European Alliance for Access to Safe Medicines

ASOP EU Alliance for Safe Online Pharmacy

July 2015

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 supported by ASOP Global, CSIP and NABP. Mike Isles presented at SECURIKETT "Forum Unique Codes 2015 Conference" Vienna

April
Mike Isles presented at FakeCare/FakeShare conferences in Rome. Contributed to .Pharmacy Supporter Advisory Committee Members teleconference

May
Significant patient safety amendments accepted for the Parliament "Patient safety - Own Initiative Report" on safer off label use and promulgation of Common Logo by Member States. Market research proposal completed to ascertain future consumer understanding of the Common Logo

June
EU Parliament Debate One entitled - "Managing healthcare costs - can patient safety be traded off?"

July
EU Parliament Debate Two entitled - "Illegal sales of medicines over the internet – how will the implementation of the FMD's Common Logo enhance Patient safety?" Google, EAASM and ASOP EU announce collaborative search optimisation adwords campaign. Publication of Technical recommendations to support Member States IT security on the Common Logo

New educational website for Italy on falsified medicines

English translation of home page of Medicineperte

The EAASM with technical and translation support from the Italian Medicines Agency (AIFA) have developed an educational website called Medicineperte (Medicines For You) to be launched in the Autumn. It will attract visitors using Google sponsored adwords (see page 2). It contains useful information about the risks of buying medicines online, comprising three main headings to help navigation. The first, "Buyer Beware" informs about the law pertaining to buying medicines online in Italy. The second, "Falsified Medicines" explains what a fake medicine is and the third, "Stay Safe" tells the visitor of the pharmacy checker tool that AIFA operates. The visitor can complete an online survey to reveal useful buyer motivation behaviour. If the Italian campaign bears fruit then the vision is to run the campaign in other Member States. The EAASM would like to thank Bayer, Lilly and Pfizer for their sponsored support of this project.

ASOP EU welcomes two new members and thanks them for their support

aegate The Medicine Digital Network

IRACM International Institute of Research Against Counterfeit Medicines

Successful collaboration to raise patient awareness

Google, EAASM and ASOP EU are working closely to produce an adwords campaign to raise public awareness about falisfied medicines, with the aim to display sponsored ads with educational material about buying medicines online safely. In the first instance this approach will be used to attract vistors to the Medicineperte educational website.

Clearly this type of educational programme will be most helpful in raising public awareness. A similar campaign currently operates in the US and to date, there have been tens of millions of impressions (when the advertisement appears on the first search page) - 1.9milliion in March 2015 alone with 23,460 converted clicks on to the advertisement resulting in a desired action - in this case routing through to **LegitScript's pharmacy verification tool.**

Recommendations for Member States to support their initiatives to secure the Common Logo for legally-operating pharmacies/retailers offering medicinal products for human use for sale at a distance

ASOP EU supports Common Logo with recommendations on IT security and plans market research project

Following the ASOP organised meetings with Member States in the PGEU offices, Brussels in early March 2015, an ASOP EU taskforce created a recommendations document to help support the IT security of the Common Logo.

The delegated acts clearly state the specifications of the elements of the individual country Common Logos. However, no technical specifications are given to indicate what might constitute a secure technical way of making the Common Logo as secure as possible.

The recommendations set out the key technical elements to ensure that, as far as practically possible, text, visuals, logos or symbols can be made to be as "secure" as possible.

The caveat here is that criminals will be potentially capable of setting up "ghost" lookalike websites. And so a combination of IT solutions combined with patient/consumer awareness will be a neessary part of a protection plan.

Market research proposal

ASOP EU is planning to carry out research to understand the consumer behaviour connected with online purchases of prescription and non-prescription medicines in the EU and understand the extent to which Member States are being successful in raising awareness amongst the general public of the dangers of falsified medicines and how well the Common Logo is known and understood.

ASOP EU is currently reaching out to its members for funding which could potentially cover research in 10 Member States. The information can be used to inform the EU Commission, EU Council and EU Parliamentarians, Member States and interested parties. It will act as a lever to encourage further actions to raise public awareness which in turn will enhance patient safety and encourage the buying of medicines through genuine and legitimate channels.

ASOP EU supports FakeCare launch of new communication tools

ASOP EU attended the FakeCare/FakeShare conferences held in Rome April 2015 which focused on promoting a targeted set of communication tools to "at risk" customers purchasing medicinal products via the internet.

ASOP EU presented a paper entitled "Awareness of the risks in order to protect public health". The presentation given by Mike Isles can be viewed here as well as the new FakeCare communication booklet called "Trick or Treat (ment)" guidelines for safe online purchased for medicinal products in the EU.

EAASM and ASOP EU host a series of Parliament debates

Parliament debate - "Managing healthcare costs: can patient safety be traded-off?"

