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## Challenges for national competent authorities on the sale of medicinal products over the internet

### Proceedings

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# Introduction

The International Conference of Fakeshare Project, held on February 24<sup>th</sup>, in the Spanish Agency of Medicines and Medical Devices, in Madrid, joined together representatives from the competent authorities, police forces and stakeholders from different European and Latin American countries.

The agenda was structured in three sessions, covering a range of topics, from the different actions taken against the illegal sale of medicines over the Internet at national and international level to an overview of the supervision of legal e-commerce on medicines.

The first session dealt with actions against the illegal sale of medicines over the Internet, and counted with the participation of the Italian Medicines Agency (AIFA), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Spanish Agency of Medicines and Medical Devices (AEMPS). In addition, the participation of a representative from the National Administration of Medicines and Medical Technology of Argentina (ANMAT), expanded the perspective to become global.

The second session was focused on the Internet legal framework, by providing an overview of the regulation applicable to the legal sale of medicines over the Internet that will be soon in place in the European Union, both from a EU-wide and a national perspective.

The European Commission, the Central Authority of the Länder for Health, Medicines and Medical Devices (ZLG), the National Authority of Medicines and Health Products of Portugal (INFARMED) and the Spanish Agency of Medicines and Medical Devices (AEMPS) shared their expert views on this topic.

The last session of the conference expanded the discussion by providing views of authorities involved in the supervision of the Internet other than the authorities for medicinal products or for other categories of products, such as medical devices. Outstanding speakers from the Technical Unit of Judicial Police (Guardia Civil), the Internet Observatory of the Spanish Agency for Consumers, Food Security and Nutrition (AECOSAN) and the Austrian Medicines and Medical Devices Agency (AGES).

To conclude, the University of Rome presented buyers' profile of illegal medicines over the Internet, based on a set of international carried out surveys. Speakers, coming from different organizations and with a notable experience in their field of expertise, offered a good overview of the enforcement and supervisory activities from a multidisciplinary perspective and provided occasion to discuss on the approach to the problem by the different authorities and organizations.

# Opening – welcoming

Belén Crespo. Director of the Spanish Agency of Medicines and Medical Devices (AEMPS). Spain

As Director of the Agency, I want to give you a very special welcome to this International Conference that we are organizing as part of the Fakeshare I Project, a European project co-funded by the European Commission.

Its aim is to enhance the exchange of experiences and information in the area of the illegal sale of medicinal products over the Internet, as well as good practices of other national competent authorities. Hopefully we will be able to increase the efficacy of our work until now, to achieve a better protection for the consumers.

The Spanish Agency of Medicines and Medical Devices considers of the highest importance the fight against medicinal products falsification in which, in order to be entirely effective, a multidisciplinary and coordinated approach is needed for all the stakeholders. This is the reason why in our National Strategy against Falsified Medicinal Products, in place since 2007, has always involved all the national stakeholders. In fact, in the last edition of the strategy, this multisectorial approach to the internet trade has an outstanding position, as Internet is nowadays the primary way by which falsified medicinal products reach our patients, this is why we quickly agreed to AIFA invitation to participate in this project.

The illegal sale of medicines over the Internet is a widespread phenomenon that concerns all the health authorities and we also know that these illegal sales at a distance, for its own characteristics, are very difficult to fight.

We are used to protect our “physical supply channel”, while now we face the challenge of millions of websites, with holders and servers located all over the world. It is difficult to keep this fight effective be-

cause after closing an illegal website, following burdensome legal procedures, it is very easy and fast to create a new one. We also need to perform communication campaigns, so that our citizens are aware of the risks of acquiring medicinal products outside the legal channels.

Given the increasing importance of the electronic trade all over the world – with enormous figures of sales – we cannot just forbid the Internet sales of medicinal products but instead we need to help our patients to buy safely over the Internet. This is why, in 2011, a European Directive (2011/62/UE) included the requirements for these sales and established a European system that will be starting next July 2015.

I would like to mention that, besides this Fakeshare Project, our Agency has been always very active in any international initiative against falsified medicinal products, participating in the initiatives of the European Council – Spain was the second country to ratify the Medicrime Convention against the falsification of medicines and other similar crimes involving a serious threat to public health. Also the Agency participates in, among others, the WHO mechanism against Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products (SSFFCC), with the European Commission, the European Agency of Medicines and the European network of regulatory national agencies of medicines in this field. We also have a special collaboration in these issues with the countries of Latin America through the Ibero-American Medicines Authorities Network (EAMI Network).

Lastly, I want to express my gratitude to all the speakers for the time dedicated to prepare their presentations and to all the assistants, for travelling from your countries to be here today.

# Session one:

national competent authorities activities against illegal sales of medicinal products over the internet

# AIFA's strategy on falsified medicines results

Domenico Di Giorgio. Director of the Product Quality and Counterfeiting office. Italian Medicines Agency (AIFA). Italy

The strategy that Italy applies against illegal e-pharmacies is really multisectorial because it represents a complex framework, including rogue e-pharmacies, unapproved ones – working according to the law for another country – and fake e-pharmacies.

So AIFA has set up a long list of different opportunities for counteracting the non-approved activities. It has also set up a lot of different possible actions using the existing regulation at different level either at the registrar level, or the registrant, or the webmaster in order to classify the platforms and also to be able to start acting against unapproved sites, e.g. by blocking the access from Italy to another EU Member State where that activity is legal.

AIFA has implemented the Directive 2011/62/EU by Legislative Decree n. 17, of 19 February 2014, regulating the sale at a distance to the public. The national implementation of the regulation has established a national anti-counterfeiting Taskforce, involving the Ministry of Health, the Official Medicines Control Laboratories (OMCL) of the ISS National Institute of Health (ISS), the Carabinieri NAS and Customs, all

in collaboration with the referred ministries and the support of Ministry of Economic Development.

