

# Outlines of presentations

## Counterfeit medicines and public health

### Mr Christopher A. VIEHBACHER

Chief Executive Officer, Sanofi-aventis



Counterfeiting is huge business across many industries, with exploitation of manufacturing principles, disgraceful job conditions and of course power of the crime lords. In the case of counterfeit medicines, the danger goes even further as it threatens and can even kill patients. Christopher A. Viehbacher looks at the extent and proliferation of the problem and how as leading

healthcare company, sanofi-aventis, has a responsibility not only to deliver innovative, safe and effective solutions to the potential 6.8bn people in need, but to ensure they receive the medicines they should. The importance of healthcare companies joining forces with those tasked with fighting the issue on the ground - enforcement officers, customs officers and healthcare professionals – is key to addressing this huge threat to public health and safety.

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## Legislative proposal 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

### Agnès Mathieu

European Commission, DG Health & Consumers, Unit Pharmaceuticals



On December 2008, the Commission adopted an ambitious proposal which aims to protect the EU from falsified medicines. Falsified medicines pose serious threats to the health of EU citizens. Therefore, the Commission proposes to tighten the requirements throughout the whole supply chain, i.e.

from the import of active ingredients, through manufacturing and distribution to the patient.

## Recent developments on keeping falsified medicines out of the supply chain.

### Dr Katrin Nodop

Compliance and Inspection European Medicines Agency



The European Medicines Agency (EMA) is a decentralised body of the European Union and its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines. In the field of GMP and GDP, the Compliance and Inspection Sector coordinates GMP

inspections, develops harmonised procedures and guidance and works closely with the European Commission on the implementation of the anti-counterfeiting initiatives. An important part of the fight against counterfeited (falsified) medicines entering the legal supply chain is to introduce more stringent Good Distribution Practices (GDP). The EU GDP guideline revision is an important part of this work. Greater transparencies in information sharing of compliant distributors in the supply chain of medicinal products is being introduced by developing Community databases. The development of these guidances and procedures is done with the Inspectors Working Group at the EMA. Close cooperation is maintained with other international actors in this field, like WHO and EDQM.

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## The new Convention of the Council of Europe and its potential impact on law enforcement

### Mr Claude Debrulle

Honorary Director of the Belgian Ministry of Justice



Mr Debrulle is the Chairman of the international drafting group of the Medicrime Convention of the Council of Europe. He will present the Medicrime Convention on counterfeiting of medical products and similar crimes involving threats to public health: its background, advantages, weaknesses and universal call.

## Clarification and scope of the two main approaches against counterfeit medicines

### Mr Christian TOURNIE

European Commission, DG Home Affairs



Mr Tounié, seconded national expert within the European Commission, is responsible for criminal measures related to counterfeit and piracy, and for financial investigations at the Fight against organised crime Unit of the DG Home Affairs. He has been involved in all issues related with criminal measures enforcing intellectual property rights and for pharmaceutical crime. Today counterfeit goods is a major issue for our societies. With growing international trade, all sorts of goods are transiting with relative ease, including counterfeit goods such as counterfeit medicines, often under the control of criminal organisations. For criminal groups, counterfeit medicines ensure high financial gains with relatively low risk of detection. There are two main criminal law approaches to fight production and distribution of counterfeit medicines: “intellectual property” and “public health“. The presentation will argue that a complementary intervention in these two domains, without exclusivity for one or the other, could permit to elaborate the most effective legislative response against this major threat for individuals and the society as a whole.

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## EUROJUST experience in dealing with cases related to counterfeit medicinal products

### Benedikt Welfens

deputy of the German National Member at Eurojust



Mr Benedikt Welfens is deputy of the German National Member at Eurojust. He is an experienced prosecutor in the field of white collar crime and organized crime and the drug representative of Eurojust. Eurojust is supported by the 27 EU Member States and is responsible for supporting cross border investigation between the EU Member States in the field of serious crime by coordinating worldwide simultaneous action, the creation of JITs and other means as financial support.

