fakeshare.eu

INTERNATIONAL CONFERENCE

OCTOBER 14, 2016
ROME, ITALY

Pharmaceutical crime:

FALSIFIED, ILLEGAL AND STOLEN MEDICINAL PRODUCTS

How is the scenario changing?

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Programme of the European Union

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Welcome

Mario Melazzini, Chairman of the Board – AIFA

It is my pleasure to welcome you to the Conference organized by AIFA in the framework of the European project Fakeshare II; since the early days of my mandate in AIFA I watched with great interest the initiatives aiming at fighting the so-called "pharmaceutical crime", carried out by the Agency in collaboration with other European Agencies, many of which participate today through their respective delegates.

During the speeches scheduled for today we will address and discuss the illegal phenomena in the pharmaceutical field related to the manufacturing and distribution of counterfeit or illegal medicines, to the promotion of dangerous medicinal products through unauthorized e-pharmacies and / or social networks, and to the theft and laundering of medicines.

A number of extremely important issues, in respect of which regulatory agencies and other authorities, health-related and not, are called upon to intervene, in order to ensure the safe access to medicines, which is primarily a health advocacy tool.

Recent tragic cases of lethal side effects related to medicines bought from unsafe sources – it is of last April, the news of the death of a young bodybuilder of Foggia, due, according to preliminary reports, to the consumption of an illegal anabolic substance – in fact prove that medicines, without all essential requirements of quality and safety, might become nothing but a health advocacy tool.

The today conference is therefore an important meeting, to discuss not only about what has been done but above all what has to be done in the future, especially in light of recent developments which confirm that the scenario is continuously changing and thus regulatory authorities need to change, in some ways, consolidated paradigms.

The new types of falsification, which more and more involve life-saving drugs such as anticancer or antiviral, represent the next challenge for all Authorities called upon to protect public and individual health.

On behalf of the Italian Medicines Agency I thank all the representatives of the institutions and associations that take part in the Conference today, certain that this is the starting point of important new initiatives.

I wish you all the best in your work!

Fighting counterfeiting: a contribution from the pharmaceutical industry

Antonio Messina, Industrial Relations Responsible- Farmindustria

In Italy, thanks to the accurate supervision of the competent Authorities and to the National Health System, which allows patient access to most the pharmaceutical products, counterfeited medicines are almost absent in the official distribution chain. In addition, any activity in the pharma sector requires several authorizations.
Any step of medicine life-cycle is strictly monitored, starting from manufacturing sites up to the point of dispense.

According to the Pharmaceutical Security Institute (PSI) medicine's counterfeiting keeps on spreading worldwide threatening citizens' health.
The number of incidents occurred worldwide is increasing: from 2177 registered by PSI in 2014 to 3002 in 2015.

Medicine counterfeiting causes an economic loss both for companies and Healthcare Systems. According to the report of European Union Observatory on Intellectual Property, the economic impact of pharmaceutical counterfeiting is estimated in about 10 billion euro every year.

Counterfeiting affects different kind of pharmaceutical products, depending on their geographical distribution: while in developing Countries most counterfeited medicines are those used for the treatment of serious diseases, such as malaria or high spread diseases, in developed Countries counterfeiting is mostly focused on pharmaceutical products intended to improve physical and sexual performances.

Counterfeited medicines are extremely dangerous for public health, they are not equivalent to the original product since they have not been properly evaluated to check their quality, safety and efficacy, as required by the strict EU requirements that Pharmaceutical Companies must observe.
Counterfeited products might contain ingredients, including active ingredients, which are of bad quality, in the wrong dosage and, in some cases could be highly toxic.
The phenomenon severely undermines doctors' and patients' trust in medicines and in the Pharmaceutical Industry

Counterfeiting is a matter of great concern also at European level, sure enough with the Falsified Medicines Directive (Directive 2011/62/EU) the European Parliament introduced tougher rules to improve the protection of public health with new harmonized, pan-European traceability system to prevent medicine's counterfeiting in European Countries.
These new measures include mandatory safety features to be applied on the outer packaging in order to allow the verification of the authenticity of medicinal product, and for the first time medicine sale via web is structured and ruled in order to guarantee the safety of online purchasing.

In Italy, from 1st July 2015 online pharmacies are allowed.
Only medicines without medical prescription can be sold online, whereas the sale of prescription medicines remains forbidden.
Authorized websites must display a EU-wide logo to identify legal online pharmacies plus a link to the website of the local competent Authority. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union.
However, in our country online purchasing of pharmaceutical products is still limited, thanks to the strong relationship between citizens and pharmacists.

Counterfeiting is a phenomenon to be fought and defeated through the cooperation among the stakeholders of the Pharmaceutical chain of medicine, Law Enforcement and Authorities as a whole.

Pharmaceutical companies have always been active partners to ensure the safety of medicine global supply chains and to protect patient's health.

The pharmaceutical crime

The market of falsified medicinal products: how is the scenario changing?

Manuel Ibarra Lorente, AEMPS

Falsified medicinal products pose a big challenge to drug regulatory authorities at a global level. Despite the lack of reliable statistics, falsified medicinal products continue to be seized by customs or in police raids and the trade in falsified medicinal products is still far from being solved.

Level of risk and types of medicines being falsified vary significantly among countries or regions. One of the factors contributing to trade of falsified medicinal products is the unsatisfied demand for pharmaceutical products. In countries with a mature pharmaceutical regulatory system and good health system coverage, presence of falsified medicinal products in the legal supply chain is rare, but not unprecedented. However, falsified medicines in the illegal supply chain of those countries are very frequent, mostly sold over the internet and delivered by mail.

Reinforcement of customs controls and proper liaison between customs and drug regulatory authorities would not only reduce the entry of falsified medicines in the EU, but also the use of the EU as a transit to other territories with weaker regulatory systems. A better cooperation and exchange of intelligence are key elements to increase effectiveness in the fight against falsified medicines.

Despite its global nature, the risks posed by falsified medicinal products for public health are very much depending on the structure of the national healthcare systems, in particular, the structure of the medicines supply chain in a particular country or region.

Medicines pricing, availability of medicinal products, pharmaceutical regulatory system and enforcement... among other factors, are elements which have an influence on risk, as it has been indicated by previous cases of falsification in the EU. Evolution of these factors and the deployment of measures envisaged by the falsified medicines directive would configure the scenario in the forthcoming years.

Some of the features of national scenarios which may have a protective role are a proper licensing system, that includes announced and unannounced Inspections, a fully functional custom service, including Inspection at postal hubs, coverage of national reimbursement systems and mechanisms ensuring coordination and information exchange among stakeholders at national level. These elements are normally implemented in most EU Member States, and this would explain why falsified medicines entering the legitimate supply chain in the EU remain to be rare.

One of the main drivers for medicines counterfeiters are meeting customers' demands and unmet needs. In developing countries, customers' needs focus on life saving drugs, but the markets are different in developed countries. In developed countries, with functional national health systems, most of the patient's needs are covered when they are medically justified. However, patients in developed countries may look for other elements, such as better prices, or more convenient supply, or the avoidance for medical prescription. Patients may look for in the internet to get the medicines they need, and may or not be aware of the risk this represent.

Member States are working to strengthen the legal supply chain, as all the elements of the falsified medicines directive are now being implemented. However, while legitimate supply chain is being reinforced and subject to continuous monitoring, efficacy of the measures applied outside of the legal supply chain remain to be uncertain.

Illegal websites selling medicines continue to operate, and the numbers of postal parcels seized containing medicines are growing. Moreover, the amounts of medicines found in each package indicate that consignees may be acting as resellers/distributors. These risks have not been satisfactorily addressed. Awareness raising campaigns have been launched, but its efficacy seems not to be optimal.

Another challenge is the "import-for-export" trade of medicines, and the complex customs procedures that can be applied to medicines in these flows. Medicines can stop over the EU and their true origin may be obscured. The need for proper coordination and information exchange between customs and national competent authorities are of the utmost importance.

The priority for national competent authorities should be to protect national legitimate supply chain. However, work in other areas, such as the internet, postal and international trade should continue.

Domenico Di Giorgio, AIFA

Recent cases managed by AIFA allowed to identify a number of developments of Pharmaceutical Crime. Recent examples on the illegal distribution of unauthorized pharmaceutical products, manufactured by Italian pharmacies and in some cases also exported to other countries are object of this paper, along with an overview of the ongoing investigation regarding the falsification of Sovaldi, sold to Israel through a Swiss wholesaler/trader and supplied via India/Hong Kong.

In recent years AIFA managed different cases regarding falsified or illegal medicinal products, that confirm the evolution of the problem on several fronts.

Case I

In June 2016 we received a request from Carabinieri NAS regarding laboratory analysis on suspected active substances and medicines found in a pharmacy.

The analysis results identified the APIs minocycline, fluconazole, atorvastatin and the presence of atorvastatin, minocycline and aciclovir in the tablets.

The investigations demonstrated that the pharmacy produced *miracle medicines* – containing the APIs identified through the analysis – for patients suffering from neurodegenerative diseases.

The name of the anauthorized cure protocol was "Sven to stand", and this was promoted by the head of the organization in the Beauty Center "Forme di bellezza". Globally 6 person of this organization were arrested.

Case II

Another case object of our investigations involves a number of packages of original Sovaldi (sofosbuvir) from the Pakistan "Access" program, that were repackaged as Harvoni (sofosbuvir + edipasvir) and sold to Israel through a Swiss wholesaler/trader, supplied via India/Hong Kong.

The Swiss wholesaler was supplied by VAMA (India): upon request of the Swiss and Israel authorities, India confirmed that the licence of VAMA was revoked. Invoices of the supply from Hong Kong to VAMA are not accessible at the moment.

It is not possible to know where label falsification was done: nevertheless, since there are well known typos in the label (1/l mistake: "1edipasvir"), it is likely that the original label was scanned in a facility where people do not use the Latin alphabet. Note that the white label in Hebrew is a label that a pharmacist stuck while dispensing the drug to the patients and reports patient's details, dosage and the pharmacy name: it hiddens some typos, that anyway were visible during the trades between India, Hong Kong, Switzerland and Israel.

The Israeli inspections confirmed the low level of GDP verifications in the company. In spite of the relevance of the trade for the business of RCC Pharma they reported a poor verifications on the product. Further requests for data/inspections regarding the source of the product (Pakistan? Hong Kong?) are still ongoing.

Case III

The last case is from July 2016 and moves from the request of information from the Norwegian Authority about pharmacy preparations manufactured by an Italian pharmacy (prescriptions provided by a Norwegian doctor) and delivered to Norway:

- Liothyronin Slow release capsules – 30 mg
- MethylB12–injections – delivered in syringes 0,2 ml (syringes marked for Insulin)
- MethylB12 spray – 20 ml

In Italy, the prescription provided by a Norwegian doctor is not effective for preparations manufactured in an Italian Pharmacy The investigations carried out by Carabinieri NAS pointed out more elements, such as that Pharmacy preparations are delivered to other countries for the treatment of neurodegenerative deseas.

Vânia Serapicos, INFARMED

Legal difficulties comes with the circumstance of not having a typified crime for the trade of illegal and falsified medicines in Portugal. The collaboration between INFARMED, I.P. and Customs Authority is helping to prevent the entry of illegal and falsified medicines in the country. The situations found in Portugal regarding the sale of illegal medicines. and the new challenges that INFARMED, I, P. is facing – as new stores and ways of trading illegal medicines – are taking a more relevant extent.

In Portugal, medicine falsification and similar practices that threaten public health like the manufacture, distribution, storage, import, export, supply and trade of medicines and medical devices without authorization or in disconformity with legal requirements is illegal but not a crime.

However, it's imperative to change this scenario in order to guarantee a more efficient protection of public health and a more proficient prosecution of these dangerous behaviors.

Until now, some already existent crime frames have been used to fight these illegal activities. Nevertheless, none of them is ideal as all present problems, whether it's the difficulty of proof, the exclusion of some types of falsification, the prosecution initiative, among others.

One solution might be the ratification of Medicrime Convention, signed by Portugal in 2011. To make this process faster and easier, a working group has been created, with representatives of all relevant ministries and authorities to this matter.

While the criminalization doesn't occur, Portugal, has been actively working to keep falsified and illegal medicines out of its territory. One of the most significant activities in place is the daily screening by the Customs Authority of packages sent from foreign countries. Together with INFARMED, I.P., that provides help on the analysis and assessment on the products found, Portugal as able to keep out of its borders, in 2015, more than 619.980 units of illegal/falsified medicines. Only on the first semester of 2016, INFARMED, I.P. issued more than 3.600 assessments and more that 283.281 units of illegal or falsified medicines were identified.

The most common medicines found were analgesics (19%), anti-inflammatory (14%), central nervous system drugs (9%), erectile dysfunction drugs (7%) and cardiovascular medicines (7%). The majority of these products come from USA, Canada or Brazil, except for the erectile dysfunction medicines that mainly proceed from India, China or Singapore.

One of the main concerns for INFARMED, I.P. and the Portuguese authorities is the maritime ports, as this is one of the easiest ways to introduce medicines in a large scale in any country with a big coastline, like ours. This will be a reality to take in to account and that will demand even more attention and action from all the authorities involved in the fight to illegal commerce of goods.

Looking into the internal market, and although this isn't still a reality with massive proportions in Portugal, some websites have being found offering to sell illegal medicines. Most of the situations happen in consumer to consumer and business to consumer type of websites (similar to EBay). Until now, the notification of the owners of these websites have been proven effective in the removal of online illegal medicines adverts.

A reality that has gained a bigger relevance lately is the selling of illegal medicines in and through sex shops. This motivated several inspections to these shops by INFARMED, I.P. in collaboration with the Economic and Food Safety Authority (the competent authority to supervise these establishments), which resulted in products seizing and prosecutions of crime and administrative offences by both authorities to the owners.

In Portugal, until this date, only three medicine thefts have being reported to INFARMED, I.P, none of which posted a risk for public health as of the quantities stolen were very insignificant. It's important, however, to make notice that the theft of any merchandise is a property crime, there is no obligation of stakeholders to reports these events to INFARMED, I.P., and it's the owner that decides if a prosecution is initiated, by filing a formal complaint. Nonetheless the perception that INFARMED, I.P. has about this issue, based on contacts held with wholesalers and other stakeholders during inspection, is that it's not a reality that concerns them, as most of them didn't had any prior situation of theft.

Being a multidisciplinary matter, the fight of illegal and falsified medicines demands, from authorities also a multidisciplinary approach. Because of that, INFARMED, I.P. created an internal working group that discussed and attends any matter regarding falsified medicines. The goal is to have a joint definition strategy and action on falsified medicines, with contributions from all relevant departments for this matter.

Given all of the mentioned above, INFARMED, I.P. sees as the most important challenges to the future, the need to improve legislation and increase penalties, the growing number of places to inspect as new entities and ways of commerce of falsified medicines appear every day, which will compel authorities (internal and form different countries) to cooperate more and more with each other, and to be aware of new realities and trends happening in each countries.

Mark Jackson, Athiqur Meah, MHRA

An emerging threat to the UK supply chain – The presentation covers the identification of a growing trend of diversion of licensed benzodiazepines (diazepam) and hypnotic drugs (also known as Z drugs) from the legitimate supply chain to the black market. It highlights the intelligence picture identified to date and what action the MHRA has taken to deal with the problem. Information established to date suggests that the diversion of the licensed products is fuelled by street level drug dealing and illegal sales online.

Introduction

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has identified new and emerging issues within the UK regulated supply chain involving diversion of Controlled Drugs which are also prescription only medicines in the UK and beyond. The products specifically are benzodiazepines and other hypnotics/anxiolytics such as Zopiclone and Zolpidem – which, for the purposes of this paper, are termed as "Z" drugs.

It has been established that large volumes of these medicines are being diverted unlawfully from the regulated supply chain for sale and supply on the criminal market by a number of entities within the regulatory system, employing unethical and potentially illegal practices. Loopholes in UK legislation are being exploited in order to obtain and sell these products.