The national anti-counterfeiting system is intended to prevent the circulation of counterfeit medicines through: the receipt and management complaints; the recall of medicinal products from the market; the withdrawal of the products (even among the patients). AIFA may also send a Rapid Alert notification to the competent authorities of the Member States and all stakeholders in the chain of distribution on the national territory. In addition within 24 hours public announcements may also be launched.

AIFA regularly organizes a Conference of stakeholders, which aims to examine the cases reported or detected in the monitoring carried out in agreement with Carabinieri NAS and to identify violations to the rules on selling at a distance of medicinal products to the public. The MOH is the competent Authority for measures aimed at preventing access to illegal websites. The measures are carried out by the Carabinieri NAS and in cases of non-compliance, there are administrative penalties.

# Activities of AEMPS against illegal sales of medicinal products over the internet

Manuel Ibarra, Technical Advisor, Area of Illegal Medicines. Pharmaceutical Inspection and Enforcement Department. Spanish Agency of Medicines and Medical Devices (AEMPS). Spain

Internet has become a source of health information and it is a global market, with a clear trend towards growing numbers. However, being a global market raises some issues on jurisdictions and capacity to take actions by competent authorities. Shut down a website is a costly process (in time and resources) and success is not guaranteed – the main problem we face is that some of these agents cannot be reached to make them comply with our regulation.

It is important to highlight that the AEMPS acts in the administrative field supporting the police if the cases reach the criminal phase, but the authorities can only go as far as the law or regulations allows them. Basically the framework at EU level is the directive on e-commerce that has been transposed differently on several member states. In Spain, administrative authorities have been empowered to take action on the administrative field.

According to the Spanish Law 34/2002, of July 11, hosting service providers are exempted from liability, as long as they have no actual knowledge of illegal activity or illegal information provided by the seller/user and after upon obtaining such knowledge, they act expeditiously to remove or to disable access to the information.

The main principles in Law 29/2006, recent development of detailed regulation for legal sales, in accordance with Directive 2001/83/CE requirements, indicate that the sale of prescription only medicines (POM) over the Internet is prohibited and that the internet sale of non-prescription medicines is allowed only if medicinal products are authorised and they are sold by a licensed pharmacy.

The cases are started once a signal is received from another authority or other sources and then the

AEMPS proceeds to search for web sites selling that particular product. For the investigation, open source intelligence tools and resources are being used -such as WHOIS databases- and also there is close contact work with the authority managing the .ES top level domains to help to identify the registrants of the web page or, at least, the ones hosting it. In this way the need of action and risk is evaluated and also information and evidence are gathered to be able to build a case in the future.

If the registrant is identified and located in Spain, a formal request for withdrawal of the illicit information is issued. Also, the AEMPS cooperates with the authority of .ES top level domains, but they do not share the same criteria for shutting down a web site, and they also have different rules, but sometimes the information provided for registration is false and that is for them a cause for cancellation of the domain name. In those cases that the registrant is not identified, but the hosting service provider is located in Spain, a formal request to the hosting service provider can also be issued. Beyond these cases, any action is very complex and resource consuming.

As a conclusion, it is important to overcome hurdles in investigating/enforcing legislation on internet sales of medicines by increasing international cooperation and mutual assistance, strengthening the cooperation with internet service providers and exploring other ways of tackling down websites. There is also a need to increase the public awareness through campaigns, press release and collaboration with media, and also to explore other legal leverages such as agile procedures for cooperation with network operators, on-site inspections on ISPs and access to documentation and establishing cooperation procedures with payment methods platforms.

# Medicines online: a global issue

Lynda Scammell. Senior Policy Adviser of the Enforcement Group of the Medicines and Healthcare Products Regulatory Agency (MHRA). UK

**Lynda Scammell**, senior policy adviser of the enforcement group of the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK explained the characteristics of the sales of medicines over the Internet, which constitutes a global issue. In the UK the enforcement of medicines law is the responsibility of the MHRA and not of the police.

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

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

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

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

In terms of accessibility, smartphones have become widespread, and a study showed that 4 out of 5 smart phone users use them to shop on line. It's the age of the Internet and in the last 10 years, between 2004 and 2014, Internet users have increased from 745 million

to just under 3 billion. The times are changing and we have to change with them.

The criminals are taking advantage of this, because it provides access to a vast global market – more consumers are connected and are able to purchase – and, as the WHO has seen, there is a direct correlation between access to the Internet and growth in counterfeit medicines. In this situation, there are business models that allow affiliate websites to feed into their sales site. There is also the ability to operate freely due to difficulties in enforcing rules and regulations and to remain anonymous.

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

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

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

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



# Illegal sales of medicinal products over the internet

Romina Viñas. Surveillance Directorate for Health Products. National Administration of Medicines and Medical Technology (ANMAT). Argentina

The National Administration of Drugs, Food and Medical Devices (ANMAT) is a decentralized agency of the national public administration aimed at prevention, protection and health care of the population. The primary duty of the Office of Health Product Vigilance is to provide assistance in post-marketing and vigilance of medicinal products, medical devices, cosmetic and household sanitizing products.

The Office of Health Product Vigilance is in charge of monitoring the medicines distribution chain in order to counter the delivery of illegitimate products, including internet sale of medicines, intervening in the verification for legitimacy of health products in the presence of their registration holders and checking the compliance with the national drug traceability system.

Other responsibilities of the Office of Health Product Vigilance are to propose appropriate measures to protect public health upon the detection of a risk factor related to the quality of products, to assist in the harmonization of projects relating to the combat against the falsification of medicines. ANMAT is also responsible for coordination of the institutional interaction with judicial, customs and other health authorities, police forces, professional associations, the Public Ministry and any other body so requiring it, and to file reports before the Committee of Prosecutors when situations that may entail a criminal offense are detected.

Actually the supply of medicines on the internet is frequent in Argentina but selling medicines over the internet is prohibited. The online sale does not require the submission of a medical prescription and, in most cases, no health professional monitors or controls the dispensation.

