

September 2016

NEWSLETTER

A DIARY OF ACHIEVEMENTS 2016

JANUARY

Access to Safe Medicines Conference, London. Presentations from NABP on .pharmacy initiative, ALPhA group on “Addressing Legislation Across the EU to Fill the Gaps”, ASOP “**Fighting the Fakes by Raising Public Awareness**”. ASOP EU held meetings with Institute for Research Against Counterfeit Medicines (IRACM) with Gendarmerie National HQ – Environment and Pharmaceutical Crime Department and Customs National Intelligence and Investigations Directorate. Standing Committee of European Doctors (CPME) to engage with medical community. Also met with DG Growth to discuss “Notorious Markets” concept.

FEBRUARY

ASOP EU meetings with Research Fellow, National Security and Resilience (RUSI). EAASM received comprehensive response from DG Santé Commissioner for Health in response to EAASM invoking Article 265 TFEU (Treaty on the Functioning of the European Union). ASOP EU attended Fakeshare Advisory Board meeting, AIFA offices Rome.



MARCH

Clinigen joined ASOP EU and EAASM. ASOP EU attended EU Observatory meeting in Alicante. Collaboration started with European Healthcare Fraud and Corruption Network (EHFCN). Attended international expert group on Off Label Usage Amsterdam (DG Santé commissioned study.)

APRIL

Meeting with MHRA to discuss Facebook public awareness campaign

MAY

Attended 10th European Patients' Rights Day - Reducing Waste and Inefficiency in the Healthcare Systems. Extension to Google AdWord educational grant applied for.

JUNE

ASOP EU invited as speaker and panelist at the Joint 22nd Medicines for Europe and 19th IGBA Annual Conference - Dubrovnik.

Meeting Spanish medical agency - AEMPS Madrid (ASOP,

ASOP Global, ASOP EU, NABP). ASOP EU - Roundtable on “EU Strategy and Messaging on Falsified Medicines and Internet Sales” with Member States and NFP patient safety stakeholder organisations - Brussels. Speaker at “Present and Future of Countering Pharmaceutical Crime” ALPhA consortium, Osnabruck. Meeting with Dutch medical agency on new digital public awareness-raising campaign on the Common Logo.

JULY

Official release of “Fighting Fakes by Raising Public Awareness” report.

AUGUST / SEPTEMBER

Preparation for ASOP EU Roundtable on “Best Practice Sharing” amongst experts in communicating to the public about falsified medicines and the Common Logo, 14 Sept 2016 Microsoft Offices, Brussels.

Participated in ASOP Global's All-Hands meeting in Washington, DC on 14 Sept 2016. More than 20 organisations were represented including partners from around the world.

NEW MEMBERS

CLINIGEN

We were delighted to announce that Clinigen has become Members of both ASOP EU and EAASM.

Steve Glass, Group Managing Director, Clinigen commented on this new development.

“As the global market leaders in providing trusted access to unlicensed medicines to meet unmet medical need, we share many common goals with the EAASM and ASOP. Healthcare professionals and patients worldwide face major challenges in guaranteeing safe access to the medicines they need.

Clinigen is committed to raising the standards of access to and supply of drugs in both clinical trial and unlicensed medicines, becoming the trusted source of genuine product. Our Global Access division is dedicated to providing an ethical, alternative solution, and we are proud to be able to support the EAASM and ASOP in their valuable work to protect and educate patients across Europe about the dangers of falsified medicines.”



NEW MEMBERS

BIOGEN

We are also delighted to announce Biogen as new members.

Emanuele Degortes, Associate Director, Public Policy & European Government Affairs summarises below this new beneficial development for patient safety.

“We have been liaising with the EAASM for some time and watching with great interest the patient safety initiatives around the activities on falsified medicines and how important it is for organisations such as this to champion raising public awareness. Clearly the public needs to be made aware of this critical issue. In addition, we

applaud their activities in the area of off-label usage. This again, in certain situations, constitutes a serious public health issue and the activities of the EAASM in raising this with the European Commissioner for Health again is a very welcome step forward to protect patients. We look forward to supporting their endeavours, as we at Biogen share the objective of the EAASM to always put the patient first.”



FIGHTING FAKES BY RAISING PUBLIC AWARENESS - THE ITALIAN ADWORDS CAMPAIGN

This project was designed to accurately and directly target and warn people tempted to purchase prescription medicines online, more usually without a prescription from their doctor.

