European Alliance for Access to Safe Medicines

ASOP EU Alliance for Safe Online Pharmacy

January 2016

# Newsletter

## A diary of achievements 2015

**February**

The publication of a collaborative position paper supporting the implementation of the Common Logo

**March**

Meetings held in Brussels with DG Sante, DG Digital Single Market, Health Attaches and Member States to support the implementation of the Common Logo

**April**

ASOP EU presented at FakeCare/FakeShare Conference - Rome. Contributed to .Pharmacy Supporter Advisory Committee Members teleconference

**May**

Significant EAASM patient safety amendments accepted by the Parliament's "Patient safety - Own Initiative Report" on safer off label use and a call for promotion of Common Logo by Member States to raise public awareness

**June**

EAASM Parliament lunchtime debate One - "Managing healthcare costs - can patient safety be traded off?"

**July**

Parliament lunchtime debate Two - "Illegal sales of medicines over the internet – how will the implementation of the Falsified Medicines Directive's Common Logo enhance patient safety?". Publication of Technical Guidleines to support Member States IT security on the Common Logo

**August**

Contributed to .Pharmacy Supporter Advisory Committee Members' teleconference

**September**

Google sponsored adword campaign commenced in Italy using EAASM generated educational website. EAASM Board meeting where key 2015/16 objectives were reviewed. EAASM speaker at Pharmaceutical and Medical Device Packaging and Labelling 2015 - Berlin

**October**

EAASM and ASOP EU speaker at European Cancer Congress on Oncology - Vienna. EAASM attended Middle East and Northern African patient group meeting to support initiatives to increase quality of medicines. ASOP EU and Italian Medicines Agency coordinated a "best practice" Member States meeting on implementation of the Common Logo - AIFA Offices Rome. ASOP Global, ASOP EU and CSIP present at ICANN 54 Dublin. ASOP EU attended EU Observatory meeting in Alicante

**November**

ASOP Global "All hands" Strategy meeting Washington DC. EAASM/ASOP EU Speaker at Pharmaserialisation and Traceability conference 2015 Geneva. Interviewed by DG SANTE-commissioned pan EU study on off label usage.

**December**

ASOP EU "All Hands" Strategy meeting in Google offices Brussels. EAASM sends formal letter to Commissioner for Health Vytenis Andriukaitis entitled "Letter of formal notice" according to Art 265 TFEU.

# Chair of EAASM - 2015 reflections

### *Cathalijne Van Doorne*

I hope that you have had a peaceful Christmas and New Year. This time of year gives us all the chance to reflect on the year before and how to make the New Year an even better one. Within our area of interest then, of course, patient safety and how we can improve this, springs uppermost to mind. As you may be aware, I am active as the Vice President of the European Federation of Neurological Associations, an umbrella group representing pan European neurology patient groups. However, in my capacity as Chair of the EAASM, as well as an active member of ASOP EU, I have been very impressed with the degree of successful activities combined with an ever increasing collaboration with the stakeholders during 2015. The catalogue of achievements on page one summarises these. Of particular note was the progress made within the EU Parliament and the Commission. The EAASM was particularly influential in achieving important amendments to a Parliamentary patient safety report. This report has real teeth, and will help to keep the spotlight on Member States which will ultimately require them to continue to be even more pro-active to increase patient safety within their healthcare systems. That has to be a good thing, as whilst we know that the Parliament has not been granted the "competence" to be directly involved in MS health issues, it can cast a strong light over those issues that are causing patient harm and thus produce positive and influential change.

The granting by Google of an adword grant to enable powerful and impactful digital campaigns to reach out and educate "would be" buyers of medicines online, marks a significant step forward. It now gives us the means to potentially change behaviour on a large scale by informing patients and consumers on the inherent dangers of taking themselves out of their national health systems by circumventing their local doctor and reverting to the web. I believe that patient groups can also play an active role here and adding links to educational material from their websites can greatly supplement the Google adword campaigns and this will be a further aim of the EAASM 2016 objectives.

I look forward to continue to contribute to all that the EAASM and ASOP EU is involved in. Our collaboration with ASOP Global as well as CSIP and forging ever closer ties with all those involved should be a major part of what we strive for in 2016. I have every confidence we can achieve that with your continued support for which we are very grateful.

# Director of ASOP EU - 2015 reflections

### *Klaus Gritschneder*

I was delighted to accept the offer to become a Director of the not-for-profit patient safety community interest company - ASOP EU - during 2015. A lot has happened during last year and I knew that many aspects of the goals and ambitions for the ASOP EU group would need support and attention. In particular the implementation of the Common Logo by 28 Member States, I felt, was a very useful step forward from a patient safety point of view but it is an initiative which needs careful planning and implementation. That ASOP EU produced a supportive position paper in Q1 2015 followed up shortly after by meetings with the key European institutions gave me added confidence.

