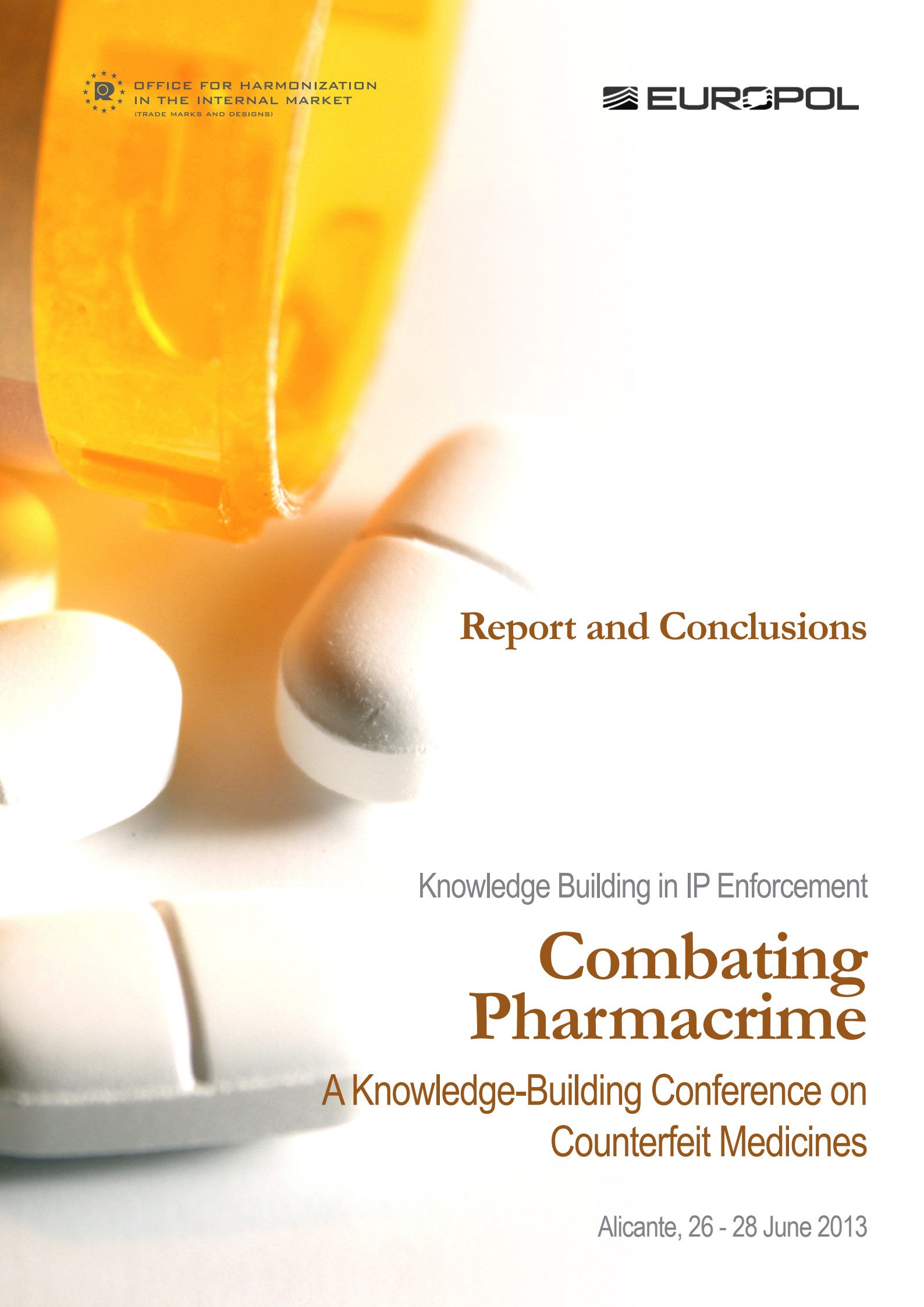

OFFICE FOR HARMONIZATION IN THE INTERNAL MARKET
(TRADE MARKS AND DESIGNS)

EUROPOL

## Report and Conclusions

Knowledge Building in IP Enforcement

# Combating Pharmacrime

## A Knowledge-Building Conference on Counterfeit Medicines

Alicante, 26 - 28 June 2013

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Knowledge Building in IP Enforcement

# Combating Pharmacrime

## A Knowledge-Building Conference on Counterfeit Medicines

Co-hosted by

**EUROPOL**
&
**The European Observatory on Infringements of Intellectual Property Rights**

Supported by

the **Pharmaceutical Security Institute (PSI)**

**Office for Harmonization in the Internal Market (OHIM)**

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# Contents

# 1 - Background

The illegal manufacture, distribution and sale of counterfeit medicines and pharmaceutical ingredients have led to an extremely lucrative and dangerous criminal business which is threatening the health and safety of people around the world.

Access to basic technology has allowed an increasing number of organised networks of counterfeiters and traffickers to produce and supply fake and illicit pharmaceutical products. These are convincingly manufactured and packaged to deceive wholesalers, retailers, buyers, patients and, in some cases, even pharmacologists. Often these medicines contain improper, wrong, too much or even no active ingredients and therefore, they can be highly dangerous. Furthermore, the preparations can be frequently packaged with incorrect labelling and instructions, which can also have a drastic effect.

The use of the internet for direct buying has added even further problems, giving unsuspecting people speedy access to a growing range of therapeutic, prescription and lifestyle preparations.

Moreover, this is not simply a problem for well-developed economic countries. Developing and less developed countries have become lucrative markets for counterfeit painkillers, antibiotics and even anti-protozoans, which treat parasitic diseases such as malaria.

To help EU Member States to take appropriate action in a very complex sector and to help strengthen cooperation between agencies in this field, the European Observatory on Infringements of Intellectual Property Rights, at the Office for Harmonization in the Internal Market (OHIM), joined with Europol to co-host a specific knowledge-building event. This was fully supported by the Pharmaceutical Security Institute (PSI).

The conference gathered together a wide range of responsible authorities involved in combating the trade in fake and illicit pharmaceuticals and included representatives from enforcement authorities (police, customs and health regulatory agencies) and prosecutors from across the EU. It also involved representatives from patient safety, the European Anti-Fraud Office (OLAF), Eurojust and DG TAXUD (Taxation and Customs Union), and included expert participants from pharmaceutical industries who are continuously involved in the fight against ‘pharmacrime’.

This event had the aim of improving understanding, highlighting the difficulties being faced by enforcement authorities, regulatory agencies, policy makers and customs, and bringing to light more effective responses based on current practices. To do this, the event engaged participants in helping to raise overall levels of understanding in several key areas. It also employed a series of practical workshops that spotlighted main problem areas and worked through relevant issues.
In total, 97 participants took part in the event, covering 28 EU Member States, plus Switzerland and Norway.

This report covers the discussions and conclusions reached by participants. It also provides indicators of how work in this area might be taken forward.

# The Event
# 2 - Day 1 Scene Setting

## 2.1 - Introduction

The event was introduced by EU Observatory and Europol and included a general overview of the problem. As part of the introduction, it was explained that the Observatory has fundamental objectives aimed at supporting IP enforcement, by helping to build knowledge and by fostering greater working partnerships in the EU on many levels. In this respect, it was emphasised how Europol and the EU Observatory are jointly working to promote a variety of responses to the overall growth of IP infringing products.

In this context, the event had been jointly designed to help build greater awareness, competences and cooperation in the fight against 'pharmacrime', which is a growing and destructive trade that is clearly being driven by organised crime.

## 2.2 - Theme 1: Pharmaceutical crime, definition and legal tools

To help introduce the issues in more detail, Europol set out to define 'pharmacrime'. Firstly, it was explained that the term 'pharmacrime' has no legal meaning and is merely an expression used to cover health-related crimes. The connotation being that 'pharma' refers to pharmaceutical products and therefore, 'pharmacrime' can be said to cover offences related to such products.

