

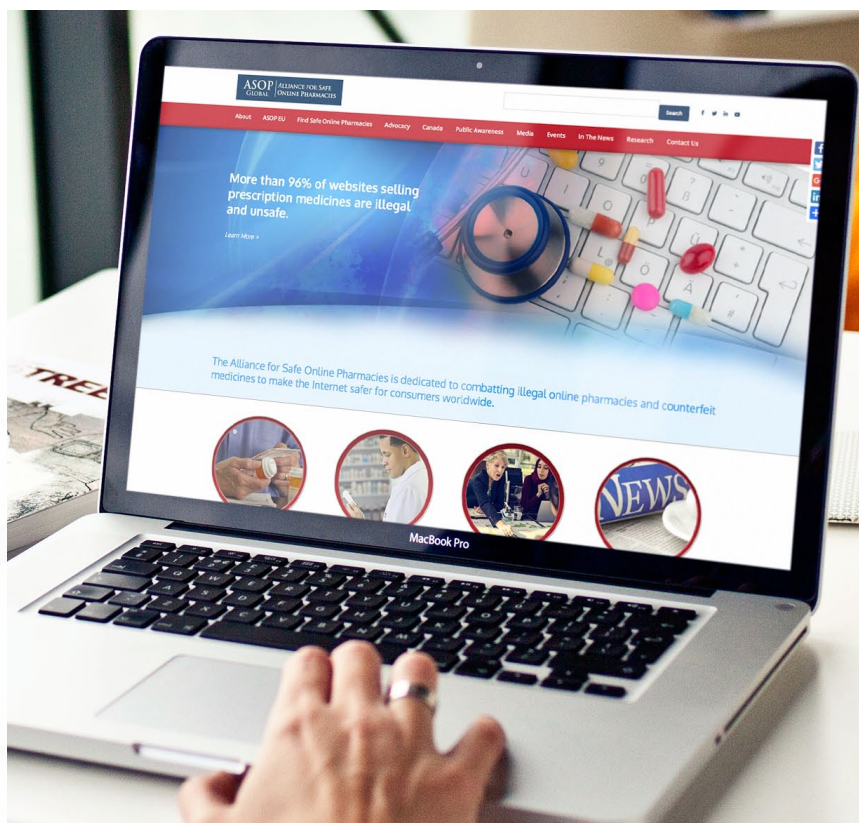
NEWSLETTER

September 2017

New ASOP Global website launched January 2017

In order to provide consumers, healthcare providers, regulators, media and others with a single source of information, ASOP Global launched their new website in January 2017. This was developed in consultation with ASOP Global's Communications Committee. Now consolidated to one global website, ASOP EU will retain an independent EU-related materials section. In compiling all materials onto one website, stakeholders will have easier, more efficient access to valuable and topical information about how to stay safe online.

[Please take a look!](#)



A DIARY OF ACHIEVEMENTS 2017

JANUARY

Launch of new ASOP Global website with dedicated section of EU members and stakeholders (www.buysaferx.pharmacy/eu/).

ASOP EU Member State roundtable teleconference on "Best Practice Sharing" amongst experts in communicating to the public about falsified medicines and the Common Logo. Participated in [PACT](#) (Patient's Access Partnership). EAASM met with Lydie Meheus of the Anticancer Fund.

FEBRUARY

ASOP EU/EAASM as a Speaker at SMI Parallel Trade conference London on 'Fighting Fakes By Raising Public Awareness'. Participant in ASOP Global Communication Strategic development programme. Attendance at Global Illicit Trade Summit - sponsored by The Economist.

MARCH

Presentation of the ASOP Global Internet Pharmacy Safety E-Commerce awards at ICANN58, Copenhagen to Rightside and Realtime Register. Speaker at European Association of Hospital Pharmacists - satellite symposium, Cannes. ASOP EU speaker at 3rd Anti-counterfeiting Pharma conference, London. Panelist and Speaker at World Customs Organisation - Law Enforcement Committee, Brussels.

A DIARY OF ACHIEVEMENTS 2017 APRIL - AUGUST



APRIL

Google educational AdWord campaign commences in Germany with high first page research results from the keywords selected and a higher than average click through rate. Attendance at “Universal Access to Health - How Can We Help” meeting, hosted by Medicines for Europe, European Patients Forum, European Social Insurance Platform and the European Public Health Alliance.

MAY

ASOP EU and EAASM invited as a Civil Society Member to EUIPO (European Union Intellectual Property Office) Plenary and Working group meetings. Meeting with new secretariat of Fight the Fakes campaign - IFPW (International Federation of Pharmaceutical Wholesalers). TC with senior Microsoft representative to further collaboration talks. ASOP Global quarterly TC. Collaboration meeting with Health First Europe, Brussels. Discussion with French documentarist for ASOP EU to contribute to a film on anti-counterfeiting of medicines.