I was particularly encouraged when Domenico Di Giorgio, a senior official from the Italian Medicines Agency (AIFA), who has spearheaded the FakeShare and FakeCare initiatives, agreed to co-sign an ASOP EU letter of invitation to host a knowledge sharing webinar with Common Logo Member State implementers. This took place in the AIFA offices in Rome on October 15th 2015. This said to me that influential partnerships between the private and public sectors were becoming even more tangible and we should be proud that we had arrived at this point.

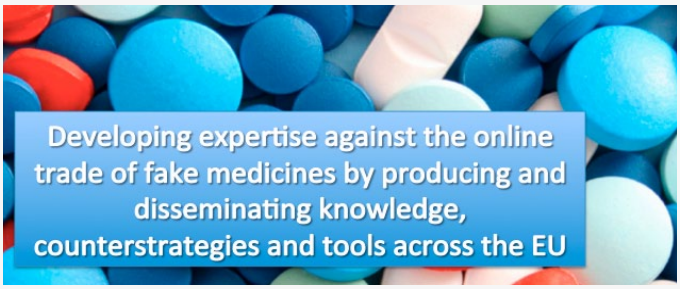
The productive ASOP EU "All hands" Strategy 2016 meeting on December 8th at the Google Offices in Brussels which mirrored the approach that was taken by ASOP Global, confirmed that we should continue to build on the strong dialogue with Member States as well as stakeholder Commissions of DG Sante and DG Digital Single market. It was agreed that we should continue to develop the awareness of key ENVI Commmittee MEPs who are taking a keen interest in this important area of health. This relationship can be demonstrated clearly by ASOP EU's facilitation of MEP Jose Faria Inacio's (Portugal/ALDE party) agreement to speak at the Access to Safe Medicines conference 19–20 January 2016 London. The MEP-hosted round table discussions held in the Parliament, undoubtedly added to the reputation of ASOP EU.

The plans to develop the dot pharmacy NABP initiative marks another important European development and ASOP EU's Members and Observers will be taking an active interest in this.

I look forward to supporting ASOP EU as well as I can in this New Year. Patient Safety on the internet should be uppermost in our minds in 2016 and together we will make a difference.

# Fakecare Project - a collaborative success

ASOP EU participated in the FAKECARE conference hosted by the Faculty of Law, University of Trento




17-18th December 2015. The conference brought together the team of "Project FAKECARE" comprising university researchers, supported by institutional actors and other relevant stakeholders, which had adopted a multidisciplinary and integrated approach (law, criminology, statistical and information science). The conference marked the culmination of this major project which has developed a more accurate picture of online trade of falsified medicinal products and has identified and created new tools for its investigation and prevention. For the full set of briefing notes and the materials please click here.


*Andrea Di Nicola, Scientific Co-ordinator of eCrime University of Trento, addressing the audience*

# EAASM 2016 Objectives

The strategy and objectives of the EAASM were discussed and developed at the EAASM Board meeting held at the end of September 2015; since then the objectives have been refined and are listed here.

1. Protect patients by awareness-raising activities via the EAASM educational website using Google adwords grant to attract visitors
2. Ensure FMD actions are kept to the fore with key stakeholders; Member States, EU Institutions (via Parliamentary EAASM debates), the public and patient groups
3. Monitor and follow up on advice and input given to "Off-Label Use of Medicines" pan European study commissioned by DG Sante
4. Contribute as a Permanent Advisory Supporter Member of the NABP .pharmacy initiative
5. Follow up on formal call to action letter to Commissioner of Health and Safety requesting concrete measures to address the health safety concerns arising from non-regulated off-label use
6. Continue to influence the Parliament in respect of the "Own initiative Patient Safety report"
7. Participate in conferences and forums to keep the EAASM profile high

