



**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 MÉDICAUX
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. октября 2011

SLIDES SESSION IV

Pharmaceutical
Security
Institute




Burkina Faso




Argentina



Vietnam

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


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The Pharmaceutical Security Institute, (PSI).

The **PSI** is a fact finding, non-profit organisation dedicated to:

- Protecting the public health***
- Sharing information on counterfeiting activity***
- Initiating enforcement actions with the appropriate authorities***

PSI gathers information about counterfeit medicines from around the world and analyses that information turning it into intelligence, which it then shares with its members & the appropriate authorities.



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Challenge ~ Improving our knowledge!




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Challenge ~ Improving our knowledge!




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The Pharmaceutical Security Institute, (PSI).

PSI and its members work together and work with law enforcement and the drug regulatory authorities worldwide to investigate counterfeit and illegal medical products and similar crimes and support prosecutions with scientific analysis and expert evidence.

PSI currently has **26** members, which are all major international Research & Development pharmaceutical manufacturing companies.



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Current Members ~ The PSI Network





















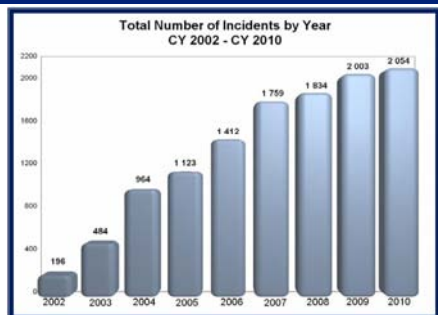








Incident Trend – Highest in Nine years



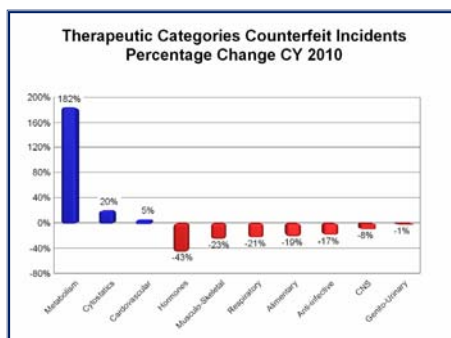
2.5% increase in pharmaceutical crime incidents

Incidents by Country

Top Ten Ranked

Country	Counterfeiting	Diversion	Theft	Total Incidents
1 China	599	5	0	604
2 United States	101	79	10	190
3 United Kingdom	110	38	1	149
4 India	107	36	0	143
5 South Korea	102	0	0	102
6 Brazil	46	49	5	100
7 Pakistan	80	15	1	96
8 Peru	86	7	0	93
9 Uzbekistan	84	1	0	85
10 Japan	77	0	0	77

Therapeutic Categories





**Illegal Pharmaceutical Manufacturing Facilities
& Legitimate Supply Chain Penetration.**

➤ 65 IPMFs identified and
raided in 2010 in 21 countries.

➤ 536 incidents recorded in
2010 where counterfeit
medicines reached licensed
wholesale distributors and/or
pharmacies in 37 countries.

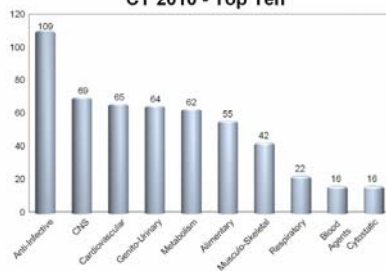


Malaysia 2010



Penetration of the Legitimate Supply Chain.

**Legitimate Supply Chain Incidents
CY 2010 - Top Ten**





Reported Global Arrests

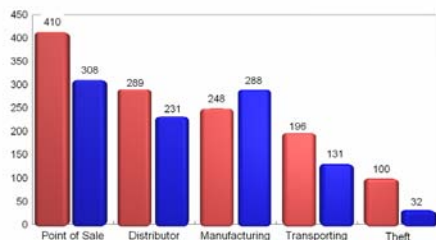


- 2008 = 917 arrests
- 2009 = 1,468 arrests
- 2010 = 1,148 arrests



Arrests

Arrests by Activity
CY 2009 - CY 2010





A Need for Training.

- **Raise awareness...**

- The issues
- Where to find assistance

- **PSI & Members provide training to...**

- Law Enforcement
- Drug Regulatory Authorities
- Judiciary

- **Outcomes...**


- Coordinated investigations
- Better quality case preparation
- Improved conviction rate





What else does industry do to combat counterfeit medicines?


- Pack security utilising latest technologies
- Tackling illegal on-line pharmacies


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➤ Working with the IPEC in the US.

➤ Engagement with governments, LEAs and key stakeholders.

➤ Proactive internet investigations.



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What else does industry do to combat counterfeit medicines?

➤ Pack security utilising latest technologies

➤ Tackling illegal on-line pharmacies

➤ Raising patient & healthcare workers awareness

The Partnership for **SAFE MEDICINES**




All Patients need information



***What else does industry do to
combat counterfeit medicines?***

- Pack security utilising latest technologies
- Tackling illegal on-line pharmacies
- Raising patient & healthcare workers awareness
- Identify counterfeit manufacturers & distributors
- Conduct investigations within the law
- Work with national & international law enforcement groups



PSI works with:

1. **INTERPOL**
2. **World Customs Organisation**
3. **Europol**
4. **National and international enforcement agencies**
5. **Operation Pangea**
6. **Regional Pharmaceutical Industries & Associations**



Conclusion.

- It is important that the role of Industry in the investigation and prosecution of offenders worldwide is understood and recognised.
- That information & Intelligence is no use unless it is shared with those organisations that will use it, and it is used.



Thank you!

Mr. Ashley How

Director EMEA

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Website: www.psi-inc.org

The role of manufacturers in tackling crimes related to medical products

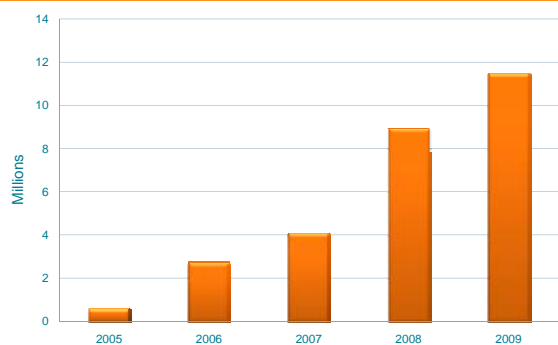
Hugh Pullen

Council of Europe International High-level
Conference

Moscow, 26-28 October 2011







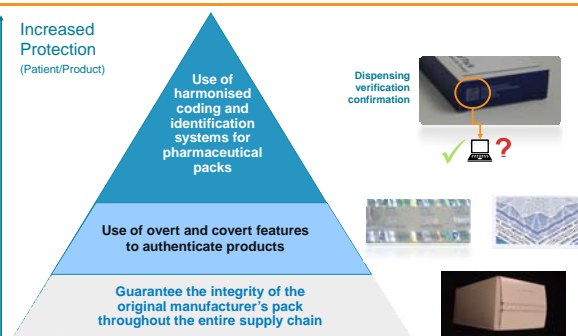
Counterfeits have no R&D costs

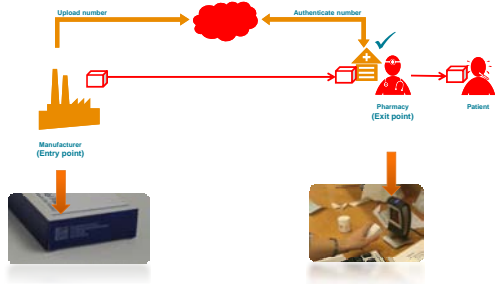


Rogue traders invest in packaging



Three measures to protect packs





Data Matrix – Coding proposal derived from GS1 standards (EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN or NTIN)	14 digits
Unique Serial Number (randomized)	up to 20 alpha-numeric characters
Expiry Date	6 digits (YYMMDD)
Batch Number	up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN: (01) 07046261388572
 Batch: (10) TEST5632
 Expiry: (17) 130331
 S/N: (21) 19067811811