In Argentina, medicines can be obtained only from health establishments authorised to supply to the public and, therefore, the dispensation out of these channels involves risks as the source is unknown. These unlicensed channels of sale facilitates the entry of falsified, adulterated or stolen products or those with no due authorisations-. Illegitimate suppliers operate outside of the legal supply chain and dismiss all controls, not only in terms of product acquisition but also in terms of storage conditions, handling, transportation and delivery, and therefore, product quality, safety and efficacy cannot be ensured

Sales with no medical prescription and the absence of medical follow-up favour self-medication and the irrational use of medicines resulting in negative consequences for patients. In some cases it generates drug resistance or adverse effects.

The manufacturing conditions of falsified and/or illegitimate products are not known. These products may have, in addition to the negative effects, lack of efficacy which may worsen the health condition of the consumer, thus increasing the risks for patients' health.

The speaker pointed out the difficulties in identifying the user who committed the crime, in obtaining evidence and in determining the jurisdiction as well as the applicable legislation. E-commerce poses a significant challenge as it faces the original concept of jurisdiction. There are challenges for the future, such as entering into agreements with other websites to multiply our efforts, to work cross-functionally with other public agencies, private players such as sales websites, customs office and other health authorities and to discourage or reduce internet medicines supply.

## Questions and answers

In the closure of this session, some members shared their experiences and discussed about the topics in the presentations.

The growth of the internet over the last 10 years has encouraged this culture of self-diagnosis and self-prescription and that has led to this irrational use of medicines –which are easily obtained over the internet- undermining their effectiveness. This poses a real challenge and there is a need to share information and to strengthen the cooperation between the different competent authorities.

It is very difficult to enforce and regulate this environment because of inter-jurisdictional issues, but

it is possible to tackle illegal sales through awareness and education campaigns and by providing patients and consumers sufficient information to decide whether they wish to take the risk to obtain medicines on the Internet.

Those education campaigns should find an effective channel to communicate to the target public and should not only focus on the public health risks, but they also should send some other messages that may discourage people to go to these sites, such as the economic impact that illegal websites can have on the individuals and that may concern them, namely the loss of their identity or their credit card details and risks of virus.

# Session two:

legal sales of medicines over the internet  
in the European Union

# Legal sales of medicines over the internet in the EU: overview of the initiatives by the European Commission

Fabio D'Atri. Medicinal Products, Quality, Safety and Efficacy. Health and Food Safety Directorate- General. European Commission

A “Falsified Medicinal Product” is any medicinal product with a false representation of *its identity, its source, its history*. Unintentional quality defects and intellectual property rights issues are excluded from this definition.

The Directive on Falsified Medicines outlines some requirements for online sales of medicines. The aforementioned Directive enshrines into law previous judgements of the European Courts of Justice (ECJ). Provisions on distant sales of medicines will entry into force on July 2015.

In addition to legislation there are several groups/organizations, such as HMA WGEO or the European project Fakeshare, working to ensure a proper enforcement of these provisions.

The “online pharmacy” has to be entitled to sell medicines in accordance with the law of the country where it is established and the medicines sold by internet have to comply with the law of Member States they are being sold to.

Member States may restrict/impose conditions to the online sales for reasons of public health. For instance, they are able to ban online sale of the prescription medicines. Nevertheless they cannot impose a total ban to the online sale of OTC medicinal products.

Apart of the logo, each Member State shall create a website showing the list of all legally operating online retailers, including information about: the national

legislation; the online logo, and the risk of online sales from illegal websites. In addition, EMA will create a website providing access to the national lists.

The European Commission has adopted the new common logo through the Implementing Regulation 699/2014. The logo shall be displayed on every page of the Web site which offers medicines online. This regulation will also establish the technical electronic and cryptographic requirements to verify the logo authenticity.



SPAIN (ES)

The logo will have the flag of the Member State where the online seller is established and it will be hyperlinked to national list of legally operating as online retailers, to cross- check the webpage legality.

This logo is protected by the Commission’s trademark, at the moment, the license agreements are being signed by the Member States. Trademark rights are equally enforceable, and this can help taking action against someone using the logo illegally.

There will be communication material in all European languages, focused not only on communicate possible health risks, but also on how to use the logo and verify it; the dangers of online sale of medicines, i.e. your credit card and your email may be stolen.

# Legal sales of medicines over the internet in Spain

Belén Escribano. Head of Department. Pharmaceutical Inspection and Enforcement Department. AEMPS. Spain

The increasing importance of the e-commerce makes necessary to implement a legal system for these sales. In the European Union, the Directive on electronic commerce (Directive 200/31/EC) as well as the Case 322/01 (Doc Morris) of the European Court of Justice set the main principles applicable. In 2011 the 'Falsified Medicines Directive' 2011/62/UE established specific rules for the distant sales of medicinal products that were transposed into the national legislation in Spain in 2013 (Royal Decree 870/2013) and the system will be running from the 1st of July 2015. Previously to this Royal Decree, in 2006, the Law 29/2006 limited these distant sales to non-prescription medicinal products and in addition requires that these sales are performed only by authorized pharmacies, with the intervention of a pharmacist and with his professional advice.

Royal Decree 870/2013 in addition to the requirements of the EU Directive includes other requirements intended to a better protection of patients and citizens.

These requirements are:

- About the **pharmacy website** content, that must include information about delivery times, pharmacy holidays or closings, price of the medicinal product and the transport services... Access to the website must be permanent, easy, direct and free and a link to the information centre of the Spanish Agency for Medicines and Medical Devices (AEMPS) must be included.
- The **pharmacist intervention** and advice is considered very important, in line with Law 29/2006, so customer information is required to facilitate the contact by the pharmacist and an assessment of the order must be made to detect unusual quantities, repeated requests that may indicate a potential misuse. The pharmacist must also ensure that the customer receives all the pertinent informa-

tion and must reply to any request of information he receives and must guarantee the transport and delivery of the medicinal products (even if the activity is outsourced to a courier by a written contract).