JUNE

Attendance at UNIFAB World Wide anti-counterfeiting day with focus on fake medicines. EU Member State meeting on “Sharing best Practice on the Common Logo and Public Awareness Campaigns” with input by 70% of Member States, Google Offices, Paris. Speaker and panelist at the 13th European Congress of Clinical Pharmacology and Therapeutics. Collaborative meetings with French Chamber of Pharmacy, French Customs, IPSEN and Servier.

JULY

Announcement of ASOP Global’s Consumer Survey findings on online pharmacy use, perception and consumer behaviour. Medicrime Convention - official contact made by Directorate General of Human Rights and Rule of Law, Council of Europe to participate as a member of the Committee of Parties with special input in Victim Support law development. Official response by DG Santé Commissioner Vytenis Andriukaitis to EAASM letter asking for guidelines to be initiated on off-label usage of medicines. Google educational AdWord campaign commenced in Spain.

AUGUST

Call for action paper progressed - “Protecting European citizens using the most suitable skin disinfectants before medical treatment” endorsed by the EAASM. ASOP Global quarterly teleconference covering year-to-date progress. Response by the EU health commission to the questions posed by MEP Jose Inacio Faria of the European People’s Party based on amendments tabled and contained within the European Parliament (EP) own-initiative report on “Safer Healthcare in Europe: Improving Patient Safety and Fighting Antimicrobial Resistance”.



EUROPEAN MEDICAL ASSOCIATION

We are delighted to announce that the European Medical Association (EMA) will be joining ASOP EU and EAASM.

The official signing of these memberships is planned to take place at the [EMA General Assembly](#) on 21-22 November 2017 at the Excel Centre London. The European Medical Association was created in 1990 by doctors from 12 member states, and was established as an “international foundation pursuing a scientific aim” according to the Belgian law dating 25/10/1919. It is a unique, independent non-profit organisation, which offers every European Community doctor the opportunity to: join a European network of doctors,

add a European dimension to their professional and social life and actively influence the development of European healthcare. In terms of collaboration with ASOP EU and the EAASM, plans are under way. As an example an educational leaflet for patients informing them about the dangers associated with falsified medicines is being progressed. This has the potential to be effective in raising awareness across the EMA network and thus enhance patient safety greatly.



BECTON DICKINSON

We were delighted to announce that Becton Dickinson (BD) has become a member of both ASOP EU and EAASM.

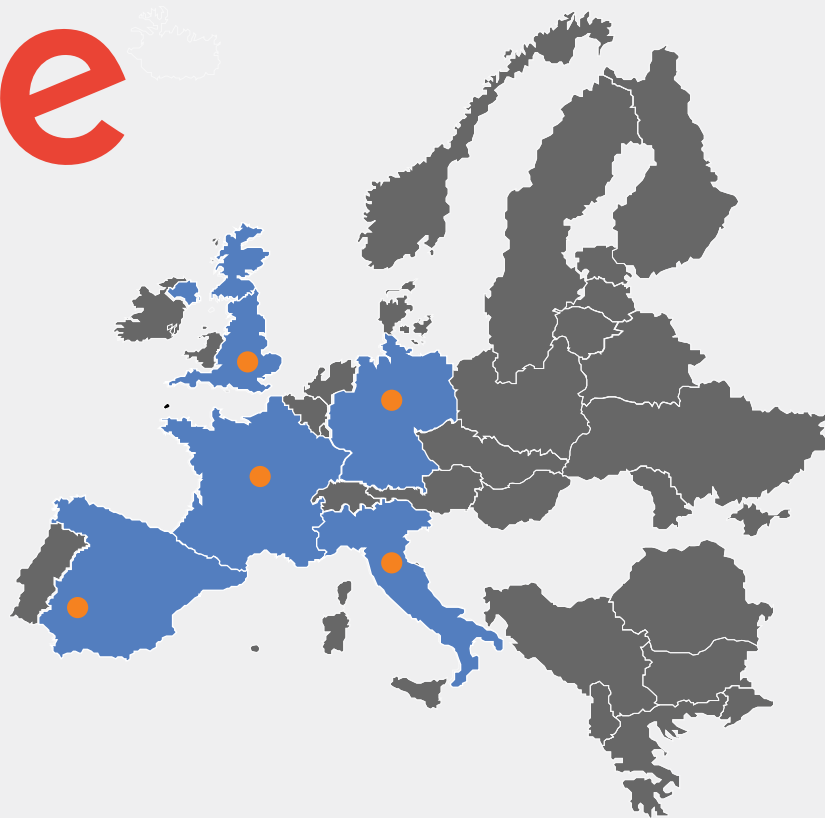
Jose Luis Gomez Ruiz, Vice President Public Policy Europe commented on this new development.

“BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD leads in-patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication

management, promote infection prevention, equip surgical and interventional procedures and support the management of diabetes. In addition, BD has developed technology that will help healthcare organisations address the new European Falsified Medicines Directive. We are proud to support the EAASM and ASOP EU in their valuable policy work to protect patients from unsafe medical practices as well as impactful campaigns that educate patients and consumers about the dangers of falsified medicines along with their many collaborative initiatives with like-minded influential parties.”