The educational website aptly named “Medicineperte – medicines now” provides all of the information to educate people going online to buy prescription medicines. Supported by a Google AdWord grant, keywords such as “pharmacy online” were bought and this triggered the ASOP EU advertisement to appear on the first Google search page, encouraging browsers to visit the educational website. Over a 6 month period, (September 2015 to February 2016) this pilot project achieved, on average, over 13,600 first

page impressions per day.

With a “click through” rate of nearly 2%, this extrapolates to nearly 100,000 people in one year being exposed to the educational website. With an average dwell time of more than one minute on the website, with many visits recorded of far greater length (the longest being 29 minutes), these statistics give a developing picture that such educational vehicles are effective.



Facts about Fake Medicines

[Home](#)
[Buyer Beware](#)
[Stay Safe](#)
[Help Us](#)
[Information Bank](#)
[Private Contact](#)

Buying medicines online is a risky business

This website is here to help protect you from criminals who might sell you dangerous fake medicines, steal your identity and/or commit online fraud.

Buyer Beware

The sale, supply or purchase of prescription medicines online is not permitted in many countries throughout Europe.

[To learn more, click here](#)

Falsified Medicines

Falsified medicines are dangerous.

[To learn more, click here](#)

Stay Safe

To find out how to obtain your medicines safely and legally.

[Click here](#)

Facts about Fake Medicines home page - www.eaasm-asop.eu

CONVINCING RESULTS THAT RAISING AWARENESS CAN CHANGE BEHAVIOURS

Of particular importance was being able to measure if the visitors would change their behaviour having been exposed to the content on the educational website.

This vital information was made possible by a short questionnaire implanted on each website page. Visitors were asked to answer just 5 questions.

One critical question was **“Having visited this educational website, has it changed your motivation to buy medicines online and obtain your medicines from your local pharmacy?”** To this question, there is a clear and growing trend that people, once they are made aware of the dangers, will change their behaviour and revert to going

to their pharmacy. This report demonstrates the significant impact that an AdWord campaign can achieve. The ASOP EU and EAASM organisations would like to extend the reach of such a powerful educational tool to other European countries. This will undoubtedly add greatly to raising public awareness and enhance patient safety, ultimately supporting health outcomes across the European landscape.

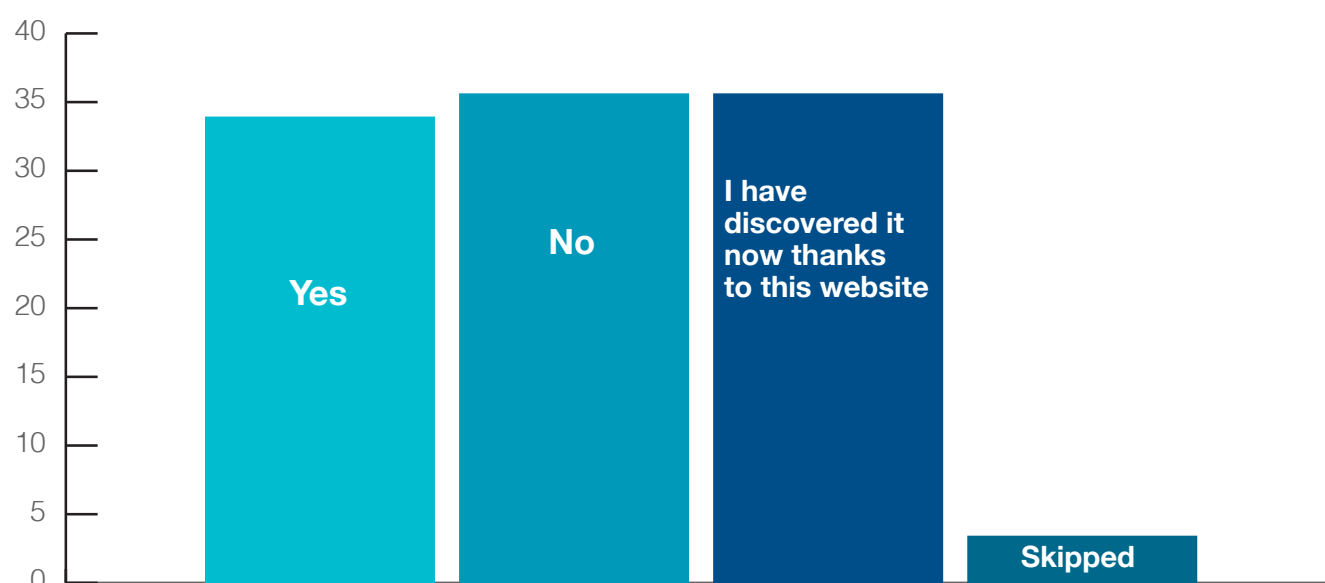


QUESTION 3

Are you aware that the websites you are visiting are most likely operating illegally?

