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## Proceedings

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# Introduction

We cannot afford Europe to be a mere aggregate of countries: on the contrary, we must have the continuous ambition to bring about an exchange of experiences, best practices and information.

In this respect the European projects play an important role, since necessarily pre-condition is the joint cooperation among the different MSs in promoting high-profile innovation initiatives.

This cooperation in fighting specifically against the pharmaceutical crime is even more relevant considering it is the starting point of every truly effective strategy and activity.

A few recent cases, appeared on the press recently, proved how illegal activities in Europe are spread and interconnected, included those online, while the operations set in motion proved the importance of sharing tools and information to tackle those activities.

In this scenario the cooperation between Regulatory Agencies and Police Forces, two different skills and responsibilities that complement each other, is an essential prerequisite for any effective action, such as the collaboration between public and private sectors.

The **International Conference** of Fakeshare Project, held on April 24<sup>th</sup> in Rome, joined together representatives from the competent authorities and stakeholders from different European countries. It was addressed to consumers, health professionals, police forces, associations and other public and private bodies, interested in selling medicinal products at a distance through the internet.

The agenda was structured in two sessions, covering a range of topics from an introduction to the online sale of medicines, the regulatory aspects and the different

actions taken against the illegal websites at national and international level, to an overview of tools developed in the framework of the Fakeshare project.

The first session was an overview, through a description of the general framework, of the significant increase in the online purchase of drugs, strictly connected to the strengthening and extension of e-market and social networks. The illegal drugs most sold through the internet were described along with the related risks to the health. A few aspects of online sales were examined in depth: the characteristics of the common logo, that will allow all consumers to distinguish between legal and unauthorized websites, the role of police forces and enforcement authorities, and the procedures today in use in some European countries to shutdown illegal websites.

The second session dealt with the outcomes of Fakeshare project. In particular, the database of e-pharmacies, result of the ongoing collaboration between the partners involved in the Project, along with in-depth analysis and case histories made available on the website [fakeshare.eu](http://fakeshare.eu), represent an important tool to support the activities carried out by the administrations and by the police forces. During the same session, the communication tools are introduced. By following EU Dir. 2011/62 provisions about awareness-raising initiatives aimed at the patients, communication materials have been developed ad hoc, on the basis of scientific researches conducted in Italy, Spain and Portugal, aimed at investigating behavioral and psychological factors linked to online purchase of medicines. The communication tools have been developed in order to raise awareness on the risks associated with the purchase of medicinal products from uncontrolled sources among consumers, health professionals and health associations.

# Opening – welcoming

Luca Pani. Director General of the Italian Medicines Agency (AIFA). Italy

The added value of collaboration in fighting against pharmaceutical counterfeiting: Luca Pani launch the International Conference of Fakeshare.

After two years from the start of the European project “Fakeshare” in which the Italian Medicines Agency is leading a team of public and private, National and International bodies, involved in intelligence activities and citizens safeguard against risks of the illegal sale of medicines over the internet, AIFA today promotes a meeting in order to compare what has been achieved until now. Representatives from European and American pharmaceutical field, Police Forces, industry and University share their expertise to evaluate the issue of worldwide pharmaceutical counterfeiting and take stock of the initiatives carried out and still to be implemented to stem it. Incentives, to operate on, are stimulating actions on patients in order that they acquire awareness of the problem and shared informational instruments.

The value of collaboration represents the requirement to promote any activity of high innovation. If we used some “hashtags” - like in Twitter- to highlight key-concepts in this context, it would be first “#sharing”. Europe, indeed, puts in use the “union” principle and explains the benefits of its system by sharing good practices, experiences and knowledge. That is mainly valuable, talking about the fight against criminal phenomena that concern everybody’s health: pharmaceutical counterfeiting is a threat of variable boundaries, globally spread. It is not, as it used to think, about isolate theft cases committed by small criminal groups. On the contrary, we face targeted operations committed by real criminal organizations. The hashtag

“#innovation” is strictly connected with the hashtag “#economic value” that innovative medicines take on and makes them attractive to be stolen and illegally supplied. If we consider the cost of monoclonal antibodies, it is not difficult to understand why anti cancer medicine are the most stolen.

For this reason technological tools, such as the database of e-pharmacies, implemented in the framework of the Fakeshare project and one-of-a-kind initiative in Europe, represent a precious step towards coordination and optimisation of our common efforts, otherwise less effective. Shared commitment at all levels: from Police Forces to regulatory agencies; from suppliers to pharmacies; from physicians to patients. There must be “#network” building.

“#Proactivity” is the last keyword, but not less important, to advocate the process of awareness raising on the issue of pharmaceutical counterfeiting, according to the requirements of the new postmarketing drug surveillance legislation. The point is that instead of reacting promptly to a specific suspect, we must take action before it arises. Ineffectiveness of a medicine - potentially falsified - is a real side effect that needs to be intercepted by health workers, but also by citizens in order to make them understand it is the first signal from which an intelligence process, regarding quality and legality of products, could be triggered.

AIFA undertakes to guarantee and strengthen a proper information on this issue, and this could make the difference. Today we don’t introduce the end of a project, but the beginning of a new course.

# Session one

# Fighting counterfeiting: the contribution of the pharmaceutical industry

Massimo Scaccabarozzi, President of Farmindustria

In Italy, thank to the accurate supervision of the Authorities, counterfeited medicines are almost absent in the official distribution chain. In addition, a lot of authorisations are requested to perform any activity in the pharmaceutical sector. Any step of medicine's life-cycle is strictly monitored and checked, starting from manufacturing sites up to the pharmacies and other points of dispense.

The Pharmaceutical Companies have always been active partners in fighting counterfeiting, and they cooperate with all the stakeholders to ensure safety and security of the global supply chains.

## The side effects on health caused by counterfeited medicines

According to the "American Journal of Tropical Medicine and Hygiene" medicine's counterfeiting keeps on spreading threatening citizens' health worldwide. This is a big challenge that requires the cooperation of all stakeholders.

## Medicine counterfeiting: not only an economic loss

For Pharmaceutical companies counterfeiting represents an economic loss. It causes a decrease of sales resulting in reduced return in terms of investments, and in fewer assets available for Reserch. In Italy almost the 90% of the pharmaceutical reserch is self-financed by the Pharmaceutical Companies.

Medicine's counterfeiting may also severely undermine doctor and patient trust in medicines and in Pharmaceutical Industry.

## Italy's fight against counterfeiting: the pharmaceutical companies' commitment

Farmindustria has always been an active partner in fighting counterfeiting, and cooperates with all stakeholders in order to prevent damages caused by falsified medicines.

Since 2013 the Pharmaceutical Companies have been collaborating with SIAC, the anti-countefeiting system developed by Guardia di Finanza (Financial Police). The goal of SIAC project is to collect all information on counterfeited products into a database and to update consumers on the ongoing actions taken by the Authorities in order to protect them against counterfeting.

## The Medicrime Project

It was initially a pilot project leaded by AIFA and the Companies member of the Logistic Group of Farmindustria, and subsequently it was extended to all Farmindustria's Companies, involving also the other stakeholders of the system. Today the partners of the Medicrime project are AIFA, Farmindustria, Assoram, AssoGenerici, EAEPC, ADF, FederFarma Servizi.

As from by the first months of its life the project has given positive outcomes in preventing the counterfeiting, both at national and international level.

## Fighting counterfeiting at European level

The issue is strongly felt also at the European level, it is not a coincidence that the Directive 2011/62/EU introduced a series of provisions in order to prevent medicine's counterfeiting in the European Union. The Directive clearly defines the meaning of "counterfeited medicine" and sets forth a European medicine verification system. The provisions of the Directive also included the introduction of an anti-tamperig device in order to verify the integrity of the medicine's packaging.

## Online sales

For the first time with the Directive 2011/62/UE medicines' sale is structured and regulated via web in order to grant the safety of online purchases. It is foreseen to include a common logo on the authorized websites plus a link to the website of the local competent Authority.

In Italy online sales will be authorized from July 1<sup>st</sup> 2015. Only medicines without medical prescription will be allowed to be sold online, whereas the sale of prescription medicines remains forbidden.

### **The importance of a correct information**

Citizens must be aware about the risks involved in buying medicines through illegal channels. They need to know how to recognize the safe websites authorized by the competent Authorities. The cooperation of all the stakeholders is needed in order to spread the

correct informations and the Pharmaceutical Companies can play their own role..

### **A challenge we can win together**

Counterfeiting is a phenomenon to be fought and defeated through the cooperation of the Pharmaceutical chain of medicine, Law Enforcement and Authorities as a whole, in order to ensure the safety of global supply chains and to protect patient's health. Networking is important, because together we can win the challenge against counterfeiting.

# Sale of medicines online: an introduction

Domenico Di Giorgio, Italian Medicines Agency – AIFA

According to LegitScript's<sup>1</sup> data (April 2015) on 35.610 active e-pharmacies, 33.579 are illegal e-pharmacies (94,3%) and only 212 of them are legal e-pharmacies (0,6%).

## AIFA activities

In the field of online sales of medicines AIFA has been carrying out for a long time a series of activities, summarized below:

### Offer characterisation (2007-2008)

Anonymous internet purchases and IT Intelligence.

### Demand characterisation (2009-2010)

IT Intelligence, survey (CAWI) on e-pharmacy customers.

### Public awareness campaigns and publications (2010-2011)

Sharing science and reliable information with general public, health professionals, other stakeholders.

### E-pharmacies shutdown (2012-2014)

MoH with LegitScript, cooperation with Italian Competition Authority.

### Regulation and cooperation (2014-2015)

Consolidation of the cooperation between stakeholders (EG, Conference of stakeholders on illegal e-pharmacies, involving MoH, Carabinieri NAS, MiSE, Registro.it, Competition authority); rules for legal e-pharmacies.

## Type of intervention

Even before the transposition of the Directive 2011/62/EU providing for the first time that all member states regulate the sale of medicines at a distance to the public, AIFA appealed to regulations not specific of the pharmaceutical industry in order to close illegal web-

sites. These are measures for the closure of websites not related to pharmaceutical legislation, but based on what exists in the area of free competition.

### Procedures on illegal e-pharmacies | 2012-2013

- Registrar – LegitScript, Conference of stakeholders
- Registrar – Registro.it
- Registrant – Carabinieri NAS
- Registrant (competitions rules) – Italian Competition Authority (or Antitrust Authority)
- Webmaster (websites that shows ADS) – Conference of stakeholders

## Some results: 121doc:

An example of effective inter-institutional collaboration is represented by the results obtained in the case of “clinic 121doc”, case in which the regulatory framework has been the “Consumer Code”, since the Directive 2011/62/EU was not transposed in Italy yet and there was no specific legal framework.

“121doc” is an English legal website selling medicines at a distance. It started advertising and selling medicines in Italy, included prescription only medicines.

### Infringement contested

- Regulatory basis: “Consumer Code”.

### E-pharmacies categories:

- **Legal**  
Authorised/verified, according to EU Directive 2011/62 rules
- **Illegal/Rogue**  
Website operating outside normal or desirable controls, selling illegal and falsified products
- **Fake**  
Website using medicines as a mere bait for other kind of cybercrimes (EG: identity theft, phishing)

<sup>1</sup> Verification and monitoring service for online pharmacies, endorsed by the American Association of Boards of Pharmacy (NABP)



- » Art. 23, par. 1, letter i), of the Consumer Code provides that it is misleading “to falsely assume anyhow, or give the impression that the sale of the product is lawful”;
- » vulnerable target;
- » Art. 20, par. 2 of the Consumer Code: Violation of professional diligence.

#### *Hexpress' defence:*

- Decline jurisdiction of Antitrust Authority;
- Infringement of Article 34 TFEU:
  - » measure equivalent to a quantitative restriction;
  - » recall the judgement of the Court of Justice - Case C-322/01 Deutscher Apotekerverband.
- Infringement of Article 56 TFEU (Restrictions on freedom to provide services).
- Medicines dispensed effectively by existing English pharmacies with online prescription.

