSO through:

- Protecting rights of victims
- Promoting national and international cooperation

The Convention is open to members and non members of the Council of Europe – universally relevant

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Implementation of the Convention

The implementation is based on 3 pillars:

1. Strengthening existing and promoting new legislative and administrative procedures and measures
2. Strengthening 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
3. Strengthening expertise and means in the identification for detection and awareness for prevention

OMCLs specific role in the Medicrime Convention

- OMCLs play a key role in certain articles in The Medicrime Convention
- Chapter iv Cooperation of Authorities and information exchange - Article 17
- Chapter v Measures of Prevention – Article 18
- Chapter vii International cooperation – Article 22
- Chapter viii Follow up mechanisms – Article 25

Article 17 of the Convention
National measures for coordination and information exchange

- OMCL s already have information sharing tools in place that facilitate rapid dissemination of information and data exchange on counterfeit medicinal products between OMCLs and Competent Authorities
- If a network of single points of contact (SPOCS –Customs, Police Competent Authority for drugs, Judicial System) exists this can lead to a more multi sectoral,coordinated, integrated and holistic approach (Cooperation can involve industry for further information)
- Strengthening collaboration with all stake- holders thus saving time and resources

Article 18 –Preventive measures can establish the quality and safety requirements of medicinal products

- The OMCL s can support this article at a practical and technical level through surveillance testing of products but also API' s and prior to the granting of marketing authorization
- Sampling in surveillance can be on a risk base system and targeted to products that are prone to counterfeiting

Article 22-International cooperation

- Networking and International cooperation are the cornerstones of the OMCLs with
- EMA
- PICS
- Working groups of HMA
- The EDQM in conjuction with the OMCL's has the expertise to coordinate and run specifically tailored programmes for counterfeit analysis within and outside the Network
- The OMCL 's have a robust network under EDQM and provide through Quality Assurance VALID AND ESSENTIAL DATA for enforcement purposes

Article 25- the Committee of Parties to monitor the implementation of the Convention

- The OMCL network can efficiently support the projects and activities that relate to the goals of the Convention through its analytical capacity ,long term data collection and expertise
- The EDQM which is represented in the Committee of Parties coordinates the activities of the OMCL Network. So the OMCL Network has a line of communication with the Committee of Parties

Utilisation of existing networks/infrastructure

- OMCLs/EDQM network:
- ❖ analyse counterfeit products and results and information are disseminated to
- -Members of the Network
- -Drug regulatory Authorities
- -Law Enforcement
- ❖ share knowledge and experience with members of the network (83 Laboratories within the countries of the CE)
- ❖ initiating and support enforcement actions with the appropriate Authorities
- ❖ Initiate awareness through media/training

OMCLs mandate

- Unless mandated by National Competent Authority OMCLs should not have as normal responsibility the certification of the presence of a counterfeit product during routine surveillance testing
- Should be provided with sufficient indications that sample may be a counterfeit product
- Adequate training to analytically cope with unknown substances
- Adequate technical equipment to confirm the presence of unknown /toxic substances

OMCLs :An invaluable support to Drug Regulatory Authorities and Law Enforcement

- OMCLs : Can Help to solve the difficult puzzle

- Is it a counterfeit?
- Does it have the right Active ingredient and right concentration
- Does it have the right Excipients ?
- How does it compare with the genuine ?
- Can it be linked to another /previous case?
- Can traceability be achieved ?
- It is a printing /packaging counterfeiting and not due to its composition?

Capacity of OMCLs

The OMCLs through the network activities organised by EDQM are gaining more experience and

- have a plethora of data collected over the years on original and generic drugs –less on APIs which they share
- 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
- Can have the capacity to link a counterfeit product with illegal/unauthorised manufacturing premises

The OMCLs

- have a plethora of data collected over the years on original and generic drugs –less on APIs
- 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
- Can thus link a counterfeit product with illegal/unauthorised manufacturing premises

OMCL s need to improve on the following to improve their technical support to the Convention

- Use existing intelligence to <u>tailor specific sampling schemes</u> targeted for the identification of counterfeit drugs
- Cover the whole distribution chain (including internet pharmacies) with the collaboration of the Drug Authorities
- More information on traceability (if known)of a product should be given to OMCL s by Regulatory Authority
- Have a Closer look and apply more techniques for labelling and packaging (training needed)

OMCL s need improvement on the following to enhance their technical support to the Convention

- Look more into API s 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)
- Availability of Reference Standards eg Anabolics – Sometimes spurious web sites that sell them through DR GOOGLE !