It is important to note that 34% of respondents state that they are aware that the websites are likely to be operating illegally. However 36% said that they were not aware and a further 36% said that this website had informed them about this illegal activity, indicating that overall it might be

assumed that a high percentage (72%) of the viewers of the website were not originally aware of the fact that websites being visited were operating illegally. Please note that due to 5 respondents ticking more than one answer, the cumulative percentages add to more than 100%.



QUESTION 4

Having visited this educational website, has it changed your motivation to buy your medicines online and obtain your medicines from your local pharmacy?

52% of the respondents say that they are “sure” or “probably” to this question with 32% saying that they are “unsure” with 12% saying that “No I will continue to buy online”



RECOMMENDATIONS

It is a key objective of ASOP EU, the EAASM and other closely aligned not for profit patient safety organisations to raise public awareness and tackle the “demand” side of purchasing medicines online. A number of research projects have revealed that the public is

under-educated in this area and so there is a pressing need.

“Fighting Fakes by Raising Public Awareness” campaign has proved such campaigns have the power to achieve tackling the “demand” side created by this patient/consumer behaviour. Without the support and commitment

of Google and the adgrant, this could not be achieved, as not for profit organisations could never be funded sufficiently to realise truly effective ongoing campaigns that we have seen here with this Italian educational campaign.

ACKNOWLEDGMENTS

ASOP EU and the EAASM would like to thank the following for their support in this project: Google for the adword grant; GIRP for their support in helping with the report; AIFA for their technical and translations support;

the three pharmaceutical companies, namely Bayer, Lilly and Pfizer who have sponsored the development of the educational website and for their continued support as the EAASM and ASOP EU look to extend

the campaign to other European countries; and finally to all the ASOP EU and EAASM Members and Observers, without which these patient safety organisations could not carry out the important work that they do.

ROUNDTABLE ON EU STRATEGY AND MESSAGING ON FALSIFIED MEDICINES AND INTERNET SALES



Outreach Events Key Outputs from Roundtable on EU Strategy and Messaging on Falsified Medicines and Internet Sales
Friday 17th June 2016 1000 - 1600CET Google Offices Brussels

This meeting was convened to share best practice activities and delegates were present from Member States and not for profit organisations engaged in public awareness campaigns.

Campaigns and initiatives were discussed in detail as well as carrying out a strategic review using marketing planning techniques such as a SWOT analysis and a stakeholder mapping exercise. The key output however was broad agreement to consider adopting a new Code of Communication Collaboration to enhance alignment of communication initiatives as follows:

1. Commit to keeping each other informed in a timely manner about any significant communication initiatives that our organization will undertake to inform the public about buying medicines online (and hence help to address the "Demand" side).
2. Inform consumers that they must be diligent when shopping online to avoid the potential harm caused by falsified medicines sold by illegal online sellers of medicines.
3. Alert consumers to the typical signs of an illegitimate site:
 - In the EU, does not display the Common Logo;
 - Offers "too good to be true" prices or deals unavailable in local pharmacies;
 - Does not require a prescription;
 - Offers medicines not licensed for sale in the country where the patient lives;
 - Hides its physical address; and does not have a pharmacy licence.
4. Direct consumers to ways they can stay safe, including:
 - In the EU, looking for the Common Logo and ensuring the logo links to the MS regulatory authority's website;
 - Looking for sites ending in the .pharmacy domain.
5. Endeavour to use the following terms our messaging:
 - "Patient safety" or "consumer safety" as this is the reason for our work;
 - "Falsified Medicine" or "fake medicine" as opposed to the term "counterfeit" which is more usually reserved for Intellectual Property crime;
 - "Medical products" for communications in the EU, as that is a statutory term.