- In relation with the **sales procedure** it should be direct from the pharmacy to the patient, without any intermediaries. Promotional presents, pricing, bonuses... are forbidden, discounts must be in accordance with the applicable legal provisions. Sales to patients in other Member States (MMSS) must comply with the requirements established in the Spanish legislation as well as with the applicable ones at the country of destination. The legislation on data protection applies and records must be retained at the pharmacy for inspection purposes.

In the regional organization in Spain, the pharmacies are authorised by regional competent authorities, so the Royal Decree establishes the requirements of both regional authorities and AEMPS websites and the links between them and the European Medicines Agency (EMA) website. An electronic system for the required notifications of the pharmacies to the regional authorities has been developed by AEMPS and after these communications are validated, the pharmacists will receive the encrypted logo to be displayed on their websites.

This future system will be our first experience in Spain in legal sales through websites and there are great expectations about it but it is yet to be seen how it will work. This will be also the first EU system that involves the supply to the public in 28 MMSS with different rules about it and some common principles are needed. From July 2015 the new system will help pour citizens to distinguish legal from illegal websites and so the Internet sales of medicinal products will be safer.

# Internet trade in medicinal products in Germany

Melanie Gräf. Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). Germany

In Germany the legislation allows to sell medicinal products (prescription only medicines and over-the-counter medicines) over the Internet. Selling medicinal products over the Internet has been legal for human use since 2004 and, since 2011, also for medicines for veterinary use, restricted for non-food-producing animals.

Selling over the Internet is only allowed to authorised pharmacies with a proper authorization for mail- or order selling. In any case it is required to have a local “store“, quality management system, obligatory expert advice for customers, requirements for fast and secure delivery. That is why pharmacies selling exclusively over the Internet do **not** exist.

Pharmacies from other (countries) EU Member States countries can apply for a German mail-order authorization, providing that they comply with the same requirements as the German ones. Online pharmacies from specific EU-countries included in a list are allowed to sell to Germany over the Internet for **Human Use**: Iceland, Netherlands (only with local pharmacy), Sweden (only POM), Czech Republic (only OTC) and the United Kingdom. For **Veterinary Use**: Czech Republic (only OTC), the United Kingdom.



There is a security logo that can be implemented on legally operating online pharmacies websites that are included in the German Register of Mail Order Pharmacies. The logo is hyperlinked to the website of the German Institute of Medical Documentation and Information (DIMDI <https://versandapotheken.dimdi.de/pdfs/var-name.pdf>); containing the pharmacy's register entry.

The register entry contains contact data of the authorised pharmacy, one or more Internet addresses of the pharmacy, contact data of the respective compe-

tent supervisory authority (Länder authority), date of the issuing of the authorization for mail order selling (issued by competent Länder authority).



GERMANY (DE)

The register will work with the new Common European Logo (Article 85c Directive 2011/62/EU) which will be mandatory used from June 2015 for trade medicinal products for human use.

In Germany the Competent Authorities are arranged on several levels, with different tasks: the Länder Authorities and the Federal Authorities. The system is complex: 18 Länder-Ministries for human and veterinary medicinal products, 21 GMP-Inspectorates, 6 GMP-Inspectorates for veterinary vaccines and 8 OMCLs, in Germany there are 35 competent authorities. In some Länder there are additional authorities for the supervision of pharmacies.

Medicinal Products Department (ZLG) is in charge of the coordination of the surveillance of medicinal products. This coordination means inter alia monitor of the Internet trade in medicinal products for human and veterinary use, not only the research of information about suspected violation of the German legislation, but also the evaluation of the investigational results by national competent authorities, Official Medicines Control Laboratories and Länder Ministries.

The investigational results can be transmitted, among other information, to: National competent authorities (inspectorates) of German Länder; Federal authorities; Police; Customs...It is important to mention that subsequent actions are solely performed by those authorities, but not by ZLG itself that plays a coordination role and liaise with authorities on national and EU/EEA-Level. The collaboration and networking is established on national and international basis.

# Legal sales of medicines over the internet in the EU: Portugal

João Martins. Director of Medicines Evaluation Department. National Authority of Medicines and Health Products (INFARMED). Portugal

The Falsified Medicines Directive 2011/62/EU published on 1 July 2011, amending Directive 2001/83/EC relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products was transposed into the Portuguese legal framework by the Decree-Law n. 128/2013, 5 September, that establishes the conditions of offering medicines for sale at a distance to the public by Internet.

The sale of medicines over the Internet must comply with a series of requirements: the natural or legal person offering the medicinal products have to be authorised or entitled to supply medicinal products to the public, also at a distance (Pharmacies and Non prescription medicines stores), they have to notify this activity to INFARMED, I.P. Notification must be accompanied with, at least, the following information: the name or corporate name and permanent address, the date of commencement of the activity, the address of the website, and the classification of the medicinal products offered.

The medicinal products sold over the Internet have to comply with the national legislation of the Member State of destination.

The sale at a distance to the public should comply with **specific requirements**. The entity is obliged to maintain records of all medicines sold over the Internet with the following information: covering the country of destination; quantities; name of medicines; date of transaction and medical prescription. This activity will also comply not only with the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare regarding the recognition of prescriptions, but also with the good distribution practices regarding the transport and the qualification of suppliers of medicines. It will define a procedure for the pharmacist's advice on every sale and any suspect of falsification must be reported.



PORTUGAL (PT)

On 24 June 2014, the European Commission adopted the new common logo through the

**Implementing Regulation 699/2014**. Therefore, by June 2015, all online pharmacies or retailers legally operating in the EU should display the logo on every page of the site offering medicinal products online.

