

**September 2018**

# NEWSLETTER

## A diary of achievements from January to September 2018

### JANUARY

Planning begins for Common Logo “Sharing best practice” meeting with DG Sante and Member States to address Article 85d and the obligation to publicise the purpose of the Common logo, what is a falsified medicine. **ASOP EU attends the GIRP “Big Data” conference in Brussels.** EU Commissioner Andruikaitis in opening address encourages all players to be ready for Falsified Medicines Directive safety features implementation on February 9, 2019. EAASM Board meeting takes place and 2018 objectives ratified. **White paper on licensed medicines vs unlicensed biocides endorsed by EAASM.**

### FEBRUARY

Fight the Fakes partners strategy meeting to establish work streams and 2018 activities under new Secretariat; International Federation of Pharmaceutical Wholesalers (IFPW). **EAASM attends PACT meeting in Brussels.** Sunday Times reporter is engaged on falsified medicines. **ASOP Global quarterly teleconference for its Members and Observers.** ASOP EU releases progress report of Member State’s implementation of the Common

Logo and addressing Article 85d.

### MARCH

ASOP EU “All Hands” meeting to discuss with key members and Observers the 2018 activities and deliverables to enhance patient safety. **ASOP EU co-hosts with MHRA “Sharing Best Practice meeting to enhance patient safety by raising public awareness”.** EAASM contributes to the NABP Advisory Supporters Committee on the implementation of .pharmacy. **Major speaking engagement at the University College of London - School of Pharmacy attended by over 200 pharmacy students.**

### APRIL

EAASM and ASOP EU as Civil Society members of EUIPO, joins NABP to give Plenary address on the Top Level Domain name initiative .pharmacy and to raise awareness about falsified medicines. **Meetings within the Directorate General for Communications Networks, Content and Technology at the European Commission with Mr Pearse O’Donohue, Director on Future Networks, Ms Cristina Monti, former Head of Sector on Internet Governance and Multi stakeholder Relations, and Mr Horst Jürgen Krämer, Programme Officer in the Unit on eHealth and Ageing Policy.** ASOP EU signs Memorandum of Understanding to collaborate with the Youth IGF Movement.



### MAY

Meeting with major pharmacy chains and institutions to discuss the .pharmacy initiative. ASOP Global Members and Observers quarterly teleconference. **ASOP EU invited to speak at the European Council of Optometry and Optics (ECOO) on falsified medicines - Croatia.** ASOP EU and EAASM invited to attend the CMED-Committee (Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes) to present credentials along with other non profit organisations who are contributing to patient safety. **ASOP EU meets Eric Peters of the Digital Single Market to discuss initiatives on how the Internet can be made a safer place to buy medicines.** ASOP EU meets Ms Annika Nowak, Health Commissioner Vytenis Andriukaitis’ Cabinet Member (since November 2014) in charge of health systems, medicines and technology. Initial meeting with potential new Member E Fundamentals. **GDPR introduced and EAASM and ASOP EU websites updated.**

**JUNE**

Initial discussions on a search engine demote initiative with guidance from the key leader of the UK voluntary Code of Practice for copyrighted products e.g. films, videos and music. [Discussion with European Pharmacy Student's Association on the Youth IGF Movement.](#)

**JULY**

ASOP EU co-hosts a EU Parliament meeting entitled "How safe are your medicines? Raising public awareness is critical to Internet patient safety". [New Memberships announced - FarmaTrust and E Fundamentals - see below.](#)

**AUGUST**

Key update meetings took place with Mental Health Europe, European Association of Euro-Pharmaceutical Companies (EAEPC), Health First Europe, Gamian Europe and the European Nurses Organisation (ESNO).

## We were delighted to announce at the EU Parliament meeting co-hosted by ASOP EU and MEP Faria on June 26 2018\* that FarmaTrust and E Fundamentals had become Members of ASOP EU

### NEW MEMBERS

## FarmaTrust joins ASOP EU

**Raja Sharif**, CEO commented on this new collaboration.

*"Like ASOP EU, FarmaTrust has at its heart patient safety so the unique blockchain distribution solution goes hand in hand with this important ethical stance. FarmaTrust's global tracking system provides absolute security against the infiltration of falsified medicines. It is therefore very relevant to pharmaceutical companies, governments, regulators and the public. The FarmaTrust Blockchain based system utilises Artificial Intelligence and Big Data analysis to provide the pharmaceutical industry with value added services. This allows for more efficient processes and methods, as well as more visibility on all of the steps along the distribution chain using a safe, secure, encrypted and immutable system. ASOP EU, like us, regards patient safety*

*as paramount so we endorse and support their endeavours to raise public awareness, as well as campaigning with influential bodies such as the Brussels' institutions. More and more consumers and patients are looking to the Internet to support their needs and so we commend ASOP EU's activity to create an environment that enables the safe purchase of medicines from the Internet where it is legal to do so."*



\*EU Parliament roundtable - "How safe are your medicines? Raising public awareness is critical to Internet patient safety". Please go to pages 15-16.

## NEW MEMBERS

### E Fundamentals joins ASOP EU

**E Fundamentals** is a British owned, world-leading eCommerce analytics firm, engaged in a project, named Photon, funded by the UK Government to build a platform capable of discovering and monitoring websites believed to be selling illicit pharmaceuticals, be they falsified, counterfeit or fake. We are interested in speaking to fellow ASOP members who can help provide insights that could shape the nature of the platform to ensure it has the greatest benefit in tackling the issue at hand and thus help support the vital ASOP EU goals of enhancing patient safety.