Background

This issue first came to light following contact by another European medicines regulator. Investigations instigated by them led to the seizure of products that appeared to originate from the legitimate supply chain in the UK. The products were identified as originating from one specific pharmaceutical company. An inspection took place and the top 10 sales of benzodiazepines and Z drugs were examined; one sale alone amounted to many millions of doses. This particular purchaser has control of a small number of pharmacies in the UK and when questioned about the product, stated that the medicines had been sold for cash and there was no paper work. The medicines were apparently sold to a distributer whose WDA (Wholesale Dealer's Authorisation, a licence granted by the MHRA) had been suspended. Following the initial intelligence referral a large number of complex and potentially linked investigations have been instigated.

A second referral was made by a UK Police force following another large recovery of Diazepam tablets. On examination these were again identified as coming from the legitimate supply chain. It was established that a suspect had managed to purchase multiple million doses by using a poorly forged WDA, ordering the products using his personal email address, paying with his personal credit card and arranging for collection rather than delivery. The wholesale dealer supplying the product was identified and inspected. The top 120 sales of benzodiazepines and Z drugs were examined and 95 deemed to be transactions that required further investigation – some were linked to the original referral.

Jurisdiction

Benzodiazepines and Z drugs are controlled in the UK under the Misuse of Drugs Act 1971, scheduled as Class 'C' drugs and consequently, regulatory responsibility lies with the Home Office and investigation / enforcement with the Police. However, it is evident that the policing of Class 'C' medicines is not a priority for law enforcement agencies. This has created an opportunity for criminal networks to exploit and the regulated supply chain has been identified as a rich source of product which can be corrupted to feed the criminal market. As these medicines are being diverted from the regulated supply chain, MHRA has a significant role to play in the investigation and enforcement; consequently, MHRA has taken responsibility for investigating these linked offences.

Modus Operandi

Early assessment of the criminality involved in the related investigations has identified a number of emerging trends which are listed below. This is of great assistance to those charged with inspecting or formally investigating such matters:

- WDA holder purchasing medicines via a legitimate supplier and then selling 'off the books' directly into the black market
- Significant changes in purchasing trends. Pharmacy(s) purchasing increasing amounts far in excess of a dispensable amount.
- WDA holders selling medicines without performing appropriate due diligence including; sales to individuals who have used personal bank accounts,

collections direct from the Wholesaler or delivery addresses which are not named on the purchasers, often fraudulent, WDA.
- WDA holders purportedly selling medicines for export outside the EEA (usually to countries without a fully functioning government such as Somalia or Syria) but without the actual product being physically exported. The medicines are then, rather than being exported from the UK, diverted into the criminal market.
- Pharmacies and bogus wholesalers purportedly from outside the EEA approaching UK wholesalers directly and ordering large amounts of medicines.
- Medicines stolen from WDA holders and manufacturers by employees – recorded as losses by industry not thefts.

Recommended Actions

- The development of a watchlist of medicines most vulnerable to diversion from the regulated supply chain.
- When inspecting the major wholesalers who account for around 80% of the market supplying medicines on the watchlist to pharmacies, GMDP inspectors to request sales data to identify the largest customers as this maybe an indicator of criminal activity.
- Intelligence Unit resources to analyse data as described to identify potential suspicious activity.
- Through communication networks encourage wholesalers and manufacturers to report suspicious orders and trades involving watchlist medicines (large sales to pharmacies, payments made to personal bank accounts, deliveries to addresses not listed on WDA and requests from overseas)
- Regular liaison between GMDP inspectors and enforcement operatives to establish and highlight the current threats and risks so that these can be communicated to wholesalers and manufacturers via the MHRA blog. This process of communication utilised by the MHRA is targeted towards professionals within the industry to provide timely and relevant information.
- Encourage international liaison by GMDP inspectors and Enforcement Officers to highlight these issues in the UK, establish any new emerging trends within the EU and identify lessons.
- Encourage the reporting of not only thefts but also 'losses' of medicines on the watchlist.

Conclusion

This report highlights the significant difficulty experienced in the UK in securing the regulated supply chain and the emerging threats and challenges that both regulators and law enforcement face. An enhanced coordinated approach from all interested parties will be required if the integrity of the supply chain is to be maintained.

Thefts of medicines: IT tools

Domenico Di Giorgio, AIFA

A presentation of the system that made it possible to identify flows, develop blacklists and eradicate the phenomenon of thefts.

Background

Since 2013 in Italy an exponential growth in the phenomenon of thefts of medicines has been observed. As the management of the investigation on thefts is carried out at local level and complaints are filed with various local police forces, there has been a urge for centralization of data on the phenomenon, which would enhance the execution of a thorough analysis.

The network of the stakeholders

AIFA (Product Quality and Counterfeiting Office, UQP&C) has initiated the development of a system for collecting, managing and sharing of data on the phenomenon of thefts of medicines.

In the project were initially involved all the stakeholders most directly concerned, namely the marketing authorization holders (MAH) and the Warehouse Service Providers (depositories), which were asked to share the data available on events of theft.

The involvement of trade associations, whose contribution facilitated the awareness raising of marketing authorization holders and Warehouse Service Providers, has been decisive. The main interlocutors were *Farmindustria* (association of pharmaceutical companies, which represents about 200 companies), *ASSORAM* the National Association of traders and logistics of the primary distribution of pharmaceutical products for human use (as well as veterinary, parapharmaceutical, medical devices and sanitary goods) and later *Assogenerici*, National Association of industries of generic drugs, which represents over 50 pharmaceutical companies and, finally, the *national association of wholesalers*.

Currently, about 80 companies or pharmaceutical groups are registered in the AIFA platform. The MAHs currently involved in the project cover approximately 49% of the whole medicinal products authorized in Italy and include, in particular, 7 out of the 13 companies holding more than one hundred products each.

The project also involved the Italian Ministry of Health, responsible for monitoring the distribution and for the tracking system ("track and trace") and the national police force Carabinieri NAS, a police force in charge of specialized investigative health-related tasks and judiciary police activities in various sectors, including healthcare.

Data collection

With the aim of simplifying as much as possible the activities of data collection, it was agreed in the operational stage to use a standard form ("thefts report form") to be sent, once compiled by the MAH/ Warehouse Service Provider / Wholesaler, to a dedicated email address. The system actually replicated the format according to which, on the basis of the regulations in force, MAHs and distributors are mandatorily required to report any case of theft to the tracking system of the Ministry of Health. The information requested on the form are strictly necessary to identify the event and the product stolen (or lost) and include, in particular, the Marketing Authorisation Number.

Managing of data

The data reported in the form are extracted and transferred in the Database on Thefts. Through the Marketing Authorisation Number relations can be established with the AIFA Database on Medicines authorized in Italy. This allows to integrate the data reported on the form (name and Marketing Authorisation Number) with the main characteristics of the product.

Developments

In the framework of Fakeshare II the Database on Thefts has been extended to the other Countries involved in the Project through an ad hoc Database which allows the gathering and sharing of data.

Management of cases of pharmaceutical crime in Italy

Diana Russo, Public Prosecutor of the Republic

The pharmaceutical crime today represents one of the most remunerative illicit activities and one of the main investment sources of organized crime.
Alongside counterfeiting, there has been in recent years a significant increase of crimes against the patrimony (thefts, robberies) related to medicines and pharmaceutical products subtracted in hospitals or during the phases of transport within the official distribution network on the national territory, to the purpose of being re-marketed in Italy or abroad, by means of "carousel frauds" (Missing trader fraud, or theft of Value Added Tax – VAT) or through the online sale.
The so called "Operation Pharmalab" – arisen from the seizure, in June 2014, of a huge amount of medicines (no. 58.222 packages of medicines of different types, genres and origins, including hospital medicines, for an esteemed market value of € 839.530,89) stored inside a deposit in Arzano – enabled to identify the members of a criminal association to the purposes of receiving and handling stolen medicines (also from hospital facilities) and robberies (mainly carried out on transport operators) and the subsequent re-marketing through the arrangement of false fiscal documentation suitable at simulating their purchase from suppliers and/or Italian pharmacies by apparent foreign companies.
We will examine the substantial and procedural aspects of this case, particularly with respect to the charged offence of "receiving and handling of stolen goods" and its consequent demonstration in Court.
We will highlight the main criticalities emerged concerning the inadequacy of the legal frame work in force to tackle such a relevant phenomenon; the perfectibility of the traceability system; the fragmentation of proceedings related to counterfeiting and/or handling of stolen goods before different Italian judicial Authorities; the insufficient catalogue of accessory sanctions, also in disciplinary proceedings.

Introduction: origin and development of investigation activities

The pharmaceutical crime today represents one of the most remunerative illicit activities and one of the main investment sources of organized crime.

Alongside counterfeiting, there has been in recent years a significant increase of crimes against the patrimony (thefts, robberies) related to medicines and pharmaceutical products subtracted in hospitals or during the phases of transport within the official distribution network on the whole national territory, to the purpose of being re-marketed in Italy or abroad, by means of "carousel frauds" or through the online sale

The so called "Operation Pharmalab" arose from the seizure, carried out in early June 2014, of a huge amount of medicines (no. 58.222 packages of medicines of different types, genres and origins, including hospital-drugs, for an esteemed market value of € 839.530,89) stored inside a deposit in Arzano, occasionally discovered by the Italian Finance Police (Guardia di Finanza) of Fiumicino (Rome), at the disposal of two subjects (one of whom is a pharmacist).

The investigations initiated by the Public Prosecutor's Office in Napoli Nord (technical verifications aimed at clarifying the criminal provenance of the seized goods; observation, surveillance and monitoring; interceptions; questioning on the suspects) enabled to identify the members of a criminal association to the purposes of receiving and handling stolen medicines (also from hospital facilities) and robberies (mainly on transport operators) and their subsequent re-marketing through the arrangement of false fiscal documentation suitable at simulating their purchase from suppliers and/or Italian pharmacies by apparent foreign companies.

In short, the criminal system proved to be organized in different phases:

- organization and execution, on the whole national territory, of thefts mostly in hospital pharmacies and robberies on transport operators;
- storage of stolen goods in hidden deposits (situated in the Campania region);
- medicines cataloguing and arrangement of false documentation by expert co-participants;
- transfer to complacent subjects (pharmacies, wholesalers, distributors), dedicated to re-introducing the stolen medicines on the official circuit.

The criminal organization, entirely composed of Italians, besides transferring the medicines to small complacent pharmacies in Naples, also supplied official wholesalers who regularized the stolen goods by means of fictitious importations of medicines purchased, only upon paper documents, from non-existing foreign companies. The

goods could, therefore, be resold in Italy to unaware pharmacies, so introducing in the retail system huge amounts of medicines, thus defrauding the National Health System, with a potentially enormous danger for the public health, being unknown the storage and transport conditions of the medicines up to the time of their seizure (most likely inadequate and, certainly, not complying with the prescriptions on environmental healthiness and storage temperatures).

Within the same investigation, in November 2014 a number of searches were carried out in the provinces of Naples and Caserta in premises under the disposal of the suspected subjects, which led to the detection and seizure of no. 3.117 additional packages of medicines, many of which oncologic or anti-rheumatic drugs, also from hospitals, for a market value of € 963.575,23.

Substantive aspects: charged offences

Though the conduct at issue in the proceeding is consistent with the wider and alarming phenomenon above briefly described, in the present case it was possible to charge the following offences:

- receiving of stolen goods (or coming from an offence, art. 648 of the Italian Criminal Code): it is an offence against the property liable to imprisonment from 2 to 8 years and a fine from € 526 to € 10.329; moreover, the aggravating circumstance laid by art. 61, no. 7, of the criminal code, in relation to the seriousness of the financial damage caused, was also charged;
- possession of narcotic drugs (art. 73, par. 1, also related to par. 4 of the d.P.R. no. 309/1990) with respect to some packages of medicines (no. 1191) containing active principles which may be rooted to the Tables enclosed to the Consolidated Law on Narcotic Drugs (specifically Table I section A and Table IV). The charge was, however, challenged by the defense, on the assumption that the Public Prosecutor would have referred to categories no longer in force, following a Constitutional Court's judgment (no. 32/2014) against the mentioned regulation, which evaluated as uncostitutional some of the provisions against the possession of narcotic drugs, and the subsequent introduction by the Law Decree no. 36/2014, converted in Law no 79/2014, of an ad-hoc Table for the medicinal products ("Medicines Table"). Anyhow, each of the Tables from I to IV enclosed to the Consolidated Law indicates, in conclusion, as substances to be considered as included in the same Table, "the preparations containing the substances as of the present table, in compliance with the tables of medicinal products". As a consequence, the possession, without authorization, of medicinal preparations based on active principles listed in the Tables of narcotic drugs, constitutes the offence as of art. 73 of the Decree of the President of the Republic no. 309/1990. The Judicial Review Court of Naples ruled accordingly, dismissing the challenge and confirming the Public Prosecutor's assumption. Such charge allowed the use of longer terms of pre-trial detention, upon consideration of a higher punishment limit (up to 20 years for the possession of the so called "hard" drugs);
- criminal association for the purposes of committing the above mentioned crimes (art. 416 of the criminal code);
- trade and administering of fault or defective medicines (art. 443 criminal code): offence charged only with respect to expired medicines found in the deposit of a purchaser pharmacy.

Procedural aspects: medicines traceability.

From a procedural point of view, the most relevant and, at the same time, problematic aspect of the Operation Pharmalab concerns the evidence of the criminal source of the seized medicines.

The offence of receiving and handling stolen goods consists in the conduct of those who purchase or anyhow receives goods of criminal origin, in order to earn profits. It is a burden of the Public Prosecutor to prove the illicit origin of the goods

With regard to the psychological element, the awareness of the criminal origin is presumed, in accordance with the case-law of the Court, when the defendant provides no justification for the possession of the goods. In the present case, all the medicines detected and put under seizure were catalogued with the support of the Pharmaceutical Department of the Local Health Authority NA1 and the distribution chain was reconstructed (traceability) with the support of Office IV of the Ministry of Health and of AIFA.

As widely known, the Ministry of Health and AIFA established the "Medicine Traceability Project". Such project is aimed at protecting the public health through the adoption of a labeling system (based on numbered stickers which identify each single package of a medicine) with the creation of a Central Data Base. The stickers are "read" at every passage of the distribution chain (company, wholesaler, distributor, etc.) and their position is notified to the Central Data Base.

A sticker is applied on each package, providing the following data:

- "M.A." code, that is the "identity card" of the medicine, as it provides the essential characteristics which identify it;
- "Production batch number" of the medicine, which indicates all the packages which are part of a determined and precise manufacturing cycle performed by a pharmaceutical company over a specified period of time;
- "tracking number" of the medicine, that is the progressive and unique number which identifies the single package of the product.

In order to corroborate their illicit origin, the Local Health Authority of Napoli 1 Center – Pharmaceutical Area drafted a list of the medicines and pharmaceutical products put under seizure, combining:

- for the medicines, their respective M.A, code and "tracking number";
- for the other pharmaceutical products, the "EAN" code (a bar code) and the "number of the batch" they belong to.

On the basis of the whole data collected, the Finance Police of the Fiumicino Group set to contact the several pharmaceutical manufacturing companies involved, in order to acquire copies of possible theft reports, or any other data or piece of information useful to ascertain the criminal origin of the medicines; among the variety of pharmaceutical companies contacted, only a limited number provided copies of theft reports.

It is useful to highlight that, generally speaking, in the reports acquired the complainant (transport operator, pharmacy or health structure, etc.) exclusively indicates the denomination, the batch number and the quantity or, sometimes, solely the number of the transport/shipping document, without specifying the single packages or the tracking numbers of the stolen medicines. Such lack makes it extremely difficult to reconstruct the distribution chain of the stolen medicines as well as the identification of the subject entitled to the restitution.

Criticalities and operational proposals.

The analysis of the Pharmalab case highlights criticalities both on the substantial and the procedural aspects.

Firstly, clearly arises the **inadequacy of the legal framework** in force to tackle such a relevant phenomenon; the charge of common offences such as receiving and handling of stolen goods appears to be actually reductive, upon consideration of the high dangerousness of the criminal conducts for the public health, particularly considering that the involved medicines are reintroduced on the market after being stored for a variable (and anyhow uncertain) period of time and in violation of the related provisions on their conservation.

In that regard, it is interesting to note that, had the conduct been detected in a subsequent phase of the "iter criminis", it would have been possible to charge the offence of receiving and handling of stolen goods laid by art. 648 bis of the criminal code (common crime against property subject to subject to a term of imprisonment ranging from four to twelve years and to a fine from € 5.000 to € 25.000), constituting the arrangement of false accounting documentation an operation aimed at hindering the identification of the criminal origin of the medicines.