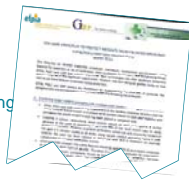


Specifications provided in EFPIA's
 "European Pack Coding Guidelines"



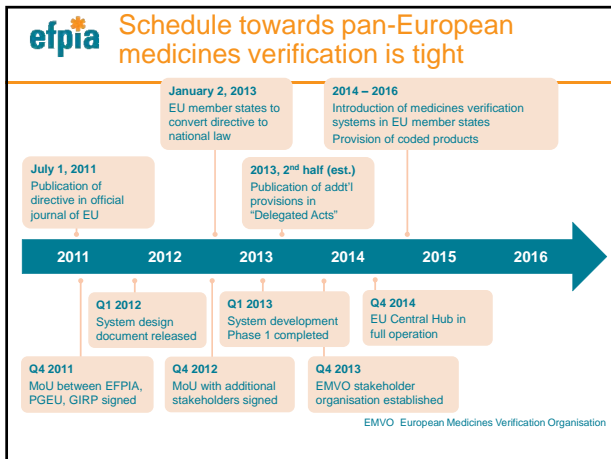
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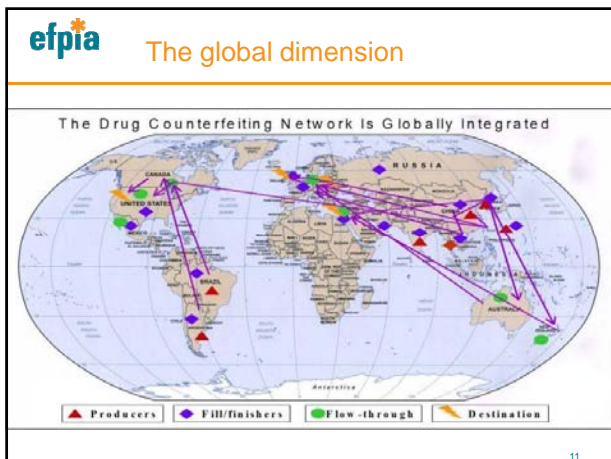
- EFPIA, GIRP, and PGEU
 - agreed upon joint position paper "Ten Core Principles to Protect Patients from Falsified Medicines"
 - are working on Memorandum of Understanding towards foundation of European stakeholder organisation
 - currently prepare Request for Proposal for implementation of pan-European Medicines Verification System (EMVS)



- Talks ongoing with AESGP, EAEPC, EGA, and HOPE

AESGP	Association of the European Self-Medication Industry
EAEPC	Europ. Assoc. of Euro-Pharmaceutical Companies (Parallel Importers)
EGA	European Generic Medicines Association
GIRP	European Association of Pharmaceutical Full-line Wholesalers
HOPE	European Hospital and Healthcare Federation
PGEU	European Association Representing Community Pharmacists



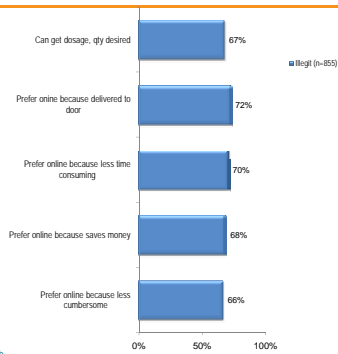


efpia Virtual pharmacies; real threats

- **62%** of medicines purchased online are fake or substandard
- **95.6%** of online pharmacies researched are operating illegally
- Over **90%** of websites supply prescription-only medicines without a prescription.

BEWARE
Is the medicine you are about to buy safe?

Source: European Alliance for Access to Safe Medicines



Source: Lilly research

SI COMPRAS FARMACOS ONLINE
ESTÁS JUGANDO A LA RULETA RUSA

— ALJEBRA7 —

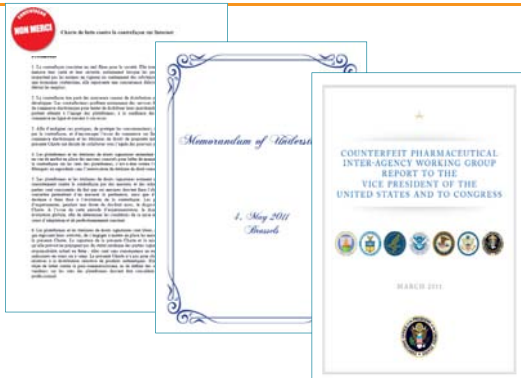
Manufacturers use specialist companies to monitor the Internet for illegal online pharmacies

In 2010, over 10,000 illegal online pharmacies were taken down as a result of these actions





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Search Engine → Online Pharmacy → Purchase → Delivery

Stronger co-operation between these organisations is a vital step to prevent online sales of counterfeit medicines.

The EDQM Traceability Project (eTACT) and its Support for the Objectives of the MEDICRIME Convention

The MEDICRIME Convention – Countering the Spread of Counterfeit Medical Products
26-28 October 2011
Moscow, Russian Federation
Dr. Susanne Keitel, EDQM



EDQM's Anti-Counterfeiting Strategy

Multiple actors / multifocal threat

Multi-level ("holistic") strategy

- Custom level (importation)
- Legal instruments (pharmaceutical crime)
- Pharmaceutical level
 - inspection
 - testing (detection / provide enforcement officers with evidence)
 - surveillance of pharmacovigilance reports from users
- traceability



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Traceability of Serialised Items = Mass Serialisation

- Mass serialisation = assigning/marketing each product with a unique, unpredictable identifier
- Marking or "tagging" of products usually at manufacturer level
 - human readable
 - machine readable technologies such as DataMatrix barcodes or RFID tags
- Distinguishing each trade item from another even if they belong to the same production batch



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Main Features of Current Multiple Systems of Mass Serialisation in Europe

- From manufacturer to Point of Dispensing = “end-to-end”
- No coverage of (legal) internet sales
- Developed bottom-up from community pharmacies or top-down from manufacturers
- No interoperability / different standards & data carriers
- Expansion country by country