AdWord campaign now extended and live in 5 major European countries



Following the educational grant from Google, ASOP EU and the EAASM have been developing five in-country educational campaigns to inform the public about the dangers of illegally operating pharmacies.

The campaigns are now live in France, Germany, Italy, Spain and the UK. But how do we know if they are truly effective? This can be measured as follows; firstly by the number of opportunities the public get to see the advertisement and secondly, how many people decide to click on the advertisement which takes them through to the educational website.

In broad terms, on average, combining the statistics from the 5 campaigns, they are achieving over 25,000 first page research results (this is when the advertisement appears on the first page of the Google search results) with over 900 people per day clicking on the advertisement and therefore being exposed to the educational website and its first landing page. In addition, another key objective is to gain an understanding of whether the campaign can change behaviour. This is investigated by inviting the visitor to

complete a survey comprising 10 questions. As well as information about age, gender and types of medicines bought, two key questions are also asked.

One asks whether they are aware that the vast majority of websites selling medicines are operating illegally. A substantial number (in Germany for instance) of respondents were not aware of this fact (74%).

The next question asked “Now you are aware of this fact, would you change your behaviour?”. Importantly, over 65% of visitors ticked the “for sure or probably” boxes saying they would visit their local trusted source to obtain their medicine. Clearly this is very encouraging news.

A full report on the results of these 5 websites will be written up by year end.

Meanwhile if you would like to visit the websites please click on the map above and it will take you through to country landing pages.

ASOP EU ADWORD CAMPAIGNS MODIFIED TO INCREASE MESSAGE IMPACT

Alle Shopping Bilder News Maps Mehr Einstellungen Tools

Ungefähr 144.000 Ergebnisse (0,56 Sekunden)

Informieren Sie sich - Bevor Sie Medikamente kaufen
[\(Anzeige\) www.sichere-medikamente.org/](#)
 Wie Sie illegale Apotheken und gefälschte Medikamente erkennen.
 Seien Sie vorsichtig Stay safe
 Anonyme Umfrage

Gefälschte Arzneimittel - wirksam bekämpfen mit Adents - adents.com
[\(Anzeige\) www.adents.com/serialisierung/arzneimittel](#)
 Schützen Sie Ihre Patienten mit unseren Serialisierungs- u Traceability-Lösungen.
 Serialisierung EU Falsified Medicines
 Adents Seriza Adents Prodig

Gefälschte Medikamente - TV-Doku zum ARD-Themenabend
[\(Anzeige\) www.german-doctors.de/medikamente/falschungen](#) 0228 38759728
 ARD-Doku zu Medikamentenfälschungen gesehen? Helfen Sie mit. Infos hier!

Gefälschte Arzneimittel: Was Verbraucher wissen müssen - Tagesschau
https://www.tagesschau.de/wirtschaft/_pharmazie-fragen-antworten-101.html
 17.05.2017 - Gefälschte und minderwertige Medikamente gelangen auch nach Deutschland - teils illegal, teils über die legalen Vertriebswege. Tobias Bönke ...

Lebensgefahr durch gefälschte Medikamente | NDR.de - Ratgeber ...
www.ndr.de/_lebensgefahr-durch-gefalschte-Medikament.medikament276.html
 16.05.2017 - An gefälschten Medikamenten sterben jedes Jahr weltweit bis zu einer Million Menschen. Die WHO hält jedes zweite im Internet angebotene ...

Arzneimittelfälschungen in der ARD: Geben Apotheker gefälschte ...
https://www.deutsche-apotheker-zeitung.de/_geben-apotheker-gefalschte-arzneimitt-
 18.05.2017 - Fälschungen in deutschen Apotheken? Einer ARD-TV-Doku zufolge landen über viele Umwege auch hierzulande gefälschte Arzneimittel.

Risiken von gefälschten Medikamenten | Apotheken Umschau
www.apotheken-umschau.de/medikamente/Risiken-von-gefalschten-Medikamenten-
 Gefälschte Medikamente. Erwischt: Von Zollbeamten beschlagnahmte Arzneimittel. dpa Picture-Alliance GmbH/Malte Christians. Sie nannten sich selbst ...



DIESES VIDEO ZEIGT, WAS PASSIEREN KANN, WENN MAN MEDIKAMENTE IM INTERNET VON ILLEGALEN ANBIETERN KAUFT – ES DAUERT NUR 4 MINUTEN.



Klicken sie hier wenn sie mehr darüber erfahren wollen, wie man Medikamente risikolos im Internet kaufen kann.



Fakten über gefälschte Medikamente
 Home Seien Sie vorsichtig **Stay Safe** Helfen Sie uns Informationen Kontakt

Stay safe - vergewissern Sie sich, ob Ihre Onlineapotheke sicher ist

Das ist nicht so einfach, aber eine EU Richtlinie hilft dabei.