The charging of the special offence laid by art. 73 of the D.P.R. no. 309/1990, undoubtedly more significant also upon consideration of the penalty that may be inflicted, is limited only to medicines containing narcotic or psychotropic active principles and, anyhow, is provided to protect a different legal good.

Secondly, the current **medicines tracking system appears improvable**, in the extent that it does not, or not always, allow to identify the subjects entitled to the restitution, with relevant consequences both for evidentiary purposes (as the demonstration of the criminal origin, required by the offence of receiving and handling stolen goods, may be reached only upon deduction) and for the handling of the seized goods.

It may be additionally underlined the issue of the **fragmentation of the proceedings** related to counterfeiting and/or handling of stolen goods before different Italian Judicial Authorities: the exchange of information between the police authorities and the Public Prosecutors Offices merely still relies on the willingness of each office. In that regard, it should be noted that art. 371 of the criminal procedure code, governing the relations between the different offices of the Public Prosecutor, provides for the possibility of coordination and connection in the investigations; such task is assigned to (and guaranteed by) the National Anti-mafia and Anti-terrorism Prosecutor as per the following art. 371 bis of the criminal procedure code, limitedly to proceedings related to mafia-type organized crimes and similar.

Finally, the catalogue of accessory sanctions that may be applied, also in disciplinary proceedings, **to those who provide their expert contribution** to the associa-

tion, practically enabling the cataloguing of the medicines, the esteem of their value, their re-entry into the distribution chain, turned out to be incongruous (in the present case, the communication arose from a spontaneous initiative of the Order of Pharmacists of Salerno); the enforcing of the detention measure led to the suspension of the suspect from the mentioned Order. Nothwithstanding, the sanction was revoked soon as the detention measure was replaced by a less afflictive one, though the criminal proceedings upon the subject were still pending.

On the basis of above mentioned considerations, the **introduction of an ad-hoc offence** case or, at least, an aggravating circumstance with specific effects for offences against the property, whether concerning medicines or anyhow products whose sale is subject to authorization, appears desirable.

Moreover: **accessory sanctions against professionals** who, at any level, contribute in the crime, should be introduced. In parallel, it would be useful to envisage the possibility, or even an obligation, for Public Prosecutor Offices, to notify to the professional orders the files of the proceedings, soon as they can be exhibited

Consideration could be given, as well, to the possibility to notify to AIFA the files related to proceedings concerning counterfeiting and/or illicit traffic of medicines, soon as they can be exhibited; the Agency could, thus, inform the different Public Prosecutor offices about the simultaneously pending proceedings against the same or anyhow connected subjects, so stimulating a coordination in the investigations or, however, a better comprehension of the criminal phenomenon.

The medicines traceability system may be further reinforced and increased also by extending to all the intermediate operators of the distribution chain the burden of cataloguing the single stocks of medicines which are object of subsequent commercial transactions. At the same time, pharmaceutical companies could be invited to manufacture smaller batches or to better inforce traceability when dealing with big batches.

Finally, differentiating the packaging of hospital medicines in order to make their marketing and retail more difficult, stimulating an extensive control.

The future safety features framework and its impact
Regulation on the delegated acts

Belén Escribano Romero, AEMPS

In this presentation the main elements of the EU regulation about the future safety features system will be explained. The types, its characteristics, the new obligations for stakeholders and the description of the main issues of repositories system will be described.

A proposal of the timelines for the different tasks to be developed by the entities responsible for the repository system, till February 2019, as well as the changes that the system will bring for all stakeholders as well as for competent authorities will be also commented. Implementing the new system is challenging for all and will result in a better protection against falsified medicinal products.

Falsified medicinal products are an important global threat to public health. Due to the increase of cases of falsified products introduced in the European Union legal supply chain, Directive 2011/62/EU[1] set out different measures to protect public health from the falsification of medicines.

One of the major aspects introduced by this Directive are the safety features that included on the outer packaging of the medicines, will allow the verification of the authenticity, identity of individual packs as well as the absence of tampering.

These safety features should be borne by all medicinal products subject to prescription unless they have low falsification risk, and so they are included in a list and only by medicinal products without prescription with high risk of falsification, that are included in another list. Also there is a possibility for Member States to extend the scope of the unique identifier for the purposes of reimbursement or pharmacovigilance. For the antitampering device, its scope might also be extended for the purpose of patient safety

The establishment of a repository system to allow these verifications was also included in the Directive. This system will have extensive information about the medicinal products supply chain in the European Union that may be useful for other purposes beyond the verification of the unique identifiers: that is why, in the Directive, the option for competent authorities to use the information of the repository for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology was incorporated.

This Directive delegated in the European Commission the adoption of a regulation in accordance with the European Union Treaty, concerning detailed aspects of the safety features, that was published last year: Delegated Regulation 2016/161[2] , that will be applied from the 9th of February de 2019 in all the Member States, except in Italy, Greece and Belgium that may use an extension period of 6 years due to the fact that they already had a safety features system in place, in 2011.

These detailed aspects include the characteristics of the unique identifier that will correspond with only one single pack of a medicinal product. Its components are a product code (allowing the identification of the medicinal product), a serial number (a sequence of maximum 20 characters), a national reimbursement number, if required by the Member State where the product is intended to be placed on the market, as well as the batch number and the expiry date.

This information of the unique identifier will be included in a two-dimensional barcode and will also be printed on the package.

An example of a unique identifier, with no real data, could be the following:

This system will be an “end to end” verification one. Safety features will be checked before the medicinal product is released for sale and then by the entity dispensing it to the patients. Nevertheless some verifications are also to be performed at wholesalers’ level.

So the manufacturers, distributors, in some cases, and suppliers to the public will verify the authenticity of the unique identifier, by checking it with the data in the

repository as well as the integrity of the antitampering device.

For wholesalers, the risk-based verifications established, must take place when the product:

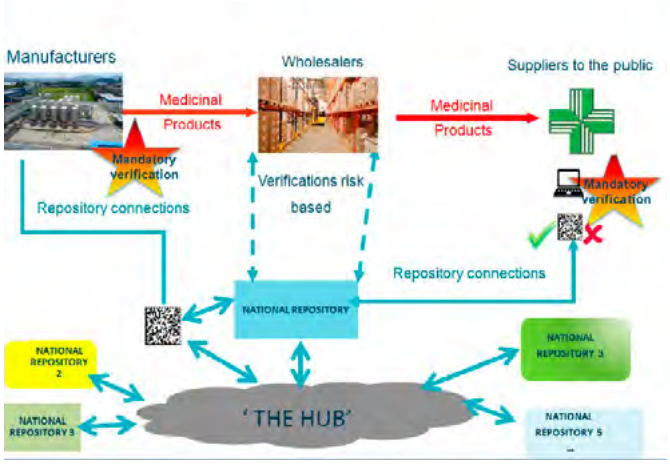
- is not directly supplied by the manufacturer or the marketing authorization holder
- is returned by another wholesale distributor or a supplier to the public

The repository system will store the information of the unique identifiers and allow the verification/decommissioning of them at any point of the supply chain. It will be established and managed by stakeholders and will be supervised by the competent authorities, this is a new approach different for the current systems in place in other countries.

It will consist of a central information and data router ('hub') and national or supranational repositories all connected to it.

The system has to ensure also the detection of potential incidents of falsification, the interoperability among repositories, data protection and virtually instantaneous response: 300 ms.

Some of the characteristics of the future system are included in the figure below.



Till February 2019 there is a lot of work to be done by all the agents in the supply chain, as well as for the entities responsible for the different repository systems, that must get ready to comply with their obligations.

It is planned that national repositories will be set up during 2017 so that then in 2018 on boarding tests of users as well as the training may take place so that everything is prepared for the big day: Saturday 9th February 2019.

It is important to highlight that not all the medicinal products in the market will bear the safety features at that moment. It is possible to release for sale medicinal products without them till the 8th of February 2019. So a transitional period of several years is envisaged where medicinal products with and without safety features will coexist in the market.

Some potential critical issues are:

- Adequate connection with the IT systems of hundreds of thousands of, only, legitimate users through the European Union.
- System response time (less than 300 ms): essential for not collapsing the dispensing system.
- Security of the system and data protection as it will contain lots of commercially sensitive information.

The implementation of the safety features system is demanding important efforts from all actors in the supply chain, as well as competent authorities, that will result in a better protection against falsified medicinal products.

Notes

1 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

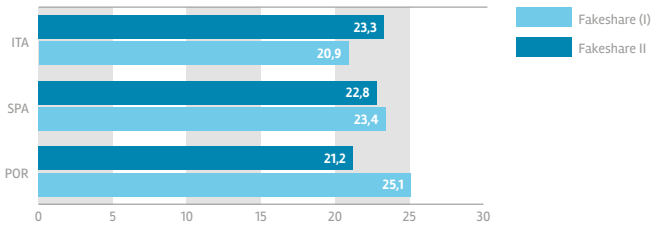
2 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

Sale of medicines online

The purchase of medicines online
The results of the 2016 survey in UK, Italy, Spain and Portugal

Claudio Barbaranelli, University of Rome "Sapienza"

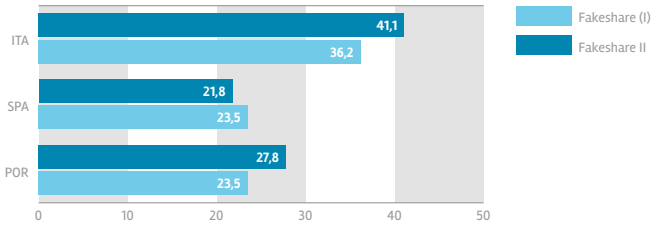
Online survey of "Fakeshare II" project has been conducted for investigating behavioural and psychological factors linked to online purchasing of medicines. The aims of the survey were twofold: to assess the prevalence of purchasing of pharmaceutical products online in four European Countries: Italy, Spain, Portugal, UK; to investigate the impact of different psychological and socio-demographic variables on the Future Intention of Purchasing pharmaceutical products online. Data were collected on about 1.000 participants for each countries between fall of 2015 and early 2016. While there is a substantial awareness of the possibility of purchasing medicines online, there is a much lower awareness of the initiatives and events aimed at raising public awareness on the risks of buying medicines online.



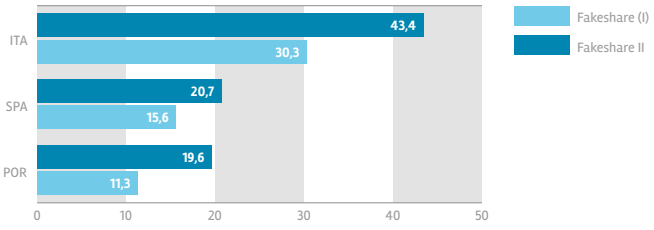
Awareness of initiatives and events aimed at raising public awareness on the risks of buying medicines online

Percentage of respondents who purchased medicines online varied from 9% (Spain) to 26% (Italy). When the prevalence of the purchase of medicines online was weighted by the rate of ecommerce prevalence (2015, Eurostat), rates ranged from about 4% (Spain) to about 18% (UK). In all four countries the medicines purchased online are those for weight loss, for curing flue, and for quitting smoking. The percentage related to medicines for erectile dysfunction is marginal in Spain and Portugal, but higher in Italy and UK. Buy medicines online through contacts via social network (mainly Facebook) is a habit limited to a percentage ranging from about 1% (Spain) to 3.5% (Italy). Positive attitude toward purchasing medicines online is stable (Spain) or increasing (Italy, Portugal). Purchasing medicines online is still a behaviour that is generally non-approved by significant others. The perception of this behaviour as safe for health substantially increased from Fakeshare (I) survey to Fakeshare II survey. However the likelihood of a future purchase (although increasing) is still substantially low (ranging from about 6% of Portugal to about 13% of Italy). Regression analyses revealed that the best predictors of future purchase intention are approval from others (subjective norm), past purchase behaviour, perception of the behaviour as safe for health, and positive attitude toward the purchase. Further regression analyses investigated the beliefs on which attitudes and perception of safety are based. Results revealed that: a) the more the purchase is perceived as economically convenient and practically useful; b) the lower is the perceived quality of the products purchased online; the more positive is the attitude and the higher is the perception of the purchase as a safe behaviour.

In conclusion, purchasing pharmaceutical products online is a behaviour mainly guided by rational beliefs that can be changed, not by impulsive tendencies that are largely irrational. For reducing this behaviour awareness of its risk must be increased with communication campaigns on different media (the web, TV, smartphones, newspapers, wallpapers). In particular, 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 online purchased medicines can be dangerous for health and economically unwise may lower the perception of this behaviour as safe, and lead to a negative attitude toward it, and to the expectation that it will not be approved by relevant others.



Attitude toward purchasing medicines online



How much safe for your health do you consider purchasing medicines online? (Safety Perception)

Evolution of the sale at the distance after the introduction of the Common Logo

Giampiero Camera, Italian MoH

The Italian Ministry of Health made available on its official website the guidelines on how to apply for the authorisation to sell medicines online.

Under the current legislation, online selling of medicines requiring medical prescription is forbidden in Italy. Only medicines that do not require medical prescription (the so-called SOP, acronym of the Italian "Senza Obbligo di Prescrizione") can be sold online. This category includes the so-called OTC (over the counter).[1]

OTCs must bear an identification code that let the customers identify them. Moreover, the external package of both OTCs and SOPs must display the statement "Medicine without prescription".

All the OTCs and SOPs must be marked with the following identification sticker, printed or glued in a prominent position on all packages (through this label, the consumer can easily identify the type of the medicinal product exposed on the counter).

Only pharmacies and shops, like drugstores and "health corner" of large retailers (provided by art. 5, subparagraph 1, of Decree Law n. 223 dated 4 July 2006), and already authorised to sell medicines in the territory can be authorised to sell online. By contrast, wholesalers are not allowed to sell online.[2]

Violation of the above mentioned legal requirements constitutes a case of illegal sale of medicines outside of authorized channels.[3]

In Italy, the authorization for selling medicines on the internet is issued by Region or Autonomous Province, or by competent authorities identified by the Region or the Autonomous Province. A prior notification of the following information (to be promptly modified in case of variations) is needed:

- name, VAT number and full address of logistics site;
- starting date of the sale at a distance to the public of medicinal products through the internet;
- address of the website used for that purpose and any information needed for the identification of the site.

Once the authorisation is obtained (since the online selling is forbidden before the registration in the list of authorized entities), the owner of the pharmacy/retail must:

i) registrer in the list of authorized entities that can sell medicines via the internet, by completing the online application form.

ii) acquire digital copy of the national identification logo (Decree of General manager of medical devices and pharmaceutical services, published in Official gazette of July 6th 2015). The national logo shall be necessarily prominently displayed on every page of the website of the pharmacy or retail, and shall be linked to the corresponding pharmacy/retail's entry on the Ministry of Health website.

Once the application form is compiled, it must be sent by email to the address dgfdm@postacert.sanita.it, attaching a copy of the identification document of the owner and a copy of the authorisation for the sale via the internet released by the competent authority.

The Ministry of Health shall verify the accuracy of the data acquired and then, in case of positive outcome, shall register the applicant in the list of authorised entities for the sale of medicines via the internet. The Ministry also send to the authorised pharmacy or retail – via certified email – a digital non-transferable copy of the national logo with the hyperlink to the list of the authorised entities for the sale of medicines via the internet, that has to be linked to the logo itself when inserted in the website. The authorised entities are required to report, within thirty days, any change in the conditions which allowed the granting, failing which the revocation of the authorisation.

The national identification logo[4] must be displayed, clearly visible, on each page of the website of the pharmacy/retail on which the medicines are sold. To avoid possible misunderstandings, the logo shall not be displayed on pages selling products other than medicines without prescription (such as medical devices, food supplements, cosmetics, etc.).

The Common Logo is copyrighted, that means that the use of it does not confer any intellectual property or

other proprietary right on the same (as per Decree of General manager of medical devices and pharmaceutical services, dated 6 July 2015). The applicant is allowed to use it only for the purposes provided by law. The authorised subjects who received the logo are personally responsible for any violation related to improper use as per the legislation in force (see Legislative Decree n. 219 dated 24 April 2006, art. 112-quater) and thus are subject, in the case of violations, to administrative and criminal sanctions.

