European Alliance for
Access to Safe Medicines

November 2013

Newsletter

CtC wins again!

Hot on the heels of its impressive win at the PM Society Annual Awards where, against stiff competition, it won the award for “Best Digital Patient Communications”, EAASM Chair, Jim Thomson, travelled to Berlin to present the results of the landmark project “Counterfeiting the Counterfeiter”.

The event was the International Symposium on Prostate, Androgens and Men’s Sexual Health, and it was very significant that a patient awareness campaign be selected to stand alongside the scientific projects. Each presenter was given two minutes to explain the project. Given that Jim’s regular CtC presentation takes upwards of 30 minutes, this was quite a challenge!

Unbeknown to EAASM, the presentations were subject to awards and, when the results were published, CtC won again! Great news, not just for the whole team that worked so hard on this campaign, but for the EAASM’s chances of developing similar projects in other countries. It is essential that patients understand the risks associated with illicit online pharmacies, and are equipped to make the right choices. Projects like CtC are the “Gold Standard” in terms of information provision.

EAASM campaigns recognised

Since its formation in 2007, the EAASM has been at the forefront of campaigning for access to safe medicines. Its innovative projects were formally recognised when, together with sister organisation ASOP EU, it was invited to become a representative association in the EU Observatory on Infringements of Intellectual Property Rights. EAASM reports are now included in the Observatory resource bank and the relationship was furthered when EAASM Executive Director, Mike Isles, was invited to a conference by EUROPOL and EU Observatory supported by the Pharmaceutical Security Institute entitled “Combating Pharmacrime” A Knowledge Building Conference on Counterfeit Medicines held at the Observatory HQ in Alicante. The audience comprised law enforcement and customs officers, health authority/regulatory, pharmaceutical, EUROPOL and Observatory personnel and, crucially, through Mike’s involvement, European patients.

EUROPOL
EU OBSERVATORY
EUROPEAN OBSERVATORY ON INFRINGEMENTS OF INTELLECTUAL PROPERTY RIGHTS
Pharmaceutical Security Institute

Mike Isles with the senior EUROPOL officer who co-chaired the Pharmacrime conference

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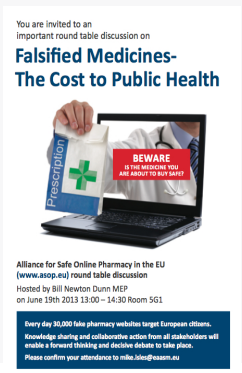
ASOP EU and EAASM spotlight on crime

In a joint publication, “Falsified Medicines - Costing the Earth”, ASOP EU and EAASM have collated the available data on the cost to the EU of the falsified medicine phenomenon. The report was requested by Bill Newton Dunn MEP who sits on the special committee on organised crime, corruption and money laundering.

This important Parliamentary group produced a draft report and the EAASM submitted a number of constructive comments as proposed amendments, to enable the components of the Falsified Medicines Directive to be mentioned, along with the need to ensure that the internet and the rising tide of fake pharmacy websites are tackled.

The report precipitated a request to hold a round table discussion in the EU Parliament entitled “Falsified Medicines - the Cost to Public Health”. The event was well attended and served the purpose to highlight this important topic. A press release was produced and the event was well publicised by posters in the Parliament and email invitations to all MEP’s offices.



Dr Ian Banks, President of the European Men’s Health Forum, EAASM Board and ASOP EU Steering Group member, addresses the Round Table, flanked on his rigtht by Jim and Bill Newton Dunn MEP. and on his left by Dr. Caroline Atlani (Sanofi), Lena Bera (Lilly), Giovanni Seppia (EURid) representing ASOP EU and Chris Vansteenkiste (EUROPOL).
Left, the event’s invitation poster.

Campaigning for Patients

Jim and Mike have attended a number of conferences where they highlight the campaigns for greater patient safety. Both presented at the 2nd Annual Pharma anti-Counterfeiting Congregation in London.

Mike presented at the Life Sciences College series of conferences. These are organised by the international law firm Sidley Austin LLP in close cooperation with EUCOPE (the European Confederation of Pharmaceutical Entrepreneurs).

In addition Mike presented at the SMI conference in London on Parallel Trade, the Clinical Trial Logistics conference and the VISA Europe Assessment Risk Forum.

Mike also had the opportunity to attend the RIPE conference in Dublin. This organisation is one of five regional internet registries providing internet resource allocations, registration services and coordiantion activities that support the operation of the internet globally and is part of the stakeholder group who can play a part in raising public awareness of illicit pharmacy websites.

Michele Neylon (above with Mike), who sits on the ASOP EU Steering Group, presented the problem of fake internet pharmacies and highlighted the need for greater collaboration between all parties.

Jim presented at major conferences in Brussels, London, twice in Berlin, twice in Vienna, in Lisbon and in Basel. In potentially one of the most important developments in internet safety to date, he also represented EAASM in Chicago at the national Association of Boards of Pharmacy. The purpose of this meeting is explained overleaf.

NABP applies for .pharmacy domains

The organisation which controls the internet (ICANN) recently invited applications for a raft of new domain suffixes (the part of a website's address that follows the dot).
The US-based National Association of Boards

NABP
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

of Pharmacy (NABP) quickly seized on the opportunity to apply for the right to allocate .pharmacy domains. The application was well received and is progressing well, having now passed ICANN's initial assessment stage.