## Customs and the WCO efforts in combating counterfeit pharmaceuticals

### Motoyuki Okura

Technical Attaché, Compliance and Facilitation Directorate, World Customs Organization



The World Customs Organization (WCO) is a sole independent international organization specialized in Customs matters and its mission is to enhance the effectiveness and efficiency of Member Customs administrations to carry out their diversified tasks. The presentation will focus on the role of Customs and the WCO in the fight against counterfeit pharmaceuticals, available WCO tools to support Member Customs, and the way forward.

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## Recent trends of manufacture and sales of counterfeit medicines in Europe and in the World.

### Ashley HOW

Director EMEA  
Pharmaceutical Security Institute, PSI



Mr. Ashley How is the EMEA Director, (Europe, Middle East & Africa) for the Pharmaceutical Security Institute, PSI. Mr Ashley works closely with the Institute's twenty five members to ensure the integrity of pharmaceuticals and, most importantly, to protect public health. The presentation will look briefly at the scale of the problem globally with an emphasis on Europe. It will examine the driving factors behind counterfeit medicine production and distribution and the challenges to law enforcement. Finally it will discuss 2 cases that demonstrate the challenges and why law enforcement, the regulatory authorities and industry need to work together.

## German Enforcement structure and impact on the effectiveness of investigations

### Kirstin Smolka

German Customs Investigation Service



Ms Smolka is a Customs Investigation Officer at the Central Office of German Customs Investigation Service, section "prohibitions & restrictions". Her main tasks are investigations related to pharmaceuticals and doping. The role of German Customs includes combating the worldwide illegal pharmaceutical trade. This presentation will provide an overview of the structure and tasks of the German Customs Enforcement in the field of illicit trade with pharmaceuticals.

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## Irish and UK health enforcement structures and impact on effectiveness of investigations

### H.K. Bonar

Enforcement Manager, Irish Medicines Board



Hugo K. Bonar, Enforcement Manager at the Irish Medicines Board, set up the Board's dedicated enforcement facilities in 2000. Responsibilities include the investigations into illegal medicines and medical devices. The presentation will outline the basic enforcement structures in place in UK and Irish agencies responsible for the investigation of counterfeit medicines. It will explore why this model is utilised so as to identify those aspects that support effective investigations. It will identify how best practices employed by trained and experienced staff have ensured the systematic investigation of a counterfeit medicine involving more than one country. It will conclude that this is a workable model that could be used to assist the harmonisation of procedures for the investigation of counterfeit medicinal product throughout the EU.

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## The Multidisciplinary approach for investigations on pharmaceutical crime

### Aline Placon

INTERPOL-IMPACT Project Manager



Mrs. Aline Placon is the head of the INTERPOL Medical Products Counterfeiting and Pharmaceutical Crime. She is the co-chair of enforcement sub-group of IMPACT ("International Medical Product Anti-counterfeiting Taskforce") Counterfeit medical products and pharmaceutical crimes are a growing problem that leads to organized crime. One way of disrupting the criminality linked to this plague is to develop a multidisciplinary enforcement approach. How did INTERPOL develop its partnership with IMPACT and how did she turn good collective will into concrete actions? By coordinating a number of regional enforcement operations, training and raising awareness tools, INTERPOL has collected good practices that can assist other regions world while. The presentation will describe this history, this model and how it can benefit to other enforcement and regulatory authorities.

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## Presentation of the international operation Pangea II

### Karen Bresard

Criminal Intelligence , INTERPOL



Ms Bresard is Criminal Intelligence Analyst at INTERPOL, working specifically on Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC Unit). With 188 member countries, INTERPOL facilitates cross-border police co-operation, and supports and assists all organizations, authorities, and services whose mission is to prevent or combat international crime. The presentation will outline the methodology and the outcomes of Operation Pangea II, carried out in 2009 by 24 countries and coordinated by INTERPOL. This international operation tackled online supply of counterfeit and illegal medicines.

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## Presentation of the Blue Project

### Mr Sieghart Vosseler and Frank Birkhold

Organised Crime Investigation Team at Customs Investigations Stuttgart (Zollfahndungsamt)

Mr Sieghart Vosseler and Mr Frank Birkhold are head and deputy head of the Organised Crime Investigation Team at Customs Investigations Stuttgart - Field Office Freiburg. The presentation will present the general situation and profits generated by the illegal pharmaceutical market in Western Europe. It will describe how to build a case against illegal online pharmacies (with examples), how to cooperate with the private sector and how to quickly and efficiently identify and stop the illegal internet structures (Project BLUE). Finally the presentation will describe how best can transport industry identify the origin of suspicious shipments.