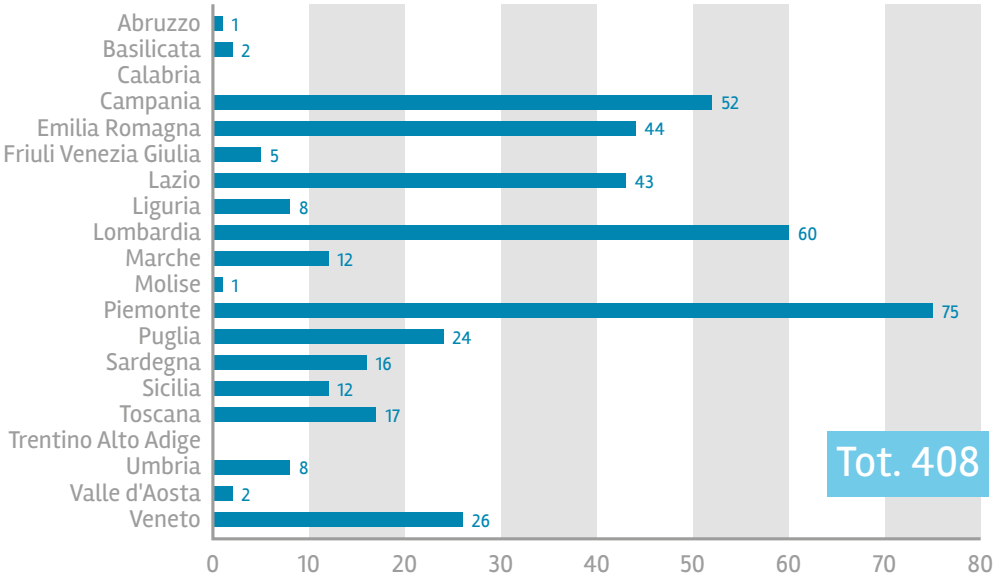
The "Common Logo" – used for all the e-pharmacies of the European Union which operates legally – is a registered trademark[5] characterised by specific graphical and verbal elements ("Composite Mark"), which allows also the identification of the Member State in which is based the entity that sells at the distance to the public.

The presence of the national identification logo on the website of an e-pharmacy has the aim to guarantee the legality of the purchase and the safety (quality) of the products offered, since every step of the distribution chain is strictly controlled, in order to guarantee both the seller and, most of all, the user-consumer.

In this regard it's easy to verify the reliability of the information given on the website: it's sufficient to click on the logo to be automatically redirected to the website of the Ministry of Health, where it is possible to verify that the online seller is registered in the list of the authorised retailers.[6]

It should be noted that the Ministry of Health has repeatedly drawn attention to the importance of respecting professional duties and to criminal sanctions as per art. 147, subparagraphs 4-bis and 4-ter of Legislative Decree n. 219/2006, involving serious consequences for transgressors.[7]

At the same time, the Ministry of Health – supported by the NAS – Comando dei Carabinieri per la Tutela della Salute – may, for justified reasons and also on an urgent basis, order cessation of the illegal trade practices concerning the sale of medicines online.



Italian pharmacies/drugstores authorised to the sale online. Update October 2016.

Notes

1 The Over The Counter medicines are self-medication drugs, that don't need a medical prescription for the purchase. These medicines can be freely purchased in pharmacy, drugstores and in the appropriate retail spaces within stores and supermarkets. The OTC are a sub-category of the so-called SOP (without prescription medicines). OTC medicines can be advertised while SOP can't. For this reason, the OTCs may be exposed on the counter of the pharmacy, while SOPs are accessible to citizens only through pharmacists. Both OTCs and SOPs belongs to group C, namely medicines to be paid entirely by patients. They can be chosen by the citizens, recommended by pharmacists or by family doctor. It should be noted that their use is not risk free: a misuse, in fact, may cause undesirable and harmful effects.

2 The pharmacist, or the cooperative of pharmacists, that own also an authorisation to the distribution, can sell online to the public only SOPs purchased by the pharmacy of which he's holder and by means of its unique code, therefore aimed to the sale to the public, and only under the authorisation of the pharmacy, and therefore intended for sale to the public, stored in the pharmacy warehouse. The pharmacist is the only responsible for the sale of medicines and must verify, as professional obligation, the integrity of the medicines he/she sells, and for the proper storage of the medicine, for verifying the correspondence between the ordered and shipped. The pharmacist must take charge of the medicines, by taking possession of them before shipping them to the client. The distributor's failure to comply with the above

mentioned obligations leads to the violation of Art. 104, subparagraph 1, letter c of Legislative Decree 219/2006, with the consequent application of the administrative sanction as per art. 148, subparagraph 13, without prejudice to the criminal penalties that may apply.

3 Any conduct, on the part of a pharmacy or shop's holder selling medicines ex art. 5 L.D. 223/2006, which infringes current legal provisions, leads to the violation of Art. 122 of Royal Decree 1265/1934, while subjects other than pharmacies and shops, that sell medicines on the internet as per art. 5, are punished in accordance with Art. 147, subparagraph 4–ter. The sale on the internet of SOP medicines without the specific authorisation which allows to sell through a specific website is a conduct punishable under the abovementioned art. 122, subparagraph 4. Measures provided in paragraphs 3, 4 and 6 of art. 142–quinques of L.D. 219/2006 still stand.

4 The use of the Common Logo for the e–pharmacies was introduced by Directive 2011/62/EU, that modified Directive 2001/83/EC dated 6 November 2001, on the Community code relating to medicinal products for human use, directive transposed in Italy with Legislative Decree n. 17 dated 19 February 2014, that modified the Legislative Degree n. 219 dated 24 April 2006.

5 The TradeMark has been added in Annex to the Implementing Regulation (EU) n. 699/2014 of the Commission and was licensed to Italy with the Licence Agreement Online Pharmacies logo, signed between EU and Italy on March 4th 2015.

6 With reference to the legal obligations related to the logo, it should be noted that the provision expressly prohibits: a) to rent, to lease, to assign or to transfer the rights related to the Common Logo and to the national identification logo, to third parties; b) to modify the layout of the Common Logo or the national logo, as well as to create, to develop and/or to use derivations or variations based on any part thereof, with the exception of proportionally increase or decrease the size of the national logo; c) the development and the acquisition of any right of registered trademark associated with the institutional logo of the European Commission, the European emblem, the national identification logo and each derivation of the same, such as any national, European or international registered trademarks, corporate images, trade name, service marks, symbols, slogans, emblems, logos, designs that incorporate, fully or partially, the national identification logo; d) to combine the national identification logo or any part thereof with any other object that may mislead third parties in relation to the meaning and appearance of the logo itself; e) to use the national identification logo for activities that are beyond the scope established by Legislative Decree n. 219 dated 24 April 2006.

7 In particular, the law sets up to one year's imprisonement and a fine of two thousand to ten thousand euro, for those who sell on the internet medicinal products requiring medical prescription; imprisonment from six months to two years and a fine of three thousand to eighteen thousand euro for those who sells medicinal products without any authorisation.

Belén Escribano Romero, Ana Fernandez Muelas and Rocio García Rodriguez, AEMPS

Only non–prescription medicinal products may be sold online and only by authorised pharmacies that have notified their activity through an electronic tool developed for this purpose. Those pharmacies are listed and display the Common Logo.
During this first year 315 pharmacies have been listed. There is a supervision of the listed pharmacies as well as the illegal use of the logo by competent authorities. Nevertheless the main fact to highlight with regard to illegal sales during the last months is the increase of advertisements in online marketplaces. The cooperation of hosting services providers has been essential for the success of AEMPS activities.
The need to raise awareness about illegal sales over internet continues to be a challenge and a priority for AEMPS.

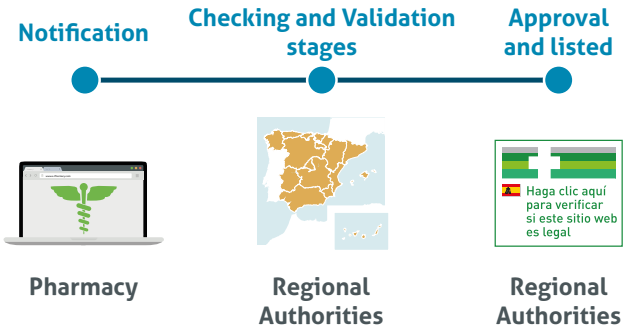
Due to the deep changes in the media and specifically in the internet as a vehicle for the transmission and interchange of any kind of information, as well as a mean for buying and selling any kind of products, it has been necessary to establish a legislative framework both at European and national level that contains the requirements needed to offer medicinal products for sale at a distance and in which the special characteristics of the products and the possible consequences of this kind of sales on the citizens health have been taken into account.

In Spain the regulation of distant sales, in addition to the EU provisions some specific characteristics, addressed to increase patient protection, have been included:

- Only the sale of non–prescription medicines is allowed
- The sale over the internet is only permitted to listed pharmacies displaying the Common Logo
- The sale has to be direct from the pharmacy, with the intervention of a pharmacist responsible for the dispensation and without intermediaries
- It is not allowed to give out presents, prizes, bonus or similar actions as means of promotion of distant sales
- The pharmacist should assess the appropriateness of the dispensation, especially when facing orders that exceed the amounts normally used in treatments
- The transport of the medicines is under the responsibility of the pharmacy
- The returned medicines should always be destroyed
- AEMPS may establish limitations for the distant sale of certain medicinal products with potential misuse, but this hasn't been done yet

Since the 1st of July 2015 any authorized pharmacy in Spain may send a notification of their intention of selling at a distance medicinal products through an electronic application developed by AEMPS for this purpose. This notification must be accompanied with some supporting information.

The process to get the Common Logo has 3 steps:



- The pharmacy sends the following documents to the regional authorities that are the competent authority for pharmacy authorisations:
  - Details of the pharmacy,
  - Address of the pharmacy
  - Starting date of the activity (notification must take place 15 days before)
  - Website address
  - Procedures for the delivery on the medicinal products.
  - Declaration of the website's responsible person
- The regional authorities assess the submitted documents and, if needed, ask for clarifications/additional information.
- When the process results in a favourable opinion, the pharmacy receives an the sniplet, including an url linkage unique for each pharmacy listed, that when inserted into the pharmacy website will make the image of the Common Logo will appear on it, and the pharmacy will included in the public list

During this first year 315 pharmacies were listed out of 21.800 authorised pharmacies in Spain. The percentage of pharmacies involved in this new activity seems to be lower than in other MMSS.

There is a periodic supervision in place for the content of the websites of listed pharmacies as well as for the potential illegal use of the logo by competent authorities.

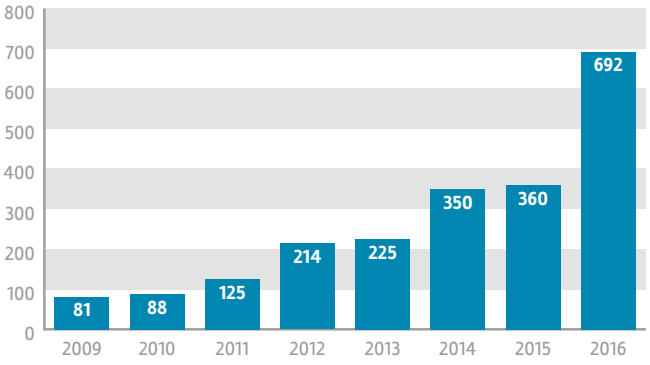
Listed pharmacies websites content is supervised periodically and in some cases substantial changes with respect to the information submitted to the competent authorities, as part of the notification procedure, have been identified.

About the potential illegal use of the logo, only in two cases an image of the Common Logo has been found, but in this cases the images were not intended to work as the EU Common Logo, connecting with the websites of the responsible authorities, nor the websites were intending to sell legally medicinal products under the Common Logo seal.

Also some new issues have arisen from this new activity and transport is one of them.

Transport companies contracted by pharmacies do not have proper documentation warranting the adequate transportation and in all the notifications sent by pharmacies, prior to begin this sale activity, the information presented non-compliances. Specially appropriate transportation <25°C remains a problem.

Nevertheless the main risk for our patients comes from illegal websites: AEMPS has been very active in this field, as it is visible in the following table.



Websites investigated and procedures initiated

For these actions 3 kinds of procedures to prosecute these illegal activities are followed:

- Procedures to require that the owner of a website stops selling illegally medicines over the internet.
- Procedures to request the collaboration of hosting internet services providers; for instance: blogs, online marketplaces or classified advertising websites which are selling medicines.
- Procedures to require the collaboration of internet service providers that facilitate access to a communication network.

These services providers are required by the EU, as well by national, legislation to perform the necessary actions to block any illegal activity once they are aware of it. So AEMPS contacts them in order to inform them about the detected illegal websites, blogs... and is obtaining a quick answer and the pertinent actions are put in place by them. This successful cooperation with internet service providers has been crucial for AEMPS developing effective actions in this field

During the last months the main fact to highlight with regard to these actions against illegal sales is the **increase of person to person medicines sale advertise-**

ments in online marketplaces. More than 600 hundred advertisements have been investigated and withdrawn both for human (329) and veterinary (278) medicinal products.

This high increase motivated the issuance of a public note by AEMPS explaining the risks of these practices, link: https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM_MI_02-2016-compraventa-particulares.htm

A couple of final thoughts:

- This new kind of sales from legal websites with the Common Logo has been operating in Spain just 15 months, since July 2015. So there is still no studies about its impact on general sales or on their acceptance from the public. Spanish Competent Authorities are supervising the websites showing the Common Logo and no illegal use of it has been detected till now. Nevertheless there is a special concern about the transport of medicinal products from pharmacies to patients.
- The effective prosecution of illegal websites remains a challenge because of the high number of potential targets as well as for the new kind of sales that continuously arise, as person to person sales. In this scenario the need to raising awareness about the risk of illegal sales over internet continues to be a challenge and a priority for AEMPS.

Vânia Serapicos, INFARMED

The Portuguese reality regarding the implementation of the Common Logo: which entities can sell medicines at a distance, the total number of authorized online medicine sellers, the scale of acceptance of the mechanism, as well as the rules that must be complied with by the market players regarding this matter.

In Portugal, only pharmacies and non-prescription medicine retailers can sell medicines to the public.

Pharmacies can only operate after INFARMED, I.P. issues an authorization permitting its opening, and all non-prescription medicine retailers have to be registered in INFARMED, I.P. This circumstance allows total control and knowledge regarding the entities that can sell medicines to the public, which permits a more capable supervision over the whole medicine chain, by our Authority, including the legal online medicines sales.

At this moment Portugal has 2806 authorized pharmacies and 1106 registered non-prescription retailers.

Even before the Common Logo legislation being introduced by the European Directive 2011/62/EU in 2011, Portugal had already implemented a system that allowed pharmacies and medicine retailers to sell through the internet, phone or home deliver medicines to the patients.

However, those activities came with some conditions: pharmacies could only sell and deliver medicines **within their municipality region** and connected regions (because they are authorized based on a population distribution criteria); all establishments had to communicate to INFARMED, I.P that activity before starting to pursue it; medicine transport had to comply with the good distribution practices rules stated in regulations; medicines had to be handed out by a pharmacy personnel and all information regarding the safe use of medication must be given to patients. It is not allowed to send medicines by courier.

To this date 489 pharmacies and only 18 medicine retailers can sell medicines through the internet.

This status quo was not changed by the introduction in Portuguese legislation of the possibility of selling medicines to other Member States, in 2013. This new set of rules just added another business opportunity to pharmacies and retailers, by expanding their potential market.

If a pharmacy or retailer wants to sell medicines to a cross-border client has to display the Common Logo on its website, in this case, it has to address to INFARMED, I.P. a request for the Common Logo. To date, **no Pharmacy or Non Prescription Medicine Retailer store made this request**.

This leads us to conclude that Portuguese pharmacies and Non Prescription Retail stores are only selling online to local customers. This might happen because the cost involved in complying with the regulations, by acquiring medicines with a market authorization on the destination countries and by transporting the medicines in a way that meets the terms set in the Portuguese legislation (that doesn't allow medicines to be sent by courier) are too immense to find this activity interesting, profitable and viable.

Nonetheless all the information about the Common Logo is displayed permanently in INFARMED, I.P. website and all the pharmacies and medicine retailers were informed about the new regulation by a letter sent to them on July 1st, 2015.