It was further explained that there are several definitions of 'medicines' used in relation to crimes involving counterfeit and illicit products. For example, the MEDICRIME Convention covers medical products and medical devices, while in Article 1 of EU Directive 2001/83/EC the description includes: "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis." Finally, in some cases, borderline products are also included in definitions; these might include cosmetics or food supplements. Clearly, this can complicate the issues in respect of enforcement, particularly when, for example, a common hygiene product contains a pharmacologically active substance or makes certain medicinal claims.

In terms of offences, the World Health Organisation (WHO) has historically considered counterfeit medicines to be products that are deliberately and fraudulently mislabelled, with respect to identity or source. This definition stretches to cover unpredictable quality, where a product may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. This definition has been now been updated to include spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines. In effect, medicines deliberately and fraudulently mislabelled in respect of identity and/or source.

Europol also outlined related offences in terms of substandard medicines and diverted products sold in different markets, which are almost impossible to track and trace.

An introduction to the existing legal framework was then provided alongside a range of statistics which highlighted the growing problem, including the effect on developing countries and losses to industry.

In conclusion, Europol identified a number of initial difficulties facing enforcers and stakeholders in tackling 'pharmacrime', namely:

- No harmonised criminal legislation
- Diverse definitions of the crimes involved
- Different penalties imposed
- Different investigative techniques used
- Different stakeholders involved (scientific, private investigators etc.) - leading to different approaches and views

Following the Europol outline, the Council of Europe (EDQM), explained the MEDICRIME Convention and a range of associated activities.

It was stressed that counterfeit, false and fraudulent medicines are crimes that impair peoples' quality of life, their capacity to work and can even result in death. As a result, it can corrupt the integrity of national healthcare systems, waste public healthcare resources, damage public security (due to the involvement of organised crime) and ultimately undermine economies and public confidence.

Unfortunately, at present, there is no specific international legislation aimed at crimes concerning medicines, doping substances or fraudulent medical devices. Furthermore, competences in enforcement can be divided and fragmented. For example, EU customs bodies only focus on IPR issues, while in many countries health authorities have no enforcement powers at all. Concerns also arise about the effective collaboration between different enforcement authorities.

In terms of sales and distribution, the internet continues to be a growing problem. Organised crime is involved and is able to conceal the origin and source of products, and to distribute fraudulent products to unwitting users. Responding to this requires systematic and effective networking and cooperation and it was explained how the MEDICRIME Convention and the Council of Europe can help.

Council of Europe conventions are international treaties that are binding for signatories. In 2001 the Council of Europe Committee of Ministers adopted a Resolution[1] that combating counterfeit medicines requires international cooperation across health, law enforcement authorities and international organisations.

In 2009, negotiations took place between international organisations including WHO, the World Customs Organization (WCO), the United Nations International Narcotics Control Board (INCB) and the European Commission. As a result, on 8th December 2010 the MEDICRIME Convention was adopted by the Committee of Ministers.

The aim of the Convention is to prevent and combat the counterfeiting of medical products and related crimes, by criminalising offences, protecting victims and promoting national and international cooperation. The intention being to focus on public health protection, but not only through the protection of intellectual property rights (IPR).

1 - (ResAP(2001)2)

This would be the first international treaty to criminalise the deliberate manufacture, supply and trafficking of counterfeit medical products and devices, including the falsification of documents. Therefore, in tune with national legislation, offences covered in the Convention embrace manufacture, supply, offers to supply, trafficking of counterfeit medical products, false representation of medical products identities and sources and the intent to pass off fake products as being genuine. However, it does not criminalise generic medical products, authorised for marketing by a competent authority or non-intentional breaches of quality standards and practices.

To help improve enforcement, the Convention also makes provisions for the collection, analysis and exchange of information, experiences and good practices. Furthermore, to assist networking and regular/systematic cooperation, it formally provides for the introduction of special points of contact (SPOCs) from police, customs, health, official control laboratories, judiciary etc.at national and international levels, based on legal agreements, or informal operational management of suspect and confirmed cases. Such operational SPOCs would be appointed by national authorities to coordinate and lead and decide on models of investigations between national authorities.

By June 2013, 22 European countries had expressed a political will to join the Convention[2] plus three non-European states, Israel, Morocco and the Republic of Guinea.

In conclusion, it was stressed that the MEDICRIME Convention is the first international criminal law treaty aimed at preventing and combating counterfeit and falsified medicines, which includes measures and legal concepts in criminal law and multi-sector administrative cooperation. The Council of Europe welcomes international cooperation and feels that through designated SPOCs there is an opportunity for genuine international success.

## 2.3 - Theme 2: The expertise of the private partners in the fight against Pharmacrime (Part 1)

To help build greater understanding, pharmaceutical sector experts from:

- The Pharmaceutical Security Institute (PSI)
- Pfizer Global Security
- The Eli Lilly and Company (Lilly), Product Protection Team
- The International Institute Against Counterfeit Medicines IRACM

Specific examples were provided, highlighting the nature of cross border 'pharmacrime', the threats posed, and the various distribution methods being used by criminals.

It was explained that the PSI is a non-profit organisation that is particularly concerned about patient health and safety. The work of the PSI covers counterfeit medicines, diverted medicines and stolen medicines. In this it acts as a central point for gathering and sharing information and intelligence for a network of 26 major companies.

PSI explained that all pharmaceutical companies are affected to some degree, but the main threat is to patient health and safety. It was stressed that ultimately people are dying as a result of counterfeit medicines. This is, therefore, a crime against public health, and a number of examples were provided to illustrate the harm being caused. Moreover, participants were reminded of the associated damage being caused, such as:

2 - (AR, AT, BE, CH, CYP, DK, ES, F, FIN, DE, ICE, IT, LUX, LIE, MD, PT, RUF, TRK, UKR – ratified (implemented in domestic law).

- The growing effect on veterinary and other related medicine areas
- The impact on local and national economies
- Losses affecting the producers of genuine goods and the related societal costs, e.g.
  - job losses to the local community
  - economic consequences to health care
  - tax evasion
  - damage to investment and innovation

Businesses are also being seriously challenged on how to maintain their R&D facilities in light of the damage being suffered.

In addition, Pfizer confirmed that counterfeiters not only finance other crimes but are normally involved in some other forms of organised criminality. In some cases this has stretched to the funding of terrorist activities, where high profits from counterfeit Viagra have been accumulated and used.

OCLAESP *(Office central de lutte contre les atteintes à l'environnement et à la santé publique)* added that diversion is also a serious issue, as many pharmaceutical companies supply medicines to Africa as donations. Unfortunately, criminals often intercept shipments and divert them to other parts of the world, where they are sold at a greater profit. Therefore, the people for whom the drugs were originally intended either get nothing or inferior counterfeits.

OCLAESP provided a range of statistics and revealed that virtually every single therapeutic drug category has been counterfeited. In OCLAESP's experience the most heavily affected category is now genitourinary, because of Viagra. However, 2012 also saw the biggest recorded increase of fake hormones.

## 2.4 - Theme 2: The expertise of the private partners in the fight against Pharmacrime (Part 2)

Theme 2 continued with explicit, expert examples of cases. Participants also discussed how their countries have been affected and how they have responded to a variety of challenges.

In relation to manufacturing, many attendees confirmed that most counterfeits can be sourced back to China and India. At present, EU countries are not regarded as being primarily involved in production.

Clearly, counterfeiters appear to have an infinite reserve of human resources and in some countries counterfeiters appear to have less ethical concern. As an example, one expert explained that in a side-street in India, people were witnessed placing labels on bottles of fake cough medicine for children.

There is further concern that shippers can inadvertently become involved in the manufacturing, coordination or selling process.