#### *AGCM's response:*

- the Authority took action on the distance sale of prescription-only medicines. The conduct on which the Authority intervened deals with the online sale of ethical medicines, i.e. medicines that can be administered (only) upon medical prescription;
- wrong invocation of “Speciality” criterion.

#### *Infringement of Article 56 TFEU:*

- the sale of medicines is the central activity of Hexpress and the “services” provided are functional for this activity, as highlighted by a simple online form to fill in;
- principle of prevalent impact (evaluation according to art. 34 TFEU):
  - » Court of Justice C-322/01 of December 11, 2003.
  - » Court of Justice C-418/02 Praktiker Bau- und Heimwerkermärkte.
  - » Court of Justice C-20/03 Burmanjer e a.

#### *Infringements:*

- the sale of medicines at a distance was not allowed when the signals came out;

- medicines were sold without a package leaflet in Italian language, as laid down by the legislation in force;
- on line prescription was acquired through a form to be filled in;
- medicines were lacking of Italian Marketing Authorisation (Country of destination).

#### *Summary of the results:*

- infringements by the three subjects Art. 23, letter i, 20, par. 2, Consumer Code;
- inhibition of the conduct;
- sanctions:
  - » 250.000 € Hexpress;
  - » 200.000 € Web Pharmacy;
  - » 50.000 € Giuseppe Pellegrino.

### **Italian Registry actions**

The Italian Registry, whenever deems it necessary or urgent, or upon request by a third party in order to protect the rights, shall verify that the Registrant of a domain meets the subjective requirements that led to, in due time, the assignment of the domain name.

Upon request of the competent authority, suspension can be disposed following the notification, as provided by law, of an order issued by a competent authority with which the Registrant is inhibited the use of the domain name.

The Registry suspends a domain name upon request of the recipient to whom it is judicially contested the use.

Revoke of a domain name can take place following a court order, or other order issued by a competent authority, notified to the Registry. It can also take place for lack of subjective requirements or for failure to submit the required documents to the Registrant.

The request of objection may be advanced to the Register by whom considers that the registration of the domain name has infringed his right or that receives an injury by the registration.

# Commercio elettronico e social network: un quadro in costante evoluzione

Enrico Maccallini, Ministry of Economic Development

## Abstract

Internet, in its constant evolution (Web 1.0; the “Generic Web”, Web.2.0; so-called “Social Network” and e-commerce), offers unlimited opportunities for citizens to purchase products and services globally. At the same time, illegal websites offering for sale illegal and/or falsified products are an established threat for EU citizens.

When transposing the new European Directive 62/2011, it was formalized in “Conferenza di Servizi” (Conference of the Stakeholders) the inter-institutional working group on illegal web pharmacies, launched in collaboration with AIFA and other administrations in 2012, in order to define and implement enforcement procedures on illegal sites.

The “Conferenza di Servizi” is convened periodically with the aim to:

- examine the cases reported or detected in the surveillance carried out in agreement with Carabinieri for the protection of health (NAS);
- identify violations with respect to the rules on distance selling to consumers through the services of the information society of medicines.

While members of the “Conferenza di Servizi”, as concerned administrations, are the Ministry of Health, the Ministry of Economic Development, and the Carabinieri for the Protection of Health – NAS, take part in the meeting also, as observers, the Italian Competition Authority (AGCM) and the National Research Council (Register IT).

On a proposal of AIFA, made as a result of the investigation carried out by the “Conferenza di Servizi”, the Ministry of Health take a motivated provision, even adopted on urgency basis, the cessation of business practices consisting on offering for sale illegal and/or falsified products through the internet, which is enforced by the Carabinieri for the protection of health – NAS

## Di che cosa parliamo

Internet è un complesso mondiale di reti di computer interconnesse tra loro e ad accesso pubblico. Attualmente rappresenta il principale mezzo di comunicazione di massa, che offre all’utente una vasta serie di contenuti potenzialmente informativi, e di servizi. Le potenzialità teoriche in termini informativi e di servizi della Rete sono enormi.

Gli offerenti nel mercato globale sono un numero indefinito, spesso tutelati da un «sostanziale anonimato», operano in contesti di «business» in continua evoluzione e sono mutevoli nel tempo e nello «spazio».

I servizi di rete, a carattere tendenzialmente globale, si innestano nei sistemi giuridici tradizionali (analogici) e questo pone una serie di problemi:

- individuazione della condotta illegittima e dell’eventuale cumulo con altre fattispecie
- diversa sanzionabilità del comportamento (civile, penale ed amministrativa)
- giurisdizione (...ed esecuzione; rogatoria internazionale, exequatur etc.)

## Il problema

La vendita e l’importazione di farmaci non autorizzata è penalmente punita ai sensi del D.lgs 219/2006.

Con il prossimo recepimento dell’Italia della direttiva 2011/62/UE, che modifica la direttiva 2001/83/CE, recante un codice comunitario relativo ai medicinali per uso umano, sarà consentita la vendita on-line di farmaci anche in Italia: siti internet localizzati in paesi terzi potrebbero minacciare la salute dei consumatori italiani offrendo loro, illegalmente, la vendita di farmaci, anche contraffatti.

Da qui la necessità di un gruppo di lavoro (WG) con l’obiettivo di:

- tutelare i consumatori nazionali dai rischi connessi all’acquisto ed all’uso di prodotti farmaceutici potenzialmente nocivi per la loro salute da siti internet illegali localizzati fuori dal territorio nazionale

- minimizzare l'esposizione dei consumatori italiani dai rischi connessi alla accessibilità sul territorio nazionale dei siti internet illegali;
- massimizzare l'effetto deterrente.

### I soggetti promotori

- Aifa, CC Nas, Ministero dello Sviluppo economico (MiSE);
- Ministero della Salute (MS);
- Autorità Garante della Concorrenza e del Mercato (AGCM).

### Le tappe fondamentali

- Gennaio 2012: Costituzione di un WG.
- Febbraio 2012: Identificazione base normativa.
- Aprile 2012: preistruttoria casi segnalati.
- Giugno 2012: Segnalazione e provvedimento inibitorio AGCM.
- Settembre 2013: trasformazione in "Conferenza dei servizi".
- Marzo 2014: Conferenza dei servizi normativa prevista.

### Costituzione del WG

- Aifa, CC Nas, MiSE (DGLC-UIBM e DGMCCVNT quale punto di contatto ex art. 20 del D. Lgs. 70/03 ed ufficio unico di collegamento ex Regolamento 2006/2004/CE).
- AGCM.
- MS.
- Registro.it.

### Identificazione della normativa

- DECRETO LEGISLATIVO 9 aprile 2003, n. 70 Attuazione della direttiva 2000/31/CE relativa a taluni aspetti giuridici dei servizi della società dell'informazione nel mercato interno, con particolare riferimento al commercio elettronico (artt. 5 e 20)

#### D.lgs 70 art. 5

1. La libera circolazione di un determinato servizio della società dell'informazione proveniente da un altro Stato membro può essere limitata, con provvedimento dell'autorità giudiziaria o degli organi amministrativi di vigilanza o delle autorità indipendenti di settore, per motivi di:



[...]

b) tutela della salute pubblica;

[...]

d) tutela dei consumatori

2. I provvedimenti di cui al comma 1 possono essere adottati se, nel caso concreto, sono: necessari riguardo ad un determinato servizio della società dell'informazione lesivo degli obiettivi posti a tutela degli interessi pubblici di cui al comma 1, ovvero che costituisca un rischio serio e grave di pregiudizio agli stessi obiettivi; proporzionati a tali obiettivi.

3. Fatti salvi i procedimenti giudiziari e gli atti compiuti nell'ambito di un'indagine penale, l'autorità competente, per il tramite del Ministero delle attività produttive ovvero l'autorità indipendente di settore, deve, prima di adottare il provvedimento: a) chiedere allo Stato membro di cui al comma 1 di prendere provvedimenti e verificare che essi non sono stati presi o che erano inadeguati; b) notificare alla Commissione europea e allo Stato membro di cui al comma 1, la sua intenzione di adottare tali provvedimenti. Dei provvedimenti adottati dalle autorità indipendenti, è data periodicamente comunicazione al Ministero competente.

4. In caso di urgenza, i soggetti di cui al comma 3 possono derogare alle condizioni poste nello stesso comma. I provvedimenti, in tal caso, sono notificati nel più breve tempo possibile alla Commissione e allo Stato membro, insieme ai motivi dell'urgenza

#### D.lgs 70 art. 20 (Cooperazione)

Presso il MiSE è istituito il punto di contatto nazionale che fornisce assistenza e collaborazione agli Stati membri e alla Commissione.

- DECRETO LEGISLATIVO 6 settembre 2005, n. 206 - Codice del consumo artt. 20, comma 1, 21, comma 3 e 23, lettera i).

#### D.lgs 206/2005 Codice del Consumo

Art. 20

1. Le pratiche commerciali scorrette sono vietate.



#### Art 21

3. E' considerata scorretta la pratica commerciale che, riguardando prodotti suscettibili di porre in pericolo la salute e la sicurezza dei consumatori, omette di darne notizia in modo da indurre i consumatori a trascurare le normali regole di prudenza e vigilanza.

#### Art. 23

1. Sono considerate in ogni caso ingannevoli le seguenti pratiche commerciali:

i) affermare, contrariamente al vero, o generare comunque l'impressione che la vendita del prodotto e' lecita;

#### Risultati del WG/conferenza di servizi

- 2 procedimenti davanti all'AGCM.
- 5 siti internet inibiti dall'accessibilità del territorio italiano.

L'attività ha portato inoltre alla repressione della vendita di prodotti contraffatti in genere (no farmaci):

- 12 procedimenti davanti all'AGCM.
- 145 siti internet inibiti dall'accessibilità del territorio italiano.

# Medicines Online – What’s the Big Deal?

Lynda Scammell, Medicines and Healthcare Products Regulatory Agency – MHRA (UK)

## UK Position – the MHRA

In the UK the enforcement of medicines law is the responsibility of the MHRA and not of the police.

The MHRA is responsible for:

- Illegal advertising
- Illegal wholesaling
- Illegal sale and supply
- Illegal importation
- Illegal manufacture
- Falsified medicines
- Clinical trial fraud
- Unlicensed medicines
- Internet supply
- Illegal herbal medicines
- Diversion
- Stolen medicines

UK allows the online sell of medicines, including prescription only medicines (POM). Regulations also allow some medicines to be sold outside pharmacy premises, under the general sales list, e.g. in supermarkets. The implementation of the logo applies to all medicines and suppliers of medicines to the public, so these establishments shall also display the logo on their web pages when the system is fully implemented on the 1st of July.

Medicines and Medical Devices are increasingly subject to illegal trading. These illegal supply routes should be tackled by competent authorities.

## Position across EU

Currently the UK is 1 of 5 MS within the EU that allows all categories of medicines to be sold online.

- A UK registered pharmacy may have a presence on the internet, however the requirements of legislation apply equally to both UK internet pharmacies and bricks-and-mortar premises.
- UK legal controls apply equally to all categories of medicines sold or supplied via the internet or e-mail transactions.
- Medicines legislation does not prohibit the remote prescribing of POM by a qualified prescriber how-

ever prescriptions must meet the usual requirements set down in medicines legislation.

Only some Member States allow online sales of OTC and prescription-only medicines. Others allow online sales of OTCs only, while the majority still prohibit both

## Past and present.

The situation today has significantly changed and is very different from 10 years ago. In particular, two main areas have changed the increase of social media and e-commerce of medicines for all of us.