**Andrei Czolak**, Head of Research, said

*“We are proud to become members of ASOP EU and look forward to working closely with ASOP and fellow members in the mission to combat the growing public health threat of illicit online pharmaceuticals.”*



## NEW MEMBERS

### ESNO joins ASOP EU

Ber Oomen, Executive Director of the **European Specialist Nurses Organisations** (ESNO), emphasises how “Empowering education is critical to healthcare professionals. Nurses play a vital role in informing their patients about falsified medicines and we look forward to collaborating on all patient safety matters as new Members within the ASOP community”.

The European Specialist Nurses Organisations (ESNO) is a non-profit organisation with the goal to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisations and its constituent members. ESNO represents the mutual interests and benefits of these organisations to the wider European community in the interest of the public health. Its vision aims at promoting,

supporting and developing academically accredited training programmes for qualified specialist nurses to address Quality and Safety of care and mobility of workforce within Europe.



## EAASM endorses MEPs Call to action – protecting European citizens by using most suitable skin disinfectants before medical treatment

Surgical Site Infections (SSIs), Catheter-Related Infections (CRBSIs) and Blood Culture Contamination (BCC) have become an increasing challenge for European hospitals and healthcare systems for which they pose a significant human and financial burden.

There is a disharmonised approach to the classification of preoperative disinfectant products which can give rise to patient safety issues. Depending on the intended application, skin disinfectants used to prevent SSIs, CRBSIs and BCC may fall under different legal frameworks and as such are currently classified as ‘borderline products’. Within the European Union, the classification of disinfectants is not uniform. The Commission recognised that a clear distinction between the Biocidal Products Directive 98/8/EC and the Human Medicinal Products Directive 2001/83/EC is a crucial issue and that, for borderline products, there is a need to give practical guidance and examples. In accordance with Article 2(2) of the Medicinal Products Directive, when, considering all its characteristics, a product may fall both within the definition of a ‘medicinal product’ and within the definition of a product covered by other

*Within the European Union, the classification of disinfectants is not uniform.*

Community legislation, such as the Biocidal Products Regulation, the Medicinal Products Directive shall apply. However, while there are guidelines on the distinction between biocidal products and other types of products (e.g., cosmetics, medical devices) the distinction between biocidal products and medicinal products for the classification of disinfectants for use in ‘preoperative skin disinfection’ seems to remain unclear. Some international authorities have provided guidance for manufacturers to help them determine how a specific Member State will treat their products.

**Biocides and medicines** are subject to very different regulatory regimes which confer different standards in terms of safety efficacy and quality. It therefore follows that using biocidal products as medicines, where biocides do not have a marketing authorisation then this may jeopardise patient’s safety. As highlighted by the MHRA, there are health risks associated with that practice and *“using the appropriately authorised product for its specific intended use, in accordance with the manufacturer’s instructions for use, is the best way of minimising harm”*.

*“ Using the appropriately authorised product for its specific intended use, in accordance with the manufacturer’s instructions for use, is the best way of minimising harm. ”*

**The signatories of this call to action recommend that the European Commission issue guidelines on the differences between biocidal products and medicinal products regarding the classification of disinfectants to be used for the safest skin antisepsis before surgery and injection.**



## ASOP EU join forces with the Youth IGF Movement to raise awareness amongst the youth about falsified medicines

“ One really effective way to stop the criminals is by educating the public about buying medicines online. Our study shows that the vast majority of people just do not understand that most websites are selling medicines illegally. So if we can educate and stop the demand that is the more than half the battle won. ”

**Mike Isles**, Executive Director of ASOP EU

This sentiment was the motivation behind joining forces with the Youth Internet Governance Forum Movement ([Youth IGF Movement](#)).

The signing of the MOU with the organisation of Together against CyberCrime ([TaC](#)), the coordinators of the Youth IGF was announced at the March European Union Intellectual Property Office (EUIPO) Observatory meeting in Brussels. ASOP EU and Together against Cybercrime International (TaC) have teamed up to educate the youth of today about fake medicines by developing and evolving the Youth IGF Movement.

### WHAT IS THE YOUTH IGF MOVEMENT?

The Youth Internet Governance Forum (IGF) is a global movement that operates as a multi-stakeholder platform. It allows young people between 15-29 years of age to discuss and take a lead on issues related to Internet governance in the format of local, national or regional debates. These debates are organised by the young on a volunteer basis. The Youth IGF is based on the principles of the United Nations IGF.

The main objective of the initiative is to allow the voice of young people to be heard by Information Society leaders on issues related to internet governance and to help young people take an active part in the decision-making processes.

Specific objectives include; promoting informal



Mike Isles, Executive Director - ASOP EU and Yuliya Morenets - Founder of TaC.

education on questions related to Internet governance and cybersecurity, raise awareness on Internet-related issues, safe and responsible use of the Internet and to promote the multi-stakeholder model amongst youngsters.

*“The phenomenon of fake medicines has massive consequences for the youth of today. With a growing expectation that the Internet enables you to buy literally anything online, then fake, falsified or substandard medicines causes real patient safety issues. Already we have cases of young girls buying slimming pills and overdosing and dying, which is a real tragedy. This collaboration can help educate the youth around the globe of today to ensure they have a safe future tomorrow,”* said **Yuliya Morenets**, Founding member of TaC.

### ABOUT TaC

Together against Cybercrime International (TaC) is a nonprofit civil society anti-cybercrime organisation established in France and working at local, national, European and international levels. TaC International works in the field of cybercrime/cybersecurity and child online protection and advises different entities on cybersecurity strategies. TaC is also actively involved in Internet governance issues by stimulating discussion on the use of information and communication technologies (ICTs) by vulnerable people and initiating debate in the format of youth and teenager dialogue.