Highly inventive concealment tactics are commonly used, examples including hollowed out blocks of marble, toys and jewellery. Passenger luggage and small postal packages are also being favoured. In terms of ordering products, the internet is a persistent problem as it has become a shop window that customers are attracted to. Moreover, counterfeiters have become very aware of market trends, and products are often packaged differently based on a specific destination. As a result, customs officers can find it extremely difficult to distinguish whether packaging is genuine or fake.

The use of “drop shippers” now appears to be a preferred method of moving products within the EU. A “drop shipper” (DS) is someone who receives large parcels (by post, freight etc.). Often operating from a domestic residence, boxes or bottles of counterfeit drugs can be packaged and supplied to secondary sellers or distributors through national postal systems. Sometimes a DS will even supply directly to a customer.

Several examples were provided. In one such case a DS was witnessed posting between 2,500 parcels a week. The subsequent raid on the hub of the operation uncovered around 100,000 tablets ready to be posted that day (through 600 envelopes) and further another 1,000 addressed envelopes waiting to be fulfilled.

In response, participants highlighted the need to build a website to share the experiences concerning investigations. Such a site might also be used to depict more clearly the harm caused by fake medicines. As a result, this information could help to influence policy maker, strategists and overall enforcement agendas.

EDQM explained that this is the reason that it has started to develop an inventory of lessons learned from closed cases. EDQM feels that lessons learned are of immense value to authorities when they come into contact with unknown products. Currently work is going on to identify a secure database structure to help national authorities to record database experiences. This might then play a part in developing a complimentary rapid learning system. In the meantime, a questionnaire will be sent out to authorities to ask for information on cases related to counterfeit medical products. Currently EDQM have access to information on 400 cases.

Cyprus explained that it is looking for something very practical and if the Observatory has developed systems to share information instantaneously with WCO and DG TAXUD it would be happy to engage and submit details.

The international Institute of Research against Counterfeit Medicines (IRACM) added that unfortunately, most people involved in enforcement activities seem to have less expertise in identifying counterfeit medicines. It was stressed that people can only combat what they know. Training is being delivered by Interpol, but enforcers need to fully understand the pharmaceutical market. It is also necessary to have some knowledge about trademarks and patents.

IRACM explained that investigative, skills training is essential to understand what to look for in packaging and particularly on information printed on accompanying documents. This can include destination details, phone numbers, and even suspicious addresses. Therefore, more analytical and fact finding training is vital.

To conclude the session, a detailed debate took place on what can be done.

PSI explained that its member companies employ specialist people in their security departments, most of whom are former investigators. These people are ready to work with law enforcers on the ground. PSI feels there is also a need to foster the SPOC concept through regular meetings and then ensure this concept is developed in conjunction with the wider use of systems for sharing information and intelligence.

Europol added that it is encouraging the sharing of information through its EPE (Europol Platform for Experts) which has different sections for different crime areas. Lines of communication between agencies are vital.

The French Gendarmerie agreed that it is essential to have people working together. However, a recognised problem has been in gaining the involvement of the judiciary in investigations. The courts must have a greater understanding of the problem.

There is also a need to remove demand by raising public awareness. The Medicines and Healthcare products Regulatory Agency (MHRA) agreed and suggested that a pan European awareness campaign about legal online drug sellers would be a huge benefit. A lot of research has already been done about those involved and people must know that they are taking risks when buying medicines online.

Moreover, MHRA explained that in the UK the proceeds of crime legislation can be used to gain important funding to assist enforcement.

In conclusion, the pharmaceutical representatives reminded the participants that industry is serious about partnering to tackle this problem. Pfizer, for example, has worldwide resources investigating counterfeit criminality. These experts are all accessible to enforcers and contact should be made to gain help in dealing with cases.

# 3 - Day 2 Exchanges of Best Practices - Regional Approaches

## 3.1 - Theme 3: Case Workshops - Regional Perspectives

### 3.1.1 Workshop 1

Jointly Chaired by the Irish Medicines Board and the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

Participants: Iceland, Norway, Sweden, Finland and Denmark

By way of introduction the Group briefly explained the way their authorities work in each individual country.

In UK the MHRA has powers, alongside the police, to prosecute and take offenders to court. Customs have authority at the borders but have no prosecution powers. In Norway, police has the main responsibility, while in Finland it is jointly shared between customs and police. The Finnish model also applies to Ireland, Iceland, Sweden and Denmark.

The Irish Medicines Board explained that in many countries it has been found that police agencies carry out the prosecution of offenders. However, as Customs are generally the first to find things there is usually strong collaboration between police and customs authorities.

The work of the Irish Medicines Board was covered in more detail. It was explained that the Enforcement Section of the Board controls operations, including those on mail order supply, which is illegal in Ireland. On the investigation side the Board has investigators in several areas, including cybercrime, and also covers the forensic analysis of pharmaceuticals. It was stressed that there is close liaison with customs officers and national police. However, other agencies and bodies are also linked in, including the Irish Revenue service, the National Drugs Unit, the PSI, Agriculture, Irish Sports Council and the anti-doping unit which has lists of all registered athletes.

The Board also has responsibility for inspecting Irish pharmacies and has two laboratories in place, one for inspecting narcotics and the other for medical products.
In terms of taking action, the Board conducts risk assessments based on the threat to public health. Once a potential breach of the Irish Medicines Act has been identified, the Board does not require search warrant to act. However, it does not have powers of arrest; these lie with Irish police. Therefore, the Guards of national police assist Board officers to make arrests and to seize and detain products. The Board also has Memorandums of Understanding (MoU) with customs.

Furthermore, the Board does not carry out background checks themselves, but builds evidence through open source information, including company registration, land registry, electoral registers.

Surveillance is considered to be paramount, and several examples were provided of how cases have been developed.

Finally, it was stressed that cross border cooperation is also vital to success.

In the UK, the MHRA have numerous enforcement powers. However like the Irish Medicines Board they cannot arrest, and always require police officers. The MHRA does have the power to enter business premises, but needs a warrant for private access, unless 24 hours advance notice is given.

Currently the UK is under pressure from the volume of small parcels arriving from Asia. The scale of business for online medicines is massive.

In terms of helping to identify offences, UK legislation allows surveillance devices but official approval must be gained.

Iceland explained that it only reacts if there is a breach of its Medicines Act. However, it cannot use private company assistance. Customs work with police but customs has no power of prosecution. An added problem in Iceland is that some offences are not regarded as being threatening enough to bring police in. The existence of fake steroids or manufacturing equipment are two examples.

The Group agreed that organised crime is behind most of the cases and the fact that it is now common for criminals to be involved in fake medicines. In similar circumstances a narcotics dealer would receive 30 years in prison.

With regards to operations, the Norwegian and Swedish medicines agencies must work with police. If something suspicious is found, they are currently unable to seize samples without police. Moreover, customs are also not allowed to seize, they must hand a case over to police for investigation. Cooperation is very good between customs and police.

In Norway it is legal to buy online from countries where it is legal to sell, but not from Norwegian pharmacies without prescription.

In Finland the Medicines Agency has no comparable powers. If a minor violation is identified, they are able to send a “cease and desist” letter but investigation responsibility is otherwise with customs and police that have their own laboratories. The Medicines Agency sometimes gets information from customs, and good relations exist but despite wanting to formalise interactions, no official MoU is currently in place. To date no counterfeit medicines have been found in the legal chain.

A discussion took place about available assistance and equipment to help identify counterfeit medical products. Following this, three cases studies were presented.

**Presentation 1**

The first presentation was of an operation carried out in Scandanavia where six persons were convicted for the possession and/or trafficking of fake Rivotril. The tablets were seized in their original packaging and intended for the Hungarian market. This was evident from the batch numbers and the Hungarian text.
Controls were also carried out from warehouse to wholesale, and thousands of tablets were seized from a courier. These can sell for approximately four to five euros per tablet on the street Scandanavia, but for as little as 20 cents in in other countries.