OFF-LABEL USE OF MEDICINES

- EAASM INPUTS TO EXPERT GROUP

Together with NIVEL (Netherlands institute for health services research)/RIVM (National Institute for Public Health and the Environment) and EPHA (European Public Health Alliance), this group is nearing the completion of a study for the European Commission on off-label use of medicinal products in the European Union.

The general objective of this study is to provide the EC with a clear overview of existing and foreseen practices of off-label use across Member States. It will also provide a factual analysis of all parties' positions towards the existing measures and possible future tools to regulate off-label medicine use. The EAASM was invited to complete a questionnaire and also attend a "brainstorming" expert working group which took place in March in Amsterdam. The minutes reflected a number of major concerns by the stakeholders which comprised paediatric hospital pharmacists, Member State Medical agencies, EMA, EFPIA, patient groups and pharmacy bodies. Key issues raised were the absence of any

representation from the medical profession, getting closer to clarifying the definition of Off Label Usage (OLU), the prevalence of OLU, the key drivers, policy tools at patient and healthcare professional levels, data bases and awareness raising campaigns. The EAASM voiced the opinion that compounding should be included in the scope of the study but this was ruled out. The EAASM plans to raise this subject as a separate and very important patient safety issue. Any changes in formulation carried out with less than GMP constitutes a potential danger to patients. Currently the research group is formulating its final report which will be presented to DG Santé by the end of 2016.



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



Top to bottom: Logos,
NIVEL (Netherlands
institute for health services
research), RIVM (National
Institute for Public Health
and the Environment),
EPHA (European Public
Health Alliance)

European
Parliament
in Brussels



Response from Commissioner of Health to EAASM letter invoking ARTICLE 265

Article 265 is a treaty that grants the right to a European citizen to call upon the Commissioner of Health to investigate a potential situation that is causing harm to patients.

On December 2nd 2015, the EAASM wrote to the Commissioner Vytenis Andriukaitis referenced as "Letter of formal notice to Commissioner for Health and Food Safety". The letter highlighted Off-Label Usage (OLU) in an Italian hospital had caused significant patient harm. Some Member States are encouraging off-label use to reduce public expenditures. Based on this incident, the EAASM felt it appropriate to invoke article

265. The response from the Commissioner was comprehensive and duly acknowledged the fact that "...OLU is a highly complex issue". EU Legislation does not regulate the "off-label" use of medicinal products and in most Member States it is the responsibility of the prescribing physician. However, EU legislation insists that any adverse events in whatever prescribing circumstance must be reported to the competent authority. The Commissioner emphasised that the pan-European scoping study of OLU will deliver a clear description of existing and foreseen practices. The conclusions will be further assessed by the Commission services and discussed with Member States. A recent meeting



Commissioner Vytenis Andriukaitis

held with the EAASM and DG Santé revealed that the report is in draft stage and that it will be finalised by the end of the year. The letter actually stated that the study would be ready by June 2016 so it is all moving rather slowly. However what was encouraging in the letter was the statement by Andriukaitis implying that outputs might be "...possible envisaged tools to regulate the off-label use of medicines". This leads nicely in to the next news item.



Professor Marc Doms Hospital Pharmacist and author of the Declaration on Good Off-Label Use Practice (GOLUP)

EAASM endorses independently derived guidelines on off-label usage to be underlined at EU MEP Parliament meeting 27th September 2016

Many will be aware that there are a number of very useful and well thought out medical guidelines on the topic of off-label use practice. Of note is the General Medical Council's (GMC) entitled GMC prescribing guidance 2013 points 69-71. More recently a guideline has been released by Prof. Marc Doms called "Good Off-Label Use Practices" (GOLUP). To mark the publication of this important guideline, a EU Parliament event on **"Safeguarding patient safety and quality of care in Europe: Good practice for the off-label use of medicines"** to be hosted by MEP Piernicola Pedicini in Brussels on Tuesday 27 September 2016, between 10.00 and 12.00. **If you would like to attend this event [click here](#) to register and for more information about this subject [click here](#).**

The EAASM has endorsed the GOLUP guidelines and been asked to speak at this event.

OUTREACH EVENTS - THE REAL McCOY - GLASGOW

The MHRA extended an invitation to ASOP EU and the Pharmaceutical Security Institute to be a speaker at an established annual event entitled Keeping it REAL in Scotland - **The Real McCoy**.