## EAASM Board meeting – celebrating 10 years of patient safety activity

During the Board meeting, it was duly noted that the EAASM had been in existence for 10 years. During that time there have been many milestones. Most notable was the influence that the EAASM had on the Falsified Medicines Directive.

Here the EAASM commissioned a 104 page support entitled *“European Patient Safety and Pharmaceutical Parallel Trade – a potential public health disaster?”*



This supply chain report provided a robust evidence platform for the EAASM to engage with the European Commission (EC) and Parliament resulted in:

- 2 expert submissions to the Commission on the issue
- EAASM exhibitions in the Parliament and the Commission
- Responses and engagement from 65 MEPs
- 3 MEP letters on the issue
- Participation in: EC Internet Working Group, EC consultation on fake medicines, CoE internet and

counterfeiting forum and WHO IMPACT working group.

In response to a MEP question about the EAASM report on the supply chain Günter Verheugen, Vice President of the European Commission recommended that steps be put in place to safeguard the pharmaceutical supply chains and the Falsified Medicines Directive was conceived.

Over the past 10 years, the EAASM has contributed significantly to enhancing patient safety such as speaking at many conferences on falsified medicines with customs and police organisations, representing Civil Society at the Observatory EUIPO meetings and being a NABP .Pharmacy Registrant/Supporter Advisory Committee member

Many reference reports and documents were created to enhance patient safety. The report “Packaging Patient Protection” was submitted to the European Parliament, calling for enhanced legislation to improve the protection of Europe’s patients against the intensifying risks and dangers of falsified medicines. Nearly all recommendations were taken up in the Falsified Medicines Directive.

In 2014 ASOP EU was founded. An MOU with ASOP Global was formally signed and the manifesto



Jim Thomson, EAASM Chair, Bill Newton Dunn, MEP and Baroness Sarah Ludford, MEP discuss the problem of counterfeit medicines during the EAASM exhibition held at the European Parliament from 9–12 September 2008

*‘together we will create an environment that enables patients to buy their medicines online safely where it is legal to do so’* underlines the comprehensive set of objectives and activities involving all stakeholders.

- The report *“Falsified Medicines Costing the Earth”* highlighted key facts about the growing threat of falsified medicines.
- A groundbreaking report which highlighted the issue of the problem entitled *“The Counterfeiting Superhighway”*.
- A major online educational campaign in Germany in 2014 with the publication of *“Counterfeiting the Counterfeiter”*.
- And a more recent educational AdWord campaign which ran in France, Italy, Germany, Spain and the UK with an interim report covering the Italian campaign entitled *“Fighting Fakes by Raising Public Awareness”*.

## Fake Medicines Continue to Threaten Consumers – EU Member States have an Obligation to Act

As a result of the Falsified Medicines Directive, each EU Member State is obliged to enable legal sellers of medicines (pharmacies and retailers of medicines) to sell their medicines on the Internet. This is achieved through the implementation of a mandatory common logo on each and every website page, which links through to an official Member State registry. All legal sellers of medicines must register with the Competent Authority in the EU Member States where their business is operating.

Public facing campaigns (Article 85d) to raise awareness about the risks of buying medicines online are also a legal obligation within the FMD for EU Member States and the EU Commission for Health and Food Safety.

To better understand how countries are working to educate and protect patients/consumers, ASOP EU and the EAASM have convened a series of discussions with many Member States to share best practices. Based on these meetings, a [comprehensive report](#) was published in February entitled “FIGHTING FAKES BY MEMBER STATES –

Falsified Medicines and the Common Logo – Raising Public Awareness.” The report includes a foreword by Lynda Scammell of the MHRA and words of encouragement by EU Commissioner for Health and Food Safety Vytenis Andriukaitis. The report provides a detailed snapshot of the progress each EU Member State has made to educate the public about the risks of buying medicines on the Internet.

*“ We applaud our partners’ commitment to raising awareness about the dangers of buying medicines online. However, it is clear that more activity by Member States, with their own campaigns is needed to build on the many initiatives across the EU that combat this growing threat to public health ”*

**Mike Isles,**  
Executive Director of ASOP EU



Report to reveal status of Member States activities in relation to Article 85d

# Overview of Member State public awareness raising activity

Country	Competent authority website set up with campaign material	Public facing campaigns running now or in the past	Future campaigns planned	Measurement of campaigns and awareness of common logo and falsified medicines
Austria	Yes	Yes	Yes	Not known
Belgium	Yes	Yes	Not Known	No
Bulgaria	Yes	Not known	Not known	Not known
Croatia	Yes	Yes	Yes	Not known
Cyprus	Yes	Yes	Not known	Not known
Czech Republic	Yes	Yes	Yes	Yes
Denmark	Yes	No	Yes	No
Estonia	Yes	Yes	No	No
Finland	Yes	Not known	Not known	Not known
France	Yes	Yes	Yes	Not known
Germany	Yes	Not known	Not known	Not known
Greece	No	Not known	Not known	Not known
Hungary	Yes	Yes	Not known	Not known
Ireland	Yes	No	No	No
Italy	Yes	Yes	Yes	Yes
Latvia	Yes	Not known	Not known	Not known