The group agreed that this type of activity is happening in other countries in Europe and therefore the information must be passed to Europol, as information could trigger other actions and investigations.
In total the convictions totalled over 16 years, with the main organiser being born in Libya. Fake Hungarian ID cards in the organisers' name were also seized.

**Presentation 2**

The second presentation covered 'Operation Robin' carried out in Sweden, which started with a relatively minor seizure of cigarettes, in June 2009. From this a links were made to payments made for steroids.
Evidence gathering, surveillance and analyses of bank accounts identified the movement of approximately 450 million euros through Egypt, Hong Kong, Dubai, and Europe, to pay for substances and for money laundering in UAE, Marshall Islands, and the Cayman Islands. It also portrayed a very advanced smuggling operation of Illegal products, through small packets, from Asia, Egypt, the UK Denmark and then Sweden.
During the operation, steroids, narcotics, computers and two steroid-producing factories were uncovered, containing 4.8 million units of steroids and 400 thousand narcotics, plus needles, etc.
Offenders were prosecuted for 11 million units and 1 million narcotics and 1 million other tablets and were found to have sports cars, a house in Spain, money in other bank accounts and assets to the total of 50 million euros. Most of the money was for laundering.
In total 23 persons were sentenced to prison with two offenders receiving 16 and 14 years.
Four leaders were sentenced for life in Thailand, while another received seven years.
Customs are now able to sell assets and the money will go to the state.

**Presentation 3**

In June 2011 a parcel from Pakistan to Galway, Ireland, was discovered which was labelled as plastic parts, but actually contained tablets. The Irish Medicine Board and police were contacted. As a result a raid was carried that, although led to no drugs, the removal of documents led police to enlarge the investigation. The outcome was the seizure of 26 thousand tablets and further information on a major drug dealer.
The conclusion was that interaction between different agencies is paramount.

### 3.1.2 Workshop 2

Workshop 2 was jointly chaired by Maltese Customs, and OCLAESP, France

Participants: France, Spain, Portugal, Greece, Bulgaria, Romania, Croatia, Slovenia, Albania, FYROM, Malta, Cyprus.

The Chairs opened the workshop explaining that counterfeiters have found fake pharmaceuticals to be an extremely lucrative commodity.

Before 2002, most counterfeit pharmaceuticals arrived by air. Today the trade has moved towards shipping and small parcels. The main sources appear to be India, China and North Africa but the sheer volume of containers means that it is difficult to control.

**Presentation 1**

It was explained how Maltese Customs work with legitimate companies. It was stressed that applications for action are essential in helping customs to risk analyse and function properly in terms of border controls. France agreed that advance information is vital.

The applicable laws were explained, including the new customs regulation and the changes that will affect the way small consignments will be handled. The IPR law relating to free zones and free warehouses was also covered.

Malta described how it examines documents, and manifests and creates specific alert lists to help it identify suspect shipments. The use of systems is vital and several are used, including a vehicle and cargo identification system and other tools that help to verify containers.

OLAF stressed that shippers must be made more aware of their growing responsibility in the supply chain.

In terms of analysis, Europol commented that the Falsified Medicines Directive (FMD) 2011/62/EU introduces an obligation to track and trace products. The PSI accepted this but felt that it places too much expectation on smaller companies. The supply chain is very complex and an originating manufacturer might not necessarily be aware that a violation had occurred further down the chain until much later.

**Presentation 2**

France outlined a major case in which inspectors of the production headquarters of a major poly implant company discovered a number of plastic containers of Silopren, a liquid silicone designed for industrial, not medical use.

Gendarmes investigating the case established that the cheap silicone had been used for approximately two years. As a result, roughly 400,000 people worldwide had been affected by breast implants that had split open. The company was closed down and the owner was arrested and placed on trial for aggravated fraud.

The case has become a model of cooperation between medical experts, enforcers and international communication approaches.

Discussion throughout the workshop led to the following conclusions:

- Multi-disciplinary approaches are vital as models for cooperation, as pharmacrime covers a range of offences
- There is a need to take proactive approaches, although this has to be fed by reactive actions
- Some countries face difficulties in taking action unless a crime is committed
- The supply chains are complex, and manufacturers cannot trace all consignments. In addition, track and trace systems place a burden on smaller companies
- Shipping agencies and freight forwarders need to be included in the enforcement chain
- Small consignments (postal and courier) are difficult to control in many countries
- It should not be for victims to prove the crime in counterfeit medicine cases
- More use needs to be made of the Europol platform to foster more effective information sharing.

### 3.1.3 Workshop 3

Workshop 3 was chaired by the Carabinieri, Italy, and Switzerland Customs,

Participants: IRACM, Luxemburg, EDQM - Council of Europe, Switzerland, Nederland, Belgium, Austria.

A joint presentation was made by the Chairs. In this, they described a case being handled by both Swiss and Italian authorities to investigate counterfeited steroids and doping substances. This case needed information to be exchanged as quickly as possible, regardless of some bureaucratic burdens.

The main aim of this workshop was to get proposals on how to improve communication and cooperation between different authorities, in the different countries.

The Chairs explained that the case involved materials shipped from China, and the final products being packaged and distributed to Poland, USA, South Korea, Portugal, Switzerland, Romania, Canada, Japan, Germany and Belgium.

Over a number of years the counterfeiters had moved their organisation and laboratories several times to avoid being investigated by authorities. The products had been mainly distributed and sold through the Internet, using resellers and shippers. As the consignments have mainly been small, the offenders had further covered any potential losses

The case is still ongoing but throughout, international cooperation had been vital. The USA, Malta, South Africa, Belgium, Germany, Israel and Canada have all been involved in the investigation, which has now led to 19 people being arrested and 25 other people being charged.

To conclude the presentation, Switzerland underlined the significance of national and international collaboration. Furthermore, having a fast reaction capacity to know exactly who does what, so that the right person can be contacted has been essential.

A number of questions and observations followed the presentations. As well as good communication, there is also a need for will. Moreover, until recently, doping substances had not fallen within Europol's mandate. Nowadays it is easier to use Europol channels as they now focus on pharmacrime.

It is extremely useful to share as much information as possible with Europol. If a case falls within its mandate, the information is kept for five years. Therefore, there is greater encouragement to send as much information as possible.

### 3.1.4 Workshop 4

Workshop 4 was chaired by, Hungary and Germany

Participants: Hungary, Slovakia, Czech Republic, Poland, Estonia, Latvia, Lithuania, Germany.

The Chair explained that the objective of the workshop was to exchange views and experiences. To do this, a number of specific experiences would be presented. Following these, specific questions would be raised and discussed.

**Presentation 1**

The first topic was presented by Hungary and concerned the seizure of over half a million pills and the arrest of eleven suspects. As a result of this, it became clear that a large network had been involved in distributing and selling around 100,000 products on a monthly basis.

The conclusion had been that Hungary had become a transit country and a target distributor for products mainly arriving by courier and postal traffic, from India. The suggestion was that a packaging activity was also operating within the country. There was a clear need to cooperate and share information to find the packaging operation.

Following this, the group discussed how counterfeiters operate and how best to counter any changes on methods. The concern was that perpetrators closely follow the work of enforcement agencies and then adopt different methods of supply, for example, sending consignments through the express postal system or using assorted express courier services.

The UK suggested that a way forward might be to take a more strategic approach to educating those within the courier, transportation, and shipping and distribution system.

**Presentation 2**

The German Central Office for Customs Investigation Service covers pharmaceuticals and doping. It was explained that this is effectively the criminal police of the customs administration and as such, can investigate the case from the beginning to end. An additional power is that the office has the power to commence tax investigation proceedings.

In carrying out its work the Office coordinates with all relevant public and private sector bodies including those engaged in excise, taxes, money laundering, IP crime and smuggling.

From a customs perspective the Office has responsibility for two pillars related to 'pharmacrime' and one of the main problems being faced involve lifestyle drugs, where the volumes are continually increasing.