Die Fälschungsrichtlinie ermöglicht es legale Onlineapotheken (und in einigen Mitgliedsstaaten auch andere legale Anbieter) zu kennzeichnen. Dabei darf jedoch nicht vergessen werden, dass die einzelnen Mitgliedsstaaten der EU unterschiedliche Gesetze haben, wenn es um den Vertrieb von Arzneimitteln im Internet geht. So ist es zum Beispiel in Deutschland und einigen anderen EU Ländern möglich, verschreibungspflichtige Medikamente online zu erwerben, sofern der Patient/die Patientin ein Rezept eines Arztes erhalten hat.

Derzeit kann man in den meisten EU Ländern nur freiverkäufliche Medikamente, sogenannte OTC, online erwerben. Dies regelt die EU-Richtlinie 2011/62/EU im Artikel 85c. Sie besagt, dass sich die Mitgliedsstaaten unter bestimmten Umständen verpflichten, zumindest „OTC“ Medikamente der Öffentlichkeit online zugänglich zu machen. „OTC“ Medikamente sind Arzneimittel, die kein ärztliches Rezept benötigen.

Helfen Sie uns, damit wir anderen helfen können
 Bitte helfen Sie uns, indem Sie sich kurz Zeit nehmen und unseren Fragebogen ausfüllen. Persönliche Daten werden nicht gespeichert oder an Dritte weitergegeben.

Klicken Sie hier, um an unserer Umfrage teilzunehmen



Fakten über gefälschte Medikamente
 Home Seien Sie vorsichtig Stay Safe Helfen Sie uns Informationen Kontakt

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.

Seien Sie vorsichtig
 Der Verkauf von verschreibungspflichtigen Medikamenten über das Internet ist nicht in allen Mitgliedsstaaten der EU erlaubt.
 Für mehr Informationen klicken Sie hier →

Gefälschte Medikamente
 Gefälschte Medikamente sind gefährlich!
 Für mehr Informationen klicken Sie hier →

Stay Safe
 Finden Sie heraus, wie Sie die Unterschiede erkennen können.
 Klicken Sie hier →

In line with the principle that ASOP EU and the EAASM should continually develop the Google AdWord campaigns to optimise effectiveness, ways of enhancing the attractiveness of the website by changing messages and visuals to obtain the best engagement rates will be developed.

The German website, for example, now has the Fondation Chirac powerful “Pharmacide” video. The visitor can view the whole video or click off, which then takes them to the educational website - see the visuals above showing the flow of the routing.

By developing new approaches to visuals on the landing pages, the aim is to optimise attractiveness and encourage visitor exploration leading to an increase in the click through rates and “dwell” times on each page of the website.

OUTREACH EVENTS

MEMBER STATE “BEST PRACTICE SHARING” ON THE COMMON LOGO - PARIS 29TH JUNE 2017

Convened on 29th June at the Google Offices in Paris, this was the 5th meeting with Member States to share best practice around raising public awareness about the Common Logo and falsified medicines. Over 70% of Member States had some form of input to the meeting, either by attending or completing information beforehand.

Of particular significance was the fact that DG Santé underlined the importance of Article 85d of the Falsified Medicines Directive which obliges Member States to carry out public facing awareness campaigns.

Many different campaigns were shared to those present. One section was devoted to setting up and running a Google AdWord campaign under the expert guidance of Dana St Mary from the Google offices in California. In addition, a very useful update by Ines du Plessis - EDQM presented the latest news about the Medicrime Convention (which has now in fact been ratified - see update article on page 10 of this newsletter).

A report is currently being circulated to Member States ready for an Autumn release. This will act as a reference document for all interested parties to help to support and catalyse further pan-European public facing campaigns.

From left to right back two rows Hanne Hanken, Quentin Duteil, Monika Macisowicz, Marion Barreau, Klaus Gritschneider, Mike Isles, Sammy Kohl, Sasa Polovic, Alain Denis, Philippe de Buck, Paul Brewer **Front row** Lynda Scammell, Melissa Madigan, Libby Baney, Felicia Faz, Aline Plancon



OUTREACH EVENTS 22ND CONGRESS OF THE EUROPEAN ASSOCIATION OF HOSPITAL PHARMACISTS



EAASM was invited to speak on the subject “Falsified Medicines; the Role of the Pharmacist in Raising Patient Awareness”. This satellite symposium had the objective of exploring the need for access to a safe and ethical supply of medicines that are unlicensed or unavailable at the point of care.

Through a series of presentations and panel discussions, the panelists examined the considerations pharmacists need to take into account when faced with unmet patient needs and how the rise of falsified medicines is increasing the risk to patient safety.

Mike Isles concluded: “Pharmacists have a duty to understand the growing online pharmacy environment, gain feedback from their patients on the subject as well as informing them that fake/falsified medicines exist on the Internet and that they can cause harm. It is a fact that 95% of websites selling medicines in to the EU are operating illegally and so solid advice on how to check on finding genuine online pharmacies is crucial”.