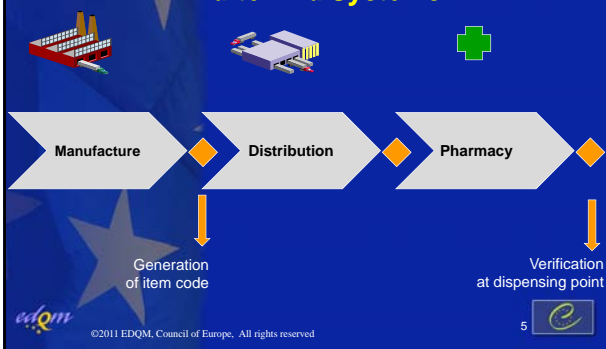


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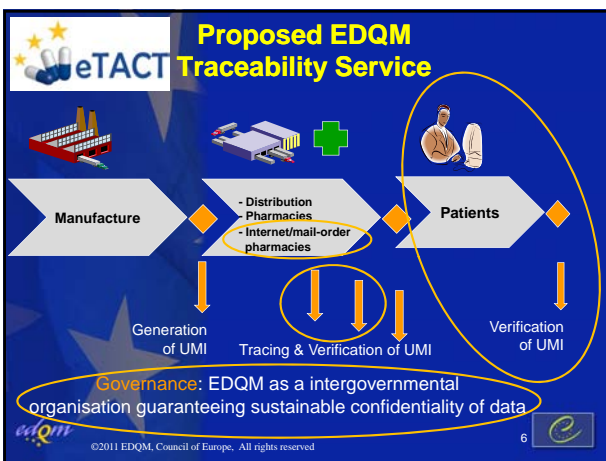
Current Situation in National European Systems & EFPIA : End-to-End Systems



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EDQM Traceability Service

- Adopted EU Directive on falsified medicines 2011/628/EU will impose safety features for identification and/or traceability of packs
- Mass serialisation with UMI = Unique Medicine Identifier per item
- UMI unique, unbreakable and interoperable with other existing systems using GS1 standard






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EDQM Traceability Service

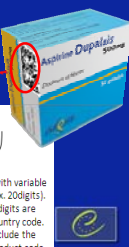
NOW




1D barcode coding for product number only

NEXT





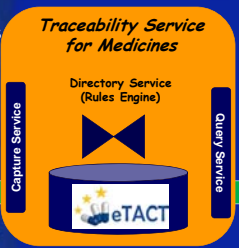
UMI

AI(90): temporary solution waiting for GS1 standard

GS1 GTIN (product number)
B. Serial Number
C. Expiry date
D. Batch Nr.
EDQM AI with variable length (max. 20 digits). The first 3 digits are the GS1 country code. The rest include the national product code.

Directory vs. Repository


1 - Manufacturers uploading their UMIs

2 - Manufacturers with own UMI repositories

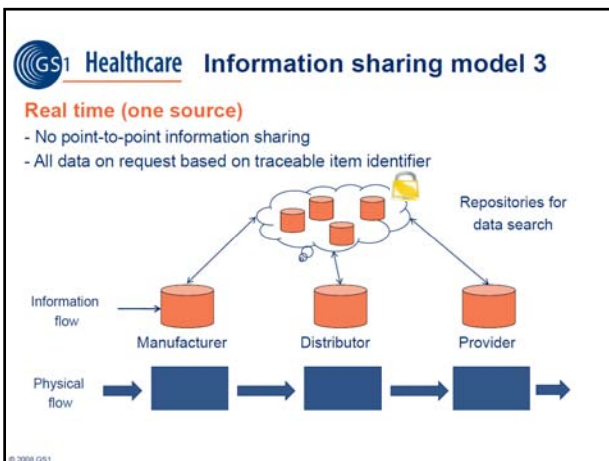


Traceability Service for Medicines
 Directory Service (Rules Engine)
 Capture Service
 Query Service

UMI Queries: Pharmacies, patients, customs, etc.



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eTACT Scope of the EDQM project

- Any Pharmaceutical products on a voluntary basis
- Any registered business stakeholders within distribution / patients / authorities
- Any of the 36 member states of the European Pharmacopoeia and beyond, if interested
- Primary or secondary packaging (e.g.: bottle, folding box)

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Why a Public Pan-European Governance Model

- Mass serialisation = a logistic business topic..... but not only
 - handling tracing data has a public health impact, e.g.: efficiency of supply chain and availability of medicines
- Regulatory bodies to be integrated as early as possible

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Why a Public Pan-European Governance Model (2)

- Different national systems without pan-European governance => lack of interoperability
- Cost control
 - phasing of implementation
 - economies of scale
 - no uncoordinated upgrade of manufacturers' packaging lines for individual countries one after another



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Why a Public Pan-European Governance Model (3)

- Extensive EDQM ability to guarantee confidentiality
 - Certification of Active Pharmaceutical Ingredients (APIs) = preferred tool for the evaluation of quality of APIs (Dir. 2001/82/EC and 2001/83/EC)
- Preventing mass serialisation from being used for blurring the border between patient information and advertising



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Governance and Internet Pharmacies

- Mail-order and Internet pharmacies authorised in several European countries
- Risk = giving patients a false sense of security with any Internet transaction
- EDQM-promoted awareness campaigns by health authorities about the danger of illegitimate e-pharmacies
- Architecture and governance of European traceability systems can influence the development of this part of the European dispensing network in one way or another



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Proposed Shared Governance Model

Technical prominent role for business stakeholders

- feeding the system with data on a daily basis
- owner of their data and only theirs, and responsible for accuracy

Administrators of systems(s) = national and European regulatory authorities, EDQM

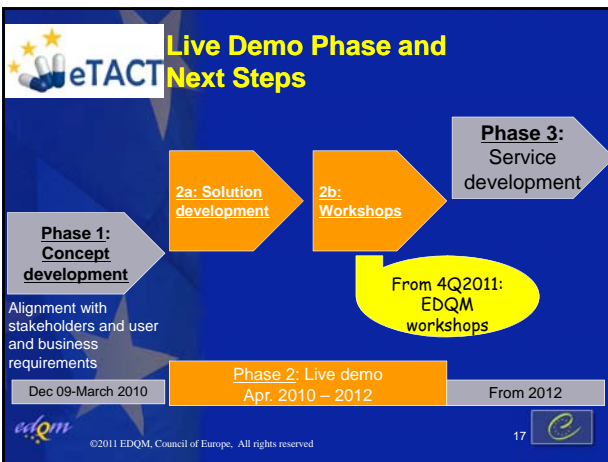
- interoperability (internal, external)
- appropriate general control and risk control



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Live Demo eTACT System

Commissioning Dispensing

Returning Alerting Decommissioning

Recalling Shipping

Packing Querying Capturing

Verifying

Many functionalities and many debates....
In order to develop the most suitable system(s)



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Conclusion

- A criminalising legal framework and
- An instrument for stakeholders, notably patients, to verify the authenticity of a medicine, regardless of the source it was acquired from

are two important preconditions for effectively combating and preventing counterfeiting of medical products.

The adoption of the MEDICRIME convention and EDQM's traceability project, eTACT, are significant contributions to this fight.