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## Presentation of the techniques of investigations for counterfeit medicines sold over the internet

### Luke Strohmann

DNRED / DCLE / Cyberdouane  
French Customs



Mr. Luke Strohmann the head of Cyberdouane, the internet monitoring unit of the intelligence division of the French customs. The presentation will present strategies of Cyberdounaes against counterfeit drugs: ongoing internet monitoring and measure against illicit trade. The presentation will demonstrate

how collaboration between government services and the French industrial sector can lead to a better understanding of the organization of fraud and operational results. The presentation will also show the willingness of the French customs authorities to cooperate with its foreign counterparts.

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## How to use information available by acquiring banks and credit card companies in investigations on counterfeit medicines?

### Mr Bernd-Ludwig MULLER,

Expert financial crime Financial expert from Acquiring bank CONCARDIS in Frankfurt.

Mr Muller will invite the audience to have a look into the credit card world to understand the different parties, the data- and money flow and the responsibilities of an Acquirer, Issuer and the cardschemes. Who are the participants and how the system is working.

## Online pharmacy and involvement of tax authorities in Germany

### Jürgen Röder

Essen Customs investigation office (ZOAR)



Jürgen Röder is from the Essen Customs investigation office where he has worked on investigations for about 25 years, with the position of Head of the Division of Prohibitions and Restrictions for 4 years. Investigating smuggling of illicit and counterfeit drugs is an area of responsibility of this

department and it will be one of the main targets of the future. The presentation will focus on a successful investigation case concerning the destruction of an online pharmacy in a regional area. A summary will be given about the flow of information received from different sources, the combination of both and the cooperation with colleagues from Freiburg customs investigation and tax investigation authorities. The presentation will include some pictures of the pills that seized during the operation and some specials in modus operandi will be explained. The conclusion will be that German tax law is an effective instrument for fighting smuggling illicit and counterfeit drugs.

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## Lessons learned from large investigation case in UK and Europe

### Mike DEATS

Group Manager, Enforcement Group, Inspection, Enforcement and Standards Division, UK Medicines and Healthcare products Regulatory Agency (MHRA)



Mr Mike Deats is the Goup Manager of the Enforcement Group of MHRA. The UK have had 10 known incidents of counterfeit medicines reaching pharmacies in the past 6 years that led to the recall of those medicines from the market. Each of these cases have been investigated by the Medicines and Healthcare products Regulatory Agency. This

presentation will focus upon the UK approach to dealing with these incidents and the lessons learnt from those investigations, focusing on the twin responsibilities of ensuring public safety and securing evidence to prosecute the offenders. Specifically the issues to be covered include the initial steps following notification of an incident through to the gathering of evidence from other countries, following the audit trail, the value of computer evidence, and proving guilty knowledge of those involved.

## Presentation of an investigation case in the USA

### Rich Halverson

Unit Chief, IPR/Outreach & Training



Richard Halverson is the Unit Chief for Outreach & Training at the National Intellectual Property Rights Coordination Center (IPR Center) in Arlington, Virginia. Led by Homeland Security Investigations (HSI), the IPR Center brings together 12 key U.S. federal agencies plus the Government of Mexico to combat IP theft that poses

a threat to health and safety, the economy and the war fighters. The presentation will focus on how law enforcement in the U.S. is interdicting, investigating and prosecuting the criminals trafficking counterfeit drugs. It will demonstrate the value of using certain techniques and importance of international cooperation in order to dismantle an international smuggling organization.

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## Close working relation between Dutch Healthcare Inspectorate and Dutch FIOD (IRS) in case of IPR counterfeit medicines. The B case.