Country	Competent authority website set up with campaign material	Public facing campaigns running now or in the past	Future campaigns planned	Measurement of campaigns and awareness of common logo and falsified medicines
Lithuania	Yes	Not known	Not known	Not known
Luxembourg	No*	Not known	Not known	Not known
Malta	Yes	Yes	Yes	No
Netherlands	Yes	Yes	No	No
Poland	Yes	Yes	Yes	Yes
Portugal	Yes	No	No	No
Romania	No*	Not known	Not known	Not known
Slovakia	Yes	No	No	No
Slovenia	Yes	Not known	Not known	Not known
Spain	Yes	Yes	Yes	Yes
Sweden	Yes	No	No	No
UK	Yes	Yes	Yes	Yes
EAA Member States				
Iceland	No*	No	No	No
Liechtenstein	No*	No	No	No
Norway	Yes**	Yes**	Yes**	No
Other countries active on Falsified medicines				
Serbia	Yes	Yes	Yes	Yes

## All-Hands Meeting

On March 8, 2018 ASOP EU convened an “All-Hands” Meeting with Members to discuss its 2018 objectives and share highlights of patient safety activities. Of particular significance was the collaboration shown by key Members, notably Becton Dickinson, Clinigen, Fight the Fakes, FMEDS, GS1, MHRA and Sanofi, who took the opportunity to give details of their own initiatives against falsified medicines as well as endorsing the ASOP EU 2018 goals.

### The key ASOP EU 2018 goals are:

- Support EU Commission DG Digital Single Market on strengthening measures against illegal content.
- Explore putting in place a specific public relations campaign at Member State level to gain governmental support to carry out Article 85d
- Contribute to the Committee of Parties of the MEDICRIME Convention, if invited.
- Continue to develop close liaison with Member States’ implementers of the Common Logo and hold further sharing best practice meetings.
- Continue to develop the five country (France,



L to R: Mike Isles, Laura Cigolot, Lucia von Bredow, Clinigen, Tania Snioch, GS1, Misa Ogawa, Fight the Fakes spokesperson, Oksana Pyzik UCL School of Pharmacy, Lynda Scammell MHRA Law Enforcement

Germany, Italy, Spain and UK) Google AdWord campaign and publish report.

- Engage stakeholders to enable Principles of Participation, which is a voluntary code of practice for Internet intermediaries namely: Advertising Service Providers, Registries/Registrars, Shipping Companies, Payment System Operators.
- Become active in ICANN policy discussions on several issues; EU General Data Protection Regulation (GDPR), WHOIS transparency, new generic Top-Level Domains
- Continue the publication of the ASOP EU and EAASM newsletters.



# ASOP EU and MHRA Member State Best Practice Sharing meeting on 9 March 2018 at MHRA premises in London

**This was the 7th sharing best practice meeting with Member States organised by ASOP EU.**

**The key outputs are summarised below:**

- Public facing campaigns should focus on segmenting the public. In one case focusing on the “vulnerable” patient such as young women buying slimming pills online was the target audience. This segmented approach has been taken by the MHRA in the UK with each of their many campaigns;

1. Member States were reminded of Article 85d and the legal obligation to inform through public facing campaigns the meaning of the Common Logo and a falsified medicine. Various initiatives were suggested and found favourable by the group, such as the creation of a public health case to enable funding for a specific and costed campaign using social media to deliver messages to the public. This could be done with the endorsement of many patient groups, to mount a powerful and succinct public relations campaign in the form of targeted letters to key national newspapers;

- An overview the ASOP EU 5 country AdWord campaigns

results revealed that consumers /patients were willing to change their behaviour in the knowledge of the number of illegally operating online sellers. However there was a very low awareness of the Common Logo in the 5 Member States where the campaign is running (France, Germany, Italy, Spain and the UK);

- **MEDICRIME Convention (MC)** – 13 countries have now ratified. Next milestone is a meeting later in year to decide on composition of the Committee of the Parties which will determine future actions to enable the MEDICRIME Convention to be developed. The Committee of Experts and CMED (which sits within the EDQM) will be vital in supporting this. The European committee on Crime Problems (CDPC) will also be instrumental in the MC with such pivotal actions as the drafting of legal opinions on the compliance of certain national criminal codes to name but one;

- **TELEMEDICINE - The 4 working group break out sessions revealed some very useful principles to be adopted and pursued namely:**

1. Understand all of the parties involved. Patients are likely to be more wary if consultant GP/ prescription facility/delivery mechanism are all in different

*‘Results revealed that consumers/ patients were willing to change their behaviour.’*

countries. For example Identification of the patient and knowing their current prescription history is essential

2. Fulfilment of prescription; what controls are desirable/feasible. With prescribing specifics and volumes being important
3. Absence of language barriers is essential to avoid online diagnosis errors
4. A map of all the players (commercial private parties involved vs national systems) to provide clear transparency is important
5. The panel discussion revealed that in the UK a multidisciplinary approach was required e.g. the Quality Care Commission (CQC), The General Medical Council (GMC – representing the interests of doctors), General Pharmaceutical Council (GPhC – responsible for the issuing of pharmacy trading licences and oversight governance of pharmacists in the UK).

## High-level meetings with the European Commission and contribution to the public consultation on measures to further improve the effectiveness of the fight against illegal content online

On 17 April 2018, Mike Isles and Laura Cigolot together with Melissa Madigan, Policy and Communications Director at the National Association of Boards of Pharmacy (NABP), and Marty Allain, Senior Program Manager, .Pharmacy Verified Websites Program at NABP, met Mr Pearse O'Donohue, Director on Future Networks at the Directorate General for Communications Networks, Content and Technology, at the European Commission, and Ms Cristina Monti, Head of Sector - Internet governance and Stakeholders' engagement.

The illegal manufacturing and distribution of fake medicines online is an enormous public health risk with an untold cost to lives. Price, convenience and secrecy have driven consumer demand, as well as an uninformed public as to the dangers, creating the perfect environment for over 35,000 illegally operating websites.