The logo **will be linked to a website of INFARMED**, I.P. listing all legally operating online pharmacies/retailers. By clicking on the logo, a purchaser of the medicines online will be sent to the entry of the pharmacy on that national list, thus completing the verification process. The logo **can be trusted only if** the purchaser, after clicking, is redirected to the entry of that pharmacy on the list of legally operating on-line pharmacies and retailers registered in that Member State on the national authority web-page.

The website of INFARMED I.P. will also provide information about the national legislation applicable to the offering of medicinal products for sale at a distance to the public on the website, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply; information on the purpose of the common logo; background information on the risks related to medicinal products illegally supplied to the public by means of information society services and also an hyperlink to the website of EMA.

Some of the weaknesses identified so far on the selling at a distance to the public are the **risk of duplicating a website** simultaneously with the risk of **reproducing the common logo and the link** to the list of national authority; the threat of purchasing of medicines by pharmacies directly to **distributors in another Member State, which are unknown in the national market**, the possibility of handling medicines in pharmacies **labelled in a different language** and the **potential errors in dispensing**. This situation could generate potential errors on communication between pharmacies and patients. Finally, other potential weakness is the **transport conditions**, storage conditions and security; it should comply with GDPs Rules.

Weaknesses and challenges should be discussed by Fakeshare group; a proposal for a common approach, with a focus on the protection of public health, would be welcome.



## Questions and answers

In the closure of this session, some members shared their experiences and discussed about what has been presented so far.

Sales over the Internet represent the main challenge; EUFMD aims to tackle these problems, but some clearer reference to the Internet (not only to distant sales) is missing. It may have included words as online, email and pharmacy to strengthen it. The Commission will follow this approach in the follow-up communication campaigns.

The idea of the EU common logo is similar to the one already used in Germany: they have the same system hyperlinked to a national list of legally operating as online retailers, to check the legitimacy of the logo. The general pharmaceutical Council of the UK has im-

plemented a voluntary accreditation scheme for pharmacies that can legally operate online that also allows them to know how people use this logo.

It has to be reminded that the logo is just a part of a broader strategy, and awareness campaigns are going to explain how to use the logo and how to recognize when it is fake logo. These topics will be interpreted and clarified during the application.

The requirements for distant sales between two EU Member States were also discussed. It was agreed that the requirement of compliance with both the regulations at the country of origin and the country of destination would apply. It was questioned about how this EU-wide market would be functioning and how regulations would be enforced.



# Session three:

other initiatives against illegal internet sales

# Initiatives against illegal internet sales

José Carlos Herrera, Drugs and Consumption Group. Technical Unit of Judicial Police. Guardia Civil. Spain

The presenter begins by explaining the motivations of consumers to buy on the Internet and summarizes the risks associated to buying medicines from illicit websites. Illicit sales of medicines over the Internet may be connected to different infringements, such as documents forging, illegal manufacture, smuggling, falsification of prescriptions, falsification of medicinal products, etc.

Internet has evolved as a great tool for selling medicines illegally. Several persons are involved (hosting service providers, payment platforms...).

Consumers may seek convenience, anonymity, waiving prescription requirements or better prices. But these perceived advantages are not always achieved.

Guardia Civil is deployed throughout Spain and develops multiple functions, including customs, public

security and judicial police, and has been involved in many successful cases of fight against crimes in the field of public health.

The investigational approach to cases in which the illegal sale of medicines is detected is summarized in the presentation. Efforts are oriented to identify the persons involved in the illegal trade and gathering evidence to be presented to court cases.

A set of case examples is also discussed in detail. One, which is very much related to this event, is the participation of Guardia Civil in Operation Pangea.

Operation Vigorali, which also exemplifies the international connections of these criminal networks, is also explained. A cross-national network of distribution of medicines was dismantled, with the joint effort of international investigational teams.

# Observatorio de internet: a low cost initiative

Antón Aller. Responsible of the Internet Observatory of the Spanish Agency for Consumption, Food Security and Nutrition (AECOSAN). Spain

The 'Observatorio de Internet' emerges as an initiative of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition, in order to protect online consumers. The beginning of this project was the summer 2011.

It promotes a safer use of Internet and provides the user with greater protection, not only by handling their complaints, but also through security guidelines and training conferences.

The 'Observatorio de Internet' deals with: the need to support the consumer; fight fraud and encourage responsible consumption on the Net. It will require a direct communication with both consumers and institutional organizations.

The Observatorio de Internet was created in response to the continuous growth in the Spanish e-commerce sector.

The Consumer Protection Cooperation (CPC) Network brings together the public authorities, in all the EU Member States, who are responsible for the enforcement of EU consumer protection laws. The referred CPC BEIEC project was an inspiration for the development of the "Observatorio de Internet" in 2011.

The observatory of Internet works collaborating with different authorities with, among others: Autonomous Communities; Ministry of Industry; Data Protection Agency; Civil Guard, etc. The subject and type of infringement will determine the notification to one particular authority. In this way, the Spanish Agency of Medicines and Medical Devices shall have competency in cases relating to the sale of drugs via Internet.

Since its inception, as result of its activity, around 830 cases have been processed (55% of them closed favorably), 65 sweeps have been carried out (two per month) where more than 1800 traders have been analyzed in detail, around 50% of them showed irregularities.

The Observatorio de Internet actively participates in regular teleconferences, sweeps and other cross border activities for consumer protection. As for example, it has participated in **The International Consumer Protection and Enforcement Network (ICPEN)** and **The Latin American Forum of Consumer Pro-**

**tection Agencies (FIAGC)**; this last one promotes the cooperation (between) among Government Consumer Protection Agencies from South America, Portugal and Spain, these are examples of this powerful cooperation.