Even if the Common Logo isn't still practically implemented in Portugal, INFARMED, I.P. realizes that it's of the most utterly importance to continue to monitor all websites, investigate websites with false logos and prosecute the responsibles for those websites and to inform patients and all those involved in the legal medicines e-commerce about the regulation and the best way to safely purchase medicines online.

Lynda Scammell, MHRA

A vast array of medicines is available from tens of thousands of websites and can be ordered in one click. But all is not what it seems, many offer prescription medicines without requiring a prescription and the products dispatched are unlicensed or falsified medicines. But this is not the end of the story, websites that have been awarded Logos go on to offer products that they cannot sell. A monitoring system needs to be put in place to maintain a safe online environment.

The internet is a fantastic thing!

You can obtain information, book holidays and tickets and purchase almost anything you want. The internet offers access to thousands / millions of websites offering a vast array of products which can be purchased at the click of your mouse. But it does have a sinister side, you can buy medicines – so are not licensed for use in the European Union, some are prescription only medicines but are offered without a prescription and, often, no involvement of a doctor or medical professional. Buying medicines online also increases your chances of receiving a falsified medicine or a counterfeit medical device. Therefore, the online sales of medical products can be risky – it brings a threat to patients and wider public health.

The EU Common Logo system – is it the solution?

The Falsified Medicines Directive (EC 62/ 2011) introduced new legal requirements applying to the retail sale and supply of medicine. The European Common Logo scheme applies to all sellers of all categories of medicines "at a distance". In the UK, there are 3 categories of medicines:

- **Prescription only (POM) –** the UK allows the online sale and supply of POMS *provided all other provisions in legal requirements are met*.
- **Pharmacy only (P) –** can only be dispensed by a pharmacist, or under the direct supervision of a pharmacist, at a registered pharmacy premises.
- **General Sales List (GSL) –** can be sold in other retail establishments such as supermarket chains and online trading platforms such as Amazon and E-bay.

The MHRA has registered nearly **600 suppliers**.

Is this the end of the problem?

Although the logo is of great assistance to both regulators and the public, it is not a complete solution. From a regulators perspective, it is easier to identify illegally trading websites and take enforcement action. For members of the public, looking for site that displays the logo offers some guarantee that the medicines offered are coming from a safe and secure source. The MHRA has found websites that, after being granted the Distance Selling Logo, start to offer medicines that they are not allowed to sell – for example, prescription medicines from a non-pharmacy premises, unauthorised medicines being advertised and offered for sale and veterinary medicines on offer (the logo scheme is for human medicines only.) All of these issues require further investigation.

Further monitoring is required.

This brings us to the conclusion that the responsible authorities in the MS need to operate post registration checks to monitor compliance. This does require resources but otherwise non-compliance with the conditions puts the integrity of the logo scheme at risk.

Also, Regulatory Authorities should consider removing the Logo if a site breaches the requirements for the provision of the Logo.

The online list of suppliers must be kept up-to-date and a check can be made on an individual seller.

Conclusion

My "take home" message is – there is never an end to the story in a rapidly changing world. Technological advances mean more access to consumers and we have to respond to the challenges that this brings to the health and safety of our citizens.

Paul Brewer, MHRA

UK FakeMeds Campaign

The campaign was designed to educate consumers about the safest way to buy medicines and medical devices online, as well as encouraging them not to buy from unsafe and unregistered online sources. We want to raise awareness of some of the risks of buying falsified and non-compliant medicines and medical devices, and in our efforts to tackle this issue generate feedback on criminal activity and adverse reactions. With the introduction of the FMD we are using simple signposting methods such as the CE mark and the EU Common Logo

What are the basic elements of the campaign?

We planned to run the activity in a number of stages, firstly a pilot wave targeting slimming pills which was launched in August 2016, using unpaid activity promoting messaging through digital and partnership channels, followed by a fully integrated campaign which will be implemented in 2017 and which will introduce new products and paid media. The pilot enables us to test impact, engagement, and content for future activity. In addition, the focus on digital allows us to introduce 'in-campaign' improvements as we develop the campaign. We are treating this pilot phase as an opportunity to test our messaging to the public and tackle different angles of the issue to learn and refine our offering, ensuring that we are taking the right approach to achieve our communications objectives. It is important to stress that slimming pills are the first wave in campaign targeting of medicines and medical devices. We chose to launch with them because of seasonal prevalence of product purchase, risk to the public of these products when falsified, and the fact that we know much more about them and the attitudes/behaviours in consumers towards these products. Currently we are not spending any budget on paid-for advertising, but we have invested in quantitative and qualitative research to improve our customer insight and inform our creative approach. This has enabled us to develop all the necessary creative assets and materials in-house at MHRA. The campaign priority has been to look at what works – this has meant moving to a different tone from our traditional government campaigns messaging, based around our consumer insight. FakeMeds uses humour to gain attention in the context of the digital and social media channels where messaging is delivered and then to communicate the serious nature of potential health risks and side effects. When we move to a fully integrated campaign we will introduce product waves focused on particular product categories and consumer audiences including users of condoms, dental equipment and sexually transferred infections, (STI's) self-test kits. We have not confirmed our paid media approach yet, but it is likely to include digital advertising and some out of home material in relevant environments. We will be clearer once we know from this pilot wave what works and has the most impact on our audience

What were the objectives of the Slimming Pills Pilot Campaign?

To deliver our pilot campaign we identified a number of campaign specific objectives: Raise awareness in 18-30 year olds in UK of potential falsification of products sold online for slimming, enable 18-30 year olds in UK to identify falsified product retailers online, signpost 18-30 year olds in the UK to legitimate online medical product retailers, and increase reports made in relation to unlicensed or inauthentic websites or products purchased that are suspected to be falsified

How did we connect with our audience?

Through a series of targeted images and short videos designed to stimulate "moments of doubt" about purchasing slimming pills online amongst our audience during their digital purchase journey we aimed to make consumers stop and consider the potential risks and outcomes of their behaviour. Alongside the specific activity we also used broader communications channels to seed the messages including press releases with topline messages across relevant media, encouraging consumers to find further information on our campaign webpages and partner specific content to reinforce the campaign message to our audience in a more social environment. In particular we were able to exploit a fake

medicine storyline on the UK's longest running TV soap opera Coronation Street, and through encouraging debate on a widely respected target audience specific BBC radio programme. We wanted to work with relevant and influential stakeholders and to date we have seen Twitter on the #FakeMeds hashtag reach more than 100,000, local and student press activity deliver the messages very contextually, and as a result traffic to website benefiting from the launch & Coronation Street storyline. Other key bodies sharing relevant content included TRAC (The Regulatory Affairs Consultancy) who shared our content, sent a FakeMeds themed newsletter, and published a blog and The Food Standards Agency integrating with their food supplements campaign in January. Other important stakeholders participating included EMA and General Pharmaceutical Council. Here are some examples of our visual approach:

When consumers were driven to our website what advice did they receive?

Content was direct and practical including advice and tips on how to identify suspicious websites generally, specific advice on purchasing medicines online, information on how to report adverse reactions and typical side effects based on products/ingredients. To ensure consumer have strong confidence in the work of the MHRA in this area we also provided information on the agency, our role and previous enforcement work to tackle supply e.g. Operation Pangea

What have we learnt so far?

The estimated reach of campaign in UK has been over 2 million based on a variety of channels secured, and engagement with campaign webpages is 70.5% higher than average webpage engagements. Our highest performing content is video on Facebook, and Facebook is generating most traffic towards campaign webpages, demonstrating the value of social media in this audience context. Staff engagement with the campaign has been excellent and we are seeing the positive impact the campaign is having on the distance selling logo scheme

Editorial TV Media Exposure: In ITV's 'Coronation Street'

The role of the Social Networks and Market Places in the fight against pharmacrime

Delphine Dauba-Pantanacce, eBay

eBay has a long track record of successfully working with monitoring authorities and law enforcement in the area of illicit trade with medicines in various countries. This cooperation is key for eBay in order to provide its users with a safe place to shop.

eBay is a marketplace where buyers and sellers can connect in a trusted transaction. eBay does not possess or sell any of the items offered on its marketplace but it still expects all customers to adhere to local laws and safety regulations.

Consumer safety is of the utmost importance to eBay, and the company's listing policies are designed to protect consumers first and foremost. For eBay, nothing is more important than trust. eBay is dedicated to providing a safe and secure marketplace for its customers, which includes making significant investments each year to ensure its platform is the most trusted way to shop. eBay has set up various policies including its Medicine and Healthcare Products policy, which provides safety guidelines. eBay also proactively filters its site and removes any listings that contravene its guidelines.

eBay has a long track record of successfully working with third party authorities and law enforcement agencies in the area of fake medicines in various countries.

This cooperation is key for eBay and complementary to its policies.

FDA pursuing illegal web pharmacies

Daniel Burke, U.S. FDA

2014 has marked yet another year of frustration in the fight against illegal online drug sales. Yes, we have had our successes; arrests, takedowns, seizures and convictions, but when I reflect upon the true magnitude of the problem, the overwhelming ease at which criminal organizations can call themselves "pharmacists" and in some cases pharmacists becoming part of criminal organizations, I know we, everyone in this room today, can do so much more.

Over the past few years, we have seen a number health benefit plans particularly in Maine, Massachusetts and New York turn to supposed "Canadian online pharmacies" to source cheaper drugs, not from Canada in most instances, but sources in countries such as India, China, Pakistan and Turkey. I have heard the arguments, that the high cost of medications is driving consumers to look for cheaper options on the internet. I get it, I am a consumer too, I don't want to pay more than I should for medications found elsewhere for much cheaper and years of free market experience tells us that competition is good for the consumer. But years of public health experience, beginning with the snake oil salesmen of the old west, also tells us that the manufacture and distribution of pharmaceuticals must be regulated to protect the consumer. Buying pharmaceuticals is not caveat emptor, or buyer-beware, it is *"Caveat venditor"*, let the seller beware.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 gave the U.S. Drug Enforcement Administration powerful tools to fight the distribution of controlled substances on line. But perhaps even more sinister is the growing distribution of non-controlled pharmaceuticals that threaten the integrity of our drug supply chain and our legislative and investigative tools need to be strengthened in this area.

Consumers who buy any drug online have no idea the source of that medication: in our investigations we have received drugs from online sources that are sub or super potent, counterfeit, have no active pharmaceutical ingredient, drugs tainted with poisons such as lead and arsenic, drugs contaminated with mold, substitute drugs, drugs that are not yet controlled but have addictive qualities, drugs that are new and untested but sold anyway, cold-chain drugs that are not stored or transported properly and stolen drugs. Consumers have no recourse if they don't receive the therapeutic benefit promised and even determining this is difficult if the person doesn't drop dead right there.

The taxpayers of this country pay the FDA to ensure that drugs are safe and effective for their intended use. That the processes and facilities used to manufacture these products are free of contamination and the supply chain remains stable and intact. In short we are first and foremost a consumer protection agency. The taxpayers of this country pay me and the very capable special agents in our Cybercrime Investigation Unit, to bring to justice those that place profits over public health and completely disregard, through the operation of supposed online pharmacies, the important consumer safety mission of the FDA.

Our Center for Drug Evaluation and Research is actively engaged in getting the word out. Through educational programs such as the BeSafeRx Campaign and through consumer advisories, warning letters and alerts.

Our Division of Import Operations works daily with U.S. Customs and Border Protection to identify and seize drugs illegally imported in to the United States through global efforts such as Operation Pangea and Operation Safeguard.

My office, the Office of Criminal Investigations is tackling this issue through the specialized work of our Cybercrime Investigation Unit and we are engaged on all fronts; We target the supporting infrastructure; from filing an unending stream of abuse complaints to registrars that seem to cater to illegal online drug sellers, to complaints to ICANN when they fail to respond. We have investigated companies like UPS, Google and FedEx and we are targeting the financial infrastructure that support those that profit off of the sick and most vulnerable.

We are also focusing the bulk of our investigative resources to bring to justice those that operate large online drug distribution networks, most of which operate outside of the United States. These networks are the central operators of the estimated 30,000–50,000 illegal online "pharmacy" websites active at any one time.[1]

The proliferation of purported "Canadian online pharmacies" continues to be a problem in our efforts to ensure integrity of our drug and medical device supply

chain. Some organizations, mostly from outside of the United States, advocate for supposed Canadian online drug sellers that completely disregard U.S. laws and regulations. They want us to just trust them to regulate the U.S. supply chain. They promote websites that say they are run by "licensed Canadian pharmacists", but what they fail to say is that they are not operating under the authority of their Provincial pharmacy license at all.[2] This is even a violation of Canadian law. According to Health Canada, "It is a violation of the Food and Drugs Act and Food and Drug Regulations to advertise or sell, at retail or via the internet, drugs that are not approved for sale in Canada. This applies to all Canadian pharmacies selling over the internet, even in cases where the unapproved drugs do not enter Canada but are dispensed by foreign pharmacies and delivered to patients outside of Canada. Pharmacies licensed in Canada that engage in such activity are considered to be advertising and selling unapproved drugs in Canada."[3]

Many of these supposed Canadian online pharmacies rarely distribute drugs from Canada, but hide behind a global distribution network making it appear the drugs are from say, the European supply chain but are often sourced elsewhere. They sell from websites that are either not accessible in Canada or use IP address geolocation tactics to sell different medications to Canadian residents and they offer no recourse to U.S. residents in case of an adverse event. This is a fraud on the U.S. consumer, our regulatory system, and the result to the American taxpayer is the expenditure of thousands of hours of investigative work and tens-of thousands of U.S. taxpayer dollars as our agents attempt to unravel the clandestine and unregulated supply chain when their cheaply sourced drugs do harm to U.S consumers.

A Case

Betty Hunter was a Lung-cancer patient. In May 2011, Ms. Hunter went to Four Winds Hematology and Oncology in Chandler, Ariz., for an infusion of what she believed was Avastin, a drug she had taken previously. Soon after the infusion began, Ms. Hunter started to shake, and became nauseous and feverish. The nurse reported "patient complaining of feeling very jittery, hands shaking, and appeared to be red in face... doctor notified and infusion stopped.....patient given Benadryl"

Like Mrs. Hunter, another patient named Wanda Young also had a bad reaction to the Avastin. The attending nurse noted in the report, "patient complaining off shakiness in hands....Benadryl given...needle removed.

The drug Mrs. Hunter and Mrs. Young received was stamped—Altuzan, the Turkish brand name for Avastin. Our agents subsequently searched Four Winds Hematology and Oncology, as the result of an unrelated tip. There, we seized Altuzan vials supplied by Ozay Pharma in Turkey via a company known as Richards Pharma in the United Kingdom. The Altuzan was found to be counterfeit, containing water and mold but none of the drug's active ingredient.

Our investigation showed Ozay Pharma sold the fake Altuzan to Richards Pharma in 2011. When Richard Taylor, owner of Richards Pharma discovered it was fake and U.S. patients had bad reactions, he tried to send the remaining vials back to Ozay Pharma, and they refused. Richard Taylor then sold the remaining vials to River East Supplies in England.[4] River East Supplies is a subsidiary of Canada Drugs.[5] River East Supplies then shipped those same counterfeit Altuzan vials back to the U.S. At the time, Canada Drugs U.S. supply and distribution chain involved a myriad of subsidiaries and re-shippers including Montana Health Care Solutions, Rockley Ventures, QSP and Volunteer Distribution.[6,7]

When interviewed by the Wall Street Journal, employees of Canada Drugs acknowledged shipping the fake Altuzan but say they weren't aware it was counterfeit,[8] and, according the fine-print disclaimer on their website, it's not their problem.