### Social media

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Regarding the social media, Facebook was founded just ten years ago and now it has over 1 billion users worldwide. YouTube was founded 9 years ago and 72 hours of video footage uploaded every minute each day, lots of them are harmless but not all of them, and they have found there are many adverts of medicines being run on YouTube. Twitter arrived 8 years ago and, since then, it has become one of the 10 most visited websites on the internet and there are now 200 million active Twitter users worldwide and a billion tweets are sent every 48 hours.

### Accessibility

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In terms of accessibility, smartphones have become widespread, and a study showed that 4 out of 5 smart phone users use them to shop on line. It’s the age of the internet and in the last 10 years, between 2004 and 2014, internet users have increased from 745 million to just under 3 billion. The times are changing and we have to change with them.

## Medicines online – A global issue

The criminals are taking advantage of this, because it provides access to a vast global market – more consumers are connected and are able to purchase – and,

as the WHO has seen, there is a direct correlation between access to the internet and growth in counterfeit medicines. In this situation, there are business models that allow affiliate websites to feed into their sales site. There is also the ability to operate freely due to difficulties in enforcing rules and regulations and to remain anonymous.

The greater use of social media in the future, with the associated engagement, accessibility, targeted and mass audience they provide, increases the threats to public health because it provides the ability to advertise to millions at a minimal cost.

The World Health Organisation (WHO) has seen a direct correlation between access to the internet and a growth in falsified medicines.

### **Threats to public health and economic factors**

This is a serious problem as these medicines that are purchased online can have dangerous ingredients, cause adverse reactions, interaction with other medicines, no improvement in health conditions, and can disincentive to take prescribed medicines and create a loss of faith in healthcare systems. There are also some economic factors behind this such as, for example, goods failing to arrive, the credit card can be scammed or your e-mail address can be hacked.

### **Medicines online: tackling the illegal supply chain**

In order to tackle the illegal supply chain and dismantle these criminal enterprises, we must attack and remove each component part: the hosting platform, the domain name and in particular the removal of the payment method is essential – if they can't get paid then they cannot operate – they are not selling fake medicines to improve people's health they are doing it for profit.

### **FMD Requirements**

The Directive requires Member States to introduce national arrangements to register suppliers of medicines "at a distance".

This will involve the establishment of a national website and the adoption of the common EU logo.

All websites supplying medicines at a distance will be required to display the EU logo and provide a hyperlink to the national website of the Member State in which the person offering to sell medicines at a distance is established.

The EU logo has been agreed and implementing legislation was published on June 24, 2014. MS have until July 1, 2015 to implement national systems.

We have to tackle the demand as well as the supply chain, public awareness campaigns in all Member States in order to raise awareness in the lead up to the implementation of the common logo system and we need to work together.

# Regulatory aspects: future scenarios in selling medicines online

Giampiero Camera, Ministry of Health

The Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, was transposed into Italian decree n. 17/2014.



**Article 112-quater** states the sale at a distance to the public in implementation of the article 85.C of the directive 2011/62/EU.

Only medicines without prescriptions (SOP) can be sold online, which include Over The Counter medicines (OTC).

Only pharmacies, parapharmacies and “corner of health” of Department Stores are authorised to sell drugs without prescription online.

## The Italian law

The Royal Decree of July 27, 1934, n. 1265, art. 122 provides that: “the public sale of medicinal dose or form of medicine is not allowed but to pharmacists and must be effected in the pharmacy under the responsibility of its holder” (*la vendita al pubblico di medicinali a dose o forma di medicamento non è permessa che ai farmacisti e deve essere effettuata nella farmacia sotto la responsabilità del titolare della medesima*).

Decree Law of July 4, 2006 n. 223, converted with the Law of August 4, 2006 n. 248, art. 5 provides that: “parapharmacies and health corners in the mass distribution can perform activities of public sale of OTC and SOP pharmaceuticals” (*le parafarmacie e i Corner della salute della Grande Distribuzione Organizzata possono effettuare attività di vendita al pubblico dei farmaci SOP e OTC*).

## Who authorises the online sale in Italy?

Region or autonomous province or other competent authorities, identified by the legislation of the regions or autonomous provinces

## Procedure

Pharmacies, parapharmacies and corner of the health of Department Stores shall notify the competent authority for the territory in which they are established, the following information:

- 1 the corporate name, VAT number and full address of the place of activity from where those medicinal products are supplied;
- 2 the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;
- 3 address of the website used for that purpose and all relevant information necessary to identify the website.

The website offering the medicinal products contains:

- the contact details of the competent authority which authorised the sale;
- the hyperlink to the page of the website of the Ministry of Health dedicated to online sale;
- the common logo established to identify persons offering medicinal products for sale at a distance to the public, clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products.



Ministry of Health promotes initiatives, in collaboration with the Union of Chambers of Commerce, in order to ensure the identification of websites through which pharmacies carry out selling drugs online.

The common logo shall contain a hyperlink to the entry of the person in the list of pharmacies and oth-



er actors authorized, published on the website of the Ministry

On the website of the Ministry of Health will be published:

- information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply;
- information on the purpose of the common logo;
- the list of persons offering the medicinal products for sale at a distance to the public by means of information society services and their website addresses;
- background information on the risks related to medicinal products supplied illegally to the public by means of information society services.

## Common Logo

Article 85c(3) of Directive 2001/83/EC provides that a common logo recognisable throughout the Union should be established, which will enable the identification of the Member State where the person offering medicinal products for sale at a distance to the public by means of information society services is established.

Among the candidate logos proposed to the concerned national authorities, the European Commission has sought and obtained trademark protection for the adopted logo in the name and on behalf of the European Union; The registered mark is now included in annex to the Commission Implementing Regulation (EU) No 699/2014.

Licence Agreement between European Union and Ministry of Health for the use of the Composite Mark: the Trademark as combined with additional distinctive word/graphic elements.

The licence royalty-free, non-transferable sole licence to use the Composite mark in conformity with the Field of Use and for the Territory, granted to the National Authority includes the right to:

- use, print and reproduce and store;
- publish, distribute copies thereof, display, broadcast, transmit and/or communicate to the public by telecommunication, press information services, messages and wire service, electronic and

non-electronic publications or any other media now known or later developed.

Licence limitations and obligations:

- rent, lease, assign or transfer any kind of rights regarding the Trademark, and the Composite Mark to third parties - any such stipulation in violation hereof being null and void;
- modify the appearance, create, develop and/or use derivations or variations based on any part of, the Trademark and/or Composite Mark other than proportionally increase or decrease in size the Composite Mark in compliance with the format specified;
- develop or acquire any trademark rights associated with European Commission's institutional logo, the European emblem, the Composite Mark and any derivation thereof including, but not limited to, any national, community or international registration of trademarks, trade dress, trade names, service marks, symbols, slogans, emblems, logos, designs or incorporating the Composite Mark or any part thereof.

Ministry of Health shall use its best effort to protect, and require protection of the integrity of the Composite Mark. In particular, shall neither itself nor allow any third party to:

- combine the Composite Mark or any part thereof with any other object which might deceive third parties as to the meaning and form of the Composite Mark;
- use the Composite Mark in any manner that expresses or might imply the EU affiliation, sponsorship, endorsement, certification, or approval, for activities falling outside of the Field of Use.

The web pages devoted to online sales of medicines in the sites of pharmacies and other commercial establishments authorized must bear the logo (Composite Mark) that will be delivered by the Ministry.

The common logo shall contain a hyperlink to the entry of the person in the list of pharmacies and other actors authorized, published on the website of the Ministry.

## "Storefront"

On the authorized websites may be shown photographs or graphic representations of the external packaging of medicines, the price and any discounts limited to drugs for which online sales are permitted;



The web pages will eventually reproduce in full and without modification, the indications, contraindications, precautions for use, interactions, special warnings, side effects described in the leaflet, with the possible addition of a photograph or a graphical representation of the external packaging of the medicine.

Any advertising relating to the product should not be visible. In this case, the message falls within the cases that require authorization from the Ministry.

## Discounts

Pharmacies may offer discounts on all products and all medications paid directly by customers giving adequate prior notice to customers and practicing the same conditions to all buyers. It is not allowed:

- to establish systems of customer loyalty that discriminate between them in the application of the discounts on the purchase of drugs (eg. fidelity cards);
- to apply to the sale of drugs promotional methods such as selling “3x2”.

## Transportation

The transport of medicines sold online, is carried out in compliance with the guidelines on **good distribution practice**.

During transport it is required to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.

Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.

Medicinal products should be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

## Penalties

Unless the act constitutes a serious crime, the owners of pharmacies who sell to the public at a distance, through the services of the information society, medicines on prescription are punished with imprisonment up to one year and a fine of two thousand euros to ten thousand euros.

Except for pharmacies authorized, unless the fact constitutes a more serious crime, anyone who, in Italy, is selling products to the public at a distance through the services of the information society shall be punished with imprisonment from six months to two years and a fine of three thousand euros to eighteen thousand euros.

# Illegal products and health risks

Patrizia Hrelia, University of Bologna

## Counterfeit/illegal medications: a worldwide problem

An estimated 10% of all medicines are counterfeit worldwide. Much as 30% of the medicines sold in parts of Asia, Africa, and Latin America are counterfeit.

In West Africa alone, the illegal antimalarial drug market may exceed US\$ 400 millions. In 2011, 64% of antimalarial drugs in Nigeria were found to be counterfeit.

In developed countries, life-style drugs, such as phosphodiesterase type 5 inhibitors used for the treatment of erectile dysfunction, seem to be the main targets for counterfeiting.

Counterfeit versions of cancer drugs and other life-saving medicines are also on the rise worldwide.

Any medication that is in high demand is an attractive target for counterfeiters.

## A silent tsunami

The true extent of the problem is unknown. Biomedical literature reports only few studies with sufficient methodology to determine the relevance of counterfeit drugs. A significant part of the published evidence derived from government and organizational websites and from journalism.



### World Health Organization (WHO)

Counterfeit medicines are those that are “deliberately and fraudulently mislabeled with respect to identity and source” (1992).

## Poor quality medicine

Poor quality medicines is a term inclusive of counterfeit, substandard, and degraded medicines and also for medicines that fail chemistry analysis but with insufficient information to determine whether they are counterfeit, substandard, or degraded.

### Key definitions



<b>Life saving drug</b>	A pharmaceutical product designed for or used in saving lives.
<b>Lifestyle drug</b>	A pharmaceutical product characterized as improving the quality of life rather than alleviating or curing disease.
<b>Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines</b>	Medicines that are deliberately and fraudulently mislabeled with respect to identify and/or source.
<b>Counterfeit drug</b>	<p>Deliberately and fraudulently produced and/or mislabeled with respect to identify and/or source to make it appear to be a genuine product.</p> <p>It contains less or more than the required amount of active pharmaceutical ingredients (API) used in the authentic version or even contains the correct amount of API but have been manufactured in unsanitary and unsafe conditions.</p>
<b>Substandard drug</b>	Genuine drug products which do not meet quality specifications set for them.
<b>Falsified drug</b>	It usually has no active ingredient or dangerous substances and can cause serious harm to patients.
<b>Gray pharmaceutical</b>	Space is emerging where illicit profiteers are ostensibly marketing competitive brands without regulatory approval.



## Factors contributing to poor-quality drugs

### Substandard drugs

- Reduced stability of drugs
- No good manufacturing process
- Poor quality control manufacture
- Poor surveillance about expiration dates and storage conditions
- Use of non standardized pharmacopoeias

### Counterfeit drugs

- Financial interests: crime, corruption of politicians and industry
- Inadequate resources
- High demand for antimicrobials and vaccines exceed supply
- High prices of original drugs
- Development of Internet
- High rate of illiteracy and very low income of population
- Lack of sensitization of people to the impact and dangers of counterfeit drugs

The quality of commercially available drugs varies greatly among **developing countries**, due to the lack of strict regulations and to deficient quality control practices.