A case was outlined where mislabelled testosterone had been detained. This led to a laboratory where thousands of labels and vials were seized, plus several litres of steroid solutions and other active pharmaceutical ingredients. This supply had been put together by a German national for the German market.

It was remarked that the situation in Germany is generally very good in that a strong range of powers exists, which may be a good example of better practice.

Participants felt that an important issue is to harmonise the legal systems of all EU countries. There are many systems but at present there is a lack of knowledge about which is the best. Therefore there is need for greater understanding.

**Presentation 3**

Germany also presented a case regarding the drug API omnipasol. The case was started in March 2013 by the Spanish regulatory authority, working with Guardia Civil. This subsequently involved the German federal police as a case was already ongoing in Germany.

In brief, the counterfeit products had been detected when the patient found that the information on dosage, on the package leaflet, was different to the package itself.

Consequently, the Ministry of Health became interested in the infiltration of the legal supply chain and the potential harm to patients. It became clear that the supply chain had been infiltrated between the wholesaler and patient. Pfizer explained that this can be difficult to counter as there can be as many as 33 different traders in a single chain.

In such cases licensing can be a problem. In the UK alone 1,550 licences are issued every year, therefore stringent checks are vital.

Following this the Chair asked for several topics to be considered, in country groups, to help others to understand the situation in various countries and regions.

The topics related to specific experiences in 'pharmacrime' and how much work is carried out on the issue. Within this, the participants were asked to reflect on the number of cases, the legal situation, whether units work solely on 'pharmacrime' and whether a specific IP enforcement unit exists. Participants were also asked to provide a short situation report on 'pharmacrime', including the scope of the problem and whether there seem to be any solutions.

Lithuania explained that during 2011, through cooperation with UK, national customs detected 1,000 fake and illicit medicines. Lithuania is not a big country but it has a large internet based business. In legal terms, the criminal code contains a special article, but experience shows that it has not been a police priority, only for some activities such as internet pharmacies, which are illegal. At present there is no cooperation with the Lithuanian drug regulatory agency, but this needs to be considered.

In the Czech Republic IPR crime includes 'pharmacrime'. Although this is not currently regarded as a major problem, websites now exist that advertise drugs for sale; therefore it has the potential to become much more problematic.

At present it is not Czech citizens but foreign nationals that run the websites in the Czech language. Unfortunately though, Czech authorities do not have the power to block websites. Nevertheless, with court permission it is possible to make sample purchases, to make simulated purchases and to control deliveries. In some cases it is also possible to change packages. A number of investigations had commenced in 2010 which involved cooperation between police, customs and this has led to a several successful cases.

In Slovakia, customs offices have competences for detecting and preventing cases if there is a suspicion that there is a breach. The customs criminal office also has the right to investigate in the field in relation to counterfeit medicines. Currently, sanctions for this type of crimes carry less than a three-year sentence. Some other key problems involve gaining and verifying information about smuggled products and detecting illegal manufacturing in Slovakia. At present the main goal is to initiate changes in the penal code regarding the manufacturing and distribution of anabolic steroids and to initiate and establish special legislation to allow greater cooperation in investigating internet crime.

Poland seizes many small quantities of fake medicines, which generally result from split shipments. Usually the counterfeiters declare very low quantities and price so the shipments are normally out of Polish declaration limits. Seizures usually include anabolic, lifestyle products. However, more and more consignments of active ingredients such as methamphetamine are being uncovered. Moreover, orders made through the internet are growing. Unfortunately there is a low penalty for 'pharmacrime' at present; only two years

Polish customs do not carry out investigations; these are all passed to police who have investigatory measures at their disposal. As such, cooperation is based on personal contact, which is not easy as customs are unable to use the evidence. However, formal cooperation meetings are held four times a year to discuss a wide range of issues. These meetings include police, customs, the veterinary inspectorate and the regulatory agency. Currently Poland is working on the preparation of an awareness campaign. Alongside this, the main pharmaceutical inspector regularly issues warnings about buying medical products from illegal websites and tries to encourage media and press to pick up on the dangers surrounding these products.

In Latvia, customs have responsibility for dealing with counterfeit, but the Latvian health inspectorate is also involved and works in the same way as in many other countries. In relation to the supply of products, illegal Latvian internet sites exist which offer medicines online. These can be brought down, but other websites continue to offer pharmaceutical products for sale.

In Estonia, while the police have general responsibility, the main player is customs, which has the right to share investigative techniques. Therefore, cooperation is excellent between police and customs, with investigation information being shared regularly. At present there are between 10 and 20 recognised cases per year.

## 3.2 - Theme 4: International and European Cooperation

### 3.2.1 Fighting 'Medicrime': A Customs perspective

The WCO Regional Intelligence Office of Western Europe described the SOTERIA programme, which is framework for working between national customs, DG TAXUD, OLAF, the WCO and the Regional Intelligence Liaison Offices (RILOs). The framework requires concrete activities to be defined as a result, a number of stakeholder countries met at the end of 2012 and established concrete activity planning.

As an introduction it was explained that despite a wide range of common perceptions about customs work, the mission of EU customs authorities is basically the supervision of the Community's international trade. As such, it contributes to fair and open trade and to overall supply chain security. Therefore, a key aim is in maintaining a proper balance between customs controls and the facilitation of legitimate trade.

The WCO was formed in 1952 as an inter-governmental organisation. It currently has 11 regional intelligence offices across the world.

The aim of SOTERIA is to support countries to combat the illegal cross-border trade of goods which can potentially harm the health and safety of their citizens and to target criminal organisations involved in this trade, depriving them of their illicit proceeds. The programme has a number of key objectives involving greater awareness and training, operations and intelligence and strategy building (including market and risk analysis, multi-sector cooperation and financial investigations, to fight illegal trade over the internet).

At present there is a network of 13 participants, including public bodies such as the WCO, the Council of Europe, the Commission, WHO, Europol, INTERPOL, Eurojust, police and private sector experts.

### 3.2.2 The Existing and Future Framework for EU Customs to act

The Commission provided its views on the existing and future legal framework for EU Customs. Regulation 1383 will soon be replaced by a new Regulation , which will be applicable from 1 January 2014.

Participants were reminded that EU customs deals with counterfeits but not with criminal law enforcement. Article 51 of TRIPS makes specific reference to Members, adopting procedures to enable a right holder to lodge an application with competent authorities for the suspension of goods by customs authorities, in respect of infringements of intellectual property rights.

The Commission also referred to the Nokia judgement from the European Court of Justice, which stipulates that customs may only detain or suspend the release of in-transit goods when they have suspicions that such goods might in fact be destined for the EU market.

In addition, Chatham House (home to the Royal Institute of International Affairs) is a world-leading source of independent analysis, had signalled that a significant barrier to action against counterfeit medicines had been that definitions developed by stakeholders, including the WHO, which had not been universally accepted. This failure to reach an agreement on the definitions of counterfeit, falsified and substandard medicines has hampered collaboration at an international level which is necessary to take effective action against the producers and distributors of these medicines.

On the basis of all this, EU customs need to make a clear differentiation when dealing with IPR and goods that affect public health. However, in the new regulation, Article 22 relates to the sharing of certain information between customs authorities (which may ultimately help rights holders). On this the Commission commented that it was felt that some information should not be disclosed and this is also reflected in the regulation. Finally, Article 37 relates to a requirement for a report, by 31 December 2016, on any relevant incidents concerning medicines in transit across the customs territory that might occur. This could help pharmaceutical companies after 31 December 2016.

OLAF explained that the new regulation would also be a valid instrument for them, particularly Articles 31 to 33 which overlap with other useful legislation by focusing on exchange of data and the establishment of a central database.

In this respect the Commission referred to a new information database called COPIS, which has been developed by DG TAXUD.

Questions were asked about whether information from the system could be exchanged with domestic health authorities. In response it was explained that the information in COPIS is primarily for use by EU customs authorities.