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High Level Conference Countering the Spread of counterfeit medicinal products and similar crimes "Medicrime Convention"




(Patients perspective) Trade in counterfeit medical products via the internet

Stephen MCMAHON
Treasurer and Board Member I.A.P.O.
Chairman Irish Patients Association

Thursday 27th Oct. 2011 - Izmailovo Concert Hall Moscow

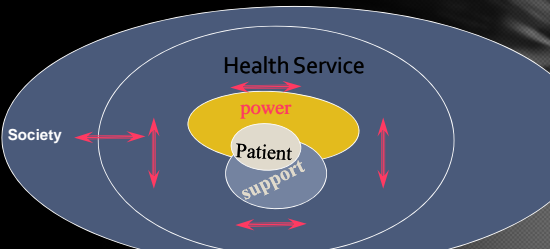




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Medicrime convention Izmailovo Concert Hall Moscow

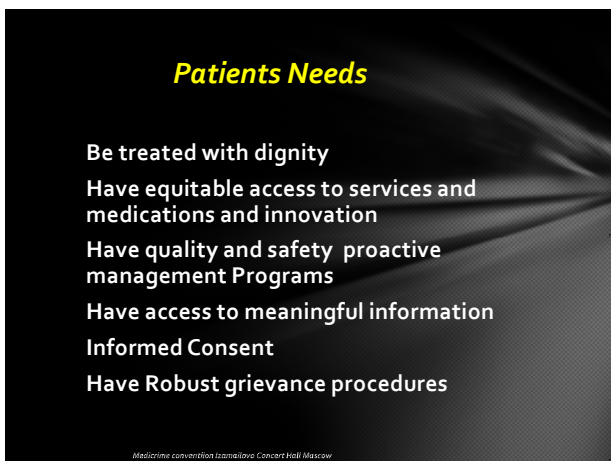
Patient Centered Health Service



Inter woven relationships

Medicrime convention Izmailovo Concert Hall Moscow







EUROPEAN PATIENTS' CHARTER FOR IRELAND





Irish Patients' Association

PRESENTED AT THE ROYAL COLLEGE OF SURGEONS IN IRELAND APRIL 18TH 2005

BY THE IRISH PATIENTS ASSOCIATION AND DUBLIN CITY UNIVERSITY
(SCHOOLS OF NURSING AND LAW AND GOVERNMENT)

1. RIGHT TO PREVENTIVE MEASURES	8. RIGHT TO THE OBSERVANCE OF QUALITY STANDARDS
2. RIGHT OF ACCESS	9. RIGHT TO SAFETY
3. RIGHT TO INFORMATION	10. RIGHT TO INNOVATION
4. RIGHT TO CONSENT	11. RIGHT TO AVOID UNNECESSARY SUFFERING AND PAIN
5. RIGHT TO FREE CHOICE	12. RIGHT TO PERSONALIZED TREATMENT
6. RIGHT TO PRIVACY AND CONFIDENTIALITY	13. RIGHT TO COMPLAIN
7. RIGHT TO RESPECT OF PATIENTS' TIME	14. RIGHT TO COMPENSATION







Irish Patients Association & Medicines Convention

Counterfeit Medicines

Re Call

Medicine convention & medicines Convention

Re-Call Counterfeit Medicines EC Security FP7 Call 2010 1.3-2



- Threat to Patients Lives?
- Threat to Public Health
- Criminal's Gain Advantage
- Terrorist's Gain Advantage
- Companies loose Revenues for reinvestment and shareholder return

Counterfeit breach undermines Trust In Institutions of the State

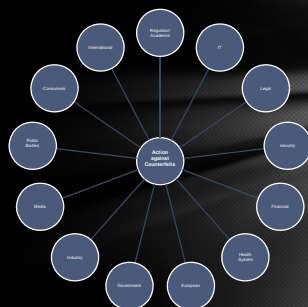
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FP 7 2010 1.3-2 Mission

- **Focus on identifying genuine medical Products and Devices**
- **Secure their legitimate Supply**
- **Research on Profiling Counterfeit Internet Traders**

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Action against Counterfeits Stakeholders



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Irish Patients Association S McMahon

Medicrime meets Most and indeed exceeds what we recommended

Recommendations

Ireland should encourage and actively engage with the development of an International Framework Convention on counterfeit drugs through the WHO.

Laws that specifically address counterfeit drugs should be passed, putting civil and criminal sanctions in place for those who engage with counterfeit drug trade.

All government departments with an interest in any aspect of counterfeit drug trade should cooperate in responding to this issue both locally and globally.

Public health authorities should develop clear and efficient mechanisms that allow healthcare professionals and the public to report suspected counterfeit drugs.

A media campaign is needed to bring accurate information on counterfeit drugs to the public's attention.

More to DO!

Pharmaceutical companies should openly report cases of counterfeit drugs and cooperate with anti-counterfeit police and customs operations.

Intensive international discussions are needed to find ways to reduce the cost of authentic pharmaceuticals in the developing world.

Healthcare professionals should educate themselves on counterfeit drugs and ensure these issues are discussed in training programmes for future professionals.

Healthcare professionals should be vigilant in checking for counterfeit drugs and alert patients to drugs, the dangers with counterfeit

Financial and Other Resources required to Tackle issue in Global Economic Environment

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Working Together to help public connect with the System .

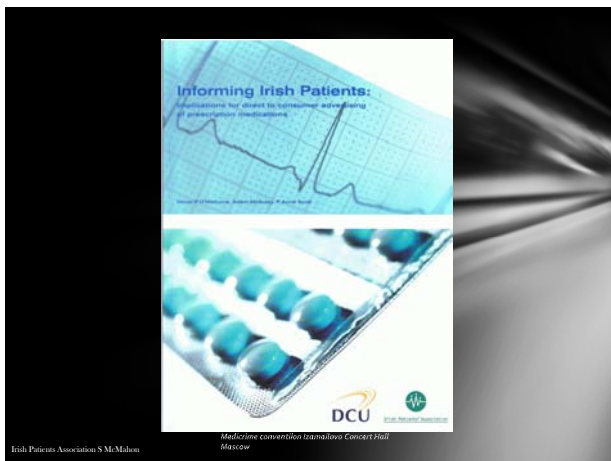
WWW.HEALTHCOMPLAINTS.IE

Collaboration possibly a first

Medicrime convention Izamalayo Concert Hall Moscow

The image displays a collection of logos for various Irish organizations, including:

- An Bord Alleanas
- Citizens Information Board
- CORU
- Dental Council
- Food Safety Authority of Ireland
- Health and Safety Authority
- Health Information and Quality Authority
- Health Service Executive
- Irish Medicines Board
- Irish Patients' Association
- Medical Council
- MHC
- Office of the Ombudsman
- Ombudsman for children - do léanaí
- PSI
- Pre-Hospital Emergency Care Council
- Radiological Protection Institute of Ireland



General Recommendations

A right to be informed rather than a right to information should be conferred on patients in Ireland through appropriate legislation

Information Bearers

Patients should take seriously their responsibility to inform themselves about their health their medications and any other treatments they might be receiving

DTCA should not be permitted in Ireland or the EU

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Medicrime declaration

- Article 5 – Manufacturing of counterfeits
- Article 6 – Supplying, offering to supply, and trafficking in counterfeits
- Article 7 – Falsification of documents
- Article 9 – Aiding or abetting and attemptts
- Article 10 – Jurisdiction
- Article 12 – Sanctions and measure
 - 3. ii proceeds of these offences, or property whose value corresponds to such proceeds;
- article 13 – Aggravating circumstances
- Article 17 – National measures of co-operation and information exchange
- Article 18 – Preventive measures training/public awareness
- Article 19 – Protection of victims
- Article 20 – The standing of victims in criminal investigations and proceedings

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Article 18/19

- They Need to be Warned regularly
- They Need to be supported when under threat
- They Need to be supported when affected
- Patients, their family's, and advocates have a voice listen to them
- They are your partners

Unprotected "Patients Can Die from one click of t heir mouse"



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Information Bearers

Patient Groups and Patient Advocates have an important role to inform patients and the public of the risks from counterfeit medicines

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Medicrime Convention will save lives –
Internet a challenge



Medicrime convention trainallown Concert Hall Moscow

Thank You !