L to R: Laura Cigolot and Mike Isles - ASOP EU, Pearse O'Donohue and Cristina Monti - DG CONNECT, Melissa Madigan and Marty Allain - NABP

There are a number of important initiatives to help protect the public. One which guarantees arriving at a genuine legally operating website are those that are certified and approved by the National Association of Boards of Pharmacy (NABP). This non profit organisation acquired and governs the use of the **TOP LEVEL DOMAIN NAME .pharmacy**.

The .Pharmacy Verified Websites Program is an NABP website verification program that uses a highly restricted top-level domain (TLD) .Pharmacy (dotpharmacy) as its seal of approval.



L to R: Mike Isles - ASOP EU, Martin Allain and Melissa Madigan - NABP, Horst Jürgen Krämer and Soushma Sougoumarin - DG CONNECT

Consumers around the globe can be sure the medications they buy online are safe by simply “looking to the right of the dot” (think .edu or .gov). Google, Bing, Yahoo, Twitter, Snap, Visa, and Mastercard require NABP website verification to participate in select pharmacy merchant programmes.

Mike Isles, Laura Cigolot, Melissa Madigan and Marty Allain also met Mr Horst Jürgen Krämer, Programme Officer on EU Policies in the Unit on eHealth and Ageing Policy, and Ms Soushma Sougoumarin. Clearly as we enter into an even more technical world the objectives to support innovative digitally-enabled solutions and policies so that people can enjoy healthy and independent living are vital. The .pharmacy approach complements and supports this goal.

On 3 May, Mike Isles and Laura Cigolot met Ms Annika Nowak, Member of the Cabinet of EU Commissioner for Health and Food Safety Vytenis Andriukaitis. Ms Nowak is a lawyer, in charge of cross border healthcare matters, eHealth, medical products quality, safety, innovation, medicines policy, authorisation and monitoring, health protection and legal affairs. In the past, Ms Nowak has been team leader in charge of the implementation of the Cross-border healthcare Directive.



Laura Cigolot and Mike Isles - ASOP EU, with Annika Nowak - Cabinet Member of EU Commissioner Andriukaitis

The meeting had the purpose to exchange views on the Commission initiatives and ASOP’s current work on patient safety, with particular focus on falsified medicines and the meaning of the Common Logo on legal online pharmacies. The meeting was designed to understand which follow-up actions DG SANTE intends to take in relation to Article 85d of the Falsified Medicines Directive, which highlights the legal obligation to raise awareness about medicinal products supplied illegally and the common logo.

*ASOP EU contributed to the “Public consultation on measures to further improve the effectiveness of the fight against illegal content online” which ran from 30 April 2018 to 25 June 2018, and highlighted the need to speed up law enforcement.*

Other institutional meetings include Mr Eric Peters, Expert on Digital Single Market within the Cabinet of EU Commissioner Mariya Gabriel, whose main responsibilities are the Digital Single Market / Digitising European Industry, E-commerce, Online platforms including removal of illegal content and Internet governance matters.

ASOP EU contributed to the **“Public consultation on measures to further improve the effectiveness of the fight against illegal content online”** which ran from 30 April 2018 to 25 June 2018, and highlighted the need to speed up law enforcement. There is a rising tide of falsified, substandard or fake medicines exposing the public to significant health risks. At any given time, there are around 35,000 active online pharmacy websites – approximately 96% of which do not comply with applicable laws and pharmacy standards.

Illegal sales via the Internet are global structures of organised crime and so fast access to a local host to shut down a website are not that useful, because these websites are ex-Europe. To be successful the money flow needs interrupting and an official prosecution against the owners of the illegal website. According to ASOP EU Director, organisations with a privileged status should have a faster access to law enforcement authorities, such as national authorities, as well as international task forces like Pangea (Interpol). One of the big issues is the mutual trust between all parties. The Medicrime Convention is a real possibility to organise such an initiative. Voluntary actions by intermediaries are crucial to a successful strategy and initiatives such as principles of participation should be encouraged.

# ECOO

ASOP EU was contacted by the **European Council of Optometry and Optics** to present on the subject of falsified products and to stimulate thoughts on how ECOO might respond to the rising tide of falsified/counterfeit products, as in this field, although few instances of counterfeit optical products have been noted, Mike’s talk stimulated strategic thinking as more and more people go to the Internet to buy for their needs.



L to R: Peter Gumpelmayer - President, Cindy Tromans - Vice President, Mike Isles, Fabienne Eckert - Secretary General

# EuropaColon

ASOP EU was invited to speak at the second **EuropaColon** Masterclass which took place in Barcelona in June alongside the 19th World Congress on Gastro

Intestinal Cancer. The presentation included slides showing that it was easy to search for oncology treatments on the Internet. Plans to place an Icon on the EuropaColon

website are underway to help raise awareness amongst that community.



# EAHP



L to R: Laura Cigolot, Mike Isles - ASOP EU, Gonzalo Marzal Lopez and Stephanie Kohl - EAHP

ASOP EU started to establish a collaborative approach to raise awareness amongst healthcare professionals and the public about the increasing activity by criminals to sell medicines via illegally operating websites. In this frame, on 3rd May 2018, Mike Isles and Laura Cigolot met Gonzalo Marzal Lopez and Stephanie Kohl of the European Association of Hospital Pharmacists (**EAHP**). We very much hope that ASOP EU and EAHP will jointly develop concrete measures to educate both healthcare professionals and the public about the dangers of buying medicines online.