OUTREACH EVENTS EUIPO OBSERVATORY WORKING GROUP MEETING - ALICANTE

3



The EAASM is a Civil Society member of the EUIPO working groups. Three work streams were attended at the 3-5 May meeting in Alicante: law enforcement, public awareness and IP in the digital world

The EAASM/ASOP EU made the suggestion that a meeting with internet Intermediaries would help to facilitate greater collaboration and tackle the issues relating to Internet crime.

Collaborative discussions took place in order for ASOP EU to participate in the Youth IGF Movement, operated by TaC International. This initiative will deliver information to youth groups around the world to spread the message about the issue of fake medicines that can be found on the Internet. ASOP EU is therefore working closely with TaC-Together against Cybercrime International, represented by Yuliya Morenets Executive Director and a key driver of the Youth IGF Movement (www.youthigf.com). The Youth IGF is a global movement that operates as a multi-stakeholder platform. It allows the young (15-30 years old) to discuss and take a lead in issues related to the Internet in the format of local, national or regional debates.

OUTREACH EVENTS

EUROPEAN ASSOCIATION OF CLINICAL PHARMACOLOGY AND THERAPEUTICS CONGRESS (EACPT)



Mike Isles speaking at the European Association of Clinical Pharmacology and Therapeutics Congress (Prague 24-27 June 2017) joined a panel of experts on the subject “Global Health – Access to medicines - ensuring the supply chain for access to safe and effective medicines”.

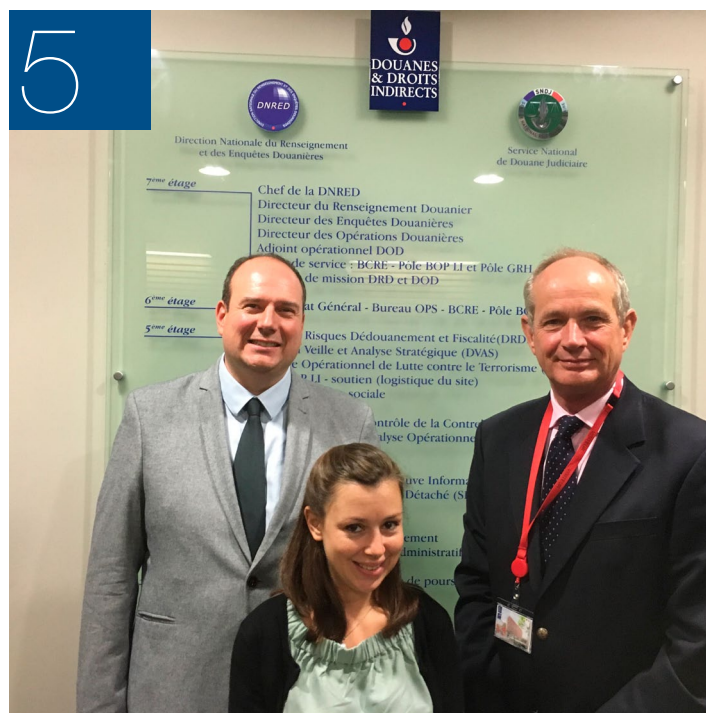
Tackling the demand side Mike says “...is all about educating the public – that is you and I – about the risk of buying medicines online. Public awareness campaigns in each country, like the ones that ASOP Global and ASOP EU are running, will be critical if we are to address the demand side dynamic. Initiatives such as the NABP secure top level domain name .pharmacy where a website with this address will be a genuine pharmacist, is a very complementary initiative to the EU’s Common Logo which must appear on every webpage selling a medicine.”

For an informative resume of the topics discussed by the panel please click here to see a short [video](#).

From left to right: Pavle Zelic, Medicines and Medical Devices Agency, Serbia; Jozef Glasa, Slovak Medical University in Bratislava, Slovakia; Prof. Donald Singer – Clinical Pharmacologist, EACPT and President of the Fellowship of Postgraduate Medicine and Mike Isles ASOP EU and EAASM – Pan EU patient safety organisations.

OUTREACH EVENTS

ASOP MEETS FRENCH CUSTOMS



A productive meeting took place on 30th June between ASOP EU and French Customs, specifically the MEDIWATCH -FRANCE department with Frédéric LAFORET and Solveig de-Rancourt. where the origins, responsibilities and achievements of Customs Mediwatch were discussed.

Frédéric also mentioned that PANGEA was about to take place and how Customs Mediwatch was, as ever, very active in contributing to this world effort against criminals in falsified medicines.

OUTREACH EVENTS

UNIFAB WORLD ANTI-COUNTERFEITING DAY



ASOP attended the 20th world-wide anti-counterfeiting day hosted by **UNIFAB** on 7th June 2017 at the Museum of Anti-counterfeiting in Paris which focussed on falsified medicines. Presentations gave a comprehensive overview of the supply side and the demand side actions that were combatting the rise of this criminal activity. The activities of ASOP in this context were highlighted as being very supportive and productive. During the event the Global Anti-counterfeiting Group (GAC) presented 8 awards representing a broad spectrum of anti-counterfeiting activities from the continuing success of national customs services to the growing importance of international co-operation to combat fraud.