In time, this will mean that only verified, legitimate online pharmacies will be able to have a .pharmacy domain name. NABP has formed a Global Advisory Committee to develop the standards that will be applied to applications and Jim represents the EAASM on this important committee, which recently held its first meeting in Chicago. Libby Baney represents ASOP on the same committee.

FMD action

As the Implementing Acts' phases of the Falsified Medicines Directive continue, the EAASM has actively campaigned to ensure that the spirit of the Directive is preserved.

Jim and Mike have been in regular communication with DG SANCO, particularly with regard to the need to ensure that the secure logo for internet pharmacies is in fact secure, and that an adequate level of protection and identification for individual packs of medicine is achieved. By adequate, we mean that the level of protection should be proportionate to risk and should include all prescription medicines including generics. This appears particularly timely given recent discoveries of falsified generics.

The EAASM and ASOP EU will also be striving hard to establish a Memorandum of Understanding amongst stakeholders to combat illicit pharmacy sales, support the introduction of the common logo, to raise public awareness and support DG SANCO.

Pharmacy Facade update

EAASM's plans to undertake evolution projects based on the success of Counterfeiting the Counterfeiter, are continuing to take shape. We have now secured concrete funding and support. We also have input from the regulatory authorities in two countries and are in discussions with a third.

Given the nature of these projects (specifically the tactic of attracting patients to seemingly genuine but illegitimate websites) it is not possible to give specific details of the location and timing of the campaigns.

Unlicensed Medicines

Following the research detailed in the last newsletter, Jim and Mike produced a draft Interim report which highlighted key shortcomings in the administration and monitoring of unlicensed and off-label medicine usage in the UK NHS. Perhaps most worryingly, there appears to be no formal reporting procedure when adverse events occur.

As a result of the findings, plans are being developed to undertake similar research in other EU Member States. The importance of this strand of the EAASM's work was starkly underlined earlier this year, as Denmark reported 106 suspected adverse events since 2007, with 41 of the cases reported having been described as serious. In five cases babies died and, in seven cases, the woman's womb ruptured after she received a drug developed and approved to treat gastric ulcers, but used to induce labour. Hospital pharmacists have taken the gastric ulcer drug and prepared it in smaller doses for use in childbirth, it would appear with tragic results. There have also been incidents in France and Ireland, and the EAASM is currently reaching out to patient groups in these countries to join its campaign for improved standards.

In the last newsletter we reported on Phase one of a survey the EAASM commissioned and which was carried out by the internationally renowned research agency Insight Research.

Phase two is now complete and an interim draft report is being finalised entitled:

"Understanding safety practices and risk management in unlicensed and off-label medicines, as well as refurbished medical devices"

It led the EAASM to believe that nothing was found to reassure that the robust systems are in place to control, and effectively monitor; the use of medicines outside of their approved indication, the substitution of unlicensed for licensed ones, and the re-use of single use medical devices. In particular it raised concerns that there are inconsistent levels of informed consent obtained from patients prior to off-label use. These findings were used as the basis for commenting authoritatively on the draft report by the Commission on the implementation of the Council Recommendation (2009/C151/01) which reviewed the progress being made by Member States on patient safety, including the prevention and control of healthcare associated infections (2013/2022(INI)). The recommendations were given in writing to Dr. Renate Sommer, a key MEP.

Four concrete additions were recommended:

1. Actively involve patients in patient safety and education on understanding complaint procedures, and core competencies for patients, and encourage patients and their families to report adverse events.
2. Patients should be told appropriately and consistently when they are being given an unlicensed medicine and that a culture of openness and transparency should be developed and encouraged.
3. The EAASM would recommend the collection of information on adverse events through further developing reporting and learning systems
4. The EAASM believes that feedback on future progress of the Council recommendation (2009/C151/01) be carried out by independent research organisations to ensure the integrity its findings.

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The EAASM also put the following to Mr. Noel Wathion, Head of Unit, Patient Health Protection, European Medicines Agency (EMA) :

"Is EMA considering any guidelines to ensure that the following two important patient safety aspects are covered?"

1. When a medicine is prescribed to a patient which is outside its licensed indication that within all Member States patients consent is sought and required and
2. that there is an absolute obligation that any adverse event is duly reported as if the medicine was being prescribed within its indications.

As the vote drew nearer, it became apparent that further campaigning would be needed to ensure that the recommendations remained robust. EAASM wrote to the Committee asking, in particular, that Members support the following:

1. Amendment 38, submitted by Renate Sommer, and amendment 48, submitted by Oreste Rossi, providing further clarification on the usages of medicines with high risk of adverse events, including off-label use;
2. Amendment 54, submitted by Renate Sommer, drawing attention to the recent increase in off-label prescriptions as a cost-cutting measure;
3. Amendment 132, submitted by Renate Sommer, requiring health professionals and patients to be informed when drugs are used off-label;
4. Amendment 182, submitted by Oreste Rossi, calling for precautions to ensure the quality and safety of medicines during storage and use, and reaffirming the importance of informing patients of the risks of off-label use;
5. Amendment 233, submitted by Renate Sommer, calling for the EMA to produce guidance on safe and appropriate off-label use.

After a tense wait, we heard that the Recommendations had been adopted without being diluted, which is great news for all concerned with patient safety.

Jim and Mike