For Information Purposes only no part hereof intended as advice.
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Operation PANGAEA IV



Lynda Scammell
Senior Policy Advisor
Enforcement Group
Medicines and Healthcare products Regulatory Agency

Outline

- What is the issue?
- Concept
- Objectives
- Methodology
- Participation
- Operational Activity Options
- Results

Internet Pharmacy



- Professional Site
- Responsible policies
- Patient Information
- Secure
- Private
- Good value

Rogue Pharmacy

- Unlicensed medicine
- Controlled drugs
- Withdrawn medicines
- No prescriptions
- Unregulated site
- No address
- Registered in China
- Hosted in Russia

to buy drugs like the

'In two / enough to KILL

prescription from ! for online compan And the consequ Last month a

Are you sleeping safe and sound?

Following the tragic death of Laura Lambden, who bought insomnia pills on the web, we look at the hazards of online drugs and test safer ways to drift off.. By Caroline Jones

Concept

Aim

- Global response to a global issue
- International Internet Week of Action (IIWA) involving Medicine Regulators and Law Enforcement Agencies:
 - tackling the **demand**, through raising public awareness
 - tackling the **supply**, through targeting the illegal on-line sale of medicines including unlicensed and counterfeit products
- Protecting public health

Operation Dates

20-27 September 2011 – Operational enforcement activity

29 September 2011 – Press Release

Objectives

- **Safeguard** public health
- **Raise public awareness** of the increased risks in obtaining medicines from unregulated websites
- **Seize** counterfeit and illegal products and remove from the market
- **Disrupt, dismantle** and **close down** websites and businesses acting illegally
- **Identify and investigate** the producers and distributors of counterfeit and illegal medical products and the criminal networks supporting them
- **Prosecute** those responsible where appropriate and seize their assets
- Enhance **co-operation** amongst domestic and international agencies combating the illicit trade of counterfeit and illegal medical products

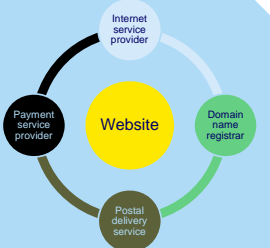







Methodology



- Focus on the four components required by a website illegally supplying medicines
- Engage specialists on the best way to disrupt the sites
- Engage the media in the most effective way to raise awareness
- Obtain the biggest impact for the minimum cost and effort






Participation

- MHRA – IIWA Secretariat
- 81 countries, 165 agencies
- Participation breakdown by agency:
 - Customs – 72 countries
 - Medicines Regulators – 30 countries
 - Police – 26 countries
 - INTERPOL offices – 37 countries
- Payment providers:
 - PayPal, Visa Europe, Visa Inc, Barclaycard, Western Union and Mastercard Europe




Operational Activity Options

- Public Awareness
- Customs/Postal Hubs
- Website identification and takedown
- Visits/Inspections ('Raids')
- Results Coordination – INTERPOL
- Payment processing facility removal




PANGAEA IV Results - International

- **Auction sites** - 606 adverts removed
- **Websites** – 13,495 websites taken down
- **Postal hubs / ports** – 399 postal hubs inspected with 45,519 packages inspected
- **Seized at hubs / ports** – 7,901 packages seized containing nearly 2.5 million doses
- **Types of medicines** - epilepsy, asthma, acne, narcolepsy, breast cancer, cholesterol reduction, contact lenses, skin conditions, antibiotics, anti-histamines, erectile dysfunction, weight-loss, pain relief, hair-loss, human growth hormone, anabolic steroids, anti-depressants, skin-lightening creams, sedatives, stomach ulcers.
- **Public Awareness** – 17 campaigns
- **Total** – nearly 2.5 million doses, valued at approx £5 million