A case study is the following: in the summer of 2011 it was carried out an internal seasonal sweep of **sun protection lotions**. A seasonal sweep is an investigation based on recurring and periodic events (e.g.: clothing sales, holiday trips, back to school campaign, Halloween/Carnival...). At that time 37 traders were analyzed to check if they informed properly about the safety labelling, presentation and advertising to the consumers according to Spanish and European regulation. As result of this "sweep" exercise it was concluded that none of the studied websites displayed the CE marking on the products.

Another case of research was **'Huayruro' seeds investigation**. Huayruro seeds are used to make toxic products oriented towards children. In this case, a study is undertaken to determine if this banned product was being sold and distributed from Spanish websites. Around 10 sellers, who operated at a national level, were identified. It was required a collaborative effort with the Directorate-General of the Spanish Civil Guard.

The current situation over the Internet actions can be summarized in: speed and effectiveness in the required activities. There is a contrast between the slowness of the Administration and the speed of the internet issues. There are no borders on the Internet: it has become a worldwide market. As the resources are limited it will be necessary act with determination and persistence against the illegal websites by using all the tools we have close at hand, such as payment platforms, faxes, etc.

**SECIR project** is a cooperation initiative within the Consumer Protection Cooperation (CPC) network. The main goal is the level of knowledge and efficiency of all the participants when investigating e-commerce issues. The project will last from April 2014 to October 2015. The objective is to promote the creation of specialized investigation teams to face e-commerce issues in order to: not only the adaptation to the new and changing threats in e-commerce and the im-

provement of consumer protection in Internet; but also facilitate communication among the members for mutual advising.

The development of the [www.e-observatorio.es](http://www.e-observatorio.es) involved no additional costs for the Spanish National Institute for Consumer Protection. The technicians used free software tools to build and design the website, with over 50 pages of content, both in English and Spanish. We created the corporate image as well.

As information from January 2012 to November 2014, the Observatorio de Internet received a total of 3,784 external visits that translate into 10.963 visited web-pages (2,9 per visitor). At a national level, visits are distributed as follows: Spain - 85.8%; Mexico - 2.59%; Portugal - 0.86%; Argentina - 0.81%; Colombia - 0.76%; Other - 9%.

# Medical devices. Risk for health - illegal imports from third countries

Hannes Wörkner. Senior Enforcement Officer, Medical Market Surveillance. Austrian Medicines and Medical Devices Agency (AGES) .Austria

Medical Devices is a term that refers to a very heterogeneous group of products; it refers to instruments, apparatus, appliances or even software, used specifically for diagnostic and/or therapeutic purposes but which do not act primarily by pharmacological, immunological or metabolic means. In this legal category we can find products such as condoms, syringes, first-aid compresses, sterilizers, ECG recorders, breast implants, dental drillers, HIV – Test kits or medical software.

The risk of falsification exists in these products as it does for medicines. One case example of falsification of a dental driller is explained in detail. As it happens with medicines, it is important to have an expert insight to establish if the devices are falsified by comparison with samples of the genuine product. The intended use of one medical device in particular would determine the risks arising from the falsification (i.e. damage/lesions if the dental driller goes off while rotating at high speed inside a patient's mouth during an intervention).

In the field of medical devices there is a lack of specific regulation regarding e-commerce. Only general (transverse) e-commerce regulations would apply. Specific challenges for medical devices can be mentioned: declaration of actual manufacturer or authorized representative missing or ignored, importers unknown, release by fulfillment centers missing...

Illegal traders also dismiss mechanisms provided for in the directive to ensure medical devices are fit for intended use. The guarantees provided by the CE mark and the role of notified bodies and declaration of conformity are also breached.

In spite of having an EU- tradition on regulation of medical devices, they pose a significant challenge to competent authorities. Agents participating in the production, importation and distribution of these products are not subject to the same authorization/registration regime as medicinal products. Moreover, there are no enforcement specialized in particular features of these products.

# Fakeshare (I) survey: profiles and characteristics of online consumers

Claudio Barbaranelli. Department of Psychology. Faculty of Medicine and Psychology. Sapienza University of Rome. Italy

## Aims of the Survey. Methodology and Descriptive data.

The online survey of “Fakeshare I” Project has been conducted to investigate the behavioral and psychological factors linked to online purchasing of medicines. The theoretical framework is the Theory of Planned Behavior and by psychological models that addressed the study of risk perception and of risk propensity.

The aims of the survey were twofold: on the one hand to assess the prevalence of purchasing of pharmaceutical products online in three European Countries: Italy, Spain, and Portugal; on the other hand to investigate the impact of different psychological and socio-demographic variables on the Future Intention of Purchasing pharmaceutical products online. Three samples were considered in the three countries included in the research. The Italian sample consisted of 1,000 participants, aged from 18 to 84 years. The Spanish sample consisted of 1,255 participants, aged from 18 to 74 years and The Portuguese sample consisted of 1,000 participants, aged from 18 to 74 years.

The online questionnaires were used in order to measure the constructs of interest. Each questionnaire consisted of 60 questions and it was composed of different items investigating and different domains.

## Knowledge and Prevalence data

- The percentage of people who know about the possibility of buying medicines online is much smaller in Spain.
- The awareness of citizens about the risk of buying medicines online is very similar in the three countries; in any case, the awareness campaigns about the risk should increase in order to reduce the risk of online purchases.
- Participants who have purchased medicines online were 20% in Italy, 9% in Spain, and 2.5% in Portugal.
- The most purchased medicines over the Internet by participants are as follows: medicines for weight

loss; medicines for flu and medicines for chronic pain.

- The evaluation of the possibility of purchasing medicines directly from your home computer or via any Internet connection is higher in Italy than in Spain and Portugal.
- It is higher the percentage of Italians that consider the purchase of medicines online very or fairly safe for health (30%) compared to those in Spain (15%) and in Portugal (11%)
- The future probability of purchase is very low in Portugal (91% consider it highly unlikely the future purchase). It is higher the percentage of Italians who believe very or quite likely to purchase medicines online in the future (approximately 10%) than that of the Spanish (about 5%) and Portuguese (about 1%).