Next to treatments for erectile dysfunction, slimming pills or anabolic steroids are in high demand in **developed countries**. Non-treatment with these drugs does not lead to detrimental health effects, but their use can result in dangerous adverse effects caused by overdosed content or contaminations. Consumers of life-style drugs often bypass the healthcare system, so that underlying diseases, such as coronary artery disease, obesity, or anorexia, cannot be detected and interactions with other drugs or substances cannot be identified and prevented.

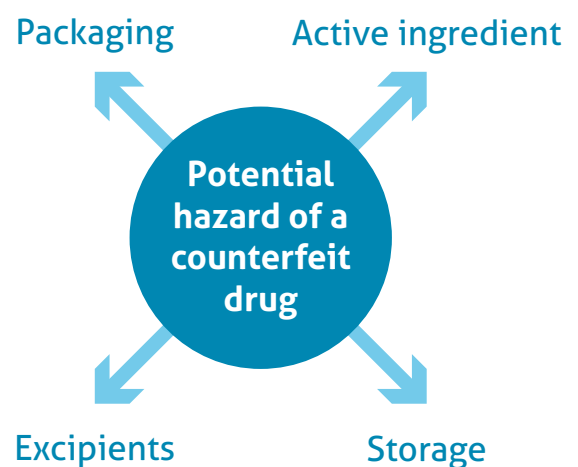
## Health effects

Counterfeit medicines have a disastrous effect on global health and on individual patient safety, including patient injury, non treatment, and death.

The impact of counterfeits in essential drug stocks has a profound and disproportionate impact in resource poor countries. These include increased morbidity

and mortality, adverse effects, therapeutic failure, inaccurate reports of drug resistance due to substandard medicines, and rise of drug-resistant pathogens.

## Hazard of counterfeit drugs



## Different scenarios

### First scenario

A counterfeit drug contains no active ingredient or no harmful ingredients. The counterfeit drug that has no active ingredient, the drug fails to help the patient get better, which can ultimately harm the patient.

*Avastin that did not contain bevacizumab, but salt and starch (United States, 2012)*

### Second scenario

The counterfeit drug has no active ingredient and may have any number of harmful ingredients, including bacteria-laced water, toxic yellow paint, floor wax, colored dye, powdered cement, boric acid, and antifreeze. More than 500 children around the world died from counterfeit cough syrup that was tainted with ethylene glycol.

### Third scenario

Wrong drug is used in the counterfeit agent. Counterfeit versions of over-the-counter weight-loss medication orlistat contained the controlled substance sibutramine instead of orlistat (United States, 2010).

### Other scenario

A counterfeit drug that contains the wrong concentration or wrong dose of the drug. A physician was supplied with a research version of onabotulinumtoxinA (Botox) that was much more concentrated than the real medicine, and is not intended for human use. This resulted in respiratory paralysis and near death for several patients, including the physician who was using it himself (United States, 2006).

## Same drug different scenario

### Substandard antimicrobials

Reduced concentration of active ingredient

Reduced stability (dissolution failure) and bioavailability

Impurities/unknown ingredient

### Counterfeit antimicrobials

Absence of pharmaceutical active ingredient

Reduced amount of active ingredient

Increased amount of active ingredient

Altered chemical content/wrong ingredient

Impurities/unknown ingredient

Inappropriate packaging

Mass uniformity test failure

## Drug contaminations

Drugs may be contaminated with other substances:

- PDS5 inhibitors contaminated with glyburide (Singapore, 2008).
- Heparin contaminated with oversulphated chondroitin sulphate (United States, 2007).

Drugs may be contaminated by poor storage conditions, when humid, tropical environments may contribute to chemical degradation.

## Microbiological contaminations

The presence of microorganisms may have the potential to reduce or even to inactivate the therapeutic activity of a product and has the potential to adversely affect the health of the patient (US and European Pharmacopoeiae). Microbiological contaminations may directly cause adverse effects by producing toxins or causing infections.

- Bevacizumab contaminated with endotoxin (Shangai, 2008)
- Paclitaxel with excessive endotoxin (India, 2009)
- Methyldopa with fungal growth (Tanzania, 2011)

Product alterations may occur in herbal products.

## Defective drug formulation

It arises through inadequate production process, rather than through deliberate falsification of the drug. The lack of quality may be the result of a variety of factors:

- inadvertent use of substandard or incorrect active principles or excipients;
- poor control of drug quantity;
- manufacturing processes that cause contamination or do not adequately ensure sterility;
- inadequate packaging quality;
- ineffective quality control measures.

## Drug content

Any formulation of a medication may be regarded as substandard if it has either too much or too little of the active pharmaceutical ingredient compared with the formulation specifications. Inappropriate packaging can affect formulation in certain storage conditions. Deliberate falsification but also accidental mislabelling may occur.

- The antibiotic rifampicin was mislabelled; bottles actually contained the anti-epileptic clonazepam (Canada, 2009).
- One lot of minocycline was mislabelled as amlodipine (Canada, 2011).
- One lot of bottles containing finasteride was labelled as containing citalopram (USA, 2011).

## Impurities

Impurities fall into one of three categories – organic substances, inorganic substances and residual solvents – as well as extraneous contaminants. Impurities can arise in formulations due to poor manufacturing procedures and storage conditions.

- Contamination with diethylene glycol (mass poisoning over the last 70 years).
- Particulate matter in injectable cefotaxime.
- Degradation products in docetaxel, streptokinase and clopidogrel.
- Potentially genotoxic impurities in batches of nel-finavir.
- Clopidogrel with methylchloride.
- Sildenafil with talcum powder, paint and a range of active ingredients.

## Pharmacological variability and stability

Small changes in excipients can alter the properties of a formulation (e.g. lead to differences in particle size, or modify the shelf-life) and hence affect drug efficacy and safety.

- Tacrolimus with different dissolution profiles (Mexico, 2008)
- Stability of a formulation may change in a variety of storage conditions.
- Chloroquine phosphate tablets with altered stability after 6 months (Tanzania, 2002)

Drug stability can be influenced by packaging, and appropriate packaging is particularly important in conditions such as high humidity, heat or strong light.

## Potential consequences

Counterfeit/Substandard drugs pose a serious health concern from several perspectives. A formulation with no active ingredient or with insufficient active ingredient lead to a lack of clinical response and possibly, death. Adverse events also occur due to drug–drug interactions with contaminants, the presence of excess active contamination with poisonous substances, or allergic reactions to contaminants or substituted excipients. The inadvertent use of suboptimal doses of drugs is likely to be one of the key factors contributing to antimicrobial resistance and thereby leading to the wider spread of disease (malaria, tuberculosis, helminthiasis, HIV). In Niger over 50 000 people received falsified meningitis vaccine during a meningitis epidemic in 1995; 2500 people died, and many were permanently handicapped.

## Impact of illegal/counterfeit drugs

Counterfeit drugs create:

- uncertainty
- confusion
- loss of trust and confidence in healthcare stakeholders/system
- doubts about the value of the real drug and may lead to the use of alternative, less-desirable drugs or therapies.

## Conclusions

Combating counterfeit drugs is a complex task. A multidisciplinary approach is required to combat the problem, for the development of a counterfeit-free future.

# Actions against pharmaceutical crime at the international level

Christian Tournié, Office central de lutte contre les atteintes à l'environnement et à la santé publique – OCLAESP (FR)

Addressing pharmaceutical crime at the international level needs devising normative as well as operational strategies. Nowadays, an efficient response can be envisaged solely through international actions.

Criminal networks are borderless. They exploit jurisdictional hurdles between states and existing obstacles to cooperation between law enforcement relevant services.

OCLAESP (Central Office Against Public Health and Environmental Crime)

Two divisions

- **Investigative Division:**  
One of the groups is dedicated to Public Health Crime:
  - » **Specialised investigators**
  - » **Case managers**
  - » **National contact points for criminal investigations**
- **Intelligence and support Division: Three groups:**
  - » **International cooperation**
  - » **documentation and strategic vigil**
  - » **Technical platform and case assessments financial investigations, operational criminal analysis, IT and cyber investigations**

In this respect, the international community isn't without answer, including in the area of pharmaceutical crime. National and international institutions have been mobilised since many years at all levels where an answer is needed. This is the case concerning the adjustment of good pharmaceutical practices out of which inspection, comprehensive criminal law, operational responses on the field by law enforcement services as a result of investigations or coordinated actions, capacity building in countries requesting technical assistance, strategic and operational cooperation amongst drug regulatory agencies, law enforcement, customs and justice services, without mentioning, as far as possible, public-private partnerships. Of

course, this list is not exhaustive. Those actions mobilise competent authorities amongst States, numerous organisations and international institutions to which, to name only a few, national experts, academics, and field practitioners are closely associated.

The importance of the issue, including the introduction of falsified medicines in the legal supply chain, as well as the extent of the threat, notably linked to the use of the internet, explains this global mobilisation.

Very often, those are coherent and complementary actions, since, for instance, the elaboration of a normative framework in the area of comprehensive criminal law, with a global purpose (MEDICRIME by the Council of Europe) and actions concerning the operational coordination of law enforcement services on the field (PANGAEA by Interpol including Europol and the WCO).

OCLAESP (Central Office Against Public Health and Environmental Crime)

- **French national criminal office**
  - » **within French Ministry of Interior**
    - **joint Police Nationale / Gendarmerie Nationale**
    - **not a medicine regulatory agency**
  - » **with (inter)national jurisdiction (incl. overseas territ.)**
  - » **70 investigators & staff**
  - » **Advisors seconded**
  - » **Interpol NCB, Europol SPOC**
- **Network of 350 local specialized investigators**
- **Network of 80 embassy interior attachés worldwide (police/gendarmerie)**

This approach that consists in bringing coherence overall is also found in areas such as the one of the elaboration of a “model law” UNODC, that creates the opportunity for an international dialogue aiming at all regions of the world.

This search for a shared strategy, national and international, can also be found in projects aiming at reinforcing capacity of the States expressing such a need. This is the case of the “REPT” program by the European Commission, in the field of falsified medicines, taking place in the Middle-East and Africa. Initiatives are

numerous, including, when appropriate, the support of the private sector.

Those actions are mutually and internationally conducted in the fight against pharmaceutical crime at the normative and operational level.



# Investigations on cybercrime: recent case studies

Patrick Holland, Food and Drug Administration – FDA (US)

The FDA – Office of Criminal Investigations (OCI) was established in March 1992 by the Commissioner, with the urging of Congress, in response to concerns of increased criminal violations of the FDCA and related acts, to investigate suspected criminal violations of the FD&C Act; the Federal Anti-Tampering Act (FATA); and other statutes including applicable Title 18 violations. OCI has the primary responsibility for criminal investigations conducted by the FDA and for all law enforcement and intelligence issues pertaining to threats against FDA-regulated products and concentrates its resources on investigations of significant criminal violations that pose a danger to the public health.

The general areas of enforcement are:

- manufacture and sale of counterfeit and unapproved drugs and devices;
- illegal diversion of pharmaceuticals and other regulated products;
- product tampering and product substitution crimes;
- health fraud - treatments/cures/devices;
- safety and integrity of the nation's blood supply;
- adulteration and/or misbranding of food;
- internet facilitated crimes involving FDA regulated products;
- illegal importation of FDA regulated products;
- counterfeit tobacco.
- CBER – 2%
- CFSAN – 19%
- CDRH – 9%
- CVM – 2%
- CDER – 68%
- CTP – <1%

Origin of Cases

- FDA Centers & ORA
- OCI's Proactive Initiatives, Informants, Spin-offs from other cases, etc.
- Foreign & Domestic Law Enforcement
- Intelligence Agencies
- General Public
- Regulated Industry

OCI – Historical statistics

- Criminal cases: 8812
- Arrests: 6925
- Convictions: 5783

- Fines and restitutions: over \$ 21 billion
- Forfeiture actions: over \$5 billion since 2006

## Counterfeit and substandard drugs

FY (Financial Year) 2008 through FY 2012

- Cases opened: 455
- Number of arrests: 395
- Number of convictions: 376
- Total amount of fines: over \$7 million
- Total amount of restitutions: over \$178.1 million

FY 2013

- Cases opened: 437
- Number of arrests: 204
- Number of convictions: 182
- Total amount of fines: over \$900 million
- Total amount of restitutions: over \$800 million

FY 2014 (up to June 16, 2014)

- Cases opened: 133
- Number of arrests: 157
- Number of convictions: 107
- Total amount of fines: over \$700 million
- Total amount of restitutions: over \$ 1billion

## Around the Globe

Why are OCGs involved in manufacturing/distributing counterfeits?