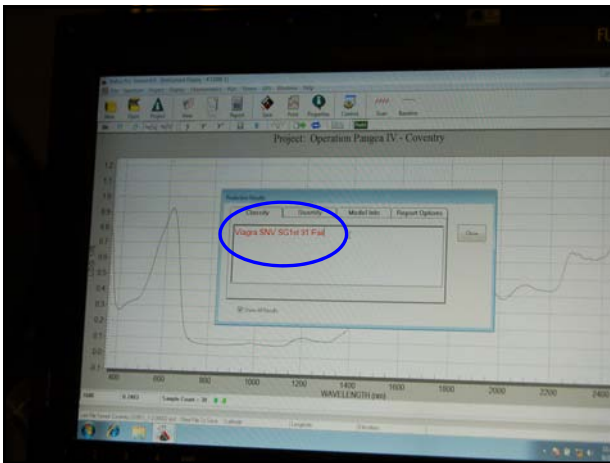
Working with UKBA

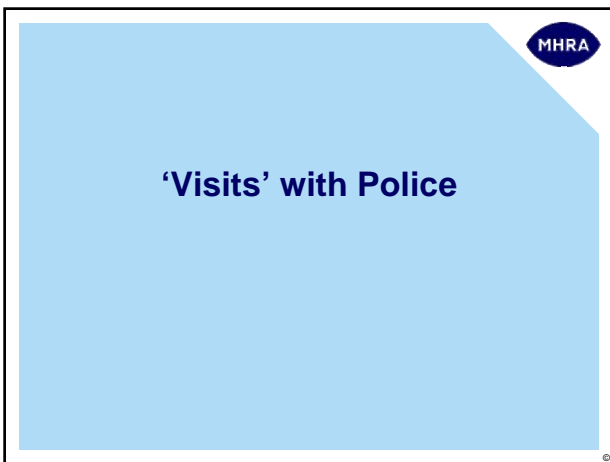


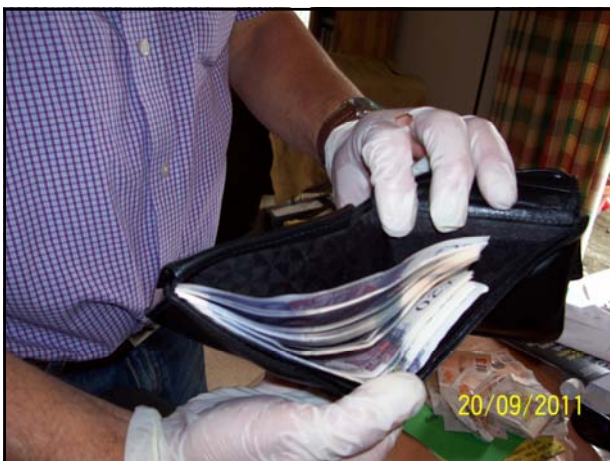



















PANGEA IV Results - UK



- **Seizures with UKBA** – over 1 million doses of unlicensed medicines worth approximately £2m including over 52,000 doses of counterfeits worth an estimated £100,000
- **Websites taken down** with Metropolitan Police – over 12,800 (plus 600 auction/marketplace/social nw)
- **Visits with Police** – 16 warrants executed, 13 arrests, nearly 100,000 doses seized worth estimated £200,000
- **Additional seizures** – approx £17,500 cash, computers, phones, correspondence including financial
- **Other criminality** – discovery of stun-gun, crossbow, starter pistol, knuckle-duster, knife and cannabis plants
- **Medicines seized** – epilepsy, asthma, acne, narcolepsy, breast cancer, erectile dysfunction, weight-loss, pain relief, hair-loss, human growth hormone, anabolic steroids, anti-depressants
- **Press coverage** – Press Briefing, BBC 1 O'clock news, BBC Fake Britain, Press Association, Sky News, BBC Radio 4, BBC Radio 5Live, BBC Radio London, BBC Radio Sussex, The Guardian, Daily Mail and more...

Total – approx 1.2million doses seized, valued at approx £2m



Fake medicine den shut down

Police uncover £90,000 of illicit prescription-only drugs



Man imported fake medicines

Fined £10,000 for selling illegal impotence drug

THE former landlord of the Tiger Lounge in Hayes has been fined £10,000 for selling illegal impotence medicine. Jaganjit Bhambra, 27, ran the company Khatanga and Talla. The Medicines and Healthcare products Regulatory Agency (MHRA) launched an investigation, Operation Romeo, following a tip-off that led to a search of a warehouse's workings. This led to more than 100 boxes of an illegal online pharmacy. Bhambra, of 100 Avenue, Hayes, appeared for sentencing at Southwark Crown Court on Thursday, May 26 after admitting the offence at a hearing in April. At that time, Bhambra pleaded guilty to his father's business selling illegal and dangerous medicine. Bhambra has been fined £10,000, which, says, MHRA head of enforcement, Graham Smith, is "a very strong message". "While medicines such as these may look professional, what we see behind the scenes tells a very different story. These unlicensed medicines were being sold from a warehouse in Hayes, which means they had no quality control and were sold to the community conditions in which they were stored. "The unlicensed sale of medicines, including those to treat erectile dysfunction, poses a serious threat to public health." Bhambra was formerly employed as a landlord of the Tiger Lounge in Hayes Road, where the drugs were sold. He was also involved in the health and safety breaches.



FAKE MEDICATION ONLINE. YOU COULD END UP PAYING WITH MORE THAN JUST A CREDIT CARD.

GET REAL. GET A PRESCRIPTION



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

Lynda Scammell

Senior Policy Advisor

Enforcement Group

Medicines and Healthcare products Regulatory Agency

+44 (0) 203 080 6665

Lynda.scammell@mhra.gsi.gov.uk





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



The challenge for the counterfeiters.....





....to here?



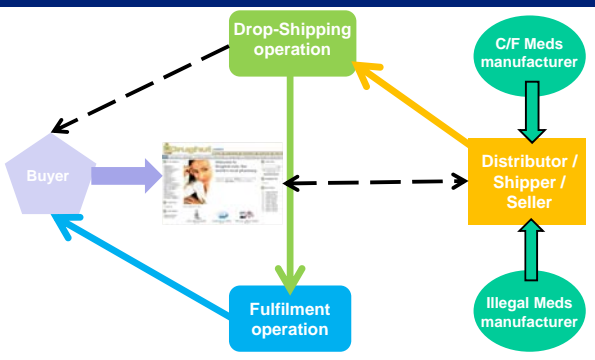


....and finally to here?





'Drop-shipping' and 'Fulfilment' operations



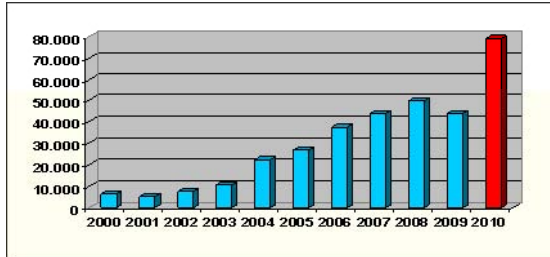


Do we know the scale of the problem?

Results for Op Pangea IV September 2011....

- Total number of websites shut down: 13,495
- Total number of packages seized : 7,901
- Total number of items seized: 2,422,636
- Total number of countries of origin : 48

The scale of the problem in the EU...



What are we talking about?





A Challenge for the Authorities





What are the issues for Customs?

- Not a priority
- Lack of manpower
- Scale of the problem
- Time consuming
 - Scanning of parcels
 - Open, examine and assess contents
 - Counted
 - Evidential process
 - Information/Intelligence process



Conclusion - What can be done?

- Cooperate - Identify partners & intervention points
- Collaborate - Gather & collate the intelligence
- Communicate – Share the intelligence effectively
- Investigate.....
- Training – Risk assessments & what to look for
- Awareness raising of the public and authorities



Thank you!

Ashley How

Director

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Presentation

RISK COMMUNICATION ABOUT COUNTERFEIT MEDICINES AND SIMILAR CRIMES:
PRINCIPLES, MODELS, PRACTICAL EXPERIENCES

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

October 2011
Moscow


AIFA



Risk communication about counterfeit medicines and similar crimes:
principles, models, practical experiences


DEFINITION OF THE FRAMEWORK:
"FALSIFIED MEDICINAL PRODUCTS"

Any medicinal product with a false representation of:

- ☐ its identity, including its packaging and labelling, name, composition in respect of any of its components including excipients and strength; and/or
- ☐ its source, including the manufacturer, country of manufacturing, country of origin, marketing authorization holder; and/or
- ☐ its history, including the records and documents relating to the distribution channels used.

DIRECTIVE 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. (2011).


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Risk communication about counterfeit medicines and similar crimes:
principles, models, practical experiences

DEFINITION OF THE FRAMEWORK:
"COUNTERFEIT MEDICAL PRODUCTS"

Counterfeiting: false representation as regards identity and/or source.
Counterfeiting means passing off a false product as genuine: this concept is public health focused (not covering specifically IPR).

Medical products means medicinal products (including active substances, excipients) and medical devices (including parts and accessories). Foodstuffs, cosmetics, biocides are excluded.

Council of Europe MEDICRIME CONVENTION: adopted on 8 December 2010 by the Committee of Ministers, envisaged for being opened for signature in autumn 2011.


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Risk communication about counterfeit medicines and similar crimes:
principles, models, practical experiences

DEFINITION OF THE FRAMEWORK:

SIMILAR CRIMES

Similar crimes: intentional manufacture, storage, supply (offer), place on market without authorisation/ non-compliance conformity requirements.