This past January, FDA undercover agents, working with international partners from Germany and Europol, met Ozkan Semizoglu and Sabahaddin Akman, the owners of Ozay Pharma at a hotel in Puerto Rico after they flew to the United States from Turkey. After a lengthy meeting with the undercover agents, Semizoglu and Akman were arrested. Both have since pleaded guilty to charges of smuggling misbranded and adulterated Altuzan into the United States and are set to be sentenced on November 18th. In their plea agreements, both admitted to distributing the Altuzan contaminated with water and mold.[9]

Ever since the infusions of fake Altuzan in May 2011, OCI agents have spent the past several years investigating this complex distribution network involving a myriad of front companies, foreign wholesalers and illegal online pharmacies. Although our investigation is clearly still on-going, the dogged investigative work of our dedicated special agents has led to the arrest and conviction of 14 other persons in a series of related cases.[10]

But Canada Drugs still sources foreign drugs through their subsidiary Rivers East Supply. Our investigations have shown that many of these illegal online drug sell-

ers use what they call "fulfillment centers" which make it appear to the U.S. consumer that the drugs are from the pharmaceutical supply chains of countries such as the U.K, Singapore or Australia. However, many fulfillment centers are simply mechanisms to circumvent customs laws by enabling the importation of diverted drugs for reconditioning and export. Yet another layer in an esoteric supply chain.[11]

Did the owners of Ozay Pharma, Four Winds Hematology and Oncology, Richards Pharma, Rivers East Supply, Canada Drugs or any of their subsidiaries or distributors report these problems or any adverse reactions to the FDA? The answer is no, they did not.

How much more of this is going on that we don't know about? How many of these cheaply sourced drugs are manufactured in facilities like this? We have no idea.

There are literally thousands of illegal online pharmacy websites that have bought off on the idea that Americans will trust an online drug merchant with a Maple Leaf on its website. Americans simply trust our neighbor to the north and it is this goodwill that is being exploited.

"Show me the bodies." That is what I constantly hear. "If there is such a problem with online drug sellers Dan then show me the bodies." Bodies? I ask. People generally don't just drop dead when they take a drug that does not have a therapeutic benefit. Haven't we learned from history, from years of public health experience?" Show me the bodies...if that is what it takes for government, industry, the internet ecosystem, lobbyists, payment processors, financial institutions and shipping companies, if that is what it takes, to make them understand the public health emergency we face by the reckless distribution of drugs online and the total disregard for U.S. laws and the regulatory system, then please listen to Daniel Weinstein.

On March 11, 2011, Daniel came home to find his wife Cheryl dead from an overdose of Carisoprodol that she purchased from the online drug seller topils.com. In 2011, Carisoprodol was not a controlled substance. As it remains today, Carisoprodol is widely distributed on the internet and this particular version was not approved for use in the United States. After her death, Daniel was harassed by telephone calls asking Cheryl to buy more; her inbox contained hundreds of emails offering her drugs of all kinds. Cheryl was a wife, mother, sister and friend to many and her family selflessly gave me permission to play this for you today in the hope that you will understand their absolute grief and frustration and that we, all of us in this room today, can stop talking about the problem and is some cases, stop being part of the problem, and do something about it.

Caveat venditor, let the seller beware, I am here to let the seller beware that FDA will continue this fight and we will continue to seek justice for victims like Cheryl Weinstein, Wanda Young and Betty Hunter.

Notes

1 GAO, 2013 "Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad." http://www.gao.gov/assets/660/655751.pdf. See also: NACDS.org http://www.nacds.org/Home/TabId/107/PostId/5065/global-collaboration-key-to-protecting-patients-from-illegal-online-drug-sellers.aspx

2 Ontario College of Pharmacists v. 1724665 Ontario Inc. (Global Pharmacy Canada)

3 Health Canada "**Reminder of obligations with respect to the advertising and sale of drugs**" See: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/reminder-rappel_adver-pub_tc-tm-eng.php

4 U.S. Department of Justice press release announcing the guilty of Paul D. Bottomley – District of Montana.

5 Weaver, Christopher and Jeanne Whalen "How Fake Cancer Drugs Entered U.S." Wall Street Journal, July 20, 2012

6 Whalen, Jeanne, "Turkish Drug Exporter Ozay Draws U.S. Scrutiny", Wall Street Journal, April 7, 2014

7 U.S. Department of Justice press release announcing the guilty of Paul D. Bottomley – District of Montana.

8 Whalen, Jeanne , "U.S. Sentences British Citizen for Distributing Fake Avastin", Wall Street Journal, July 11, 2013

9 Plea Agreement of Sabahaddin Akman, U.S. District Court, Eastern District of Missouri. Case: 4:14-cr-00003-AGF.

10 See FDA-Office of Criminal Investigations, Press Releases: http://www.fda.gov/iceci/criminalinvestigations/ucm123086.htm

11 UK Court of Appeals; Eli Lilly and Company/ Lilly Icos LLC v 8PM Chemist Ltd [2008] EWCA Civ 24

Gain an understanding of the current media being used within the cyberworld and its evolution: the Fakeshare project's strategic conclusions

Ryan Williams, LegitScript

Usage statistics on the major social media websites and examples of how those websites are used for illicit internet pharmacy marketing. Based on the data, overall recommendations in regards to future operations or educational campaigns.

The presentation, and this written summary, provide a briefing on current usage statistics for major social media websites, while outlining how illicit internet pharmacy operators co-opt the free account space to advertise prescription medication,[1] and offer up suggestions for education and enforcement strategies.

It is important to note that most social media companies do some proactive review of paid advertising space to ensure illicit internet pharmacies are not utilizing those services. However, the approach is more reactive in the free account space, relying on abuse complaints before suspending accounts. In general, there has been a continued increase in social media, both web and mobile, applications. Obviously, the younger generations make up the majority of users, but over the years these platforms have become more popular with older generations as well.[2]

As of July data, Facebook roughly had 1.71 billion monthly active users.[3] In addition, 91% of millennials (15–34 Yrs) use Facebook, and the platform has 233 million daily users in Europe alone.[4] According to research in 2012, there were roughly 83 million fake or duplicate accounts.[5]

Lastly, Facebook is used by 71% of the online population, with a gender breakdown of 76% women and 66% men.[6] This particular statistic indicates that educational campaigns might be more impactful if they are geared towards women.

According to data from November 2016, Twitter has 1.3 billion registered users and 100 million daily active users.[7] Interestingly, Twitter has 10 million users in China, even though the platform is blocked in that country. Lastly, research in 2013 concluded that there were 20 million fake users on Twitter.[8] As with Facebook, illicit product advertisements are predominantly made via free accounts.

Even YouTube, which is primarily used to upload and share videos, is regularly used by illicit website owners to advertise prescription medication and other dangerous products. According to data from July 2015, around 400 hours of video are uploaded to YouTube every minute.[9] There are 1 billion mobile video views per day, and 85% of adults (globally) visit YouTube regularly.[10]

In addition, more than half of YouTube views come from mobile devices.

In terms of enforcement and suspension of illicit advertisements, apart from the regular steps the social media companies use to remove accounts, there have been a few law enforcement operations of note. Operation Papworth, conducted by the Metropolitan Police in the UK, removed social media accounts as part of the operation that primarily targets websites selling counterfeit goods. In 2014, Operation Pangea VII, coordinated by Interpol with hundreds of law enforcement agencies and over 100 countries participating, successfully remove more than 19,000 advertisements on social media platforms.[11] However, while these successes are wonderful, the fact that the illicit actors use free accounts for advertising on social media means they can easily stand up new accounts after these enforcement activities.

As conclusions from the research, in terms of the overall evolution in how illicit website operators use social media platforms, things have not changed much over the years. Illicit actors still primarily utilize free accounts for advertising. While short term enforcement operations have been successful in the past, long-term strategies would be a better approach. Lastly, future educational campaigns might have a greater impact if they are targeted more towards women and are developed specifically towards mobile viewing of the social media platform.

Notes

1 The presentation given on the occasion of the International Conference provides example images of the advertisements.

2 http://www.pewinternet.org/2015/10/08/social-networking-usage-2005-2015/

3 http://money.cnn.com/2016/07/27/technology/facebook-earnings-high-expectations/

4 http://expandedramblings.com/index.php/by-the-numbers-17-amazing-facebook-stats/

5 http://www.cnn.com/2012/08/02/tech/social-media/facebook-fake-accounts/

6 https://www.brandwatch.com/blog/men-vs-women-active-social-media/

7 http://expandedramblings.com/index.php/march-2013-by-the-numbers-a-few-amazing-twitter-stats/

8 http://www.businessinsider.com/fake-twitter-users-2013-4

9 https://www.statista.com/statistics/259477/hours-of-video-uploaded-to-youtube-every-minute/

10 http://expandedramblings.com/index.php/youtube-statistics/2/

11 https://www.interpol.int/News-and-media/News/2014/N2014-089

Communication campaigns and internet communication strategies

Mike Isles, ASOP EU

Recent reports reveal that sales of falsified medicines are on the increase. This underlines the need to raise public awareness about the inherent risk of buying medicines online, unless it is known that the website source is licensed, registered and genuine. The implementation of the Common Logo, as described in the Falsified Medicines Directive, whereby Member States are obliged to publicise what a falsified medicine is and to describe its purpose, will be an important element in raising public awareness. This, combined with the efforts of other interested parties, will begin to make an impact of tackling the demand side of the equation. The presentation will review the status of the Common Logo implementation, review educational campaigns and underline the need to work even more collaboratively to face an increasing penetration of falsified medicines in to Europe.

1. Communication Strategies

It is important to understand that when devising a communication campaign that the strategic environment is understood as well as possible[1]. This means that a long term view can be taken. This is not an easy task when it comes to how the internet may look in future years, such is the rapid pace of change that we are seeing. However, it is still necessary to take a long term view based on what is known now. The term strategy has been defined as:

"A careful plan or method for achieving a particular goal usually over a long period of time"[2]

In some circles the term "hot Medicines"[3] is being used to describe those medicines that are most likely to be falsified. This term applies to both branded and generic medicines. Medicines hot on the web are usually characterised by strong demand, in the legitimate supply chain and this carries over to the illegitimate supply as characterised by sales via the internet through illegally operating websites.

The impact of the internet can be characterised in the following way:

- Impacting on the patterns of product, distribution and consumption
- Affects all classes of therapies
- Increasing individual and collective health risks
- Altering the relationship between patients and healthcare professionals
- Exacerbating the illegal diversion of medicines, thefts and other related criminal practices (e.g. ID theft, payment card, fraud, etc)

Set against this backcloth, it is a fact that we see a rising expectation by the public that everything should be available via the internet. We see this trend very clearly with the large retail stores such as Marks & Spencer, The John Lewis Partnership and others in the way that their customers are moving away from buying merchandise in the store to ordering online.[4] However, customers may still use the shop as a way to physically see and feel the product. So the trend to shop more and more online is now an established fact.

With the advent of the Falsified Medicines Directive[5] in Europe and the subsequent obligation by Member States (MS) to allow medicines to be sold "at a distance"[6], then this may add a further incentive for the consumer/patient to buy online. It may also raise questions amongst people about the variation of the laws that pertain in each country. In the UK for instance a number of categories of medicines can be sold and bought online. These categories being; Prescription Only Medicine, Pharmacy Only and General Sales List (POM, P and GSL respectively)[7]. There are currently only a small number of Member States that allow the POM category to be sold over the internet. It could be conjectured that there will be increasing pressure for all Member States to allow more categories of medicines to be bought on line, as the European citizen might come to expect parity in this area.

Within the Falsified Medicines Directive there is an obligation by each MS to introduce a common logo (CL) to be placed on each website page that is selling a medicine[6]. This requires sellers of medicines to register their legal entity and that each page of the sellers website must display a common logo. This CL icon can be clicked on and routes through to the MS's official registry to enable the patient/consumer to verify the authenticity of the seller of the medicines. The CL must appear on every page of the seller's website. Each MS is also obliged to publicise the purpose of the CL as well as the meaning of a falsified medicine. This will of course vary from MS to

MS. The FMD (as with any Directive passed in the EU Parliament) does not usually provide the resource (financial or otherwise) for the MS to implement the Directive and so depending on the MS situation there may be significant resource available or conversely very little.

To what extend are people buying medicines online? The HappyCurious study of 2014[8] can be regarded as a robust piece of market research. This was an online survey carried out in 5 countries namely: France, Germany, Italy, Spain and the UK. An omnibus of approximately 1000 online users per country was the sample size (N= 5010) and this revealed that 18% of the sample had bought a medicine online. Extrapolated up to the European population then that would mean 130 million people had bought a medicine online. This is a staggering statistic and even if the figure was 20% inflated then it still indicates that a large number of people are buying medicines online.

A number of studies have revealed the motivations behind people's purchasing behaviour of medicines. These are essentially: confidentiality, speed, convenience, uncomfortable asking the doctor, control over their health, cost[9]. In terms of medicines bought online, then these are many and varied. It is chilling to bear in mind that no less than 63 types of medicines were discovered through customs checks in UK arm of the 2016 Pangea operations[10]. Here are the medicines seized: Anorexiant (slimming medication); Hypnotic and sedative; Analgesic (painkiller); Psycotherapeutic Agents; Dermatological Agents; Herbal products; Hair Loss Agents; Anabolic steroid; Anti-inflammatory/Anti-rheumatic; Anti-depressants; Health Supplements; Gastrointestinal Agents; Anti-Cancer Agents; Muscle relaxants; Anti-bacterial/Antibiotic; Sex hormones; Anti-hypertensives; Drugs to treat addiction; Ophthalmological (eye); Analgesics; Thyroid therapy; Respiratory System Agents Miscellaneous; Anti-smoking; Nutritional products; Diuretic; Growth hormones; Medical Devices Miscellaneous; Cough and cold medication; Anti-diabetic; Cardiovascular Agents; Anti-histamine/Anti-allergy; Vitamins; Hormone Agents; Anti-parasitic; Metabolic Agents Miscellaneous; Anti-convulsant/Anti-epileptic; Cardiac therapy; Anti-psychotic; Anti-gout; Cholesterol medication; Laxative; Anti-malarial; Anesthetic; Antiseptic and germicide; Digestive enzyme; Beta blocking; Anti-fungal; Anti-alzheimer; Anti-diarrheal; Nervous System Agents; Anti-asthmatic; Immunosuppressive; Anti-viral (e.g. HIV); Blood Agents Miscellaneous; Musculo-Skeletal Agents Miscellaneous; Vasodilators.

These data are all important when working out an effective communication strategy. To define a target audience and therefore begin to segment the market goes hand in hand with this. But how should we segment? Clearly this may depend on the resources available from which campaigns to raise public awareness can be achieved. And perhaps this aspect will be the main driver when devising a campaign. Setting the size of the financial budget to support a campaign aside, what would help us decide on how to segment the target audience and hence the media to be used and the messages to be conveyed?

Should we segment by age, or gender, or therapeutic area? Taking the latter then should we prioritise to those that are most at risk? For instance, there is a younger female teenage group who seeks to buy slimming pills online who represent a more vulnerable group. We know that a young girl has died a horrible death and that the medicine and active ingredient that was supplied via the internet was highly toxic[11]. Or should we target the elderly who are potentially even more vulnerable from internet administered fraud?

We could perhaps look at the following therapeutic segments and devise ways to reach each target audience:

- Erectile dysfunction, body building, slimming pills
- Anxiolytics for treating depression
- Coughs and cold preparations
- Anti-cancer medication

The question then arises as to which media should be used that has the best reach to these target groups. Whilst more conventional media such as television and print will undoubtedly be effective, it is unlikely that the area of medicines bought via illegal websites will be high on a government's list for a large scale public awareness raising campaigns such as we saw with smoking cessation campaigns[12]. Indeed Governments are acutely aware that a campaign may upset the balance of trust in the institutions. The infiltration of falsified medicines in to the legitimate supply chain is rare in relation to the volume of prescriptions dispensed across Europe (this being manufacturer, to pre-wholesaler to wholesaler to pharmacy premises). And so a communication campaign to the public that might cause confusion and possibly risk a reduction in trust, must be carefully calculated.

That is not to say that all stakeholders should not strive to educate and highlight the seriousness to public health of the rising tide of patients/consumers buying medicines online and taking themselves out of their national health systems with subsequent potentially damaging and costly sequalae.