- High margins
- Difficult to detect
- Complex supply chain structure
- Favorable risk to benefit analysis
- Demand
- Consumers ignorant to involved risks

## Supply Chain – Methods of Distribution

- Direct to Consumer – Typically facilitated by the internet Postal Facilities used in Distribution
- Physician administered – Also facilitated by the internet Postal Facilities used in Distribution
- Drug Diversion – Diverters/Counterfeiters use same Network(s) to introduce counterfeit/adulterated/diverted product into legitimate supply chain



# Interventions in shutting down illegal websites: activities and procedures in the European countries

## SPAIN

Manuel Ibarra Lorente, Agency of Medicines and Medical Devices – AEMPS (ES)

### Current scenario: Spain

Data on B2C sales show a sustained growth in Spain: from 15,2 M customers in 2012 to 17,2 M in 2013, with an average expenditure of 848€. We expect also C2C sales to increase. Access from mobile devices and tablets shows a sensible growth. So far, medicinal products are not a significant percentage of total sales in Spain. The situation may change and foreseeably increase - both legal and illegal - after entry into force of logo and development of legal internet pharmacies. Soon the need for mechanisms and resources for enforcement and surveillance on the (proper/improper) use of logo and Article 85c of the Directive 2001/83/CE will occur, also in eventual intracommunity trade.

### Investigational approach

The number of investigated cases and procedures initiated increases every year:

	2009	2010	2011	2012	2013	2014
Websites investigated	81	88	125	214	225	350

Starting point of investigations includes:

- Complaints/reports from individuals/professional bodies or companies.
- Searches for known adulterated or rogue products (e.g after alerts).
- “Seasonal” products or products of current interest (e.g flu products).

An information gathering phase follows through open source intelligence, non specialized software, record keeping and web trafficking data, used to prioritize cases.

### Legal mechanisms for taking action

AEMPS is, by law (national implementation of Directive 2000/31/CE and e-commerce directive), the com-

petent authority for market surveillance and control of medicinal products, empowered to take action directly against web pages using of all available legal resources (recent amendment of Penal Code after Medicrime Convention).

Interventions in shutting down illegal websites ideally require:

- the procedures are initially addressed to webpage registry holder and should include the publication of the notification in the Official Journal, if the registry holder is not reachable;
- once an official decision is adopted, cooperation of internet service providers is sought, both hosting service providers and network access providers, to block access to websites located outside of Spain;
- the collaboration of country top-level domain organization (RED.ES) is expected, but if information provided when registering the webpage is false, rules of procedure enables RED.ES to cancel the domain name;
- there is an initial “amicable” request when the address of web page holder is known and in case of minor infringements;
- the request can be addressed also to C2C platforms, such as eBay and, Milanuncios.com.

### Conclusions

The possibility to act under administrative procedures is an advantage. The overwhelming number of potential targets requires prioritization, resources and procedures for case evaluation and risk-analysis.

Frequently holders and hosting are located out of our jurisdiction. Cooperation with network access providers (blockade of access to webpages) should be fostered.

Risks arising from differences in legislation among MS, need for cooperation too.

## Medicines sales over the internet: the new Legislation in Portugal

Directive 2011/62/EU was published on 8 June 2011, amending Directive 2001/83/EC relating to medicinal products for human use, as regards to the prevention of the entry into the legal supply chain of falsified medicinal products.

Decree-Law no. 128/2013 was published 5 September and transposed into the Portuguese legal framework the new rules that establish the requirements for medicines sales at a distance over the internet.

## Medicines sales over the internet: Portuguese case

a. Only Authorised Pharmacies & Nonprescription Medicines Stores are allowed to supply at distance medicinal products to the public.

b. Requirements:

- **b.1 INFARMED, I.P. notification, minimal information:**
  - » i. **Beginning of medicines selling at distance via Internet (Date);**
  - » ii. **The website address used for that purpose;**
  - » iii. **Classification of medicinal products sold at a distance via Internet.**
- **b.2 Information placed on Online Pharmacy Website, minimal information:**
  - » i. **information requirements set out in Directive on electronic commerce;**
  - » ii. **INFARMED, I.P. contact and hyperlink to the website;**
  - » iii. **Common Logo clearly displayed on every page of the website that will link to the list of authorised websites.**

»

- **b.3 Records of all medicines sold over the Internet, with the following information:**
  - » i. **Country of destination;**
  - » ii. **Quantities;**
  - » iii. **Name of medicines;**
  - » iv. **Date of transaction;**
  - » v. **Medical prescription;**
- **b.4 Comply with the Directive 2011/24/ EU on the application of patients' rights in cross-border healthcare, regarding the recognition of prescriptions;**
- **c. Medicinal products have to comply with the national legislation of the Member State destination.**

## Medicines sales over the internet: National example

How?

- A consumer submit a request to the Pharmacy/ Nonprescription Medicines Store by the website, e-mail, phone or fax.
- Home delivery should be done under the supervision of a pharmacist or pharmacy technician.
- Who delivers the product should provide the necessary information for the correct use of medication provided.

Pharmacies that wish to deliver at customers' home, are required to deliver on all neighboring municipalities?

- No. The pharmacy can select which municipalities where this service will take place.

Can a pharmacy send medicines by courier or messenger?

- No. Portuguese law states that all medicinal products should be delivered to the address, respecting the supervision standards (avoid contamination; kept in safe conditions..).

## Medicines sales over the internet: Portuguese Logo



PORTUGAL (PT)

On 24 June 2014 the European Commission adopted the new Common Logo through the [implementing Regulation 699/2014](#).

Member States have one year from this date to ensure that the provisions on the common logo are applied. Therefore,

by mid-2015, all online pharmacies or retailers legally operating in the EU should display the logo.

The logo links to the website of INFARMED, I.P., to the list of all national pharmacies authorized online.

Either the Logo is going to be provided upon request to the entities, or on INFARMED initiative, is still in discussion.

## Interventions in shutting down illegal websites: Portuguese case

Infarmed I.P. has no enforcement powers and the shutting down of illegal websites can not be made by this institute. This possibility is not provided in any legislation, Infarmed only supervises.

The enforcement authorities are involved only if asked by INFARMED IP only if a product endangers human body or life, since only these circumstances are crimes under Portuguese law.

To take down an illegal medicines website is need a decision from a court of justice; after receiving a formal notification from court the site owner should take down the site.

In almost every cases of illegal websites it is not possible to identify the owner of the site. In such cases it is not possible to file for a process in court and apply the respective sanction.

However, in case of medicines advertised in “sales” websites, by individual citizens (without the site owner’s responsibility), it has been opted the following strategy: notification of site owner to remove the illegal placed advertisement; this request has been heeded and respected by them.

In case of a specific website selling illegal medicines, where the notification was not fulfilled, it is possible to resort to the ICANN (Internet Corporation for Assigned Names and Numbers), for shutting down the website. So far, any request was made to this Entity for closure of sites.

## Current situation

Infarmed has never taken down itself any illegal medicines website.

Notifications have been sent by Infarmed to “sales” websites owners requesting (with success) to remove ads posted by individual citizens.

## Medicines sales over the internet: Weaknesses / Challenges

- Risk of website duplication;
- risk of reproducing the common logo & the link to the National Authority list;
- medicines purchased by distributors, in another Member State may be unknown in this country;
- unfamiliarity with the packaging of other countries;
- transport conditions – storage conditions.

# Session two

## The database of online pharmacies

Ade Cheek, LegitScript (US)

Statistics show that at anyone time there are somewhere between 35,000 - 50,000 active internet Pharmacies worldwide. These statistics do not take into account the thousands of illicit dietary supplements and psychoactive substances such as Flakka, which is making headlines globally. 95%-97% of these websites are operating illegally and without collaboration such as Fakeshare and through companies such as LegitScript, there is little indication to which websites are legitimate and which are rogue.

How can internet users, search engines, payment processors, e-commerce platforms and others know which ones are legitimate and which ones are rogue? It is needed a collective effort to make sense of the online healthcare market, organizing the world's healthcare websites and merchants by legitimacy, sold products and (where applicable) organization or criminal network.

LegitScript analysed data for Fakeshare and the Database of Online Pharmacies and produced a sample spreadsheet. For the sample data three Fakeshare countries were selected, Italy, Spain and Portugal and the websites were reviewed using the primary language of the content. 141 online pharmacies in total were designated rogue or illegal, that is by selling prescription only medication without the need of a prescription, selling unlicensed or unapproved medication or breaching applicable laws in the selected countries. When broken down further the statistics show that 54 were from Italy, 50 from Spain and 37 from Portugal.

LegitScript provides some **examples of websites** and pose some rhetorical questions. In this example the website is clearly selling Steroids:

- 3 Fakeshare Countries Selected - Italy, Spain, Portugal;
- 141 Rogue e-pharmacies in total;
- Breakdown by Country;
- Italy 54;

- Spain 50;
- Portugal 37;
- Websites selected by primary language;
- Snapshot in time.

But the same website is also selling unlicensed erectile dysfunction medication. How would members countries report this website? The information gathered by the database needs to be uniform across all countries and if this is not possible then all countries would need to agree that the information can be adapted to suit their specific needs when this option is available, as it is in this example.



This website is possibly breaching applicable law in Italy. But a further research shows that the offence is possibly not complete in the view of analysts outside of Italy. This shows the importance of communication between member countries to ensure that correct messages are sent.

This Criminal Network behind this website normally target German or Austrian citizens, but this is clearly in Italian. Information from the website itself states that it is based in Spain. Whose jurisdiction would this fall under? This slide highlights the importance of collaboration between member countries and private companies to ensure that multi jurisdictional websites are still targeted by one or more country and do not fall by the wayside.

# Surveys as scientific roadmap for communication activities

Claudio Barbaranelli, University of Rome "Sapienza"

## Fakeshare (I) – Survey

Online survey of Fakeshare (I) project has been conducted for investigating behavioral and psychological factors linked to online purchasing of medicines. The theoretical framework was provided by the Theory of Planned Behavior and by psychological models that addressed the study of risk perception and of risk propensity.

Aims of the survey were twofold:

- to assess the prevalence of purchasing of the pharmaceutical online products in three European Countries: **Italy, Spain, Portugal**;
- to investigate the impact of different psychological and socio-demographic variables on the **future intention of purchasing** pharmaceutical online products.

Three samples were considered in the three countries included in the research.

- Italian sample consisted of 1,000 participants, aged from 18 to 84 years ( $M = 40$   $SD = 13$ ), 54% males;
- Spanish sample consisted of 1,255 participants, aged from 18 to 74 years ( $M = 38$ ,  $SD = 12$ ), 50% males;
- Portuguese sample consisted of 1,000 participants, aged from 18 to 74 years ( $M = 37$ ;  $SD = 14$ ), 30% males.