# ASOP EU holds strategy meeting - 2016 objectives

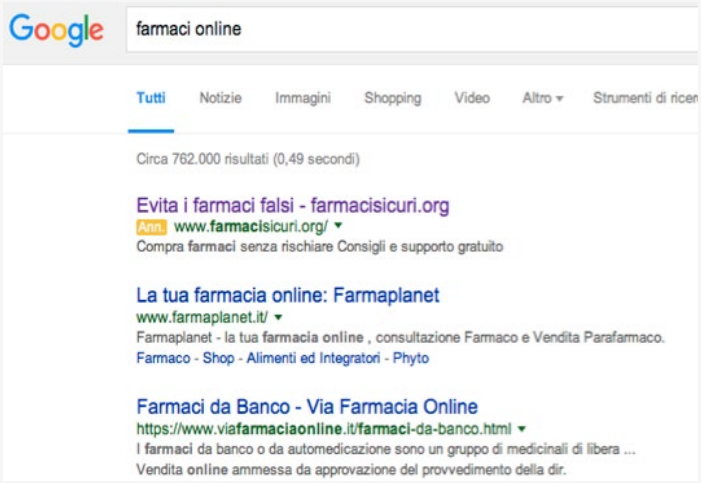
An ASOP EU "All hands" Strategy meeting took place at the Google offices - Dec 8th 2015. Key achievements in 2015 were highlighted and presentations were given by the Alpha Group, the MHRA on their plans for a digital campaign to raise awareness of the Common Logo and a review from VISA Europe of the ways that help to ensure illegal transactions are countered effectively. Click here for the website article and presentations.

**Key ASOP EU 2016 objectives** were also developed which are summarised here.

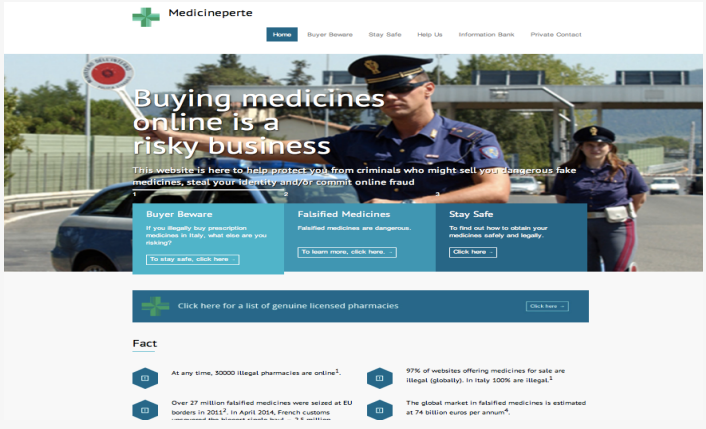
1. Work with EU Member States to implement the Common Logo
2. Expand voluntary actions by internet commerce companies
3. Expand Google adwords campaigns in to other Member States
4. Participate in conferences and forums
5. Conduct research in EU on awareness of the Common Logo
6. Develop plan to engage more with patient groups about falsified medicines
7. Continue to follow and push the implementation of the FMD
8. Assess the climate re healthcare professionals to become more engaged on the growing threat of falsified medicines

The announcement in the July Newsletter of the Google adword grant marked a high point of a successfull period of support from Google. The adwords campaign commenced on 30th August and up to 30th December, the number of times the ad has appeared on the first Google search page is a staggering 1.7million equating to an average of around 15,000 “impressions” per day. In terms of the number of visitors who click on the ad, this is an impressive 20,000 plus.

But do we know if readers are finding the website useful? So far over 30 people have completed the simple Monkey Survey that is accessible from each website page. All respondents say that it has been very useful. The survey gives us a unique window into what is being sought and the reasons why.




The ad can be seen here - the headline is in purple and the educational website is below.




A report on the statistics by Google analytics and an analysis of the visits to the educational website is planned for the end of February 2016.

ZENTRUM FÜR EUROPÄISCHE UND INTERNATIONALE STRAFRECHTSSTUDIEN

# New Member

ASOP EU welcomes new Members and none more so than ZEIS. Part of the Alpha Group coordinated out of the University of Osnabruck in Germany, it is currently conducting in depth research scoping the current legal framework relating to the recently liberalised distance sale of medicines across the 28 Member States. The results, with recommendations that may have far reaching consequences, will be announced and discussed via a pan European conference on 20-21 June 2016. If you would like to attend then please contact Uriel Moeller: uriel.moeller@uni-osnabrueck.de

# Off-Label use of medicines - EAASM sends formal letter to Commissioner

After due consideration and consultation, the EAASM sent on December 2nd 2015 a formal letter to the EU Commissioner for Health Vytenis Andriukaitis entitled “Letter of formal notice” according to Art 265 TFEU. This Article of the EU Treaties grants the right to a European citizen to call upon the Commission to investigate a potential situation that is causing harm to patients.

As far back as 2011 the EAASM published a report “When is a Medicine not a Medicine?” which highlighted many aspects of the dangers of off-label usage. One major area of medical concern was patients being severely harmed and in some cases blinded in the ophthalmological setting due to off label usage.

Recently this appears to have happened again and on 13 October 2015, the Italian press revealed that five people suffered serious eye infections following the use of a medicine off label during a procedure in the ophthalmology department of a hospital in Florence, Italy.