## ASOP EU contributes to University College London School of Pharmacy - Fight the Fakes Panel Event

As part of their mission to address the Global Impact of Substandard and Falsified Medicines, **UCL and Fight the Fakes** hosted a panel discussion bringing together world leading experts on 16 March. The event was co-hosted by the Commonwealth Pharmacists Association and supported by partners International Federation of Pharmaceutical Wholesalers and the International Federation of Pharmaceutical Manufacturers & Associations. A fantastic turnout for the Fight the Fakes Panel event with over 200 participants from academia, students, NGOs, civil society, regulatory bodies, and Pharma start-ups coming together to learn more about the growing global health threat of substandard and falsified medicines. The event was chaired by Oksana Pyzik, Senior Teaching Fellow and Global Engagement Coordinator at the UCL School of Pharmacy and moderated by SCRIP journalist Eleanor Malone.

*The event was co-hosted by the Commonwealth Pharmacists Association and supported by partners International Federation of Pharmaceutical Wholesalers and the International Federation of Pharmaceutical Manufacturers & Associations.*



Amongst key contributors were Dr HRH Princess Nisreen El-Hashemite, Executive Director, RASIT, Michael Deats, Group Lead SAV Team from World Health Organisation (WHO), Bernard Naughton, Clinical Pharmacist from Oxford University, Mike Isles, Executive Director (ASOP EU), Lynda Scammell, Senior Policy Manager, MHRA. The success of this event was highlighted in an editorial piece published in The Lancet Respiratory Medicine journal "Fake Medicines: Fighting on All Fronts".

## EDQM expert group invites ASOP EU and other organisations to share their activities

The EDQM's (European Directorate for the Quality of Medicines & HealthCare which is part of the Council of Europe) Committee of Experts on minimizing public health risks posed by falsification of medicines & related crimes countering falsified medicines (CD-P-PH/CMED) invited non-profit organisations and trade associations to Strasbourg to enhance cooperation between these groups. ASOP EU along with many other organisations (such as EAEPC, GIRP, FIP, Fondation Chirac, FMEDS) made many useful suggestions including one by ASOP EU which asked if the CMED team could



Attendees at EDQM expert group meeting

help to coordinate the various activities to do with communicating to the public. This would strengthen the activity and help avoid duplication.

## ASOP EU Recognition in the newsletter of the Standing Committee of European Doctors (CPME)

Raising public awareness and concrete collaboration are critical to internet patient safety. In this context, ASOP EU Director Mike Isles and Secretariat Laura Cigolot met with Ms Annabelle Seebohm and Ms Carole Rouaud on 22 May.

The exact size of the problem is difficult to determine but there are approximately 35,000 active online medical product sellers worldwide, and 96% of them are operating illegally. It is also quite evident that consumers/patients are becoming increasingly reliant on, and trusting of, the Internet to buy medicines.

An integrated, comprehensive approach is needed and strengthening coordination with all stakeholders is vital to drive awareness and actions across EU countries to restrict such illegal and potentially fatal trade. Mike Isles was given the opportunity to publish an article in the June newsletter of CMPE and sincerely thanks them for this valuable opportunity. The medical profession has a pivotal role to play in the education of patients and also the detection of medicines that may have been bought and are in some way not appropriate for the patient.

As stated by ASOP EU  
Director **Mike Isles**,

*“It is of utmost importance to encourage healthcare professionals, as pillars in the public health system, to contribute to combat this problem via their interactions with patients. There are many approaches that medical associations can adopt to help inform patients about falsified medicines.”*

### Do not buy from a website that:

- Doesn't require a valid prescription for a prescription medicine
- Sells medicines that are not approved by the European Medicines Agency and so will not be licensed in the EU
- Doesn't have a physical address and phone number
- Doesn't have a licensed pharmacist who is easily contactable
- Offers 'bulk discounts', 'sample packs', 'new cures' or 'amazing results' so the offers are too good to be true
- Doesn't include the EU Common logo.



## ASOP EU co-hosts a European Parliament meeting

### *“How safe are your medicines? Raising public awareness is critical to Internet patient safety”*

**On 26 June 2018, EU policymakers and stakeholders met in the European Parliament to raise awareness on Internet sales of medicines and help enhance patient safety.**

This event was jointly organised by ASOP EU and MEP José Inácio Faria (EPP, Portugal). Article 85c and 85d of the Falsified Medicines Directive (FMD) legally obliges the European Commission and each Member State to actively publicise the meaning of the Common Logo and that of a falsified medicine. The meeting was designed to focus on this fact and to find how Member States and the Commission should address this.

Amongst keynote speakers were MEP Marisa Matias (GUE/NGL, Portugal), Rapporteur of the Falsified Medicines Directive, Professor Mario Frota, President of the Portuguese Association of Consumer Law (APDC), Mr Paulo Morais, President of Frente Civica, and Ms Ilaria Passarani, Secretary General of the Pharmaceutical Group of the European Union (PGEU). The debate was enriched by the valuable contribution of Mr Tamás Király, Policy Officer



Full room on 26 June 2018 at the European Parliament, in Brussels



for international aspects of intellectual property rights at the Directorate General for Trade of the EU Commission, and Ms Yuliya Morenets, Executive Director of Together against Cybercrime International (TaC).

MEP Marisa Matias (GUE/NGL, Portugal), gave her full support to the issue of the safe distribution of medicines and highlighted how cooperation between different parliamentary groups had been critical to put in place the FMD and

thus enhance the security around the traditional routes of medicines supply.

MEP Matias and MEP Faria also stressed the need to exert further pressure and act more forcefully to make people and all authorities more committed and sensitive to the problem of falsified medicines.

[Programme summary is available on the ASOP website.](#)

**“** *We applaud our partners’ commitment to raising awareness about the dangers of buying medicines online. However, much more needs to be done and more activity by the Commission and Member States with their own campaigns is needed to build on the many initiatives across the EU to combat this growing threat to public health.* **”**

**Mike Isles**, Director of ASOP EU

## EU Parliamentary Question: Why no Commission enforcement of Article 85d of the Falsified Medicines Directive?

Following adoption by the European Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011, and applied since 2 January 2013.