Online questionnaires were used in order to measure the constructs of interest. A questionnaire consisting of about 60 items has been administered to each participant. The questionnaire was composed by different items investigating different domains. Data were collected in Italy in January 2014, in Spain in April

Q6. It is becoming increasingly widespread in recent years the habit of buying online even medicines. Are you aware of this?			
	ITA	SPA	POR
Yes	72,2	44,9	84,4
No	27,4	54,0	15,3
Prefer not to answer	,4	1,1	,3

In Spain it is much smaller the percentage of people who know about the possibility of buying medicines online

2014 and in Portugal in May 2014. A quota sampling strategy, balanced by geographic area, age and gender was used in Italy and in Spain.

Q035 Are you aware of initiatives and events aimed at raising public awareness on the risks of buying medicines online?			
	ITA	SPA	POR
Yes	20,9	23,4	25,1
No	76,9	73,5	74,2
Prefer not to answer	2,2	3,1	,7

Participants who were acquainted of initiatives and events aimed at raising public awareness on the risks of buying medicines online were much similar in the three countries

## Have you ever purchased medicines online for you or for somebody else? (past behavior)

Participants who have purchased medicines online were 20% in Italy, 9% in Spain, and 2.5% in Portugal (this lower percentage in Portugal is probably due to the sampling procedures).

Q019 What kind of medicines or other pharmaceutical products, including the following, did you happen to buy online for yourself or for someone else?			
	ITA	SPA	POR
1) Medicines for erectile dysfunctions	2,4	0,4	0,2
2) Medicines for quitting smoking	3,5	1,5	0,1
3) Medicines for weight loss	5,4	2	1,4
4) Medicines for the treatment of cholesterol	3,2	0,7	0,4
5) Anti-depressant	1,9	0,7	0,1
6) Medicines against flu	5,3	1,7	0,3
7) Medicines against cancer	0,5	0,2	0,1
8) Medicines for chronic pain	4,5	0,6	0,5
9) Birth control pills	1,4	0,5	0,1
10) None of the previous	3,6	3,3	0
11) I do not know, no answer	0,8	0,2	0

**Q012** Regardless of your buying habits, in general, how do you judge the possibility of purchasing medicines directly from your home computer or through any other internet connection? (Attitude)

	ITA	SPA	POR
1) Not at all positively (-)	20,3	29,6	37,4
2) Little positively (-)	19,2	19,5	21,3
3) Neither positively nor negatively	23,5	26,1	15,6
4) Quite positively (+)	25,6	16,2	16,5
5) Very positively (+)	10,6	7,3	7,0
6) I prefer not to answer	,8	1,4	2,2

Evaluations on the positive latitude (+) are the highest in Italy (36% versus 23% in Spain and Portugal). At the same time, scores on the negative latitude (-) are lower in Italy (40%) than in Spain (49%) and Portugal (59%)

**Q022** And from your point of view, how much safe for your health do you consider purchasing medicines online?

	ITA	SPA	POR
1) Very much	4,9	1,7	1,5
2) Quite	25,4	13,9	9,8
3) Little	32,8	32,2	38,1
4) Not at all	29,9	40,1	39,4
5) I do not know, I prefer not to answer	7,1	12,2	11,2

**Comment:** It is higher the% of Italians that consider the purchase of medicines online very or fairly safe for health (30%) compared to that in Spain (15%) and in Portugal (11%)

## Effects of Psychological Variables

Conducted regression analysis considering Intention of Future purchase as a dependent variable, evidenced the following significant predictors statistically.

	Italy	Spain	Portugal
Attitude	,175	,236	,167
Past Behavior	,198	,217	,175
Safety	,202	,197	,196
Subjective Norm	,342	,303	,234
Perceived Control	,076	Ns	Ns
Propensity to Risk	,062	Ns	Ns
% of explained variance	67,4	57,8	37,8

## Take home message

- Knowledge of prevention initiatives and information is still too low (around 20-25%) in all three countries: awareness must be increased with communication campaigns on different media (the internet, TV, newspapers, wallpapers).
- Purchasing pharmaceutical online products is a behavior guided by rational beliefs mainly that can be changed, not by impulsive tendencies that are largely irrational.
- Approval of others, attitude and perception of safety are the most important variables in explaining online purchase, to be influenced with communication campaigns aimed at reducing future purchase.
- Communicating that medicines purchased online can be dangerous for health may lower the perception of this behavior as safe, and lead to a negative attitude toward it, and to the expectation that it will not be approved by relevant others.
- Capitalize on the role that significant others may have on the purchaser: these are people whose opinion is important for the purchaser, people who are considered as trustworthy when health and health related behaviors are an issue.
- Physicians, pharmacists, relatives are fundamental vectors for influencing future purchasing behaviors, and eventually reduce it.



# Awareness-raising initiatives and communication tools for consumers

Gianpaolo Derossi, Italian Medicines Agency – AIFA

Claudia Fedele, Italian Medicines Agency – AIFA

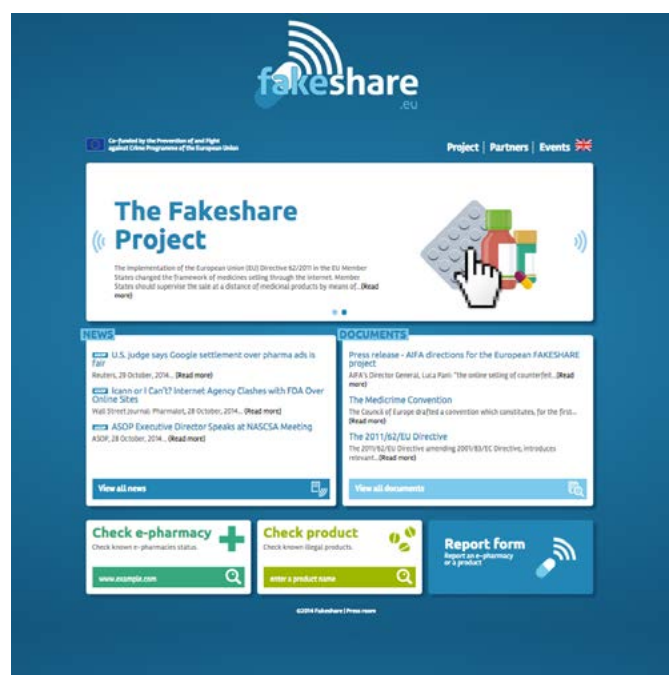
The Fakeshare Project has the goal of ensuring a co-ordination in investigation activities targeting the illegal online distribution of medicines, through an efficient sharing of information, allowing the development of coordinated initiatives against dangerous web sites.

The Project's core is a web platform to be shared between authorities of different countries, in order to manage data on illegal e-pharmacies operating from servers located worldwide and targeting the EU market.

The Project also aims at developing a proper risk communication to the general public in order to sensitize it on the threats connected to the online trade of falsified medicinal products.

## The website

The Fakeshare communication staff designed and developed the project website in order to provide the general public with information and tools to increase awareness and understanding on the purchase of medicinal products on the internet.



The website offers news, documents and in-depth analysis related to the sell at a distance of medicinal products. In addition it hosts two search modules, which let the users to check whether a product or an e-pharmacy is legal, and a reporting form that can be used to report either a suspected product or a suspected e-pharmacy.

## The Fakeshare communication, information and dissemination activities

The collaborative approach, which brings together the complementary skills of the co-beneficiaries and the partners of Fakeshare, aims at improving the quality and quantity of information, dissemination and communication services that raise awareness on the risks connected to falsified medicinal products and to the purchase of online medicines on illegal e-pharmacies or other illegal websites.

## Awareness-raising strategic initiatives

### Communication plan: objectives

#### Network building

- Building partnership and strengthening the network that should be tough and long-lasting.
- Offering to partners communication materials suitable to be used by institutions' newsletters, websites and waiting rooms for branding and advertising.

#### Dissemination activities

- Raising awareness on the risks connected to falsified medicinal products and to the purchase of online medicines on illegal e-pharmacies or other illegal websites.
- Organising and clarifying key information.
- Boosting the use of Fakeshare website by all targets.



## Communication plan: target groups

### Primary target:

- consumers associations
- patients associations
- medical associations
- medicine manufacturers associations
- professional organizations (pharmacists', the pharmaceutical sector professionals', etc.)
- international, national and MS enforcement authorities (police, customs, etc.)

Consumers and patients are a primary target that will be reached indirectly through consumers', patients' and medical's associations.

### Secondary target:

- international and national organizations dealing with counterfeit medicines (e.g. regulatory agencies)
- judicial authorities, legal practitioners
- universities, for all disciplines potentially interested in other public officials
- mass media (general and specialist press)

## Communication plan: the message

The message for consumers', patients' and medical associations is built around the following concepts:

- Buying medicine online is not a game, is not positive, is not easy, is not a simple minded thing! Use your mind!
- Ask to your physician and your pharmacist before buying! Buying medicines online is risky and might be unsafe for health!
- Be informed on legal purchase on the internet!

### Medicines online:

do you really know what you are buying?

### Medicines online:

do you know what your patients buy?

The message for professional organizations, medicine manufacturers associations and enforcement authorities is built around these concepts:

- rules on how to open an authorized e-pharmacy;
- tools to share information on crimes linked to the online sale of medical products.

### Illegal e-pharmacies:

a damage for patients and for you

## The "call for partnership"

At present, partnership building is the main communication activity. It aims at involving all identified targets, creating a network or strengthening the existing one and offering to partners communication materials (web banners, posters and news), suitable to be used on institutional newsletters, websites and waiting rooms for branding and advertising.



## The dissemination activities

A video clip will be disseminated at the closure of the project: it stresses the basic messages and emphasizes



Consumers' and patients' associations



Physicians' associations

the risky aspect of buying medicines online, organising and clarifying key information and boosting the use of Fakeshare website by all the targets. It will be available in four languages (English, Italian, Spanish and Portuguese) and distributed online under copyright free licence.



The video clip is distributed under copyright free licence.

You can join fakeshare.eu by sharing the video on your channels: participate in the dissemination activities by answering to the call for partnership!



Professional organizations and medicine manufacturers' associations

**Do you know enough  
to take the risk?**

# Evolution of the Fakeshare project: Fakeshare II

Domenico Di Giorgio, Italian Medicines Agency – AIFA

Fakeshare II may be considered as a natural evolution of the pilot phase represented by Fakeshare (I), the project approved in 2013, in order to create a shared restricted web space for European Authorities (involved in combating pharmaceutical crime, especially on the internet), to share in it the information about investigation on pharmacrime and illegal e-pharmacies according to safe and established procedures, being the illegal e-pharmacies the main door for counterfeit medicines to the EU market.

In order to achieve Fakeshare's (I) objectives, the website Fakeshare.eu was created which is divided into two areas: a restricted web space for sharing investigation documents, accessible to the Institutions involved in the project, plus an open area periodically updated with information for the general public (e.g. black list of illegal e-pharmacies, communication initiatives/campaigns).

Fakeshare II, that will avail itself of the same website and platform of Fakeshare (I), aims at broadening and strengthening the coordination in investigation activities, enforcing police forces initiatives targeting the illegal web distribution of medicines started through Fakeshare (I), by extending the scope of Fakeshare to the pharmacrime in general and to the new emerging illegal distribution channels, EG social networks, and enlarging the cooperation to MS in which there is a history of regulating (and investigating) e-pharmacies, as UK, and to non EU MS bordering the Union, such as Serbia, with the following objectives:

- ❶ data sharing about investigations;
- ❷ data analysis;
- ❸ development of expertise and new investigation methods;
- ❹ dissemination and feedback.

The main purpose of Fakeshare II is the efficient sharing of information among all the involved authorities against the pharmacrime in general, with a specific focus on investigations targeting internet and social networks distribution of illegal medicines.