At this point OLAF explained that initially there had been concerns that there would be a risk of overlap between COPIS and the AGEIS system and other databases. However, OLAF had reached agreement with TAXUD to synchronise the databases. In this way Member States can integrate nominal data.

### 3.2.3 The WGEO Initiative

The Heads of the Medicines Agencies Working Group of Enforcement Officers (HMA WGEO) Management Committee, presented the WGEO initiative.

It was explained that, after the year 2000, Europe had witnessed numerous changes, including the enlargement of the EU, which had resulted in fewer controls and restrictions on cross border movement and traffic. Criminals and illegal traders had taken advantage of this fact.

Moreover, Member States had also taken different decisions on enforcement, and consequently there was less cross border cooperation.

In 2004, the Permanent Forum on International Pharmaceutical Crime (PFIPC) members initiated the EU Medicines Enforcement Officers (EMEO) group to begin cooperation between enforcement officers in Europe and to give them the opportunity to meet and consider how to best contribute to the protection of public and animal health.

Subsequently the HMA WGEO took over the initiative and set out a mandate to contribute to the protection of public and animal health and welfare, by ensuring adherence to regulations on the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing of information.

The Group involves 27 EU countries, three EEA countries, human and veterinary medicines enforcement officers, including drug regulatory authorities, police and customs. It also includes significant partners such as the European Medicines Agency, the European Commission, and the World Health Organisation, the Council of Europe EDQM, Europol, INTERPOL, PFIPC and specific observers from Croatia, Russia, Serbia, Israel and the USA.

Its basic role and purpose is to:

- foster a basis for liaison and cooperation between Member States/agencies
- share information, including information on national matters, relevant to their Member States/agencies
- assist in the identification of emerging threats to the legal manufacturing and distribution chain
- coordinate initiatives
- coordinate communications (through a SPOC system)
- cooperate and exchange information with relevant working parties/groups and organisations (Rapid Alerts), and support proposals for improvements in legislation concerning medicinal product enforcement

Current work-streams include work to identify gaps in the EU wholesale and distribution system, to identify threats from the internet (on the illegal supply of medicines), to identify practical measures to combat counterfeit medicines and to develop training and education initiatives, including field manuals.

### 3.2.4 Day 2 Workshop Outcomes

On the basis of their discussions, each of the practical workshops had been asked to put forward a set of conclusions and recommendations that could help provide a base for future actions and work.

**Workshop 1 Conclusions**

- 84 different agencies are represented at the event which is a great advantage as sharing the diversity of experiences is vital.
- Communication is crucial. Information that individuals uncover is vital to combat the organised crime gangs.
- Sweden had given a clear indication of a cigarette smuggling investigation that had started small but had become a major ‘pharmacrime’ case.
- People should have no reluctance to exchanging information due to language difficulties.

**Workshop 2 Conclusions**

- Multi-disciplinary approaches are vital models for cooperation as 'pharmacrime' covers a range of offences.
- A number of issues face customs, including the restriction of detaining goods in transit based on IP rights.
- Enforcers need to take a proactive approach on the basis of reactive alerts and information.
- Some countries face difficulties in taking action unless a crime is committed.
- Supply chains are complex, and manufacturers cannot trace all consignments. In addition, track and trace systems can place a burden on small companies.
- Knowledge building for shipping agencies, courier, transporters, and freight forwarders has become extremely important.
- We must not confuse public health and IPR issues if we want to get the assistance of third country enforcers.
- Small consignments (postal and courier) are difficult to control in many countries.
- In counterfeit medicine crimes it should not be the responsibility of victims to prove the crime.
- There must be increased use of the Europol platform for effective information sharing to help dismantle organised crime.

**Workshop 3 Conclusions**

- First point:
  - Cases on illicit medicines should receive the same attention as counterfeit medicines.
  - Diversion and parallel markets where the anabolic steroids travel around the world is as dangerous as counterfeiting.
- Second point (most of the group were investigators) - relationship with prosecutors:
  - There is a need to increase prosecutors' knowledge. Knowledge is important in making the right decisions.
  - Training for prosecutors about the anti-doping laws is very useful, as many do not understand that trafficking is a major offence.
- Third Point:
  - It is sometimes difficult to communicate inside a country: if we cannot communicate amongst ourselves we cannot communicate effectively outside.
- Fourth Point:
  - Increase international cooperation through the use of more effective tools.
  - More explanations are required about the availability of modern information tools.
- Fifth Point: more in depth training needed:
  - Especially for countries with no specialised officers, as not every country has dedicated officers to combat 'pharmacrime'.
  - There is a need to put everyone on the same level.
  - There may be an opportunity for private industry financing training - private industry could finance and place resources in the training system as a majority of countries are cutting budgets on training.
- Sixth Point: advanced investigative techniques:
  - Modern tools and techniques should be available to all enforcement related bodies. Several examples were provided.
  - There is perceived lack of legislation. In Italy there are good laws for trafficking of doping substances that

assist enforcers.

- Enforcers are allowed to make test purchases of anabolic steroids: this facility must be available for purchases of medicines.

**Workshop 4 Conclusions:**

- It is very important to have the private sector at events such as this. As a result, it was easier for enforcers to understand the legal supply chain.
- Test purchases from regular pharmacies could offer a solution to some issues.
- Gaining experience is vital as this is a priority crime area.
- A better understanding of the legal situation is needed.
- The legal situation is not harmonised in the EU and it is sometimes difficult to find partners in other countries, including police, customs and other regulatory agencies.
- The problem of distribution is increasing, criminals constantly change host servers and many countries do not have the right to block websites.
- The event has been successful in building knowledge from a regional perspective.

In conclusion, OLAF inferred that it is necessary to have a binding legal instrument to lawfully collect and exchange information. EDQM agreed and gave an example of the Convention's provisions in this area. However, at present, only 11 countries have signed up.

OLAF added that care is needed in respect of the balance in cooperation and facilitation of trade. It is also necessary to carry out post audits.
Evidently participants also feel that there is a lack of quality in the transit system, and therefore there is a clear message for the shippers and couriers, that they have also responsibility in this issue.

The Police Service of Northern Ireland (PSNI) offered the suggestion that, in future, workshops might be divided into groups of participants that have close working connections. For example the PSNI regularly deals with Spain but has no contact with some countries. An option might be to allow participants to register for workshops in advance.

## 3.3 Day 3 – Workshops and Conclusions

### 3.3.1 Combating 'Pharmacrime' – Europol

Europol gave a detailed presentation of how it is set up and structured to combat crime. The aim of the European Law Enforcement Agency is to support and strengthen actions of the competent authorities of EU Member States and to foster their mutual cooperation in preventing and combating organised crime, terrorism and other forms of serious crime affecting two or more Member States"

It was explained that Europol officers have a law enforcement background but no enforcement powers; they are not investigators across Member States. Instead Europol provides strategic and operational support. The objective is the disruption of organised crime gangs. This is done through criminal analysis and on the spot support.

Europol has developed projects and teams according to the specific crime areas identified in its mandate. Within this a description was given about “Focal Point Copy” which was originally a project created in 2008 to combat counterfeiting and piracy. Since then, there has been a shift towards health and safety issues and a focus on hazardous and potentially harmful fake products. As a consequence, FP Copy deals with intellectual property crime and health and safety related crimes, Pharmacrime being one of its areas of concern.

As an example several cases were presented in which Europol´s expertise in criminal analysis, forensic examination and coordination of agencies have been used and have resulted in the seizure of tons of dangerous fake products and numerous arrests.

### 3.3.2 The European Observatory on Infringements of Intellectual Property Rights

Following the Europol presentation the EU Observatory explained its strategy and objectives. The Observatory is made up of the EU Member States, the Commission and European Parliament, EU and international organisations, private sector associations, consumers associations and civil society.