## Profiles on Psychological Variables

In Italy, respondents living in big cities or in their suburbs tend to have purchased more than those living in small towns, in country villages or in the countryside.

In Spain, male respondents tend to have a more positive attitude toward future purchasing, and to perceive the purchase as safer behavior than female respondents do.

Finally, in Portugal there are no statistically significant differences between past purchase and future intention due to demographic variables.

## Take home message

Knowledge of prevention initiatives and information is still too low (around 20-25%) in all three countries: awareness level must be increased with communication campaigns through different media (the web, TV, newspapers, wallpapers). Purchasing pharmaceutical products online is a behavior mainly guided by rational beliefs that can be changed, not by impulsive tendencies that are largely irrational.

Approval of others, attitude and perception of safety are the most important variables in explaining online purchase, to be targeted by communication campaigns aimed at reducing future purchase. Communicating that medicines purchased online can be dangerous for health may lower the perception of this behavior as safe, and lead to a negative attitude towards it, and to the expectation that it will not be approved by relevant others.

Capitalize on the role that significant others may have on the purchaser: these are people whose opinions are important for the purchaser, people who are considered as trustworthy in when health related behaviors are an issue.

Physicians, pharmacists, relatives are fundamental vectors for influencing future purchasing behaviors, and eventually reduce them.

## Questions and answers

In this session's closure some members shared their related experiences and discussed about what has been presented.

The measures for fighting against food supplements or consumer products advertised with medical claims were also discussed. The trader is responsible for the information on the website and, if the product described is a medicine or if it is making medical claims, then the rules of pharmaceutical and medicines will

apply to this. You cannot advertise a medicinal product that is not licensed, therefore the steps to remove it are taken.

If the product is not being marketed as a medicine, but the lab analysis detects undeclared active ingredients, which may exert a pharmacological activity, unlawfully added in order to give the product the alleged properties, then this product becomes a medicinal product and appropriate legislation should be applied.



## Closing remarks

From the presentations and discussions held at the conference, the following key messages can be drawn:

- The importance of collaboration between those authorities dealing with very similar situations and objectives in the prosecution of illegal websites.
- Fully implementation of mechanisms provided for in EU Directives from July 2015 will reinforce safety for consumers buying medicines at a distance.
- The need for awareness campaigns regarding the risks associated with purchasing medicines from illegal websites is highlighted. The participating authorities agree on considering these campaigns as one effective tool for protecting citizens.

# Annexes

# Annex A. Agenda

## Challenges for National Competent Authorities on the sale of medicinal products over the Internet

### SESSION I

**08:30 – 09:00**

Registration and accreditation

**09:00 – 09:15**

**Welcome address.**

Belén Crespo, AEMPS Director

**09:15 – 10:45**

**NCA's Activities against illegal sales of medicinal products over the Internet.**

*Moderator:* Belén Escribano, AEMPS

- Domenico Di Giorgio. Head of the Product Quality and Counterfeiting Office. Italian Medicines Agency (AIFA). Italy
- Manuel Ibarra, Technical Advisor, Area of Illegal Medicines. Pharmaceutical Inspection and Enforcement Department. Spanish Agency of Medicines and Medical Devices (AEMPS). Spain
- Lynda Scammell. Senior Policy Adviser of the Enforcement Group of the Medicines and Healthcare Products Regulatory Agency (MHRA). UK
- Romina Viñas. Surveillance Directorate for Health Products. National Administration of Medicines and Medical Technology (ANMAT). Argentina

**10:45 – 11:15**

Coffee break

### SESSION II

**11:15 – 12:45**

**Legal sales of medicines over the Internet in the EU.**

*Moderator:* Manuel Ibarra, AEMPS

- Fabio D'Atri. Medicinal Products, Quality, Safety and Efficacy. Health and Consumers Directorate-General. European Commission
- Belén Escribano. Head of Department. Pharmaceutical Inspection and Enforcement Department. AEMPS. Spain

- Melanie Gräf. Central Authority of the Länder for Health, Medicines and Medical Devices (ZLG). Germany
- Joao Martins. Director of Medicines Evaluation Department. National Authority of Medicines and Health Products (INFARMED). Portugal

**12:45– 13:45**

Lunch break

### SESSION III

**13:45– 15:15**

**Other initiatives against illegal Internet sales.**

*Moderator:* Domenico Di Giorgio, AIFA

- José Carlos Herrera, Drugs and Consumption Group. Technical Unit of Judicial Police. Guardia Civil. Spain
- Antón Aller. Responsible of the Internet Observatory of the Spanish Agency for Consumption, Food Security and Nutrition (AECOSAN). Spain
- Hannes Würkner. Senior Enforcement Officer, Medical Market Surveillance. Austrian Medicines and Medical Devices Agency (AGES). Austria
- Claudio Barbaranelli. Department of Psychology. Faculty of Medicine and Psychology. Sapienza University of Rome. Italy

**15:15– 15:30**

**Closing remarks**

## Annex B. List of attendants

FIRST NAME	SURNAME	ORGANIZATION
Antón	Aller	AECOSAN
José Luis	Alonso	AEMPS
Claudio	Barbaranelli	AIFA
Sandra	Bentolila	AEMPS
Frederic	Broise	EDQM
Jose Vicente	Coto	DNM
Belén	Crespo	AEMPS
Oliver	Csiki	NTCA
Fabio	D'Atri	European Commission
Stéphane	De Spiegeleer	Famhp
Michael	Deats	WHO
*Gianpaolo	Derossi	AIFA
Domenico	Di Giorgio	AIFA
Belén	Escribano	AEMPS
Claudia	Fedele	AIFA
Ana	Fernández	AEMPS
*Rocío	Fernández	AEMPS
Rosa	González-Cebrián	AEMPS
Melanie	Gräf	ZLG
Marta	Gramazio	AIFA
Joana	Henriques	INFARMED
José Carlos	Herrera	Guardia Civil
Manuel	Ibarra	AEMPS
Asli Esmâ	Karaca	Turkish Medicines and Medical Devices Agency
Gerard Patrick	Kelly	HPRA
Sameer	Kohli	DHMA
*Verónica	Ledo	AEMPS
Laura	López	Policia Nacional
*Margarita	Magro	AEMPS
Joao	Martins	INFARMED
Francisco Javier	Molinera	Policia Nacional
Javier	Morales	Guardia Civil
*Ruth	Mossiman	SWISSMEDIC