The proposal considers the involvement of health authorities, police forces, universities and private stakeholders, as for the following:

- AIFA (Italian drug regulatory authority – DRA): coordination, data sharing, follow up activities (EG guidelines /project development), IT system managing.
- MHRA (UK DRA): data sharing, follow up activities (EG guidelines /project development)
- AEMPS (Spanish DRA): data sharing, follow up activities.
- INFARMED (Portuguese DRA): data sharing, follow up activities.
- Trento University (Italy), faculty of Criminology: data analysis (criminal profiles), guidelines development.
- Rome University (Italy), faculty of Psychology: data analysis (customer profiles, evaluation of risk communication, messages), development of guidelines.
- Italian Ministry of Economic Development: risk communication model campaigns development.
- PSI (USA/UK private enforcement agency dealing with pharmacrime): data analysis, data sharing, evaluation of guidelines and projects.
- NAS (Italian health focused police force): evaluation of guidelines and projects.
- Guardia Civil (Spanish health focused police force): evaluation of guidelines and projects.
- ASOP - Association for Safe Online Pharmacies (USA/EU association of actors from private and public environments, ASOP EU, Google, LegitScript, American Pharmacists Associations, dealing with communication activities about “safe online pharmacies”)
- IFPMA (International Federation of Pharmaceutical Manufacturers & Associations): risk communication campaigns development, evaluation and promotion.

The outcomes of this project could also be useful in the evaluation of the impact of new regulation of the e-pharmacies (EU Dir. 2011/62), even with respect to the possible implementation of specific IT tools, like the software that AIFA and the University of Trento are developing as for the FAKECARE Finec project.

# Annexes

# Annex A. Agenda

## SESSION I

**9.00**

Registration

**9.30**

**Welcome address**

- Luca Pani, Director General of the Italian Medicines Agency (AIFA). Italy

**9.45**

**Fighting counterfeiting: the contribution of the pharmaceutical industry**

- Massimo Scaccabarozzi, President of Farmindustria. Italy

**10.15**

**Sale of medicines online: an introduction**

- Domenico Di Giorgio, Italian Medicines Agency (AIFA). Italy

**10.30**

**E-commerce and social networks: a scenario in constant evolution**

- Lynda Scammell, Medicines and Healthcare Products Regulatory Agency (MHRA). UK
- Enrico Maccallini, Ministry of Economic Development. Italy

**11.00**

**Regulatory aspects: future scenarios in selling medicines online**

- Giampiero Camera, Ministry of Health. Italy

**11.30 - Coffee Break**

**11.45**

**Illegal products and health risks**

- Patrizia Hrelia, University of Bologna. Italy

**12.15**

**Actions against pharmaceutical crime at the international level**

- Christian Tournié, Office central de lutte contre les atteintes à l'environnement et à la santé publique (OCLAESP). France

**12.35**

**Investigations on cybercrime: recent case studies**

- Patrick Holland, Food and Drug Administration – FDA. US

**13.05**

**Interventions in shutting down illegal websites: activities and procedures in the European countries**

*Panel discussion*

- Domenico Di Giorgio, Italian Medicines Agency (AIFA). Italy
- Manuel Ibarra Lorente, Agency of Medicines and Medical Devices (AEMPS). Spain
- João Cristovão Martins, National Authority of Medicines and Health Products (INFARMED I.P.). Portugal
- Stephen Truick, Medicines and Healthcare Products Regulatory Agency (MHRA). UK

**13.30 - Lunch**

## SESSION II

**14.30**

**The database of online pharmacies**

- Domenico Di Giorgio, Italian Medicines Agency (AIFA). Italy
- Ade Cheek, LegitScript. US
- Gabriele Falcioni, Italian Medicines Agency (AIFA). Italy

**15.00**

**Surveys as scientific roadmap for communication activities**

- Claudio Barbaranelli, University of Rome “Sapienza”. Italy

**15.15**

**Awareness-raising initiatives and communication tools for consumers**

- Gianpaolo Derossi, Italian Medicines Agency (AIFA). Italy
- Claudia Fedele, Italian Medicines Agency (AIFA). Italy

**15.30**

**Evolution of the project Fakeshare: Fakeshare II**

- Domenico Di Giorgio, Italian Medicines Agency (AIFA). Italy

**16.00 - Discussion**

## Annex B. List of attendants

FIRST NAME	FIRST NAME	FIRST NAME
Adriani	Antonio	Merck
Allievi	Enrico	Assosalute
Angelini	Renato	Aegate Italia
Angelone	Sara	Ministero della Salute
Angiello	Gabriele	AIFA
Arieli	Mickey	Ministry of Health (Israel)
Barbaranelli	Claudio	Sapienza
Barbieri	Gennaro	Quotidiano Sanità
Bartoloni	Bruno	Generale
Bausano	Daniela	Aegate Italia
Bentolilla	Sandra	AEMPS
Berno	Riccardo	Federfarma
Bonati	Simonetta	Ministero della Salute
Brasola	Lindio	ROCHE
Burman	Martin	Medical Products Agency Sweden
Camera	Giampiero	Ministero della Salute
Cappelletti	Gianni Antonio	Novartis Farma S.p.A.
Carletti	Damon	AIFA
Casuccio	Claudio	AIFA
Cattaneo	Maria Grazia	SIFO
Cauduro	Andrea	UniTrento
Cavalieri	Valentina	Dogane
Cesta	Emanuele	AIFA
Cheek	Ade	LegiScript
Chiavoni	Marcello	AIFA
Cingolani	Francesca	Dogane
Cocito	Paola	ASL Roma A
Coltorti	Massimiliano	Merck
D'Aliesio	Eleonora	Dogane
Dalfrà	Stefania	Ministero della Salute
Damiani	Alessandro	Maresciallo Guardia di Finanza
De Jure	Mila	Assoram
De Lorenzo	Francesco	Favo



FIRST NAME	FIRST NAME	FIRST NAME
De Marin	Marco	Lundbeck
De Meo	Gianluca	Tenente GDF
De Simone	Mark	Aegate Italia
Derossi	Gianpaolo	
Di Giorgi	Valeria	Ministero della Salute
Di Giorgio	Domenico	AIFA
Di Maio	Andrea	Security Manager di Eli-Lilly
Di Muzio	Angelo	Federazione Erboristi Italiani - F.E.I.
Di Nicola	Andrea	UniTrento
Di Palma	Andrea	Adiconsum
Di Paola	Graziano	Cultura Lavoro
Empler	Gianluca	Servier
Escribano Romero	Belén	AEMPS
Esperti	Giancarlo	FEDERFARMA SERVIZI
Esposito	Federico	Novartis Farma S.p.A.
Falcioni	Gabriele	AIFA
Fanti	Marco	Tenente Colonnello GDF
Fantozzi	Franco	BMS
Fedele	Claudia	MISE
Felsani	Edoardo M.	Assoram
Fernández Muelas	Ana	AEMPS
Ferrucci	Sara	AIFA
Francesca	Lulli	Movimento consumatori
Galli	Carlo	Teva Italia
Gea	Carlos	Agencia Española de Protección de la Salud en el Deporte
Gemma	Rossella	Doctor33
Giacomelli		
Giordano	Pietro	Adiconsum
Giudice	Giuseppe	Merck
González-Cebrián Toba	Rosa	AEMPS
Gramazio	Marta	AIFA
Heinz	Kobelt	FAEPC
Henriques	Joana	INFARMED
Holland	Patrick	FDA
Hrelia	Patrizia	SITOX
Ibarra	Manuel	AEMPS

FIRST NAME	FIRST NAME	FIRST NAME
Isles	Mike	ASOP
Klein	Andrea	Akran Intellectual Property ltd
Lalam	Nacer (FR)	French National Institute for Advanced Studies in Security and Justice (INHESJ)
Lery	François	
Longoni	Cristina	GSK
Lupo	Monica	Responsabile Area Legale Federfarma
Maccallini	Enrico	MISE
Malloni	Pier David	ANSA
Manella	Gabriele	Università di Bologna (progetto audit)
Manuela	Lepre	Kedrion
Maraglino	Francesco	Ministero della salute
Margheriti	Lorenzo	Farmaceutico militare (sotto colonnello)
Marianeschi	Maria Luce	Dogane
Martini	Elisa	UniTrento
Martins	João Cristovão	INFARMED
Martorelli	Alina	MISE
Mazzilli	Edoardo	Dogane
Medeiros	Susana	INFARMED
Melchionna	Andrea	Farmindustria
Messina	Giuseppe	Consigliere AFI
Milioni	Stefano	Italpress
Morelli	Antonio	Farmindustria Stampa
Moresca	Salvatore	Capitano Guardia di Finanza
Motta	Cinzia	AMGEN
Neri	Raffaella	MISE
Oliva	Concettina	AIFA
Orlanducci	Grazia	Ministero della Salute
Ottiglio	Mario	FIGHT THE FAKES
Pace	Deborah	AMGEN
Panci	Chiara	AIFA
Pani	Marcello	SIFO
Panicale	Serena	AIFA
Paoletti	Silvia	Lilly
Paparella	Anna Maria	Takeda Italia
Pasini	Antonio	NAS
Passarinho	Joel	INFARMED



FIRST NAME	FIRST NAME	FIRST NAME
Pav	Pietro	NAS
Pedretti	Marta	
Pieretti	Giovanni	Università di Bologna (progetto audit)
Podio Guidugli	Sara	Sapienza
Prost	Chiara	AIFA
Raschini	Riccardo	SANOFI
Riccio	Paola	MiSE
Rinaldi	Claudia	Associazione AIP
Roetenberg	Maarten	Utrecht University - Dina Siegel
Rondinelli	Angela	Adiconsum
Rossi	Rita	CNR
Santi	Luca	Università Sapienza
Santinelli	Camilla	AIFA
Scaccabarozzi	Massimo	Presidente Farindustria
Scammel	Lynda	MHRA
Scotti	Silvestro	Finger
Scrofina	Giuseppe	ADF
Serapicos	Vania	INFARMED
Silveira	Stephanie	INFARMED
Sorrone	Gaia	Assogenerici
Sparaccio	Sergio	ADF
Tchangmena B.	Odile	AIFA
Tournié	Christian	OCLAESP
Truick	Stephen (UK)	MHRA
Tulimiero	Romina	Assogenerici
Ugolini	Andrea	Medico
Ugolini	Giuseppe	Medico
Valentini	Vincenzo	DIRIGENTE MEDICO USMAF ROMA-FIUMICINO
Valero Griñan	Mar	AEMPS
Valvo	Luisa	ISS
Vecchio	Sarah	SITOX
Veloci	Stefania	Lilly
Vescovi	Cecilia	Ministero della Salute
Vignetti	Monica	
Zambito	Valentina	AIFA
Zelic	Pavle	ALIMS

## Annex C. Speakers short curriculum vitae

### Claudio Barbaranelli

Claudio Barbaranelli is full professor of methodology at the department of psychology, at La Sapienza University of Rome. His main interests are in measurement, structural equation modelling, personality, work-related stress, social cognitive theory, problem gambling.

### Giampiero Camera

Director Office Competence for pharmaceutical of the Ministry of Health. Within of his duties, he deals with drafting of regulatory measures of different nature in the field of medicines and pharmacies. He collaborated in the preparation of the texts of decrees of transposition of several European Union directives. He provides with regulatory interpretations for the Ministry in the pharmaceutical context.

Member of several working groups set up at the Ministry in the matters of the pharmaceutical sector. Member nominated by the Ministry of Health of the conference services instituted by the Italian Medicines Agency for safety of medicines offered to the public at a distance through the services of the information society and the national task force anti-fake. Representative of the Ministry of Scientific Technical Committee by the Italian Medicines Agency.

Author of several publications in the area of health legislation.

### Ade Cheek

Adrian has spent 14 years in Law Enforcement, which included working in the Police Central e-Crime Unit of the Metropolitan Police in London as the Detective in charge of internet Governance and more recently with the National Cyber Crime Unit of the National Crime Agency as the lead investigator on the Infrastructure Abuse Team. Adrian has an extensive background relating to investigating websites and online criminal networks, not only within the pharmaceutical field, but counterfeit goods and malware to name but a few.