Bernard Leroy, seen here, Director of the Institute of Research Against Counterfeit Medicines (IRACM) also spoke of the good collaborative work being carried out by ASOP. IRACM is a member of ASOP.

OUTREACH EVENTS

WORLD CONFEDERATION FOR PHYSICAL THERAPY EUROPEAN REGION (ER-WCPT) MEETS ASOP EU



Following up on a meeting with David GORRIA General Secretary, European Region of the WCPT, Mike was introduced in June to Sarah Bazin, past President and currently the Chair for the **(ER-WCPT)** and Natalie Beswetherick, Director of the Practice and Development Directorate at the London offices of the Chartered Society of Physiotherapy. Both organisations expressed a desire to work more closely together with potential mutually beneficial activities such as: an article on falsified medicines in the ERWCPT newsletter, an ICON on their website which links through to the ASOP EU public facing educational website and dissemination of an educational leaflet on falsified medicines.

From left to right Natalie Beswetherick, Mike Isles and Sarah Bazin.

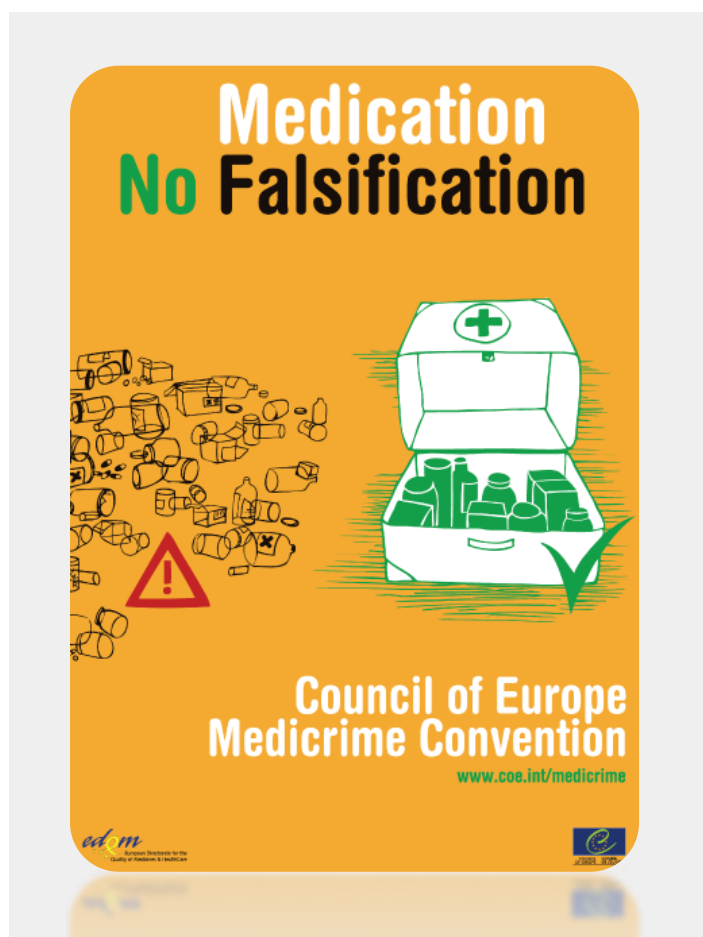
OUTREACH EVENTS

EAASM MEETS HEALTH FIRST EUROPE



The EAASM held a very productive meeting with Melina Raso, Executive Director of Health First Europe. Their over-arching healthcare initiative entitled **“Road Map 2020 - For quality care in Europe”** includes an important patient safety objective: that of improving patients’ health literacy, patient access to high quality information and supporting patients to share in health decision-making. They believe this is imperative to implementing truly patient-centred care in European health systems and are calling on the EU to develop guidelines for patient involvement in all health policies. Clearly there is a synergistic overlap with the activities of both the EAASM and ASOP EU and finding areas of mutual support will be of benefit to patients throughout Europe.