Outcomes from activities of OMCLs

The robust network of the OMCL's provides

- Better informed risk analysis
- Utilisation of limited resources to address counterfeiting by avoiding duplication
- Better Coordinated and multi-disciplinary investigations when linked to Customs, Police and Justice
- Through its analytical results integrated preventive actions
- Protection to public health and support to a reliable health care system

Further Contribution from EDQM to OMCL Network

- Efforts already in place to :
- Strengthen data on APIs involving more OMCLs (collaborative studies)
- Give OMCLs access to impurity profiles of Authorised APIs
- Provide fora for more information exchange
- Raise awareness to the public with the contribution OMCL network
- Provide training opportunities to OMCLs along with other stake holders (customs ,police)so as to have harmonised procedures and more collaboration

•OMCL Laboratories, apart from giving reliable results , keeping a good data bank, need TIME to think when investigating a counterfeit sample… to notice , to look at details, to remember details from previous cases

•They started looking at products in a more forensic approach

Examination /analysis of counterfeit products by OMCL s

- The most exciting phrase to hear in science - the one that heralds new discoveries - is not *"Eureka!"* but *"That's funny..."* (Isaac Asimov 1920 - 1992)

  OMCLs have the challenge to look for something extraordinary ,something <funny> when examining a counterfeit Pharmaceutical product -and many such cases have been reported by OMCLs

The OMCL s have distributed among the NETWORK information and data of more than 300 different counterfeit products in the last 5 years

Cyprus OMCL findings

- 2007 – 2011

- More than 40 counterfeit drugs
- Through internet ,sale of products from door to door ,customs control,
- Found undeclared substances :sibutramine,synerphine,phenophalein,tadalafil,DHEA ,Yohimbine ,Arsenic,Testosterone

Example of testing results : sample: BOTANICAL preparation

The same brand name (different lots),was tested at The State General Laboratory in Cyprus three times. It found to contain:

- First time (2009): **Sibutramine (10mg/cps)**
- Second time (2010): **Sibutramine (15,7mg/cps) and synephrine**
- Third time (2010): **Sibutramine, dinorsibutramine and Phenolphthalein**
  -no uniformity of capsules size/weight
  -each different capsule contained one or two or all of the three above substances in different amounts

Industry's input

- **The availability of such products in the regulated supply chain undermines the confidence in the health system and even more, the good status of Authorized Products**
- **So support from Industry is essential in combating Counterfeit Medicines**

The real driving force for the implementation of the Convention

- **Political will**

  and
- **legal support to strengthen and utilize further the existing infra structures**

The way forward – some key issues for EDQM with Drug Regulatory Authorities in collaboration with OMCLs

- Streamlining the expertise of OMCL s and utilising more their capacity to cope better with illegal and counterfeit medicines
- Optimizing the use of existing networks and infrastructures at both national level and a European/International level will facilitate further the implementation of the Convention.
- Set a risk management procedure/system for suspected counterfeit products
- Set up Adverse Drug Reaction (ADR) reporting and pharmacovigilence systems for counterfeit products

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The way forward – some key issues for EDQM with Drug Regulatory Authorities in collaboration with OMCLs

- Set up centres of technical expertise(in specific techniques ie NMR) in counterfeit drugs within EDQM /OMCL Network to provide either training or assistance or data if needed- thus saving resources
- OMCL s can collaborate more with Academia/forensic institutions for specific techniques
- A minimum expertise should exist in all OMCL s so that in a crisis a country must have the capacity to respond immediately.Training among OMCL's can be provided .

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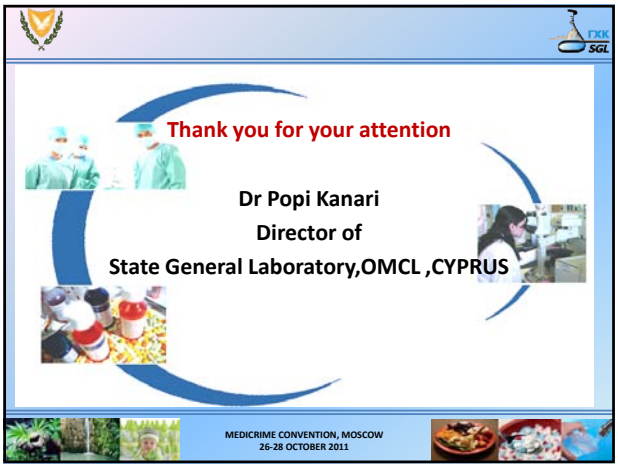
The benefit of joining forces

- Small OMCL'S like the one in Cyprus can also have the expertise in the analysis of counterfeit drugs but joining forces with the other OMCL's and the support and coordination of the EDQM this expertise and knowhow becomes a very strong tool in combating counterfeit drugs
- Big successes start from small successes through constant but committed efforts !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