The Directive introduces harmonised European measures to fight medicine falsifications and ensures that medicines are safe and that the trade in medicines is rigorously controlled. Measures include obligatory safety features - a unique identifier and an anti-tampering device - on the outer packaging of medicines, a common, EU-wide logo to identify legal online pharmacies, tougher rules on import of active pharmaceutical ingredients and strengthened record-keeping requirements for distributors.

The introduction of the safety features of the Falsified Medicines Directive (FMD) on Feb 9 2019 will undoubtedly enhance the security in what is commonly cited as the “legitimate” supply chain and can be characterised by a flow of prescription medicine from manufacturer, to wholesaler (or distributor), to community and hospital pharmacy to patient.

**Article 85d of the Falsified Medicines Directive** clearly states:

“Without prejudice to the competencies 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

“  
*The Directive introduces harmonised... European safety measures*”

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.”

It has been over three years (July 1 2015) since the Common Logo had to be implemented. However Member States’ obligations are still far from being completed and an alarming lack of uptake on Article 85d has emerged.

The Commission developed a **communication toolbox** to help countries launch targeted national information campaigns with a consistent message across the EU. However, ASOP EU questions the fact that the Commission’s website represents a key tool to address falsified and substandard

medicines. According to ASOP EU research, the awareness rate of the Common Logo and its purpose is very variable and low, ranging from 16% to 40%.

MEP Faria asked for the second time what the Commission intends to do to help enforce Article 85D. The previous answer did not indicate any clear follow-up actions. In this frame, we asked the European Commission to provide the Parliament with statistics on the relevant pages of the Commission’s website, such as number of visits, time spent and pages visited. We also asked the Commission to verify such statistics for the Member States similar website pages and provide the Parliament what target levels it holds for such statistics.

In addition to this, we enquired about the possibility for the European Parliament to send pilot letters to Member States who have not started public awareness campaigns or whose campaign falls below the Commission’s targets.





## New compounding survey initiative

### A meeting took place with Professor Marc Dooms, Senior Orphan Drug Pharmacist at the University Hospitals in Leuven.

Compounding is a legitimate practice in which a licensed pharmacist prepares medicinal products in a pharmacy by combining, mixing, or altering pharmaceutical ingredients. Prof. Marc Dooms recently published a paper with colleague Maria Carvalho on this subject entitled "Compounded medication for patients with rare diseases".

A concluding remark highlighted the need for validated procedures "When there is no on-label or even no off-label treatment for patients with rare diseases pharmacists have to compound the medication. This needs to be done in the best possible conditions by trained compounders following validated procedures."

Further work to understand the standards of practice of compounding was one of the EAASM objectives in 2018. A questionnaire to be sent to all hospitals to gain a greater



L to R: Laura Cigolot, Professor Marc Dooms and Mike Isles

understanding across Europe is currently being worked on and the findings will be coordinated with Professor Dooms. Mike and the Professor agreed that compounding can give rise to patient harm and so to highlight any issues will be an important element of the research results.

## New Patient leaflet

### Over the past months, ASOP EU has established a close relationship with the European Medical Association (EMA).

A first outcome of this fruitful collaboration is a patient leaflet that shows the risks of buying medicines online and offers valuable advice on what to look out for.

ASOP EU truly hopes that Community doctor surgeries will disseminate this leaflet locally. This important educational material has been distributed during the Parliamentary meeting held on 26 June 2018 and looks for additional support at a local country level.

On the EMA website, ASOP EU Director Mike Isles and EMA President Vincenzo Costigliola agreed to put an ICON that routes through to the ASOP EU/EAASM educational websites in 5 countries. Buying medicines online can be a risky business as there are many illegally operating websites.

You could easily become the victim of dishonest online pharmacies

**FAKE MEDICINES** **BE CAREFUL!**

A Patient's Guide to the Risks of Buying Medicines Online

**HOW TO BUY SAFELY**

- 35,000 illegal websites
- Up to 35,000 illegally operating websites target consumers and patients.<sup>[1]</sup>
- Fake medicines may have too much, too little or a different active ingredient.
- 96% of online pharmacies operate illegally.<sup>[2]</sup>
- Fake medicines may contain poisons, paint thinners and other potential harmful or deadly ingredients.<sup>[3]</sup>
- Fake medicines can be made in unsanitary or non-sterile environments with unsafe conditions.<sup>[4]</sup>

[1] Internet Drug Outlet Identification Program, National Association of Boards of Pharmacy, 2016 <http://safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf>

[2] [https://buysafex.pharmacy/wp-content/uploads/2018/02/NABP-Internet-Drug-Outlet-Report\\_February-2018.pdf](https://buysafex.pharmacy/wp-content/uploads/2018/02/NABP-Internet-Drug-Outlet-Report_February-2018.pdf)

[3] Poisons Found in Counterfeit Medicines, Partnership for Safe Medicines, 2012 <https://buysafex.pharmacy/for-the-media/toxins-found-in-counterfeit-and-falsified-medicines/>

[4] <https://buysafex.pharmacy/for-the-media/key-data-about-illegal-online-drug-sellers-and-counterfeit-medicines-2/>

[5] The Internet Pharmacy Market in 2016 <http://safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf>

# The EMA website route

This educational website contributes to help protect people from criminals who might sell dangerous, fake medicines, steal someone's identity and/or commit online fraud. The success of the website can be evaluated by the number of first page search results which was averaging 30,000 per day. The click through rate was as high as 4.5% which meant that 1350 people per day had the opportunity to view the website material.