Prohibited conducts:

- Manufacturing of counterfeits;
- Falsification of documents accompanying medical products
- Supplying (offering) & trafficking in counterfeit medical products
- Similar crimes involving threats to public health

Parties must provide for prison sentences

Council of Europe MEDICRIME CONVENTION: adopted on 8 December 2010 by the Committee of Ministers, envisaged for being opened for signature in autumn 2011

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FALSIFIED, COUNTERFEIT, ILLEGAL...



These products always represent a danger for public health caused by criminal organisations. [Image: 2009 Swedish informative campaign]

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RISK COMMUNICATION:

SOME OBVIOUS POINTS

Reactive and proactive communication, in general, **are different**, and they are both **science based**.

- ☐ You should have procedures
- ☐ You should have a strategy based on facts
- ☐ You should define what to communicate
- ☐ You should not be afraid of measuring the results of your communication

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PRO-ACTIVE & REACTIVE COMMUNICATION

In the case of a suspected or verified counterfeit medicine, communication within the authorities and with other stakeholders has to be effective in order to prevent health damage.

Communication should be opened to signals emerging from media and from the public, in a bi-directional process.

The pro-active and the reactive communication on new cases of suspected or verified counterfeit medicines are closely related.

But they have different criticalities and rules.

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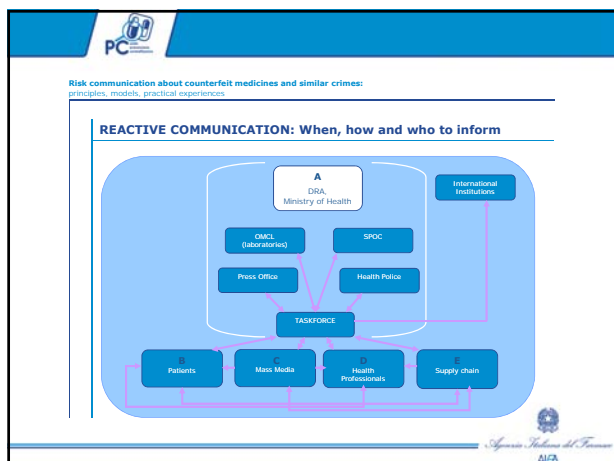
Risk communication about counterfeit medicines and similar crimes:
principles, models, practical experiences

REACTIVE COMMUNICATION: When, how and who to inform

When a confirmed case of illegal medicine occurs, the reactive communication should be quick and focused, and it should avoid generating panic.

In order to improve the efficiency of communication, it is highly recommended to DRAs to establish procedure that will need to be adapted based on the situation.

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STRATEGIES FOR REACTIVE COMMUNICATION

As shown on the previous diagram, an effective communication implies coordinated efforts among (health) authorities, health professionals and members of the distribution chain, to ensure that a coherent message is delivered.

DRA is often in charge of this coordination.

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AN EXAMPLE OF ALERT



- ☐ Formal and official communication (through the DRA channels), as for other more frequent communication (e.g. in case of batch withdrawal).
- ☐ Signal to patients filtered by health professionals
- ☐ Involvement of the different stakeholders, including legal manufacturers
- ☐ Reference to point of contacts in the relevant administration
- ☐ Disclaimers regarding the legal (and safe) products

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PROACTIVE COMMUNICATION

Article 85d
Without prejudice to Member State competencies, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products.

These campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally to the public via Internet and the function of the common logo, the national websites and the Agency website.

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principles, models, practical experiences

PROACTIVE COMMUNICATION

The DRA is the origin of the information for internal and external use and should take the initiative to launch information campaigns aimed at the public on how to prevent any damage to health from counterfeit medicines.

The goal of such a campaign should be to prevent the public buying medicines outside the regular distribution channel and to detect any cases of counterfeit medicines..

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ANVISA

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principles, models, practical experiences

PROACTIVE COMMUNICATION



Proactive communication should be "attractive": positive and negative signals may be used for the same purpose. [Images: Portuguese and Austrian informative campaigns on the Internet related risks]

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ANVISA

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TO INFORM...



Proactive communication should be "attractive": positive and negative signals may be used for the same purpose. [Images: Portuguese and Austrian informative campaigns on the Internet related risks]

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principles, models, practical experiences

... OR TO SHOCK?




Today it is clear that some customers are aware of the illegality of some behaviours, but underestimate the risk, and counter-react to the signals from the authorities (the so called "donkey game").
[Images: UK MHRA/Pfizer/RPSGB campaigns on the Internet related risks]

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principles, models, practical experiences

**EXAMPLE OF CRITERIA:
EPA'S "SEVEN CARDINAL RULES"**

The US Environmental Protection Agency handbook, "Risk Communication in Action: The Risk Communication Workbook", summarises the risk communication process in seven "cardinal rules" that are applicable both to proactive and reactive communication.
These 'rules' can be used as a starting point for a discussion on internet-based risk communication.

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principles, models, practical experiences

**EXAMPLE OF CRITERIA:
EPA'S "SEVEN CARDINAL RULES"**

Rule 1. Accept and involve the public as a legitimate partner
Rule 2. Listen to the audience.
Rule 3. Be honest, frank, and open.
Rule 4. Co-ordinate and collaborate with other credible sources.
Rule 5. Meet the needs of the media.
Rule 6. Speak clearly and with compassion.
Rule 7. Plan carefully and evaluate performance

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principles, models, practical experiences

MEASUREMENTS

Measurements of public opinion should be performed both before and after the communication exercise, using the same methods, and considering the identified target audience (Internet users, general public...).

Moreover, good knowledge after the campaign needs to be judged also in terms of changes among the public with respect to the issue being communicated, considering also if the awareness/knowledge is sustainable (or if it will disappear after a few months).

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principles, models, practical experiences

CONCLUSIONS

Both proactive and reactive communication schemes were quite successful in raising the awareness of the public: administrations began to receive notifications of suspect products and newspapers started to write articles on the risk of buying from uncontrolled sources.

However, the increased awareness regarding illegal purchases of medicines had an obvious negative side effect: an increase in the number of potential customers who had not previously considered the internet as a potential source of medicines.

Thus, the effectiveness of the campaigns had to be reconsidered: if success in terms of raising awareness is not paired with a reduction of the potential risk, the project must be reviewed.

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principles, models, practical experiences

FORTHCOMING INITIATIVES

COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES
Risk Communication

- Council of Europe/EDQM/AIFA Expert Workshop on Risk Communication and counterfeit medicinal products (Rome, November 2011)
- CoE/EDQM/AIFA book "Counterfeit medical products and similar crimes: Risk Communication" (ISBN 978-88-481-2662-5, 2011)
- Forum on Risk Communication and counterfeit medicines (2012)

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National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

NL-EDQM study

HARM
caused by falsified
medicinal products

Bastiaan Venhuis

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



The current NL situation

Falsified products with on the black market

- Substandard, impure, wrong active....