### Lex van Nes

Inspector/enforcement officer  
Dutch Health Care Inspectorate

Mr Lex van Nes is inspector and enforcement officer at the Dutch Healthcare Inspectorate since 1993. His main tasks include investigations on pharmaceutical crime specially counterfeit medicines and misuse of illegal anabolic steroids. Member of the PFIPC (Permanent Forum International Pharmaceutical Crime), WGEO (Working Group Enforcement Officers EU), END (European Network Drugs expertise) and NND (National Network Drugs expertise). The Enforcement Unit of the Healthcare Inspectorate has close working relations with Dutch Customs, local police forces and National Crime Squad to combat illicit trade with medicinal products.

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## Presentation of organizational developments in the fight against counterfeit medicines in the Netherlands and a recent investigation case

### Jack Geurtsen and Henny Koele

Dutch National crime squad against counterfeit products and medicine FIOD Utrecht

We are both project managers with the FIOD. The FIOD is the Dutch National crime squad regarding counterfeit products and medicine. We also do investigation on tax fraud and fraud relating to stock integrity in the Netherlands. Our presentation is about a case regarding counterfeit medicine which we

completed this year. It started as a small case and became an International case. It will show the way we handled this investigation to make it a success.

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## Practical cases and good practices in Macedonia

### Kiril Zajkov

Customs Administration  
Senior inspector  
Republic of Macedonia



Kiril Zajkov is a Senior inspector in the Investigation department – Anti smuggling unit in the Customs administration. Part of his responsibility includes pre-investigative and investigative procedures. His presentation will focus on two cases: The first case is smuggling of a cytostatics from

Bulgaria to Kosovo, with value amounted EUR 13,000 and without authorization for import. The second case is a seizure on 1.980 Viagra 100 pills.

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## Investigation on Internet: practical cases and good practices in Italy

### Cap. Sergio Tirrò,

Head of the training section of Carabinieri N.A.S



Capt. Sergio Tirrò is the Head of the training section of Carabinieri N.A.S., a specialized military Department of Carabinieri Corps. N.A.S. officers have both sanitary inspector and judicial police powers, so that further investigation can be developed in consequence

of a sanitary inspection. The presentation focuses on the following topics: 1) Training in pharmaceutical law enforcement procedures, sampling procedures, anti-counterfeiting activity; 2) Legal guidance on EU and national legislation, predominantly related to medicines; 3) Analysis of the most important recent investigation results; 4) Monitoring activities and investigative techniques performed by N.A.S.; 5) Development of a systematic information sharing approach among law enforcement authorities in order to enforce EU legislation

## Current counterfeit situation in Russia. Role and impact of the Roszdravnadzor

**Mr Alexey TEREKHOV**, Advisor to the Head of the Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor)

Alexey Terekhov is an advisor to the Head of Federal service on surveillance of healthcare and social development of Russian Federation (Roszdravnadzor). Responsibilities include the investigations into illegal medicines and medical devices. The presentation will outline the basic enforcement structure of Russian Federation. The place of Roszdravnadzor for the investigation of counterfeit medicines. And the latest results of investigations.

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## Training needs for operators

**Domenico Di Giorgio**, Ph. D.  
Director of Counterfeit Prevention Unit  
Agenzia Italiana del Farmaco



Mr Domenico Di Giorgio is the Director of the anti-counterfeiting unit of the Italian Medicines Agency (AIFA), and the Chairman of the Council of Europe/EDQM Committee of experts on minimising public health risks posed by counterfeiting of medical products and related crimes.

Both organisations are dealing with programs of intersectorial training on counterfeit medicines for officers from health authorities, customs and police forces, with the aim of spreading knowledge and fostering the cooperation between the authorities at a national and international level. In Italy the cooperation scheme built through training initiatives demonstrated to be a powerful tool to support the enforcement and investigative activities developed through the national anti-counterfeiting task-force IMPACT Italia: intersectorial training (delivered also through the web) improved quantity and quality of the signals to the task-force from the field (Customs, local police forces), and officers involved in the network started considering the problem of counterfeit medicines in their day-by-day activity, with good results.

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## Dismantlement of a supply chain: the medicine shop case in Sweden

**Celia Fant**

Swedish National Criminal Police  
/Intelligence Section



Cecilia Fant, Detective Inspector at Intelligence Unit at National Criminal Police in Sweden, has been working with drug related crime since 1996 and with surveillance on the Internet since 2004.