1. This event celebrated the success that has been achieved against illicit trade and provides the opportunity to bring together speakers from the world of business, academia, regulation and law

enforcement. This event was combined with a fully interactive public event in marquees within the famous George Square to help educate the public about counterfeit goods which included falsified medicines.
 2. L to R Mike Isles ASOP EU, Lynda Scammell, MHRA, Duncan Elson, Pfizer in the George Square exhibition
 3. Lynda Scammell just before going in to a live interview with Rona Dougal on the Scotland Tonight programme
 4. Mike Isles speaking to the title "Fighting Fakes by Raising Public Awareness"
 5. Ronnie Megaughin, Deputy Director, Business Resilience Centre and Lynda Scammell, MHRA
 6. Discussion in the George Square exhibition area.



OUTREACH EVENTS - MEDICINES FOR EUROPE



JOINT 22ND MEDICINES FOR EUROPE AND 19TH IGBA ANNUAL CONFERENCE

DUBROVNIK, RADISSON BLU PORTMAN HOTEL
8-10 JUNE 2016



ASOP EU was invited to speak and be part of a panel of experts under the heading **“Fighting Counterfeit Medicines.”**

The panel comprised Francois Lery, EDQM, Andreas Walter EMVO, - Benoit Goyens World Customs Organization, Elke Grooten, Sandoz and Mike Isles ASOP EU. **7.** Tako Mulder, Teva presenting the highly successful Chronic Obstructive Pulmonary Disease (COPD) campaign which was launched on World COPD Day. Entitled #Laugh4Lungs it used social media, which aimed to harness the power of laughter to promote global awareness of COPD whilst raising money for three leading charities across Europe, including the British Lung Foundation (UK), Longfonds (Netherlands) and Fundación Lovexair (Spain). **9.** Adrian van den Hoven, Director General and Mike Isles ASOP EU.

OUTREACH EVENTS - ALPhA PROJECT RESULTS

This important research project under the auspices of the ALPhA group entitled **“The effects of the liberalization of the Internet trade in Europe on the phenomenon of pharmaceutical crime”** clearly scoped the pan-European situation

and highlighted the great variability of laws and approaches from one Member State to the next and confirmed the consumer’s lack of knowledge on how to distinguish legal from illegal online sellers of medicinal products.

10

Funded by the German Federal Ministry of Education and Research for two years, the results were made public at this international conference on pharmaceutical crime 20-21 June 2016. More than 100 participants attended in the castle of Osnabrück University to discuss the findings and the future aspects of countering pharmaceutical crime. Delegates included: Interpol, Europol, the Council of Europe, the EU Commission, German Customs and Federal Police, as well as patient safety and pharmacy organisations and the German Ministry of Justice inter alia. The opening address was given by Jürgen Storbeck, retired Director of Europol. The research also revealed different safety standards of the distribution of medicinal products via the Internet and confirmed the consumer’s lack of knowledge on how to distinguish legal from illegal online sellers of medicinal products.

One of the key recommendations by the ALPhA group is to encourage the implementation of an EU-wide harmonisation exercise of the criminalisation of pharmaceutical crime and applicable sanctions and that this should be carried out with urgency given the potential impact on patient safety.



11. L to R Mike Isles, Libby Baney, Klaus Gritschneider - ASOP and Melissa Madigan NABP



12. L to R Klaus Gritschneider ASOP EU, Michael Otto, Head Investigations Europe/Russia, NOVARTIS, Marco Tripmaker, Journalist

OUTREACH EVENTS - SPANISH MEDICAL AGENCY

13 ASOP Global, ASOP EU and NABP met with the team of Belen Escribano Romero, Head of Department Pharmaceutical Inspection and Enforcement Department of Agencia Española

de Medicamentos y Productos Sanitarios (AEMPS) on June 16th 2016 at their Madrid offices.

The agenda was wide ranging and covered how the Spanish Agency was publicising the

Common Logo to the general public. In addition the NABP .pharmacy initiative was discussed.



Important Member State and patient safety group meeting “Best Practice Sharing on communicating to the Public about falsified medicines and the Common Logo”

September 14th 2016 Microsoft Offices, Brussels



A closed meeting inviting all Member States and not for profit patient safety organisations connected to the issue of making the internet a safer place to buy medicines online, took place on September 14th 2016 at the Brussels Microsoft Offices.