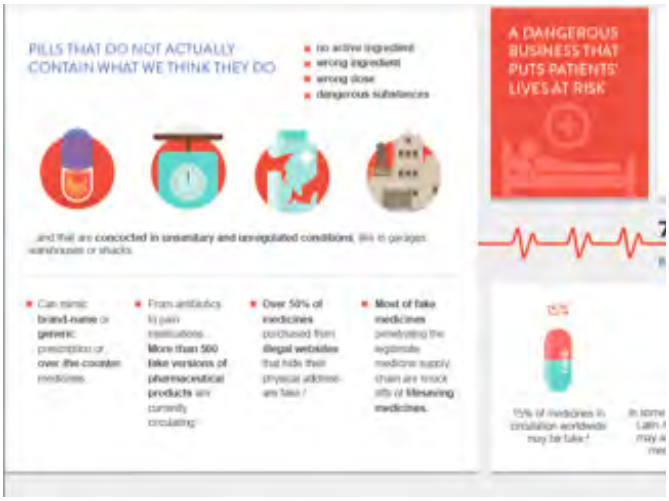
2. Communication Campaigns

2.1 ASOP EU – There are many not for profit organisations running public awareness campaigns to educate the public about how to buy medicines more safely on the internet. Recently ASOP EU has held meetings with these organisations to enhance collaboration and share best practice. In addition, ASOP EU has been supporting as many Member States as possible to share best practice. One such meeting was held on October 14th 2016 at the Microsoft offices.[13] In Brussels, Member States were invited to share their current implementation programmes of the common logo as well as their public facing campaigns. No less than 10 Member States were present with a further 4 who were unable to attend due to other commitments. As well as sharing best practice, the initiative by the National Association of Boards of Pharmacy to acquire the top level domain name .pharmacy was discussed[14]. This was primarily seen as complementary to the common logo but the possibility of confusion between the CL and .pharmacy was raised. In addition, a Code of collaboration was discussed which comprised the following:

1. Inform consumers that they must be diligent when shopping online to avoid the potential harm caused by falsified medicines sold by illegal online sellers of medicines.
2. Alert consumers to the typical signs of an illegitimate site:
   - In the EU, does not display the Common Logo
   - Offers "too good to be true" prices or deals unavailable in local pharmacies
   - Does not require a prescription
   - Offers medicines not licensed for sale in the country where the patient lives
   - Hides its physical address and does not have a pharmacy licence
3. Direct consumers to ways they can stay safe, including:
   - In the EU, looking for the Common Logo and ensuring the logo links to the MS regulatory authority's website
   - Looking for sites ending in the .pharmacy domain
4. Endeavour to use the following terms our messaging:
   - "Patient safety" or "consumer safety" as this is the reason for the work that non profit patient safety organisations do
   - "Falsifed Medicine" or "fake medicine" as opposed to the term "counterfeit" which is more usually reserved for Intellectual Property crime
   - "Medical products" for communications in the EU, as that is a statutory term.

2.2 Campaigns to raise public awareness – There is a growing number of not for profit organisations that has at its heart the objective to raise awareness amongst those countries most adversely effected by falsfied medicines.

2.3 Fight the Fakes Campaign[15] – Its membership is growing strongly and sets out to record specific case studies of where people have been directly effected by falsified medicines. It has a strong social media presence and has spearheaded many awareness raising initiatives. The instagram below is typical of the hard hitting educational material produced.



2.4 Fondation Chirac – This organisation[16] has highlighted strongly the dire need to increase public awareness around the rising tide of falsified medicines. They have produced a very powerful hard hitting short video[17]. Centered around three scenarios, the actors for health reasons, buy medicines online. The first is a an elderly couple with the husband requiring anti-cancer therapy. The second, an artist who has a bad chest infection. The third a mother with a sick child. All buy on the internet and all suffer damaging consequences to the health of those involved. The video depicts how the fake medicines are made in far flung places and shows the scale of

the operation and it sophistication and how the people receive their medication via the post very quickly. None of the actors speaks and so the messages are portrayed in a powerful and visual way. This makes the video very useful as it can be used in any country.

2.5 The International Institute for Research against Counterfeit Medicines – This organisation[18] is very active in informing the public about falsified medicines in France and beyond. Its recent collaborative campaign to educate the general public on what to do with medicines before and while travelling and during their stay involved the following organisations:

- The French National Association of Pharmaceutical Students (ANEPF)
- The French Industrial Property Institute (INPI)
- The French Order of Pharmacists (ONP)
- The National Anti-Counterfeit Committee (CNAC)

With over a million printed brochures distributed by the French pharmacy bodies it was a very far reaching campaign.

4 The Centre for Safe internet Pharmacies - CSIP

The Center for Safe internet Pharmacies (CSIP)[19] is a non profit organization chartered in 2011 to allow internet industry leaders to come together and continue their efforts to address the growing problem of consumer access to illegitimate pharmaceutical products on the internet.

Over a dozen of the world's leading internet and e-commerce companies have come together to form CSIP to focus on the promotion of safe online pharmacies through education and enforcement and the provision of a neutral forum for sharing information by and among private sector entities.

CSIP Members have produced a very useful document entitled "Principles of Participation for Members"[20] to address illegitimate online drug sellers as well as fundamentals of member involvement. It underscores the need for stakeholders to be willing to take voluntary actions that will enable all organizations involved to do more to make the internet safer for patients.

5. The Alliance for Safe Online Pharmacies ASOP Global

This is a growing organisation based out of Washington DC with a global reach.[21] The uniting purpose of ASOP Global is to protect patient safety globally and ensure patient access to safe and legitimate online pharmacies in accordance with applicable laws.

The principles of ASOP Global are as follows:

- Patients deserve access to safe medicines
- Illegal online drug sellers peddle unsafe medicine and often violate the law, regulations, and pharmacy standards required by countries to which they advertise and ship products
- Illegal online drug sellers are a global problem that requires national and global solutions
- Local, national and international governments, health industry stakeholders, internet intermediaries and non- governmental organizations all have a role to play in protecting patients from illegal online drug sellers
- More education is needed to alert consumers, providers, governments and companies that up to 97% of internet drug sellers are not compliant with applicable law
- Cooperation and commitment are essential; we all must work together to protect patient safety
- Governments should take meaningful and appropriate actions to protect patients from illegal online drug sellers
- Legitimate manufacturers, health care professionals, and licensed pharmacies should continue to caution

patients against purchasing their medication from unknown and/or illegitimate sources
- Internet intermediaries should take legal and appropriate voluntary actions to stop illegal online drug sellers from using their services to endanger patient safety

ASOP Global is very active in raising public awareness. A good example of this is the recent campaign entitled RISING DRUG COSTS ATTRACT SENIORS TO ILLEGAL ONLINE PHARMACIES: ASOP Global, CSIP and NCL Join Forces to Keep Older Americans Safe Online[22]. In addition, a new website has been created designed to be a powerful "go-to" educational consumer facing internet source of information.[23]

6. The Alliance for Safe Online Pharmacy in the EU (ASOP EU) in conjunction with the European Alliance for Access to safe Medicines (EAASM)

These not for profit organisations[24,25] work closely together and ASOP EU received a Google educational AdWord grant mid-2015 and has been running a digital based awareness campaign in Italy. The project entitled "Fighting Fakes by Raising Public Awareness" project was designed to accurately and directly target and warn people tempted to purchase prescription medicines online, more often than not, without a prescription from their doctor.

The educational website[26] aptly named "Medicineperte – medicines now" provides all of the information to educate people going online to buy prescription medicines. Using the Google AdWord account, keywords such as "pharmacy online" were bought and this triggered the ASOP EU advertisement to appear on the first Google search page, encouraging browsers to visit the educational website. Over a 7 month period, (September 2015 to February 2016) this pilot project on average, achieved over 13,600 per day first page impressions.

With a "click through" rate of nearly 2% this extrapolates to nearly 100,000 people in one year being exposed to the educational website. With an average dwell time of more than one minute on the website with many visits recorded of far greater length, the longest being 29 minutes, these statistics give a developing picture that such educational vehicles are effective. Convincing results that raising awareness can change behaviours.[27]

Of particular importance was being able to measure if the visitors would change their behaviour having been exposed to the content on the educational website. This vital information was made possible by a short questionnaire implanted on each website page. Visitors were asked to answer just 5 questions. One critical question was "Has the website made you change your mind and go to your pharmacy?" To this question, although numbers are small and should be regarded as preliminary results (59 responders) then, there is a clear and growing trend that people, once they are made aware of the dangers, will change their behaviours and revert to going to their pharmacy.

This report demonstrates the significant impact that an AdWord campaign can achieve. The ASOP EU and EAASM organisations intend to extend the reach of such a powerful educational tool to other European countries. This will undoubtedly add greatly to raising public awareness and enhance patient safety and ultimately support health outcomes across the European landscape.

7. EDQM Campaign – Open Minds, Free Minds: a psycho-pedagogical concept guide for teachers

This project[28] was financed by the EDQM (part of the Council of Europe) and had 6 consultants (3 psychologists – Italy, 1 artist Serbia, 2 IT experts Italy/Serbia) and two co-ordinators – AIFA and ALIMS. This was a science based concept to arrive at the key messages. Two age groups: 8–11 and 12–15 were focused on. The communication strategy used an interactive story where the reader could choose different outcomes. The graphics were innovative and were drawn to capture the imagination of the age group concerned. The materials used were print, PDF and Webcomic versions. The teaching concept was designed by psychologists and the base structure comprised a Web Tool and teaching tool.

8. Keeping it Real in Scotland – The Real McCoy

This is a Scottish initiative spearheaded by the the Scottish Business Resilience Centre (SBRC), and held at the Glasgow City Chambers. This event celebrated the success that has been achieved against illicit trade and provides the opportunity to bring together speakers from the world of business, academia, regulation and law enforcement. This event was combined with a fully interactive public event in marquees within the famous George Square to help educate the public about counterfeit goods which included falsified medicines. The MHRA had an important presence and ASOP EU spoke with the title "Fighting Fakes by Raising Public Awareness". Lynda Scammell spoken on behalf of the MHRA and gave a comprehensive review of falsified medicines and the way that the MHRA was contributing significantly to law enforcement whilst at the same time raising public awareness through innovative public facing campaigns such as the "Dodgy diet pills – Just don't risk it." In addition Duncan Elson from Pfizer presented compelling case studies of falsified medicines crime[29]

9 Recent Campaign in Spain

ASOP EU and the EAASM participated in a press conference following the conclusion of the Observatory Plenary meeting, to announce the launch of the Spanish Consumers Association (ASGECO) campaign on 29th September 2016.

This comprised a roadshow visiting key cities to inform the public about counterfeit goods (including falsified medicines). See following picture.

10. Key issues and next steps

10.1 Segementation – It will be important to develop skills in segmentation and understand the reach and effectiveness of the campaigns to the key target audiences. ASOP EU has recently had its Google AdWord grant extended and this will allow campaign to be run in France, Germany, Italy, Spain and the UK. This will give rise to valuable information about what are the best keywords to purchase to reach different target audiences. The Ministry of Health, Welfare and Sport Netherlands (see picture below) ran a campaign.[30] using a Google AdWord approach and they are analysing who engaged with the site and dwell times etc – to determine how to best continue in 2017, this will also reveal important visitor information.

10.2 Costs – Understanding the costs involved to run an effective campaign will be an important learning. This needs to be closely tied in to the measurements that have been put in place. This can be obtained by asking the public to give feedback through anonymous surveys. The campaigns should always feature such a tool as already demonstrated by the results from The "Fighting the Fakes by Raising Public Awareness" campaign.

10.3 Funding – Clearly without appropriate funding then the campaigns will be unable to reach their potential. If this is the case then there is the possibility of search engine optimization using the synergies of websites that naturally accrue. This requires significant co-operation by the parties involved but has been known to produce good results.

Clearly the search engines such as Google, Bing and Yahoo support the education of the public in many areas including addressing the need to educate the consumer/patient about falsified medicines and the risks of buying medicines online.

Under the Falsified Medicines Directive Member States are obliged to inform the public about falsified medicines and the purpose of the Common Logo[31].

Article 85d:

Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.

Already we are seeing useful communication campaigns by a number of Member States. The ASOP EU has a 2017 objective to continue to support "Best Practice" seminar so that Member States and Non-Profit patient organisations can combine their skills and experience to further this goal.

11. Conclusion

It can be seen that collaboration by all stakeholders to address the "Demand" side of the equation that is fueling criminals to offer medicines on an illegal basis, is vital to tackle this health issue. It requires the cooperation of all parties and the Principles of Participation if taken up with vigour by all the parties then this will support both the "Supply and Demand side" of trade in falsified medicines.

It is heartening to note that actions such as that of Fakeshare and all of the actors mentioned in this article are aligning their activities and will, through continued concerted collaborative efforts, make a difference and ultimately save the health of many patients and ultimately save lives.

Notes

1 Counterfeit medical products and similar crimes: risk communication (D. Di Giorgio ed., Tecniche Nuove, AIFA/EDQM publishing: ISBN 978-88-481-2662-5, 2011)

2 Merriam-Webster dictionary https://www.merriam-webster.com/dictionary/strategy

3 FakeCare – Research Centre on Security and Crime http://www.rissc.it/portfolio/fakecare/

4 Office for National Statistics – UK https://www.ons.gov.uk/businessindustryandtrade/retailindustry/bulletins/retailsales/2015-07-23#internet-sales-in-detail

5 Falsified Medicines Directive https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

6 Common Logo – http://ec.europa.eu/health/human-use/eu-logo_en

7 Boots web MD UK – Navigating the NHS –http://www.webmd.boots.com/nhs/medication-and-pharmacy

8 Europeans and Counterfeit medicines Opinion Survey http://www.happycurious.fr/wp-content/uploads/2016/07/36553_2014-05-15_Counterfeit_medicines_EN.pdf

9 ASOP EU online survey 2016 Fighting the Fakes by Raising Public awareness

10 MHRA Pangea VIII https://www.gov.uk/government/news/uk-leads-the-way-with-158-million-seizure-in-global-operation-targeting-counterfeit-and-unlicensed-medicines-and-devices

11 Slimming pills cause death of a teenager http://www.bbc.co.uk/news/uk-england-shropshire-33635222

12 Launch of mass media smoking cessation campaign http://www.stopsmokingwales.com/news/33936

13 ASOP EU Roundtable on EU Strategy and Messaging on Falsified Medicines and internet Sales "Sharing best practice" with Member States and non profit organisations to raise Public Awareness – page 6 http://asop.eu/cache/downloads/eqtrgxg8wdkock4g8wcc0cwck/EAASM%20-%20ASOP%20EU%20Mid-year%20Newsletter%202016.pdf

14 National Association of Boards of Pharmacy Top Level Domain Name .pharmacy https://nabp.pharmacy/initiatives/dot-pharmacy/

15 Fight the Fakes campaign http://fightthefakes.org

16 Fondation Chirac – What is a fake medicine? http://www.fondationchirac.eu/en/conflicts-prevention/access-to-medicine/learn-more-about-fake-medicines/counterfeit-defective-sub-standard-and-generic-drugs-the-threat-of-confusion/

17 Pharmacide video – https://www.youtube.com/watch?v=5vTs-vf0pjA

18 International Institute for Research against Counterfeit Medicines http://www.iracm.com/en/

19 The Center for Safe internet Pharmacies (CSIP) https://safemedsonline.org

20 CSIP Principles of Participation https://safemedsonline.org/who-we-are/principles-participation/

21 Alliance for Safe Online Pharmacies – Global http://safeonlinerx.com

22 ASOP Global, CSIP and NCL Join Forces to Keep Older Americans Safe Online http://www.multivu.com/players/English/7843951-asop-csip-ncl-fake-prescription-drugs/

23 X the Risk – verify before you buy https://xtherisk.com

24 The Alliance for Safe Online Pharmacy in the EU a Community Interest company http://asop.eu/home

25 The European Alliance for Access to Safe Medicines, a Community Interest Company http://www.eaasm.eu/home,en

26 Italian educational website http://farmacisicuri.org

27 ASOP EU online survey "2016 Fighting the Fakes by Raising Public awareness" http://asop.eu/cache/downloads/8h23cbi9xo8w4o0k8o0gwo04w/Fighting%20Fakes%20by%

28 EDQM Open Minds campaign https://www.edqm.eu/en/Counterfeit-medicines-and-similar-crimes-1625.html

29 MHRA campaigns to raise public awareness about falsified medicines https://www.gov.uk/fakemeds

30 Ministry of Health, Welfare and Sport Netherlands http://www.echt-of-nep.nl

31 DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

The tools developed in the framework of Fakeshare

The Fakeshare HUB: the advantages of a platform shared among the Member States

Giovanni Ferretti, Marco Fontanella, Gianpaolo Derossi, AIFA

The project aimed at creating a structured system for the sharing of information on criminal cases related to the production and distribution of falsified medicines, the promotion of medicines through illegal web pharmacies, online suppliers and/or social networks, and the theft and laundering of medicines.