MEDICRIME CONVENTION NEWS



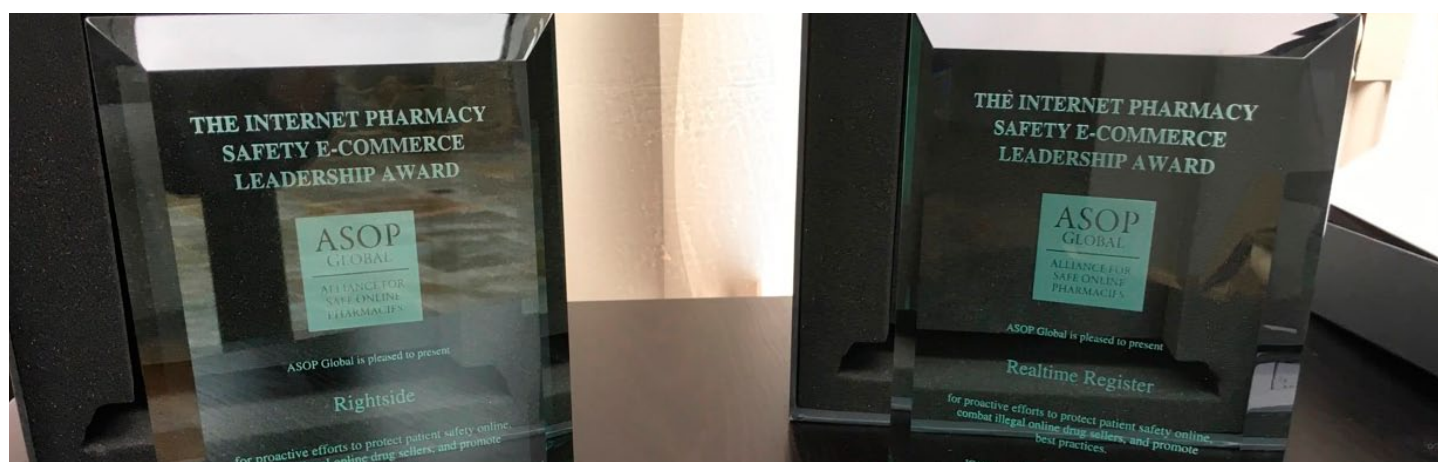
On July 2017, the MEDICRIME Convention was ratified by a 10th country. This will trigger the formation of a Committee of Parties and this Committee will oversee a number of activities aimed at monitoring the implementation of the MEDICRIME Convention.

Mr Oscar ALARCÓN JIMÉNEZ, Co-Secretary of the European Committee on Crime Problems within the Directorate General of Human Rights and Rule of Law at the Council of Europe, has welcomed the possible inclusion of ASOP and stated:

“I believe that your organization could contribute expertise in victim support and therefore could be involved in the Committee of the Parties taking into account that civil society, as established in Art 17, should also be participating in the co-operation and information exchange system in collaboration with each Party of the Convention.”

ASOP looks forward to supporting the Committee of the Parties of the **MEDICRIME Convention**.

INTERNET PHARMACY SAFETY AWARD PRESENTED AT ICANN58 - COPENHAGEN 2017



Matt Rubin and Mike Isles presented ASOP Global's inaugural Internet Pharmacy Safety E-Commerce Leadership Award to Rightside and Realtime Register during the Generic Names Supporting Organization (GNSO) at ICANN58 in Copenhagen. Established by ASOP Global in 2016, the Internet Pharmacy Safety E-Commerce Award recognizes companies and individuals in the Internet ecosystem who have made significant strides in ensuring the safety of patients online.

[Read the News Release here.](#)

PARLIAMENTARY NEWS

RESPONSE FROM COMMISSIONER OF HEALTH ON REQUEST FOR GUIDELINES ON OLU



The EAASM wrote to Commissioner Vytenis Andriukaitis on May 17th 2017 requesting guidelines to enhance patient safety when medicines are used off-label. The letter drew attention to the fact that a number of significant patient safety issues had been reported, most notably a number of patients who had

suffered serious eye infections following the use of medicines off-label during treatment procedures in the ophthalmology department of the hospital of Careggi (Florence) Italy.

The letter also drew attention to the fact the European Parliament (EP) own-initiative report on “Safer Healthcare in Europe: Improving Patient Safety and Fighting Antimicrobial Resistance” urges the Member States to:

- ensure that medical professionals inform patients when a medicine is used off-label and provide patients with information on potential risks in order to enable them to give informed consent;
- investigate possible malpractice involved in the refurbishment and re-use of medical devices originally designed and labelled for single use.

The EP report also calls on the European Medicines Agency (EMA) to develop guidelines on the off-label/unlicensed use of medicines based on medical need, as well as to compile a list of off-label medicines in use despite licensed alternatives.

The letter recommended that the EMA should issue guidelines that can be followed by the Member States and that such guidelines should be tried, tested and trusted, such as the GOLUP guidelines.



A reply was received by the Commissioner on 19th July 2017. It explained that the report on off-label use which was commissioned following the adoption of the two European Parliament resolutions in 2013 and 2015 called for specific action to be taken in the area of off-label use of medicines, in order to understand the ramifications at a national level.

The letter stated “...*The report was discussed at the STAMP Commission Expert Group on Safe and Timely Access to Medicines for Patients on 14th March 2017, in particular the options put forward as to a possible way forward regarding off-label use. Taking in to account that off-label prescribing of authorised medicinal products is not prohibited, or even regulated, by EU Law and remains in most Member States the responsibility of the prescribing physician, the Expert group considered that a reflection of possibilities for exchange of information and collaborative actions by Member States was more appropriate than developing treatment guidelines at the EU level. The collaboration between Member States is directly led by Member States Heads of Medicines Agencies’ level*”.

The EAASM regards this decision as not addressing the weight of opinion expressed in the European Parliament (EP) own-initiative report and not reflecting a body of patient safety organisations concerns and proposals.

In particular the fact that the GOLUP guidelines were not given a greater airing is disappointing to say the least.