"Patients are dying unnecessarily" this was one of the key findings of this debate, hosted by MEPs José Inácio Faria (Portugal/ALDE) and Cristian-Silviu Busoi (EPP/ Romania) and sponsored by the European Alliance for Access to Safe Medicines.

Dr Torben Mogensen, Danish Safety Council stated: *"Many patients are still dying unnecessarily within healthcare systems . Only by applying systems that capture medical records electronically and a radical shift of culture to create a blame-free highly collaborative team environment with the patient as a key actor, could lives be saved and adverse events reduced more significantly.The staggering statistic that 1 in 10 patients who enter a hospital receive some form of harm still exists across Europe."*

This situation was echoed by MEP Cristian Busoi *"Patient safety is a serious growing global public health threat, due to unsafe medical practices and healthcare that cause infections, injuries and death..."*

Closing remarks by MEP Christian-Silviu Busoi (EPP/ Romania)

According to MEP Faria financial tensions inside health systems are placing barriers to innovative medical technologies. He cited the new Transparency Directive on pricing and reimbursement to allow faster patient access to new medicines had been withdrawn due to strong opposition by the European Council.

Co-host MEP José Inácio Faria (Portugal/ALDE) on the European Parliament's priority on patient safety

Dr Aurélien Perez, European Commission's DG SANTE, explained the ongoing good work on a framework for a sustainable EU collaboration on patient safety and quality of care. This had been requested by Council Conclusions on Patient Safety and Quality of care of 1st December 2014 and by the Pedicini led report. The reports insisted on the need to better coordinate patient-related policies.

The debate covered the practice of medicines being used off–label or for conditions for which the medicine has not actually been licensed. Mike Isles, Executive Director of EAASM stated, *"There are many important situations where medicines have to be used off–label, in children's conditions for instance, however in many instances proper procedures are not in place and so patients are being harmed."*

The EAASM has called for mandatory adverse event reporting when a medicine is prescribed off label combined with the establishment of the number of adverse events. Patients should be fully informed when a medicine is being used off-label and should give their written consent.

The debate also discussed refurbishment and re-use of single use medical devices. Dr Mogensen said *"It is totally unacceptable that a medical device designed for a single use in a human being is being refurbished and used again with sometimes disastrous consequences, it is a false economy as medical compensation claims counteract this, notwithstanding the harm and suffering of the patient."*

Kaisa Immonen-Charalambous, European Patients Forum showed how patients are becoming more active and vocal, giving rise to more "Patient-centred" approaches to healthcare. She stated that *"...patients are moving from passive recipients to active partners and self-management with shared decision-making in an integrated care setting is the way forward, but this requires a fundamental change in culture towards openness, transparency and support for patients at all levels of the healthcare system."*

Patient safety and quality of care – presentation by Kaisa Immonen-Charalambous, European Patients Forum

Parliament Debate No 2 "Illegal sales of medicines over the internet - how will the implementation of the Falsified Medicines Directive's Common Logo enhance patient safety?"

From 1st July online suppliers of medicines in the EU must be registered in the country they are operating and need to display on every page of their website offering medicines for sale, the new **European Common Logo.**

These requirements stem from the Falsified Medicines Directive, introduced to help protect patients from falsified medicines in both the legitimate and unauthorised supply chains. The patient/consumer can click on the Logo to check if the supplier is genuine. This should enable patients to buy their medicines from an authorised source.

To mark this occasion a debate took place in the EU Parliament to raise awareness of the issue of patient safety and buying medicine online.

MEP José Inácio Faria who hosted the meeting put the issue into context with some startling facts. No less than 30,000 websites that look like legal sellers of medicines are targeting the EU population at any one time. Reports also show that 97% of online drug sellers worldwide are operating illegally, by failing to comply with applicable laws and standards put in place to protect patients.

Mike Isles highlighted two critical success factors: securing the Common Logo symbol from cybercrime copying and thus misleading the public into a false sense of security and the need to educate the public. He said *"Very unfortunately the Commission's Directive which obliges Member States to deliver awareness campaigns to the public about the dangers of fake medicines and the purpose of the Common Logo comes with no budget. So at best the success of this aspect will be variable across the 28 Member States which is of real concern."*

Debate at the European Parliament

A number of Member States were present who elaborated on the stages of the logo implementation. In particular, the UK's Lynda Scammell from MHRA Enforcement Group, Philippe De Buck, Belgian Medicines Agency and Domenico Di Giorgio, Italian Medicines Agency, gave their updates on the implementation. However at that time not all Member States had yet signed up to this element of the Falsified Medicines Directive and MEP Faria said that *"It is not good when there is a time lapse between the most conscientious of Member States who adopt new directives efficiently compared to those that lag behind as patient safety is at stake here."*