The activities led to the implementation of a web platform consisting of two areas, one restricted and one public. Both public and private sites run on a multi-tier fully-redundant architecture composed by 7 distinct servers and these systems are hosted into AIFA's server farm (ISO 27001 compliant) and managed by AIFA's own personnel.

The public area (www.fakeshare.eu) contains documents and insights developed in order to raise the consumers' awareness on the dangers of buying medicines through unauthorized channels. The researches carried out in Italy, Spain, Portugal and the UK during the project, highlighted the low perception by the consumers of the risks related to the purchase of medicines on the web, by investigating the behavioral and psychological dimensions involved in the purchase of medicines online.

The restricted area (hub.fakeshare.eu), accessible only to registered users, has been built and structured according to high safety standards and contains a series of documents and insights, and searchable databases. It is a tool designed and built specifically to support the activities of enforcement authorities and police forces involved in the prevention and fight against the pharmaceutical crime:

- the manufacturing and distribution of counterfeit or illegal medicines;
- the promotion of dangerous medicinal products through unauthorizede-pharmacies and /or social networks;
- the theft and laundering of medicines.

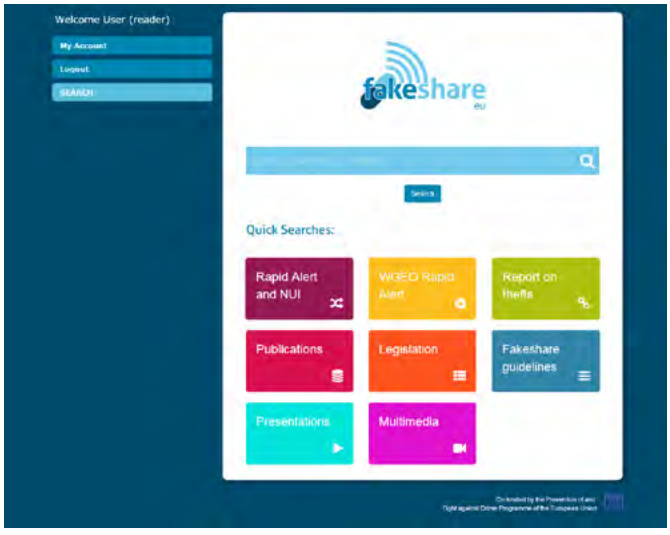
The existing Fakeshare (I) restricted web area has been opened to the new co-beneficiaries and partners in order to prepare the activity of gathering of information, reports and studies about pharmaceutical crime provided by academic/police forces and DRAs experts. Database and tools have been developed considering the broader network involved in the Fakeshare II platform and the new data on thefts to share.

The core change focussed on the implementation of three fully-searchable database (in addition to the documents' database) describing pharmaceutical crimes, such as thefts and missing medicines, illegal products and e-pharmacies. These databases are open to the contributions of all the project's partners and other stakeholders.

The search engine works exclusively with "tags". With the "tag" system we define a set of well-defined values. A tag is more than a simple word: a tag is a word or a brief sentence (more words) which has a very specific meaning. Groups of tags are referred to as "categories" and define the knowledge domain into which tags gets their meaning.

To classify a document or a data and make it searchable, a number of tags are assigned to it according to shared standards, when uploaded to the restricted area. More tags are assigned, better chances has a document to appear in the search result.

A specific guidelines document is available to all the users.



Annexes

Annex A. Agenda

COORDINATOR

Agenzia Italiana del Farmaco AIFA

CO-BENEFICIARIES

infarmed

MHRA

SAPIENZA UNIVERSITÀ DI ROMA

UNIVERSITY OF TRENTO - Italy Faculty of Law

ASSOCIATE PARTNERS

alims

ASOP GLOBAL Alliance for Safe Online Pharmacies

Cofepris

GUARDIA CIVIL

IFPMA

Ministero dello Sviluppo Economico

Pharmaceutical Security Institute

9:30 **Welcome**
Mario Melazzini, *Chairman of the Board – AIFA*
Antonio Messina, *Farmindustria*

Introduction
Domenico Di Giorgio, *AIFA*

THE PHARMACEUTICAL CRIME

10.00 **The market of falsified medicinal products: how is the scenario changing?**
Manuel Ibarra Lorente, *AEMPS*
Domenico Di Giorgio, *AIFA*
Vânia Serapicos, *INFARMED*
Athiqur Meah, *MHRA*

10:45 **Thefts of medicines: an outline of the phenomenon**
Domenico Di Giorgio, *AIFA*

11:00 **Management of cases of pharmaceutical crime in Italy**
Diana Russo, *Public Prosecutor of the Republic*

11:20 **Coffee break**

11:40 **Regulation on the delegated acts**
Belén Escribano Romero, *AEMPS*

SALE OF MEDICINES ONLINE

12:00 **The purchase of medicines online**
The results of the 2016 survey in UK, Italy, Spain and Portugal
Claudio Barbaranelli, *University of Rome "Sapienza"*

12:20 **Evolution of the sale at the distance after the introduction of the Common Logo**
Giampiero Camera, *Italian MoH*
Belén Escribano Romero, *AEMPS*
Vânia Serapicos, *INFARMED*
Lynda Scammell, *MHRA*
Paul Brewer, *MHRA*

13:20 **Lunch**

14:30 **The role of the Social Networks and Market Places in the fight against pharmacrime**
Delphine Dauba-Pantanacce, *eBay*

15:00 **FDA pursuing illegal web pharmacies**
Daniel Burke, *U.S. FDA*

15:20 **Gain an understanding of the current media being used within the cyberworld and its evolution**
The Fakeshare project's strategic conclusions
Ryan Williams, *LegitScript*

15:40 **Communication campaigns and Internet communication strategies**
Mike Isles, *ASOP EU*

THE TOOLS DEVELOPED IN THE FRAMEWORK OF FAKESHARE

16:00 **The Fakeshare HUB: the advantages of a platform shared among the Member States**
Giovanni Ferretti, *AIFA*
Marco Fontanella, *AIFA*
Gianpaolo Derossi, *AIFA*

Working language: English

Annex B. Speakers

Claudio Barbaranelli, *University of Rome "Sapienza"*

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.

Paul Brewer, *MHRA*

Senior marketing & communications practitioner with client and agency side background and substantial experience across public, NGO, not-for-profit and private sectors, with a track record of successfully developing innovative, insight-driven business initiatives. Particular knowledge of public health and behavioural change initiatives.

Daniel Burke, *U.S. FDA*

Special Agent, cybercrime investigator and Operations Manager for the Office of Criminal Investigations at the United States Food and Drug Administration.

Giampiero Camera, *Italian Ministry of Health*

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.

Delphine Dauba-Pantanacce, *eBay*

Delphine Dauba-Pantanacce, Senior Legal Counsel, works within the Global Regulatory team at eBay aimed to protect the company and its brand while supporting the business. Over the years she has built up strong co-operation with high level Law Enforcement agencies in Europe and form successful relationships with regulatory authorities in Europe and in APAC working on prohibited and restricted items area.

Delphine is graduated from the University of Pennsylvania, Law School, from the University of Paris-Sorbonne and from the University of Paris-Nanterre.

Gianpaolo Derossi, *AIFA*

Communication Technician of the Fakeshare (I) 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 in an international NGO organised as permanent research network, collaborating with local research institutions and/or individual experts He was in charge of coordinating research and publication activities and of organising and managing the events.

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

Domenico Di Giorgio, *AIFA*

Dr. Domenico Di Giorgio, Ph.D., is Head of the Post-Marketing Surveillance office and of the Product Quality and Pharmaceutical Crime Counteracting 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.

Belén Escribano Romero, *AEMPS*

Belén Escribano is currently the Head of the Pharmaceutical Inspection and Enforcement Department of the Spanish Agency for Medicinal Products and Medical Devices (AEMPS).

She holds a Doctorate (PhD) in Pharmacy from University Complutense of Madrid and a Degree in Hospital Pharmacy after the completion of the national training program.

After working in the National Health System as a hospital pharmacist, she passed the exams to become a civil servant and moved to the Health and Consumers Affairs Department of the Regional Government of Madrid where she worked as an inspector and technical advisor.

In 2007 she moved to AEMPS, and since then has been responsible for Pharmaceutical Inspection and Enforcement Department. She participated in the GDP Drafting Group of the EMA GMDP IWG. Nowadays is actively involved in the implementation of the 'Falsified Medicines Directive-FMD' (Directive 2011/62/EU) at national level and also participates in the FMD HMA Task Force for an EU harmonised implementation of the new measures.

Giovanni Ferretti, *AIFA*

Manager of health professions at the Italian Medicines Agency (AIFA), Giovanni Ferretti has a professional background in the chemical and pharmaceutical process analysis and research, and in the field of Information Technology.

As a member of the Database & Analysis Office, he participates (on behalf of AIFA) in the activities related to Master Data Management strategy for the use of data on medicinal products (Substance, Product and Referential) in the European telematics field.

He is in charge of technical-scientific and regulatory activities related to the IT workgroups of the European Medicines Agency.

PhD in pharmacology, he participated in the evaluation of authorization requests for medicines at the European level (European assessment).

Marco Fontanella, *AIFA*

Since 2004 Marco Fontanella is System Administrator in the private sector and currently works at the Italian Medicines Agency (AIFA) in the same role. He worked also as Web Developer and trainer in IT Education.

Manuel Ibarra Lorente, *AEMPS*

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.

Mike Isles, *ASOP EU*

Mike is Executive Director of the European Alliance for Access to Safe Medicines (EAASM). The EAASM is a pan-European patient safety organisation, bringing together all concerned with eliminating falsified medicines from the supply chain whilst also campaigning for safe medical practices.

Mike is also the Executive Director of the Alliance for Safe Online Pharmacy in the EU (ASOP EU), a multisectoral organization whose mission is to enable patients to buy their medicines online safely – where it is legal to do so. With over 50 participants involving many key internet stakeholders, its aim is to produce concrete voluntary actions that will make a real difference and ultimately make a significant difference to the health of patients.

Mike is also European Medicines Partnership Director for International Health Partners. This a UK charity whose Queen's Award for Enterprise for continuous Innovation in 2011 recognises the tremendous humanitarian work sourcing donated quality medicines from the pharmaceutical industry and coordinating delivery via secure supply chain solutions to disaster-struck areas in close liaison with NGOs.

Mike's professional background is in pharmaceuticals, where he held senior management and director posi-

tions covering sales, marketing, commercial and supply chain in a 32-year career.

Athiqur Meah, *MHRA*

Athiqur Meah is currently the Team Leader of the MHRA Enforcement Group's Case Referral Centre (CRC). Athiqur joined the MHRA Intelligence Unit in 2003 as an Intelligence Officer and completed an Intelligence Analyst course run by the National Policing Improvement Agency. In 2008, Athiqur was promoted to the role of Deputy Team Leader of CRC and was involved in setting up the crime desk of the Enforcement Group that has since been the focal point in receiving referrals relating to breaches of medicines regulations. The CRC team also has responsibilities for the agency's counterfeit and whistleblower referrals. Since 2009, Athiqur has represented the Agency on several Interpol operations relating to targeting illegal online pharmacies.

Mario Melazzini, *Chairman of the Board – AIFA*

Mario Melazzini, medical doctor, specialized in general hematology and clinical laboratory , and researcher in the field of hematology-oncology, is currently Chairman of the Board of the Italian Medicines Agency (AIFA).

He was previously Director of the Oncology DH of the Scientific Institute for Research, Hospitalization and Healthcare "Fondazione Salvatore Maugeri" in Pavia.

He was also contract professor at the University of Pavia – Faculty of Medicine and Surgery.

He was Director of the complex structure of continuity of care hospital-territory of the Niguarda Ca 'Granda hospital in Milan and Director of Health Planning and Development of LombardyRegional Plans.

He has covered the role of Councillor for Health, Councillor for Industry, Research and Innovation, and Councillor for Universities, Research and Open Innovation of the Lombardy Region.

He is member of the Technical Health Committee of the Ministry of Health and Chairman of the Commission for Health Research of the Ministry of Health (Section C).

He is the President of Aurora Onlus Foundation, belonging to the "Nemo Sud" Clinical Centre at the Azienda Ospedaliera Universitaria Policlinico 'G. Martino' in Messina and Scientific Director of the Clinical Center of Serena NeMo Onlus Foundation at the Niguarda Hospital in Milan.

He was Chairman of the Ministerial Commission on Neuromuscular Diseases at the Ministry of Health, where he was responsible for organizing and coordinating activities, and Member of the Working Group on Rehabilitation, in charge of updating the guidelines for rehabilitation activities, in cooperation with Italian Regional Authorities.

He was the Scientific Coordinator and Head of the Technical Discussion Group for Policies for People with Disabilities of the Lombardy Region.

He was the National President of both AISLA Onlus (Italian Association for Amyotrophic Lateral Sclerosis) and of AriSLA Italian Foundation for research on Amyotrophic Lateral Sclerosis.

He was also National Secretary of the Italian Federation for the Overcoming of Handicaps (FISH).

He has published numerous scientific articles and is author of several books related to his experience both as a doctor and as a patient.

Antonio Messina, *Farmindustria*

A. Messina joined Merck in April 1999 as Regional Neurology TA Director, then in January 2003 he took the responsibility of Hellas as Country Manager and since May 2006 he was appointed General Manager for Italy and Greece. At the present he is the Managing Director and President of Merck Serono S.p.A. Prior to join Merck, he held a number of positions in Bayer, Rhone Poulenc Rorer first in UK as Oncology PM and then in Italy as Oncology Marketing Manager. A. Messina is graduated in Biology from "La Sapienza" Rome University and then he completed both with a post graduated studies as Strategic Executive Program at Babson College in Boston, a course of Finance for Executives at Instead Milan and with Biopharma Breakthrough 2008 at London Business School.

In July 2016 Messina was awarded with an Honorary Degree in Pharmaceutical Chemistry and Technology at Bari University "Aldo Moro".

Diana Russo, *Public Prosecutor of the Republic*

Dr. Diana Russo, Public Prosecutor of the Republic at the Court of Naples North, is specialized in domestic violence crimes, pedophilia, child pornography, sexual assault, stalking, prostitution, immigration and also protection of animals.

Since 2016 she is member of the Commission of Permanent Study "Equal Opportunities" of the National Association of Magistrates.

She previously served as Prosecutor in the city of Palermo, where she was assigned to the Department I ("Common Crimes", that is crimes against property, crimes related to narcotics, smuggling, homicide and unintentional injuries not related to work injury, violations of the TULPS – "Consolidated text of public safety laws", weapons offenses, attempted murder, kidnapping, pimping) and included in the "vulnerables" section.

Prior to the judicial functions she worked as lawyer, mostly as civil attorney.

She participated as speaker in various conferences, in particular on crimes against individual freedom, sexual violence, child protection and trafficking, as well as environmental and animal protection.

She was Professor and edited several publications on civil, criminal and administrative law.

Since 2014 she is member of the Editorial Board of Legal Collection supervised by the magistrates of the District Court of Appeal of Naples, "Rights & Jurisdiction", in which she published several dissertations.

Lynda Scammell, *MHRA*

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.

Vânia Serapicos, *INFARMED*

Process Manager/Inspector in INFARMED, I.P. – Inspection Unit

Her main activities and responsibilities deal with all duties concerning the analysis of complaints about activities related to the supply and distribution of human medicines, health products and cosmetics according to pharmaceutical law; inspections to wholesales distributors, pharmacies and other entities; creation of documents, notifications and newsletters that function as regulations and guidelines to fair practices; production of legal opinions.

Ryan Williams, *LegitScript*

Ryan Williams, a graduate of West Virginia University, has been working in the field of research and analysis of cyber criminal activities for ten years. During that time, he has conducted analyses on dozens of illegal internet pharmacy networks, working to identify the actors involved in the illicit trade of prescription medications. Working for LegitScript, he continues to investigate these networks, identifying key infrastructure components to target for disruption and dismantlement. LegitScript is proud to work with internet companies, government agencies, and organizations that are dedicated to curtailing the illicit online sale of pharmaceuticals. Ryan's current position with LegitScript is as an Intelligence Analyst and Associate Director of Business Development.

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