Ten Member States were present and presentations were made to update the delegates on the various country stages of Common Logo implementation. ASOP Global and ASOP EU has had a long standing

commitment to support the successful implementation of the Common Logo. This was the fourth supportive meeting of this kind. The major priority of this meeting was to allow Member States to demonstrate and share what they are planning and what they are doing to educate the public on this important issue. This meeting clearly demonstrated that best practice sharing can be mutually beneficial and of great value to other Member States and all interested parties.

14. From Left to right: Philippe de Buck – Belgium, Alain Denis – Belgium, Jurate Svarcaite – PGEU, Klaus Gritschneider – ASOP EU, Anna Fernandez Muelas – Spain, Francois Lery – EDQM, Sasa Polovic – Croatia, Anitra Sprauten – Fight the Fakes, Ines Du-Plessis – EDQM, Lynda Scammell – UK, Pavle Zelic – Serbia, Janice Leander Nielson – Denmark, Marie Kertu – Sweden, Paul Brewer – UK, Nathalie Dewulf – EHFCN, Joanna Szajnik – Poland, Mike Klaassen – Holland, Mike Isles ASOP EU



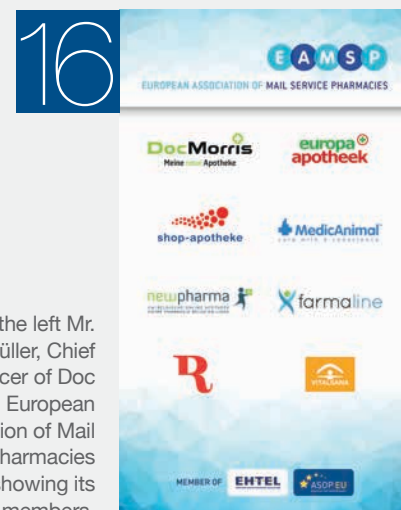
OUTREACH EVENTS - EAMSP RECEPTION

The European Association of Mail Service Pharmacies is a member of ASOP EU and is a strong supporter of their work. Klaus Gritschneider, vice-president of EAMSP emphasised this commitment by acting as a director of ASOP EU.

The occasion, on the evening of 6th September 2016 marked an end of summer EAMSP reception which enabled guests from the Parliament,



the Commission and other stakeholders to be informed about ASOP activities and the fight against falsified medicines and illegal traders.

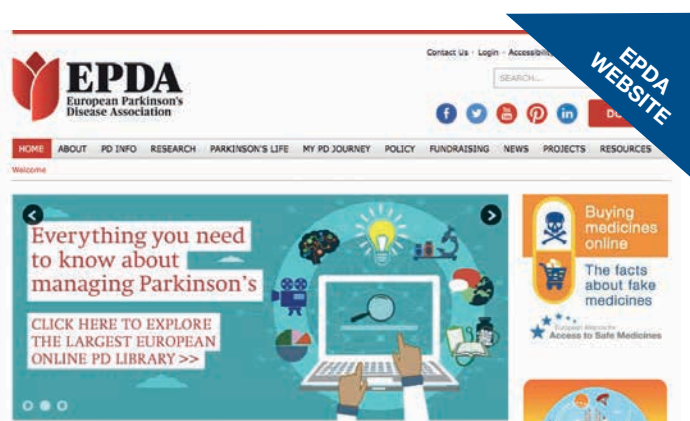


15. On the left Mr. Max Müller, Chief Strategy Officer of Doc Morris. 16. European Association of Mail Service Pharmacies poster showing its members.

KEY PATIENT GROUPS HOST LINKS TO ASOP EU'S EDUCATIONAL WEBSITE ON FALSIFIED MEDICINES

After a productive period of discussion, two leading patient groups now host an EAASM educational website link.

The **European Parkinson's Disease Association (EPDA)** and the **European Federation of Neurological Diseases** (EFNA) now host the following website icons.



Facts about Fake Medicines



Please look out for our next end of year newsletter which will summarise our 2016 achievements and share our 2017 goals. On behalf of ASOP EU and the EAASM, we would like to thank all of our Members, Observers and interested followers for their continued support. If you would like any further information relating to this newsletter or the ASOP EU or EAASM activities please email Mike Isles (mike.isles@asop.eu mike.isles@eaasm.eu).