More specifically, these patients received a medicine called bevacizumab, for the purpose of treating wet-age-related macular degeneration ("AMD") despite the fact that this drug was not approved for AMD but for cancer. It is not clear yet whether the contamination occurred during the preparation stage, i.e. when bevacizumab was divided up in reduced doses suitable for the eye, or during the injections of bevacizumab to each patient. However, what is certain is that bevacizumab is used off-label for the reason that it is less expensive than the two licensed medicines available. It should be noted that the EAASM is not against off label usage per se. However, where lack of clear processes and reporting pertains and patients are being harmed unnecessarily, the EAASM will strive to prevent this.

That is why the EAASM coordinated a consensus statement calling for the following:

- Establish the number of adverse events (AEs) relating to unlicensed/off-label use of medicines
- Introduce a professional Code of Practice for mandatory reporting by healthcare professionals of AEs involving unlicensed/off-label medicines as currently there is no mechanism for recording or reporting AEs in this context
- Improve public awareness so that patients are aware of when unlicensed/off-label medicines are used and the importance of AE reporting, and that they give their consent for those medicines to be used.

The Commissioner is obliged by the Treaty to have investigated the content of the letter within two months. We look forward to a positive response.

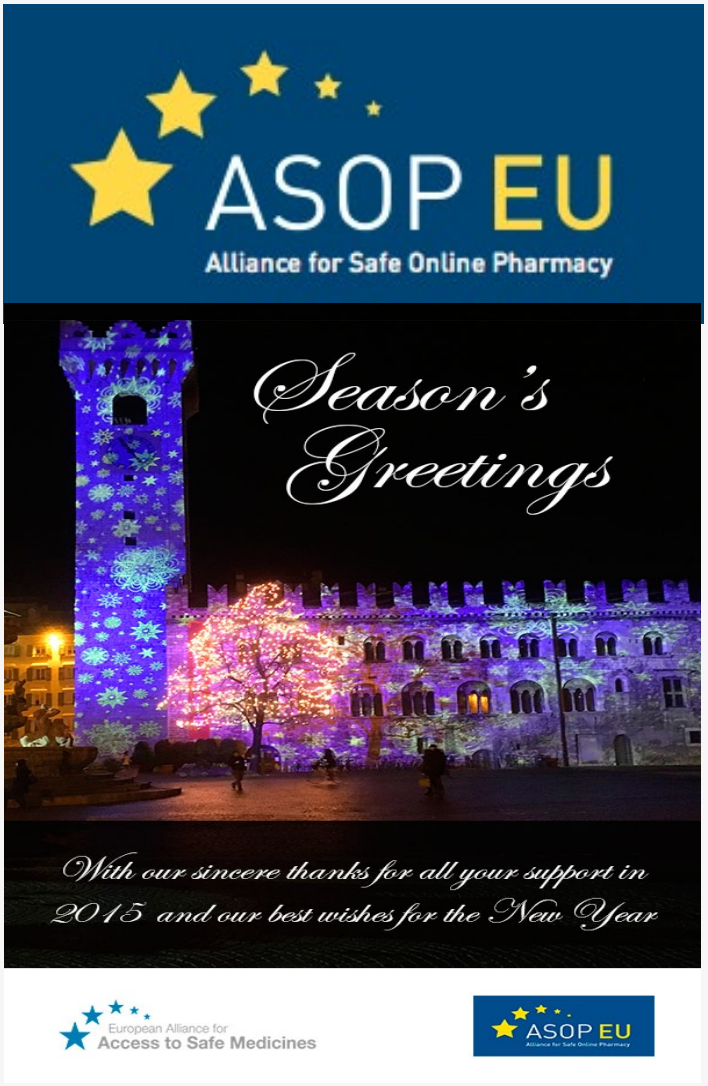
# Important study on off-label use of medicinal products in the European Union

In April 2015, the European Commission instructed a study, to review existing and foreseen off-label use practices across Member States and analyse all parties' positions

Given the importance of this topic, the EAASM pushed for as much stakeholder involvement as possible and wrote to the leading patient groups to take part in the process of being interviewed by the co-ordinating academic group which comprises: NIVEL (Netherlands institute for health services research), RIVM (National Institute for Public Health and the Environment) and EPHA (European Public Health Alliance).

The EAASM has been interviewed on this topic and its knowledgeable input given. We will keep you informed as to the progress of this study. Let us all sincerely hope that the requirements defined in the consensus statement are properly addressed.

# Season's greetings




*This photo of the Art Museum was taken at the recently held FakeCare Conference in northern Italy in the university town of Trento where ASOP and EAASM were represented.*

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