*This educational website contributes to help protect people from criminals who might sell dangerous, fake medicines, steal someone's identity and/or commit online fraud.*


Visitors to the EMA website are able to click on the icon which routes through to educational material about falsified medicines. This page asks for support from the medical fraternity in order to connect with their patients on this important subject.



## HOW DO I PROTECT MYSELF ?

Do not buy from an online pharmacy that...

- ✘ Doesn't have a licensed pharmacist or physical address and a telephone number that works
- ✘ Offers 'bulk discounts' or 'amazing results'
- ✘ Doesn't require a valid prescription for prescription medicines – *this tells you straight away it is operating illegally*
- ✘ Doesn't include the Common Logo below...





The 'EU Common Logo', introduced by a European Directive, will include your county's national flag and link you to the website of the national competent authority, listing all legally operating online pharmacies.

[http://www.ema.europa.eu/ema/index.jsp?curl=/pages/regulation/general/general\\_content\\_000630.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/regulation/general/general_content_000630.jsp)


In addition to the health risks, personal and financial information could be used or sold without consent.

BE SAFE. BUY SMART.





European Medical Association



ASOP GLOBAL ALLIANCE FOR SAFER ONLINE PHARMACIES

For more detailed information [www.buysafex.pharmacy](http://www.buysafex.pharmacy)

### We need your help please!

The EMA has recently partnered with two non-profit patient safety organizations who are deeply involved in raising public awareness around the dangers of fake medicines. They are running campaigns in 5 major countries and intend to support the EMA by supplying educational material that your surgery teams could disseminate locally. This will take the form of a leaflet which may be useful to be translated in to your language and we are therefore looking for support at a local country level to support this initiative.

If you would like to support this initiative please contact [mike.isles@asop.eu](mailto:mike.isles@asop.eu)

**Buying medicines online can be a risky business as there are many illegally operating websites**

This website is here to help protect you from criminals who might sell you dangerous fake medicines, steal your identity and/or commit online fraud.

**Es ist gefährlich, Medikamente bei dubiosen Anbietern im Internet zu kaufen!**

Diese Website soll Ihnen dabei helfen, sich vor Onlinebetrug und vor Kriminellen, welche gefährliche und gefälschte Medikamente verkaufen, zu schützen.

**L'achat de médicaments sur internet peut être dangereux. Les sites illégaux sont nombreux et difficiles à identifier**

Vous trouverez ici les conseils nécessaires et précautions à prendre afin de vous protéger du commerce illégal de médicaments sur internet.

**L'acquisto di farmaci on-line è un affare rischioso**

L'acquisto di farmaci on-line è un affare rischioso. Questo sito è qui per aiutare a proteggere dai criminali che potrebbero venderci pericolosi medicinali contraffatti, rubare la vostra "identità digitale" e / o di commettere frodi online a vostro danno.

**Comprar medicamentos a través de Internet es un negocio arriesgado**

Este sitio web ha sido creado para ayudarle: ¡protegete de los delincuentes que pretenden vender medicamentos falsificados; robar tu identidad y/o cometer cualquier otra estafa online!

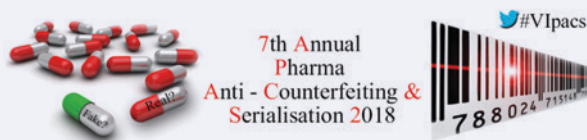


www.asop.eu www.eaasm.eu

# Upcoming Meetings

**1** ASOP EU/EAASM is a guest speaker  
12 – 13 September 2018

Sheraton Skyline Hotel  
London Heathrow, UK



**2** ASOP EU/EAASM is a guest speaker  
25 September 2018

**Medicine Quality & Public Health**

23-28 September 2018, Oxford, UK  
First ever international conference on medicine quality

**3** EAASM co-hosted meeting with MEP Faria  
7th November 2018, 3:00 PM – 5:00 PM

European Parliament, Brussels  
Improving patient safety with the FMD in the  
hospital pharmacy, will we be ready?

For more info, please contact Laura Cigolot  
at [laura.cigolot@asop.eu](mailto:laura.cigolot@asop.eu)



**4** ASOP EU Guest speaker  
14 November 2018  
8:30 AM – 3:30 PM EST

National Press Club 529 14th St NW,  
Floor 13 Washington, DC



**5** 15 November 2018  
8:30 AM – 5:00 PM

Washington, DC.



Please save the date for our:

**Annual All-Hands Strategy Session  
and Hill Day**

For more information,  
please contact  
Matthew Rubin at:  
[Matthew.Rubin@BuySafeRx.pharmacy](mailto:Matthew.Rubin@BuySafeRx.pharmacy)  
or (202) 312-7456

**6** EAASM is a Civil Society Member of the  
Observatory and will participate  
in the working group meeting  
26 – 27 November 2018

at the EUIPO HQ Alicante, Spain



**7** 31 January 2019  
2019 Risk Summit Series

Kick off meeting in Riga, Latvia

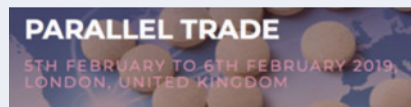
2nd meeting 5 – 6 February 2019

London



**8** ASOP EU/EAASMS  
guest speaker at the  
13th annual Parallel  
Trade 5 – 6 February 2019

London, UK



Your contacts at ASOP EU and EAASM

[mike.isles@eaasm.eu](mailto:mike.isles@eaasm.eu) [laura.cigolot@asop.eu](mailto:laura.cigolot@asop.eu)