

December 2012



# Newsletter



Mike Isles & Jim Thomson, EAASM Secretariat, at the 7th Global Forum on Pharmaceutical anti-Counterfeiting and Diversion in Washington D.C. where Jim Thomson presented the results of the landmark project "Counterfeiting the Counterfeiter".

## Seasonal Greetings!

2012 has been another notable year for the EAASM, with several landmark projects brought to fruition.

The powerful "Counterfeiting the Counterfeiter" (CtC) fake pharmacy website, set the tone for an outstanding year. 182,602 unique visits and over 12,000 patients/consumers were motivated to click on the DIMDI link to legitimate pharmacies in Germany. The media coverage was also remarkable and encompassed online, radio and press outlets.

In 2013 we will take the learnings from CtC and develop a legacy project in the UK and other European countries. Its name, "Pharmacy Facade" (PF), sums it up aptly. The aims of the new project will be similar - raising awareness, providing access to safe sources - but will have additional features enabling us to receive feedback from visitors, provide them with patient group details and, most notably, the site will be optimised for mobile devices (in the UK, 40% of web commerce is now transacted on iPads, tablets and smartphones).

## The Year of the Internet

In 2012, the EAASM made a conscious decision to concentrate its anti-counterfeiting efforts on the internet. The EAASM report CtC, combined with "Discounted or Dangerous?", demonstrated clearly the patient safety dangers associated with illicit online pharmacy. It was a deliberate tactic, designed to underline the need for the internet to be effectively considered within the implementation process of the Falsified Medicines Directive.

These marquee projects also provided the springboard for the EAASM to become the Secretariat for a new initiative, the Alliance for Safe Online Pharmacy in the EU (ASOP EU) ([www.asop.eu](http://www.asop.eu)). Its vision is an internet, safer for patients to buy medicines, where it is legal. It mirrors the organisations and excellent work that is being carried out in the US where an equivalent ASOP already exists ([www.safeonlineRx.com](http://www.safeonlineRx.com)) along with The Centre for Safe Online Pharmacies ([www.safemedsonline.org](http://www.safemedsonline.org))

## Patient Safety

The EAASM has continued to fight for a safer patient environment where medicines are being prescribed for off-label or unlicensed usage. This follows on from the EAASM report "When is a Medicine Not a Medicine?" (WIAMNAM). This highlighted the issue and led to the formation of a Consensus Group to champion this issue. The focus is now on a comprehensive qualitative and quantitative survey to better understand the processes and governance employed when procuring medicines, biocides and single use devices. If necessary, we will produce best practice guides based on the research findings. Please do read the article on this evolving topic in this newsletter.

# Falsified Medicines Directive

2013 will be the year that the fight against organised criminal networks involved in falsified medicine trafficking, steps up, yet another gear.



The European Commission has already started the consultation processes associated with the Delegated Acts and the EAASM will be campaigning to ensure that all elements of the legislation are fully focussed on its primary aim of increasing patient safety.

For example, we will be making the case that serialisation at pack level is insufficient unless effective tamper-evidence is also in place. We will be pushing for all prescription medicines to be included and, critically, that effective authentication of APIs is introduced. Together with ASOP EU, we will also input into the thinking around secure white lists of online pharmacies, and the common trust mark associated with them.



Counterfeit API - readily available online

# Campaigning for Patients

Following on from the very positive campaigns by patient groups and the EAASM, the General Medical Council (GMC) did in fact back down from proposals that would have seriously compromised the ability of patients to be fully involved in decisions concerning their treatment.

This will mean that doctors who wish to prescribe off-label or unlicensed medicines will continue to require consent by the patient. The EAASM still believes there is a lot of work to do here to raise standards, as we suspect that controls over this type of prescribing are insufficient (and insufficiently enforced) to protect patients from risk.

Hence it has embarked on a large scale survey, initially amongst hospitals in the UK. Insight Research, an internationally renowned market research agency, is conducting the research and the first phase was completed in November 2012. The report of the initial phase highlights the major findings amongst a small group of hospital procurement pharmacists and one procurement buyer. Phase two will commence in January 2013, with an interim report to follow.

One question still unanswered is the degree to which single use devices are being recycled and re-used. The EAASM recently held talks with EUCOMED and is planning follow-up to reveal the true scale and nature of this activity.



Linear cutter, cracked, holding blood & skin tissue

Phase three will be a quantitative survey of 300 key stakeholders in the process that involves the use of off-label/unlicensed medicines, biocides and medical devices. The objective is to gain an across-the-board understanding of people's awareness of the quality of the control processes and whether or not best practice may need to be spread more widely. If this is the case then the EAASM will address this need.

# Transatlantic Action!



ASOP EU Summit workshops at Google, Brussels

**The formation** of The Alliance for Safe Online Pharmacy represents a milestone in the journey to make the internet a safer place for patients. This year's activities culminated in a major event entitled - The Transatlantic Strategic Summit on Internet Pharmacy - *practical solutions to make the internet a safer place for patients.*

This summit brought together an unprecedented number of key stakeholders in the fight to improve patient safety online. The event was held at the Brussels offices of ASOP EU partner, Google, on 4-5 December 2012. Together with its US-based sister organisations, ASOP US and CSIP (the Center for Safe Internet Pharmacies), ASOP EU worked collaboratively to develop long-term plans that will be of real and lasting benefit to patients.

Day one of the Summit was opened by EAASM Chair (and part of the ASOP EU Steering Group) Jim Thomson. Jim congratulated the attendees for their vision in committing themselves to the Summit, and asked that the spirit of mutual trust and collaboration be used to produce great work going forward.

This was followed by an overview of the background on policy and laws within the EU. This presentation was given by ASOP EU Steering Group members, Camilla Kent Hansen (EFPIA) and Martin Fitzgerald (GIRP).

## Your contacts at the EAASM:

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The participants then learned of the good progress that is being made by the US-based ASOP EU sister organisations, ASOP US and CSIP. Victoria Espinel, the United States Intellectual Property Enforcement Co-ordinator for the White House, then gave the keynote speech. She congratulated the attendees for their vision in coming together to seek improvements, and reiterated that voluntary and collaborative action had proved to be the best option in the US. Ms Espinel stayed beyond her allotted time and answered several questions from the floor.



The ASOP US and ASOP EU Team in Washington D.C. Jim and Mike (ASOP EU) with Libby Baney and Jeannie Salo, (ASOP US)

## AstraZeneca joins the EAASM

You will recall that, last issue, we welcomed three new members, EPDA, ESHA and Sanofi.

We are now delighted to welcome AZ to the growing EAASM membership. AZ is focused on helping with all matters relating to patient safety and the EAASM looks forward to working with this important stakeholder in 2013 and beyond.

If you are receiving this newsletter but are not yet a member of the EAASM, then why not join? Membership details are available by contacting Mike Isles ([mike.isles@eaasm.eu](mailto:mike.isles@eaasm.eu)).

It only remains for us to thank you, so much, for your support and encouragement throughout 2012. Here's to a great New Year and, finally, to the implementation of legislation designed to protect us all from falsified medicines.

**Jim & Mike**

[www.eaasm.eu](http://www.eaasm.eu)