However, the EAASM will continue to work closely with all interested parties and are currently working on next steps. In addition, the recent questions raised by MEP Faria and the Commission’s answer casts some further light on this area and is addressed in the article on the next page.

PARLIAMENTARY NEWS

MEP FARIA POSES KEY HEALTH QUESTIONS FOR COMMISSION



Above MEP Faria and from left to right: Frederic Destrebecq European Brain Council, MEP José Inácio Faria of the European People's Party and MEP Lieve Wierinck of the ALDE Group and of the ITRE Committee of the EP.

MEP José Inácio Faria (PPE) seen here in a recent debate entitled “**Ensuring the safe prescription of medicines off-label in Europe: what role for the European Union?**” hosted by the European Brain Council where the topic of off-label usage of medicines and the need for guideline was discussed. MEP Faria also posed an important question in the EU Parliament as follows.

Subject:

Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

Parliament's resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance incorporates a number of significant amendments. These are reflected in the following paragraphs: 'Urges the Member States to implement or develop the following measures: [...] ensure that medical professionals inform patients when a medicine is used off-label and provide patients with information on the potential risks in order to enable them to give informed consent; [...] Calls on Member States to investigate possible malpractice involved in the refurbishment and re-use of medical devices originally designed and labelled for single use; [...] Calls on the European Medicines Agency (EMA) to develop guidelines on the off-label/unlicensed use of medicines based on medical need, as well as to compile a list of off-label medicines in use despite licensed alternatives; [...] Calls on the Commission and the MS to promote the introduction of the European logo provided for by Implementing REG No 699/2014 in order to identify clearly online pharmacies which offer medicines for sales to the public remotely while safeguarding consumers against the purchase of fake medicines, which are often a health hazard.

Can the Commission say what progress has been made in addressing these important amendments?

Answer given by Mr Andriukaitis on behalf of the Commission

The Expert Group will continue exploring with relevant stakeholders the possibilities for repurposing, one of the options identified in the report to move from “off” to “on” label of medicinal products.

The Commission has no information on investigations by Member States on possible malpractice involved in the refurbishment and re-use of medical devices originally designed and labelled for single use. Nevertheless, Regulation 2017/745 [2] on Medical Devices sets up strict conditions under which

PARLIAMENTARY NEWS ...CONTINUED

reprocessing of single use devices can take place.

As of 1 July 2015, in line with Directive 2001/83/EC [3] and Implementing Regulation (EU) 699/2014 [4], any legally operating on-line retailer, authorised in a Member State of its establishment to sell medicinal products on the internet, should display the logo on every webpage offering medicinal products to sell. The Commission is gathering information on the progress of implementation of these requirements and on the national information campaigns on the logo and danger of falsified medicines.

ASOP EU, having held 5 meetings with Member States to share best practice on the progress being made on the implementation of the Common Logo, is in the process of reporting on this subject and, as such, is supporting both Member States and the Commission with this important part of the Directive that directly effects patient safety.

1. https://ec.europa.eu/health/sites/health/files/files/documents/2017_02_28_final_study_report_on_off-label_use_.pdf
2. Article 17 of Regulation (EU) 2017/745 relating to single-use devices and their reprocessing.
3. Article 85 c of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011(OJ of 01.07.2011 L174/74).
4. Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity, OJ of 25.06.2014 L184/5.

WHAT'S IN A WORD? FALSIFIED/COUNTERFEIT/FAKE - THE DEFINITIONS DEBATE



A new in depth analysis of the evolution of the descriptions applied to falsified, counterfeit and fake medicines has recently been published. It aims to help clarify and simplify this hitherto controversial area. With the rising tide of criminal activity to produce and sell fake medicines online, clear and easy to understand descriptors will help to make public awareness-raising campaigns more effective.

Abstract

There is a rising tide of criminal activity to manufacture and distribute falsified, counterfeit, or fake medicines. The exact size of this problem is unknown but estimates vary from US\$75 billion to US\$200 billion per year, and evidence clearly demonstrates it is on the increase. Depending on the world region, infiltration into the legitimate supply chain versus the illegitimate (e.g., the internet) varies greatly. However, what is certain is that the direction of travel by regulatory agents is to develop supply chains that allow access to medicines via the World Wide Web. Within this context, there has been a long-running debate about how to correctly describe the various forms of medicines that are fraudulently or otherwise manufactured and distributed. This article attempts to describe the evolution of the definitions and recommends that a consensus be formed to describe such medicines that reach the public:

- Falsified medicine: This being the term used and defined in the Falsified Medicines Directive and which is primarily concerned with public health.
- Counterfeit medicine: This is closely associated and legally defined within intellectual property legislation and concentrates on trademark protection.
- Fake medicine: This is the term that best serves to communicate with the public to raise awareness about the phenomenon.

Click here to read the full scientific article.

Your contacts at the ASOP EU and EAASM :

Cathalijne Van Doorne Chair cathalijne.van.doorne@telenet.be

Mike Isles, Executive Director mike.isles@eaasm.eu

Klaus Gritschneider Director klaus.gritschneder@europa-apotheek.com