Adrian is now Director of Global Partnerships with Legitscript and is heading up the recently opened European Office in Dublin, Ireland.

### Gianpaolo Derossi

Communication Technician of the Fakeshare project, he has been in charge of designing the communication of the project and coordinating the editorial and publication activities.

He previously worked as communication officer and Assistant to the Director at Ethnobarometer, an international NGO dealing with religious and national minorities in Europe and organised as permanent research network, collaborating with local research institutions and/or individual experts based in 12 European countries, as well as Turkey, Tunisia, Algeria, Jordan and Saudi Arabia. He was in charge of coordinating research and publication activities and of organising and managing the events.

He has a background both in international relations and Middle Eastern studies, and communication and art direction. He has expertise in project management and workflow coordination.

He is also a freelance graphic designer and illustrator, with expertise in page layouts and digital publishing (ePub). He collaborates with publishers, editorial and communication agencies, public and private bodies and private clients. He is co-author of one of the first manuals in Italian language on digital publishing, published in 2012.

### Domenico Di Giorgio

Dr. Domenico Di Giorgio, Ph.D., is Head of the Product Quality and Counterfeiting Office at the Italian Medicines Agency (AIFA). Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention. He is the editor of the following books: “Counterfeit medicines: facts and case studies” (CoE/EDQM, 2009, 2011), The IMPACT Handbook (IMPACT/AIFA, 2011), and of the related publications series about investigators training and risk communication. He chairs the EDQM/Council of Europe Committees dealing with pharmaceutical products and counterfeiting, and coordinates Fakeshare (2013), project of shared IT intelligence co-funded by the Prevention of and Fight against Crime Programme of the European Union.

## Gabriele Falcioni

Webmaster of the Fakeshare project. He's a freelance software architect and developer with extensive experience into the development of applications for embedded systems (including operating system design and implementation, computer graphics and wireless sensor networks). He also developed a lot of desktop and internet applications, and built his own development tools, like compilers and other code processors.

He is also a technical and creative writer. Besides novels and short stories, he contributed chapters to an [academic book](#) for industrial designers, discussing portable power sources, wireless technologies and wearable sensors, such as accelerometers, thermometers, galvanometers (for electrodermal activity) and photoplethysmographers.

## Claudia Fedele

Graduated in Political science and specialized in European Union right, she is an expert in institutional and public communication (15 years of working experience), member of the Italian association of public communicators – ID n. 1985.

She designs and realizes marketing and communication plans and integrated communication campaigns for European projects or projects cofounded by European structural funds. She is often in charge of: expenditures accountability, budget oversight and operative coordination of working groups of European projects, but also writing texts and news, designing websites, publications and other communication outputs.

She cooperates in writing technical and economical tenders in several areas: local development policies, social policies, structural funds, European Union right and policies, etc.

Senior project manager - Senior account – Marketing and communication plans designer

In Fakeshare project she was in charge of the planning and the development of the information, communication and dissemination activities.

## Patrick Holland

Patrick Holland is currently Office of Criminal Investigations (OCI) Head of Desk of the Liaison Bureau at Europol where he is responsible for coordinating criminal investigative operations, within the jurisdiction of the FDA, involving the United States and the European Union.

Prior to this, Patrick served as the youngest serving Special Agent in Charge of OCI's Kansas City Field Office responsible for coordinating and supervising the day-to-day operations in a geographic area covering 11 states.

In 2007 Patrick was Assistant Special Agent in Charge of OCI's Metro Washington Field Office supervising 9 special agents.

In 1999, he transferred to the U.S. Food and Drug Administration's Office of Criminal Investigations, assigned to the Special Prosecution Staff, Metro Washington Field Office.

In 1997, Patrick was appointed as a Special Agent with the State Department's Office of Inspector General, conducting criminal investigations of allegations of waste, fraud, and abuse within the Department, largely conducted at U.S. missions and various facilities abroad, including Conakry, Maputo, Johannesburg, Oslo, Stockholm, Antwerp, and Mexico City.

Patrick's federal career began in 1995 as an Auditor with the State Department's Office of Inspector General auditing various programs and functions at numerous U.S. embassies and consulates, including Manila, Bangkok, Hong Kong, Athens, Lisbon, Budapest, Paris, Ankara, and Rome.

## Patrizia Hrelia

MS in Medicinal Chemistry (1981); Ph. D. in Cell Biology from the University of Bologna (1986). Visiting Assistant Professor (1987-1988), Adjunct Associate Professor (1991-2010) and Adjunct Professor (2011-2014) at the University of Texas Medical Branch, Galveston TX USA. She began her career as Adjunct Faculty (1988-1990) and then as Assistant Professor (1990-1997) at the University of Bologna. From 1998 to 2001 she was Associate Professor of Pharmacology and Toxicology. She was Director of the Postgraduate School in Toxicology (2003-2005) and head of the Department

of Pharmacology (2009-2012) at the University of Bologna.

She is currently Professor of Toxicology, School of Pharmacy (since 2001). She is an Eurotox Registered Toxicologist since 2001 whilst registered with the Italian Register of Toxicologists.

Prof. Hrelia actively collaborates with numerous international academic and government laboratories. She had published more than 150 papers in peer reviewed journals and book chapters. The task is to identify new preventive strategies for the reduction of risk factors associated to chronic degenerative diseases, such as cancer and neurodegeneration. The first contribution is the identification of critical biological targets and the understanding of the events with a pivotal role in cancer and the age-associated neuronal loss in neurodegenerative diseases. The search is toward active chemiopreventive and neuroprotective drugs that would prevent the progression of degenerative diseases, through the manipulation of endogenous cellular defence mechanisms by chemical inducers. Her name is associated with original and significant contribution to the development of new cellular and molecular approaches to detect and quantify the global cellular response to toxic stress, including measurements of apoptosis, specific metabolic capabilities and cell cycle effects, the activation of cellular death/survival biochemical pathways, and at developing methods based on biomarker analysis to improve assessment of human early biological response, susceptibility and risk. The research philosophy is a multidisciplinary approach to problems of preventive and translational medicine.

She is an active member of several national and international scientific Societies.

For her leading role in genetic and cellular toxicology and environmental toxicology, she has several committee responsibilities at national and local levels and has served on several Scientific Advisory Boards.

At the national level she served as President of the Italian Society of Toxicology. She is member of the working group on Contaminants of the Codex Alimentarius of the Italian Ministry of Agriculture.

### **Manuel Ibarra Lorente**

Manuel Ibarra, PharmD, PhD worked as a fellow researcher on pharmacology. He joined the Spanish

Medicines Agency (AEMPS) in competitive examination in 2005, working in the GMP inspection area and assisting as an expert in enforcement tasks. Nominated as an expert in the EMA, he regularly participates in GMP inspections for centrally-authorised products. He has also participated in other inspection programs at international level (EDQM, WHO). He attends as a national delegate to the Committee of Officials Meetings of PIC/S and EMA's GMDP- Inspection Working Group. He is the group leader in the enforcement area of AEMPS.

### **Enrico Maccallini**

Official at Ugo Bordoni's Foundation, a no-profit organization of the Ministry of Economic Development, seconded to the Directorate General for Combating Counterfeiting Italian Patent and Trademark Office, where he supports the legal department. He also supports the Director General for Institutional and external Relations.

From 2011 to 2012 he was Official at INVITALIA - Agenzia nazionale per l'attrazione degli investimenti e lo sviluppo d'impresa, seconded to the legal department of the Directorate General for Combating Counterfeiting Italian Patent and Trademark Office of the Ministry of Economic Development. He was previously lawyer in litigation and extra judicial civil law.

### **João Cristovão Martins**

Relevant expertise in Economics and Regulatory Affairs, being the current Director of Evaluation of Medicines Directorate, INFARMED, IP and Acting Director of Economic Evaluation, pricing and reimbursement Department INFARMED, IP.

Portuguese active member in International Committees: to discuss issues and challenges on pricing and reimbursement of medicines - Competent Authorities Network on Prices and Reimbursement (NCAPR); to plan and develop sustainable - European Network for Health Technology Assessment (EUnetHTA); to improve public health care practices, through specific programs and policies - Expert Committee on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH / PC) and to develop risk prevention management strategies - Experts on minimizing public health risks posed by counterfeit medical products (CD-P-PH / CMED).

## Massimo Scaccabarozzi

President and Chief Executive Officer of Janssen Italy and President of Farindustria.

Massimo Scaccabarozzi (Milan 1960) graduated in Pharmacy, married, with two children.

Hold positions of increasing responsibility in a pharmaceutical multinational.

Since 2001 he has been in Janssen Italy, which he hold position first as General Manager and then Managing Director. He has been President of IAPG (Italian American Pharmaceutical Group) for five years, group of Italian companies to American capital, component of Farindustria.

Foundation President Johnson & Johnson from 2001 to 2011, was re-elected Chairman of the Foundation in 2013.

He is President of Farindustria from June 2011 (office confirmed in 2013).

Member of the Committee and invited in the Permanent Council of Confindustria since June 2011.

Since 2011 he is member of the Board FIIM/IFPMA (International Federation of Enterprises and Associations of the drug).

## Lynda Scammell

Lynda works as the Senior Policy Adviser on the Enforcement Group of the Medicines and Healthcare Products Regulatory Agency (MHRA). She deals with all policy and legislative developments that affect the group and its operational activity.

Lynda is the MHRA's representative on the Council of Europe's Counterfeit Medicines Expert Working Group (C-Med) and has been involved in training events / awareness raising initiatives in the EU, Eastern Europe and Africa. She is part of the team responsible for the drafting of the Medicrime Convention from 2008 onwards. Currently, she is working with stakeholders on the implications of adopting the EU "Common Logo" for online suppliers of medicines in the UK and identifying risks and benefits.

## Christian Tournié

Christian Tournié is a special adviser at the OCLAESP where he was previously Head of the Intelligence Division. He has been involved in the implementation of national and international legal frameworks and strategies on Pharmaceutical Crime, notably in Central Europe, the Middle East and Africa.

He was a Seconded Expert within the Unit Against Organised Crime of the DG Justice and Home Affairs at the European Commission, notably in charge of policy and criminal law pertaining to fake pharmaceutical products. He actively collaborated to draft legal frameworks on crimes threatening public health such as the Medicrime Convention and the Falsified Medicine Directive. He was also involved within European bodies on strategies on cybercrime, to disrupt organised crime and in the implementation of measures to improve the effectiveness of financial investigations and proceeds of crime. He headed multi-disciplinary European working groups. He was deputy head of the "Europol and Organised Crime" Section at the Gendarmerie Directorate-General and was seconded to Europol (2004 – 2006). He headed the department of Criminal Investigation Academy for organised crime, economic crime, and cybercrime (1999 – 2004). He led successfully national and international criminal investigations.

Mr Tournié has initiated and led European training projects for law enforcement officers, magistrates and experts, in cooperation with the private sector as well. Within various Universities he lectures and/or he is in charge of programs related to Justice, Home Affairs, Information Technology and Public Health. He is a law graduate and holds a Master's degree in finance.

## Stephen Truick

Stephen Truick has worked as a police officer since 1989, and since August 2012, has been a Consultant Internet Infrastructure Manager for the MHRA, or Medical Regulator within the UK, to get internet infrastructure providers to suspend websites that are illegally abusing the system to sell pharmaceuticals or medicines. He is also a Director for Internet Infrastructure Investigation Ltd, where he works with brands and websites to protect online presences and ward off online threats.

**Fakeshare is a European project dealing with cooperation and intelligence against the online selling of falsified or illegal medicines through non authorized e-pharmacies or other resellers. Its aim is to develop web tools in order to facilitate the sharing of information among EU Member States and support the activities of the enforcement authorities.**