Lack of information on harm

<ul style="list-style-type: none"> • Pharmacovigilance • Poisons information institutes • Hospitals et cetera 	<p>virtually no data</p> <p>limited data, poorly accessible</p> <p>limited data</p>
--	---

- Medical community is unfamiliar with the problem

- What signals to look for?

- How to report?

2 Medicrime Moscow, 2011
Harm caused by falsified medicinal products



The NL-EDQM study

- Assessment of the current situation
- Methodology for detecting signals
- Monitoring signals of health damage





3 Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Goal

- To describe the **exposure** and **level of harm**
- To show the **relevance** to the **medical community**
- An internationally **harmonized** methodology
- Provide **tools for governments** to respond to changes:
 - Alert specific medical professions based on trends in seizures
 - Alert enforcement based on hospital reports
 - Monitor effects of changes in the health system

4

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Approach

- **Assessment of the current situation**
 - Literature review for signals of harm
 - A study to exposure
- **Methodology**
 - What signals to look for?
 - Where to find such signals?
 - Harmonized methodology for CoE countries
- **Monitoring**
 - Harmonized monitoring system
 - Specific medical professions are asked to report cases

5

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Scientific literature

- Literature on harm caused by falsified medicines (1970 – pres.)
- Systematic search of MEDLINE and EMBASE databases
- Limited to countries with a developed health system

Looking for:

- Number of cases
- Number of victims
- Product types
- Reasons for discovery

6

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Scientific literature

Results

- 73 incidents
- 4501 persons hospitalized
- 175 deaths

Primarily caused by: Counterfeit gentamycin
Counterfeit heparin
Slimming herbs

Victims: General symptoms
Unwitting
Unwilling to be frank

Cases uncovered because of severity or scale

7

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Exposure study (1), (2011 - 2012)

• 3 - 5 year data on seized products

- Data from RUF, S, UK, B, CH, It, Isr, NL
- Data currently coming in

- To identify: leading symptoms
product types
geographic differences
vulnerable groups
expected harm

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Harm caused by falsified medicinal products



Exposure study (2), (2012)

• Sewage epidemiology

- Approaches the actual exposure
- Feasible for medicines* and drugs of abuse
- Thus far not applied to monitor use of illicit medicines

• Method

- Using incoming water at Sewage Refinement Plants
- Measure levels of interest
- Calculate use per 1000 inhabitants
- Compare with official sales

*ED drugs in waste water of 9 EU cities (Nieto et al. 2010)

9

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Methodology (2011 – 2012)

- Study design depends on outcome exposure study
- Medical experts to draw up a TRIGGER list
 - > priapism ED-drugs Libido
 - > eye-disorders ED-drugs Libido
 - > *psychosis* Sibutramine Slimming
 - > suicide Rimonabant Obesity
 - > lack of efficacy Counterfeit Any product
- Describe WHERE in the medical system these complaints would surface

10

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Monitoring (2012 -)

- Pilot study in the participating countries on **identification** and **quantification** of harm
- Harmonized methodology
 - **Tailored** to a **country specific** health system
- Optimization, validation, implementation

11

Medicrime Moscow, 2011
Harm caused by falsified medicinal products



Conclusions

- **We know very little about the current level of harm**
- **To assess the level of harm the following is needed:**
 - Assess the anticipated harm based on exposure
 - Describe signals and signal receivers
 - Involve the medical community
 - A harmonized international pilot-study into the identification and quantification of harm.
- **All support is welcome!**

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Medicrime Moscow, 2011
Harm caused by falsified medicinal products

Our competence – for your trust in therapeutic products

swissmedic
Swiss Agency for Therapeutic Products



Sharing experiences learnt from solved cases

Ruth Mosimann
Head of Control illegal Medicines
Swissmedic, Swiss Agency for Therapeutic Products

Vice-Chair
Committee of Experts on Minimising Public Health Risks
Posed by Counterfeiting of Medical Products and related
crimes (CD-P-PH/CMED)

Swissmedic • Swiss Agency for Therapeutic Products • Hallenstrasse 7 • CH-3000 Bern • www.swissmedic.ch

Illegal trade with medicines – a global business



Example:

- 1 Website claims to be legal Canadian pharmacy
- 2 Internet order from Switzerland
- 3 Host of Website on Seychelles
- 4 Production of counterfeit medicines in China
- 5 Shipment of counterfeit medicines to United Kingdom
- 6 Dispatch from United Kingdom to Swiss customer


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Experiences across borders


- **global illegal business > international authority networks are crucial**
- **risk of harm by counterfeit and other illegal medical products > risk management & prevention (RMP) measures**
- **effectiveness of RMP**
 - rapid information
 - correct evaluation under “real-life” conditions
 - linking experiences & competencies beyond borders

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Basis for Know-X project

- since 2006 by EDQM: systematic information exchange on testing activities among OMCL (Official Medicines Control Laboratories) network
2006-2011: compilation of 540 reports, restricted to OMCL
- public health aspects underreported, not captured comprehensively by pharmacovigilance systems
- EDQM synergistic approach to support authorities in combating counterfeit medical products and similar crimes
-  aim: provide authorities with RMP approaches (intelligence) to prevent incidences of counterfeits and to prevent damage to patients and to healthcare systems

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The Know-X project

- multisectorial cooperation: OMCL – law enforcement, prosecution
- aim: inventory of “lessons learnt” for RMP, measures taken in closed cases of counterfeit medical products and similar crimes
- integrates OMCL information
- information made available & access under control of participating health (incl. OMCLs) and law enforcement authorities
- restricted to officials, appropriate management of access rights
- secured, stable IT environment

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What information will be hosted in Know-X ?

Definition counterfeit medical products and similar crimes

- **Counterfeit:** false representation as regards identity & source (criminal intent)
- **Medical product:** protected by IPR or not, generic or not, including active substances, excipients, medicinal products for human and veterinary use, medical devices, parts & materials, accessories
- **Similar crimes:** manufacturing, keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:
 - i medicinal products without authorisation; or
 - ii medical devices without being in compliance with the conformity requirements

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What information will be hosted in Know-X?

- **Administrative information relating to the case:**
 - reporter, date
 - information referencing the case
- **Specific information**
 - non-nominal information
 - description of the counterfeit or illegal product
 - analytical-technical information (OMCL)
 - information relating to the modus operandi crime
 - information relating to investigation as far as relevant for public health protection
 - information about how risks for public health were prevented or managed
 - pictures, photos, test results, communication


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What is Know-X for?

- **decision-aids: suspicious medicinal products (not including cosmetics, dietary supplements, food)**
- **help for users like “points of contact” in their daily job**
- **systematic & structured analyses (searches/reporting) < pool of knowledge and intelligence**
- **trend-monitoring of criminal phenomena**
- **support up-to-date training of officials**
- **support the cooperation between national health, law enforcement & prosecution authorities**

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The way forward.....

- **support the implementation and follow-up of the Council of Europe MEDICRIME Convention**
- **see art. 17, 22: exchange / transmit information**

EDQM with help of CD-P-PH/CMED:
Provisional plan

- **2011: feasibility study – appropriate technical solution for user requirements**
- **piloting with data and users**
- **development of final version**
- **support to expert committees & networks, possible users (sharing information)**

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