A strategic plan has been developed that focuses on a range of products decided by its stakeholders. Within these are key activities that will help to provide greater understating and knowledge such as:

- Building understanding about the value of IP to society, so that more balanced messages can be developed. In this is important to know:
  - How many people are employed in IP-intensive industries, directly and indirectly and
  - How much value-added (GDP) is created in those industries

  Better understanding of public perception, including:
  - What is the state of awareness and understanding of IP among citizens
  - What messages could be more effective to convince citizens of the importance of IP protection
  - Is the situation the same in all MS

  The development of systems to exchange data and information and model(s) for measuring the scale of IP infringements.
  - In particular the information exchange system will be an interoperable electronic tool:
    - Enabling exchanges between rights owners and enforcement authorities
    - Providing a database to help enforcement agencies to better identify counterfeit goods
    - Holding data on registered IP rights, contact information, supplementary product information and logistics to help detect counterfeit products.
    - Allowing the upload of supplementary information (enforcement contact information, product portfolio, logistic, past cases, additional webpages, IPR portfolio).
    - Providing a facility to complete customs’ applications for action, alerts etc. on counterfeited goods, trends…
    - Giving access to an enforcement repository
    - Allowing global searches
    - Connecting to other IPR databases (TMview, DesignView…) and systems

The Observatory is currently working on securing a join up of its enforcement database with WCO-IPM, DG-TAXUD-COPIS and the Europol Expert Platform.

In addition, a primary function will be to continue to develop best practices and to work to design training sessions in collaboration with law enforcement organisations, such as joint Europol and business sector training for all enforcement related authorities, joint Interpol training for police trainers, joint Europol and Eurojust training for police, customs and the judiciary.

### 3.3.3 Workshops on Exchanges of Best Practices

#### 3.3.3.1 Workshop 1 – The Internet as facilitator

The Workshop facilitated by the Observatory and Hungary focused on a case initiated by the Italian Carabinieri, which was supported by Swiss Customs and Federal Police.

The main target was a Swiss national that illegally distributed doping substances (Axiolab) across the world, through the use of internet websites.

For this operation INTERPOL was used to exchange information as this was an international case involving several countries outside the European Union.

The workshop was developed using the following questions to trigger discussions and ideas amongst the participants:

**1) Do we know the size of the problem? In particular: How much of the global production of fake pharmaceuticals is actually sold via the internet?**
Overview response: There is some information on the number of websites and the illicit profits originating from the sale of "illegal" pharmaceuticals sold online. However this information is quite fragmented.

**2) Is there a specialized unit in place for investigating internet crime in your country? Customs or police?**
Overview response: All Member States have internet crime units, but most of these do not specifically deal with "pharmacrime". Some units limit their activities to the monitoring of the websites that provide medical products.

**3) Are current preventive and repressive techniques effective? For instance, is the "blacklisting" of websites more effective than "notice and taken down" procedures or vice versa?**
Overview response: Neither technique is entirely effective. A multi-stakeholder approach is necessary to limit the proliferation of fake pharmaceuticals on the internet. The most effective approach or countermeasure still appears to be represented by criminal investigations.

**4) Which authority has the right to block websites offering illegal products in your country? Does it work in practice?**
Overview response: There is no authority in place.

**5) Is there any particular information available about active criminal networks running their business over the internet?**
Overview response: An on-going case is currently being coordinated by Europol with the involvement of several EU MS.

**6) Are servers used to host "illegal" websites always located in the same countries?**
Overview response: There is no specific information on where information is stored online. The LegitScript report contains some information on this topic.

**7) Would a centralised intelligence database, containing information related to websites selling fake pharmaceuticals, be of any value at this point in time?**
Overview response: Not useful if it only focuses on websites' domains.

**8) Are there any other suggestions or activities for actions that should be undertaken by Europol and/or the Observatory?**
Overview response: It is important to strengthen training programs to cover the sharing of best practices and techniques through Europol and the Observatory.

#### 3.3.3.2 Workshop 2 Doping Substances – the specifics of the threat

The Workshop was introduced by France and Germany and participants were asked to provide examples of how they have been affected and of their work to combat the problem. During the discussions the following statements clearly emphasised the scope and scale of the problem:

German customs – Germany has a solid legal structure in place where even small doses of steroids and human growth substances are illegal.

Portuguese judicial police – since 2009 a special law has been in place dedicated to the doping phenomenon. This has criminal and administrative provisions. As a result, investigations are carried out in a range of sporting areas.
Ireland – the sports council is responsible for administrative procedures and the IMB has list of athletes, trainers and training camps for monitoring. Recently they have increased the levels of surveillance due to the proximity to the UK.

Spain – a new administrative anti-doping law is in place that gives more competencies to the anti-doping agency. Moreover, in the penal code there is new definition regarding doping.

Norway – there is a new law which forbids the sale of any kind of doping substance.

Belgium – stressed that sportspeople are not the only ones to use steroids.
France – there is no common international definition. Even the World Anti-Doping Agency (WADA) has no harmonised definition. The definition for a sportsman is somebody who participates or prepares to participate. This is a problematic definition, as for example if a cyclist is preparing for the Tour de France and uses a substance, but the cyclist is not yet on the official list, in effect he or she is not yet defined as a sportsman.

Major problems surround products, methods and locations. The aim is also to find untraceable products. For example AICAR is a substance that is used for racers, as it is impossible to trace. It is a genetic product that is mixed with another product, to gain muscle, lose weight and increase effort. Use is also made of masking agents, such as insulin, which is impossible to detect in anti-doping tests.

Italy – drugs, such as new types of EPO, are being seized. It is not necessary to keep these new drugs in fridges, and they are therefore they can be more easily concealed. According to Italian law it is forbidden to use some substances that WADA does not prohibit, such as substances that recreate high altitude conditions.

Belgium – medicines created such as those for horses, have been ordered by a local cyclist.

France – sportspersons who use doping drugs are not working alone, they have many people around them to assist, so it is important to tackle the complete circle

Spain – one of the ways Spain is trying to gain control is to check the genetic passport of mixed substances.

China, India, Thailand are areas where the substances are mass produced, but there are also products made in Moldova, that are bought in for personal consumption. It is impossible for all Moldovan population to use such a volume of substance, so it is clear that this is for export.

Belgium – in Europe it is easy to become a producer, as it is easy to obtain raw material, and tablet machines can be bought on internet.

Germany – has seen an immense increase of cases regarding doping substances since 2005. It is against pharmaceutical law and there is up to 10 years in prison for trafficking substances.

France – there are high profits and low penalties. However, in France it is difficult to impose high penalties.

Operation Pangea, the INTERPOL operation, targeting the online sales of illicit medicines, led to massive seizures, including pills for doping. So, demand for steroids and growth hormones is growing and are easy to buy.

Italy – gyms were the first places to sell steroids before the internet explosion. When steroids became available on the internet people found that it was safe to buy. The problem is very large in Italy. There are many people who buy steroids on the internet to sell in gyms and shops that sell food supplements for sportsmen.

### 3.3.4 Conclusions by Director of the EU Observatory

The Director of the Observatory thanked all those involved in the organisation of the event, particularly Observatory partners, Europol, the Pharmaceutical Security Institute (PSI), the European Commission – DG MARKT and DG TAXUD and the expert speakers and facilitators.

It was explained that when OHIM was entrusted with the EU Observatory, it consulted widely about how it should build its projects and activities. A strong message from stakeholders was that the work should be based on a number of fundamental principles surrounding the build-up of knowledge and understanding before taking action.

This event had been designed in this way but the Observatory is keen to receive participants' thoughts on this. This information is vitally important in helping to build programmes to fit the needs of enforcers, policy makers and private sector experts and particularly in developing knowledge and competences, which is a long term aim of the Observatory.

He emphasised that tackling fake and illicit medicines cannot be done in isolation. The results of Operation Pangea VI prove this. This Europol-supported operation involved some 100 countries in a global operation to disrupt criminal networks behind the sale of illicit medicines online, and resulted in 58 arrests worldwide and the seizure of 9.8 million potentially dangerous medicines – worth some USD 41 million.