Her presentation will focus on a case of "Medicinshopen" involving criminals selling counterfeit medicines in Sweden since 2006. The case started with a simple purchase to check if the sale included medicines and finished with a seizure of 39,000 tablets! The internet has made it possible for people to start up their counterfeit medicines business and now generates new criminals.

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## Successful Public-Private Partnerships

**Philip Cottrell** Director of Security for Sanofi-Aventis UK and **Nimo AHMED**, Chief of Intelligence, Enforcement and Standards Division, UK Medicines and Healthcare products Regulatory Agency (MHRA)

Philip Cotterell is the Director of Security for S-A in the UK, part of his responsibility includes the investigation of counterfeiting which affects the UK. The presentation will focus on the cooperation between Industry and Law Enforcement / Regulatory when investigating counterfeit operations. It also includes Nimo Ahmed of MHRA and a Sanofi-Aventis principal undercover agent who will discuss a recent successful operation in the UK.

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## Presentation of an investigation case in Sankt Petersburg

**Yury Orlov**

Regional CIS Security Manager  
Sanofi-aventis group

Mr Orlov's presentation will address general information regarding the current situation with counterfeit medicines in Russia and Sanofi-Aventis activities against them in this region. Local specifics will be discussed including law-enforcement bodies involved into anti-counterfeit work in Russia, an example of successful cooperation of Sanofi-Aventis and Police in investigation, illegal production facilities in the suburb of St.Petersburg; and a video entitled "Police Raid in illegal production facilities in suburb of St.Petersburg" will be shown.

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## Investigation on Illicit Internet Purchase and Postal Parcels in Belgium

### Roy Vancauwenberghe

Head of SIU (Special Investigation Unit) DG Inspection,  
Federal Agency for Medicines and Health



Mr Roy Vancauwenberghe is a senior inspector at the FAMHP. He has introduced pharmaceutical crime enforcement at the former Pharmaceutical Inspectorate since 1995 and the last three years at the FAMHP. He will outline how the benefits of the internet are misused

by criminals favoured in their actions by the disappearance of the borders, while the authorities face national legislation colliding with virtual borders. European medicines legislations contain numerous loopholes concerning the virtual society. Different jurisdiction, lack of expertise and knowhow, and the absence of a harmonised and common approach in investigations and information-sharing are important obstacles. A condition sine qua non for fighting pharmaceutical crime in general and the illegal trade of medical products by the internet in particular is a Single Point of Contact network collaborating at national and international level. In Belgium the National Hormone Cell, a multidisciplinary and multi-sectoral unit, fights all forms of pharmaceutical crime.

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## Support of a private forensic laboratory in investigations on counterfeit medicines

### Nathalie TALLET



Head of Anti-Counterfeit Central  
Laboratory, Sanofi Winthrop Industries

Nathalie Tallet is the Head of the Anti-Counterfeit Central Laboratory for Sanofi-Aventis group in Tours, France. She has held this position since 2007. Prior to this she has worked within Sanofi Aventis, in various positions including Product Development and Project Management. Nathalie is in charge of nine person team made up of experts in the field of analytical technologies. Pharmaceutical manufacturers increase their efforts to fight against counterfeit medicines by establishing dedicated organizations. One example is the Central Anti-Counterfeit Laboratory which is an integral part of the sanofi-aventis group's initiative against counterfeiting. Inaugurated in 2008, the laboratory is devoted to the analysis of suspected products in order to identify counterfeit medicines. By correlating cases and working with various authorities the team help to track down the organised crime networks which manufacture and distribute fake drugs. During the conference Nathalie will present how her team has participated to the recent successes of the investigations conducted in cooperation between a private company and public organizations.

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## Presentation of a recent investigation case on counterfeit medicines in Poland

### Piotr ŻOŁĘDOWSKI

Komenda Główna Policji  
Biuro Kryminalne

Piotr ŻOŁĘDOWSKI is a specialist in the Department against Economic Crime at the Crime Office of Criminal Police Headquarters which duties includes the coordination of the intellectual and pharmaceutical criminality and cooperation with government and public agencies. The presentation will describe the structure of the Polish Police involved in fighting pharmaceutical crime and the type of counterfeit drugs available in Poland as well as their origins.

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