FIRST NAME	SURNAME	ORGANIZATION
Julio	Muelas	Health Service Department of the Autonomous Region of Valencia
Rafaella	Neri	General Directorate Fighting Counterfighting
*Susy	Olave	AEMPS
*Luis Miguel	Olivares	AEMPS
*Ramón	Palop	AEMPS
Paraskevi	Papadimitrov	National Organization for Medicines
Henar	Pecharromán	AEMPS
Gloria Elsa	Pinilla	INVIMA
Chiara	Prost	AIFA
Rodolfo	Ríos	Health Service Department of the Autonomous Region of Canarias
Santiago	Rivera	Guardia Civil
Montserrat	Rumoso	Health Service Dep Auton Region of Cantabria
Camilla	Santinelli	AIFA
Lynda	Scammell	MHRA
Ewelina	Siadkowska	Main Pharmaceutical Inspectorate Poland
Stéphanie	Silveira	INFARMED
Julia	Striezel	Federal Ministry of Health
Serkan	Suna	Turkish Medicines and Medical Devices Agency
*María Angeles	Tacoronte	AEMPS
María Luisa	Tarno	AEMPS
Mar	Valero	AEMPS
Romina	Viñas	ANMAT
Markus	Wittstock	BfArM
Hannes	Würkner	AGES
Pilar	Zamorano	AEMPS

\* followed by webconference

## Annex C. Speakers short curriculum vitae

### Anton Aller

Anton Aller is a lawyer that has worked for the private sector and NGO's with immigrant people, he was also the legal adviser at the European Consumer Centre in Spain for six years and, since August 2011 he has been the current responsible for the Internet Observatory at the Spanish Agency for Consumer Affairs, Food Safety and Nutrition.

### Claudio Barbaranelli

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

### Fabio D'Atri, PhD

Fabio D'Atri is the Deputy Head of the Unit "Medicinal products - quality, safety and efficacy" in the Health and Food Safety Directorate General of the European Commission

He holds a degree in biology and a PhD in biochemistry from the University of Geneva. He also holds a master in management of biotech companies from the Grenoble School of Business.

After working for several years as university researcher and as a consultant both in the public and in the private sector, he joined the European Commission in 2004.

In the Directorate General Health and Food Safety he has worked on several areas of the food legislation, from nutrition to food contact materials. Since 2011 he has joined the "Medicinal products - quality, safety and efficacy" Unit in the Health systems and products Directorate dealing in particular with implementation of the falsified medicines Directive and the negotiations for the adoptions of the new Regulation on clinical trials.

### Domenico Di Giorgio, PhD

Dr. Domenico Di Giorgio, Ph.D., is Head of the Product Quality and Counterfeiting Office at the Italian Medicines Agency (AIFA). Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention. He is the editor of the 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, PhD

Belén Escribano has been the Head of the Pharmaceutical Inspection and Enforcement Department of the Spanish Agency for Medicinal Products and Medical Devices (AEMPS) since 2007. She holds a doctorate (PhD) in Pharmacy from the UCM, a degree in Hospital Pharmacy as well as a Public Health Master degree. Before joining AEMPS she worked as a hospital pharmacist, and also as an inspector and technical advisor at the Health Department of the Region of Madrid. In 2010 she chaired the EU Council Working Party on pharmaceuticals and medical devices, when the falsified medicines directive was being discussed. Nowadays she is actively involved in the implementation of the Directive 2011/62/EU at national level as well as in related coordination activities at EU level.

### Melanie Gräf

Since June 2010, her professional designation is Regierungsfarmazierätin at Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG): Surveillance of the Internet Trade of Medicinal Products and Quality System for the Surveillance of Medicinal Products.

## Jose Carlos Herrera

Captain of the Civil Guard, Superior Officers Scale. Currently serving in the Technical Unit of the Judicial Police, which is under the Department of Crime Analysis and, specifically, involved in the Group of Drugs and Consumer Affairs. This Unit is responsible for the information analysis, preparation of studies and building expertise on drug trafficking and medicinal products. This Unit is also in charge of International coordination and liaison in its area of expertise.

In previous assignments, he worked as an investigator for judicial police in the area of Alicante, in the field of drug trafficking and drug smuggling. He was also Commander of the Police Station of Alcantarilla (Murcia).

## Manuel Ibarra, PhD

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.

## Lynda Scammell

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

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

## João Martins

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

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

## Romina Viñas

Pharmaceutical graduated from the National University of Buenos Aires. In 2005 he joined INAME / ANMAT in quality control inspector performing tasks of the various links that make up the supply chain of medicines. Since 2011 she has been developing tasks as Coordinator of the National Program Products Market Control of Medicines and Medical Products, Current Address Surveillance Health Products. She has participated as a speaker, moderator and facilitator at various conferences and seminars both nationally and internationally. Participated, in Argentina, in the Committee on Health Products SGT No. 11 of MERCOSUR, the Task Force Combat Control PAHO, in Technical Group Counterfeit Drugs and Fraudulent Iberoamerica (MAST) and the drafting of technical documents for the Mechanism of Member States Medicos SSFFC product (WHO).

## Hannes Würkner

Veterinarian, Enforcement Officer since 2004, first at the Ministry of Health, now in the Agency for Medicines and Medical Devices, engaged in HMA WGEO and national networks against medical crime.

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