The Observatory aim therefore has been to give police, customs regulatory services, policy makers and private sector businesses the platform and opportunity to exchange information and build alliances. This has been a common thread during the event.

This is a complex issue where many countries face difficulties in taking action and the conclusions of the event are that multi-disciplinary approaches are the key to success. These views accord very well with the aims of the Observatory which has been set up as a stage for engagement and collaboration.

One of the main drivers of the Observatory is to continually challenge and ensure it adds value. The intention therefore, is to produce a strategic report of the event and an action plan for the future. In this, the Observatory has invited an expert analyst to assist. The outcome will be based on what has been exchanged and achieved during the event, and a strategic picture will then be built that will be disseminated to participants and to other key enforcers. In this way the Observatory intends to create a legacy output that can be used in a practical way and will also help to measure progress.

### 3.4 'Pharmacrime' - proposals and conclusions

During the event note was made of any proposals and suggestions that might help to plan a way forward. Many of these are listed in the table below.

| Comments/Observations/Suggestions |
|---|
| 1. Help is needed to help build a SPOC network as suggested under the Medicrime Convention. |
| 2. A secure website of experiences is required. EDQM is already canvassing enforcement authorities for case details, but a searchable system is needed. |
| 3. Investigative courses are needed to help enforcers understand how to identify counterfeit and illicit medicines. |
| 4. A sponsor is required to promote, organise and hold quarterly SPOC meetings. |
| 5. The French Gendermarie would wish to take part in judicial seminars held by the OHIM. |
| 6. A pan European campaign is required on the sale of medicines online. |
| 7. Proceeds of crime legislation do not exist in all EU countries. A research study should be carried out to highlight best practices in this area. |
| 8. Multi-disciplinary approaches are vital models for cooperation as 'pharmacrime' covers a range of offences. Best practices need to be documented and circulated. |
| 9. Supply chains are complex and manufacturers cannot trace all consignment. Research is needed that can help enforcers to understand how the system works. |
| 10. Shipping agencies, transporters distributors, express couriers and freight forwarders must be included in knowledge building events and meetings. |
| 11. Small consignments (postal and courier) are still difficult to control in many countries. Best practice research is needed. |
| 12. Prosecutors need greater understanding. They should be included in events and meetings or special events should be organised. |
| 13. Clearer explanations are required about the availability and use of modern information sharing tools. |

| |
|---|
| 14. Training is essential, particularly for countries with no specialised officers, as not every country has dedicated officers to combat 'pharmacrime'. |
| 15. The legal situation is not harmonised in the EU and can be difficult to find partners in other countries, including police, customs and other regulatory agencies. A better understanding of the legal situation across the EU is needed. |
| 16. The problem of distribution is increasing, criminals constantly change host servers and many countries do not have the right to block websites. It is vitally important to provide enforcers with understanding and skills in this area. |

# 4 - ANNEX A

**4.1 Breakdown of Attendees**

Total attendees: 97

Number of public authority attendees : 77
Number of private sector attendees: 6
Number of OHIM and Europol attendees: 14

# 5 - ANNEX B

## 5.1 List of Attendees

### Representatives from EU national authorities

| | |
|---|---|
| AUSTRIA | AGES |
| BELGIUM | Federal Judicial Police |
| BELGIUM | Europol |
| BULGARIA | Bulgarian Drug Agency |
| BULGARIA | Customs Intelligence and Investigation Directorate |
| BULGARIA | National Police |
| CROATIA | National Police Office for Suppression of Corruption and Organized Crime, Service for Economic Crime and Corruption, High-tech Crime Department |
| CYPRUS | Cyprus police |
| CZECH REPUBLIC | National drug headquarters, criminal police and investigation service |
| CZECH REPUBLIC | Internet Crime Unit, General Directorate of Customs |
| DENMARK | National Customs and Tax Administration, Task Force counterfeiting |
| DENMARK | Danish Patent and Trademark Office |
| DENMARK | Danish Health and Medicines Authority |
| ESTONIA | Central Criminal Police |
| ESTONIA | Anti-Drug Division of Investigation Department |
| ESTONIA | State agency of medicines |
| FINLAND | Finnish Medicines Agency |
| FINLAND | Customs Investigation Service, Serious Crime Division |
| FRANCE | OCLAESP |
| FRANCE | SNDJ Toulouse |
| FYROM | Customs |
| FYROM | Bureau for medicines, Ministry of Health |
| FYROM | Department for financial crime, Unit for money laundering and economic organised crime |
| GERMANY | Central office for Customs Investigation Service, pharmaceuticals & doping |

| | |
|---|---|
| GERMANY | Federal Institute for Drugs and Medical Devices (BfArM) |
| GERMANY | RILO, WCO |
| GREECE | Police |
| GREECE | Customs |
| HUNGARY | Criminal Department, National Police HQ |
| HUNGARY | Department for Customs Enforcement, NTCA |
| HUNGARY | Airport Directorate 1, Budapest Airport, NTCA |
| ICELAND | Directorate of Customs |
| ICELAND | Reykjavik Metropolitan Police |
| ICELAND | Icelandic Medicines Agency |
| IRELAND | EUROPOL Liaison office |
| IRELAND | Irish Medicines board |
| ITALY | NAS Firenze |
| LATVIA | IPR Protection Subdivision of National Customs Board of State Revenue Service |
| LATVIA | Economic crime enforcement department of central criminal police, state police |
| LATVIA | Ministry of Health, Health Inspectorate |
| LITHUANIA | Crime investigation board of Lithuanian, criminal police bureau |
| LITHUANIA | Inspection Unit, Medicines agency |
| LUXEMBOURG | Luxembourg Customs Directorate |
| MALTA | Customs Department |
| MALTA | Medicines Authority |
| NETHERLANDS | Europol Liaison desk |
| NORWAY | Norwegian Medicines Agency |
| NORWAY | National Criminal Investigation Service |
| POLAND | Provincial Police HQ Gdansk |
| POLAND | Main Pharmaceutical Inspectorate, Supervision Department |
| POLAND | Customs |
| PORTUGAL | Operational Control and Planning Division of Customs Antifraud Services |
| PORTUGAL | Judicial Police, UNCC |
| ROMANIA | National Customs Authority |
| ROMANIA | National police |
| ROMANIA | National Agency for Medicines and Medical Devices |
| SLOVAK REPUBLIC | State Institute for Drug Control |
| SLOVAK REPUBLIC | Slovak Police, Bureau of Criminal Police,Department of General Crimes |
| SLOVAK REPUBLIC | Criminal Office of Financial Administration |
| SLOVENIA | Agency for Medicinal Products and Medical Devices |
| SLOVENIA | Police directorate Koper, Crime police division |

| | |
|---|---|
| SLOVENIA | Customs Office |
| SPAIN | Policía Nacional |
| SPAIN | Guardia Civil |
| SPAIN | Policía Local Alicante |
| SPAIN | Aduanas Alicante |
| SWEDEN | Customs |
| SWITZERLAND | Swiss Agency for Therapeutic Products |
| SWITZERLAND | Central office for Customs Investigation |
| UNITED KINGDOM | Organised Crime Branch, Police Service of Northern Ireland |

**Participants from representative associations**

| |
|---|
| MHRA |
| PSI |
| Eli Lilly |
| Pfizer |
| EMEA |
| IRACM |
| EMEA |
| European Alliance for Safe Access to Medicines |

**Institutions**

| | |
|---|---|
| EU Agency | EUROPOL FP Copy |
| EU Commission | DG Markt |
| EU Commission | DG Taxud |
| Council of Europe | EDQM |

**OHIM**

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|---|
| EU Observatory |
| OHIM Academy |

[i] (art 3 Europol council decision)

OFFICE FOR HARMONIZATION
IN THE INTERNAL MARKET
(TRADE MARKS AND DESIGNS)

EUROPOL