MEP Faria on the dangers of buying fake medicines online

To the important question of the Common Logo IT security, Erwin van Uffel from the Belgian Customs Office confirmed that each Member State should follow basic IT security rules *"…for instance having a secure server which has good protection from potential hackers combined with an encrypted link to and from the websites are just two of the essentials but there are more and it would make absolute sense for Member States to share best practice and IT creativity to help beat the criminals who make it their life to invade other people's cyberspace."*

Mike Isles pointed out that ASOP EU had sent to

Member States a useful document entitled *"Technical Recommendations for Member States to support their initiatives to secure the Common Logo for legally-operating pharmacies/retailers offering medicinal products for human use for sale at a distance"*

Mike's concluding remarks were important as he quoted from a sworn written statement given by the President of LegitScript, John Horton to the Subcommittee on Courts, Intellectual Property and the Internet – a powerful US Government backed committee.

Mike Isles, Executive Director of ASOP EU on the Common Logo

his company monitors online sales of drugs and maintains the world's largest database of internet pharmacies. It supports companies such as Google and Microsoft to ensure their services are not abused by criminals. Horton said: *"...the Internet Corporation for Assigned Names and Numbers (ICANN) – a company that oversees many aspects of the world wide web - needs to make its compliance processes more transparent to prevent obvious failures such as…giving a green light to certain registrars to provide domain names to criminal networks engaged in illegal online pharmacy crime."* Until this happens he said *"ICANN will continue to lack the kind of accountability and trust that internet users as a whole deserve."*

Lynda Scammell and Philippe De Buck giving their updates on the implementation of the Common Logo

ASOP EU, ASOP Global and CSIP organise a series of meetings in Brussels in support of the Common Logo

To mark the launch of this support and the publication of the ASOP EU position paper on the Common Logo, ASOP Global, ASOP EU, CSIP and NABP held a series of meetings with DG SANTE, DG Digital Single Market, Health Attachés and with Member State officials who are responsible for the implementation of the Common Logo.

The first meeting took place on March 2nd 2015 with Member of DG Santé Cabinet Annika Nowak.

Ms Nowak, who was heavily involved in the Cross-border Healthcare Directive and thus familiar with the challenges that face Member States in the implementation of new laws and regulations, commented: "We naturally want the implementation of the Common Logo initiative to be as effective and successful as possible because significant patient safety gains are at stake here. Clearly the good collaborative work with all partners can make a real difference. Especially so in raising public awareness and in cooperation with stakeholders can play a major part which we welcome wholeheartedly."

Meeting with DG Santé from L to R: Annika Nowak – Member of Cabinet, Marco Pancini - Google, Libby Baney - ASOP Global, Melissa Madigan - NABP, Mike Isles - ASOP EU

In PGEU offices a meeting took place on the challenges of introducing the Common Logo which was attended by 7 Member States (Belgium, Italy, Ireland, Netherlands, Portugal, Spain and the UK), DG Santé and EDQM. The agenda covered the potential support that ASOP and its sister organisations can offer, such as internet search advertisement grants to enable the European public to more easily reach information about the Common Logo as well as the possibility of further best practice sharing Member State meetings.

ASOP EU Common Logo meeting at the PGEU offices

European Parliament

EAASM campaigns successfully on European Parliament patient safety own initiative report – ensuring key patient safety concerns are incorporated

The European Parliament (EP) own-initiative report on "Safer Healthcare in Europe: Improving Patient Safety and Fighting Antimicrobial Resistance" which was approved in the EU Parliament Plenary on 19 May 2015 incorporated a number of significant amendments in line with EAASM/ ASOP EU recommendations.

These were reflected in the following Articles through which the European Parliament:

15. Urges the Member States to implement or develop the following measures:

j. Ensures 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;

16. 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;

18. 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;

22. Calls on the Commission and the Member States to promote the introduction of the European logo provided for by Implementing Regulation (EU) 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;

The wording adopted by the European Parliament following these recommendations will allow the EAASM and ASOP EU to exercise political pressure on the EU institutions and Member States to achieve the following:

- Ensure the Common Logo in each Member State is secure from cybercrime;
- Push for each Member State to report on how it intends to raise public awareness of the Common Logo;
- Influence any investigation on the possible malpractice involved in the refurbishment and re-use of medical devices originally designed and labelled for single use;
- Influence the development of guidelines on off-label use of medicines enshrining medical need as the overriding principle;
- Be pro-active in the Off-Label Use study commissioned by the European Commission to highlight concerns with the promotion of off-label medicines even when licensed alternatives are available;
- Call on medical professionals to inform patients when a medicine is used off-label;
- Provide patients with information on the potential risks of off-label medicines in order to enable them to give informed consent;
- Inform patients about the risks and preventive measures relating to adverse events in healthcare, and about the complaint procedures and legal options available should an adverse event occur via e.g. a patient rights representatives.

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