

June 2019

NEWSLETTER

A diary of achievements from September 2018 to May 2019

SEPTEMBER 2018

EAASM agrees to join a consortium to support a tender for Innovative Medicines Initiative project to use Digital Ledger Technology (DLT – Blockchain).

Discussions begin to champion the need for a more robust legal framework for the newly developing area for nanomedicines to enhance patient safety.

Speaking engagement at Pharma and Medical Device Packaging and Labelling conference, Munich.

Speaking engagement 7th Annual Pharma Anti-Counterfeiting & Serialisation

Participant in NABP Pharmacy Registrant/Supporter Advisory Committee Webinar to support patient safety top level domain name .pharmacy.

Meeting with Olivier Bringen Deputy and Acting Head of Unit DG CONNECT - Unit E3 Next Generation Internet to discuss ASOP EU involvement with upcoming approval of new EU Regulation for the governance of .EU top level domain name

Meeting with European Commission

Directorate-General for Health and Food Safety – DG SANTE Unit B4 – Medical products: quality, safety, innovation to discuss Article 85d of the Falsified Medicines Directive (FMD) and the legal obligation to publicise the meaning of the Common Logo and a falsified medicine and their participation in a EU Parliamentary meeting on the FMD in the hospital arena. ASOP EU/EAASM is a guest speaker at the Medicine Quality and Public Health. First ever international conference on medicine quality. Attendance at the EUIPO Observatory working groups. ASOP EU asked to chair a networking session and present in Plenary on how greater cooperation with Intermediaries can support a safer Internet.

OCTOBER 2018

Intensive work on Innovative Medicines Initiative tender – 38 page document.

Guest at the MHRA Annual Lecture Medical Innovation and the Battle against Cancer – is the health system keeping pace?

Attendance at ICANN meeting Barcelona. Presentation of the ASOP Global annual award for best practice Registry awarded to .DK operated by Hostmaster



NOVEMBER 2018

Participation in the International Alliance of Patients' Organizations (IAPO) webinar.

Discussion on how to support Fight the Fakes campaign.

Development of a compounding survey to assess best practice in both the hospital and community. Initial planning on a pan European medication survey.

Meeting with the International Alliance of Patients' Organizations (IAPO) in London.

UNESCO meeting with the Youth Internet Governance Forum Movement Ambassadors to begin a training programme for in-country education on falsified medicines.

Speaking engagement at first ASOP Global Foundation 2018 Research Symposium Washington DC.

ASOP Global All Hands meeting Washington DC.

Attendance at European Medical Association (EMA) Acute and General Medicines Annual conference.

Speaking engagement at the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes, Pharmacy and Fight the Fakes EDQM (Council of Europe) in Strasbourg.

DECEMBER 2018

Speaking engagement at the [Royal College of Physicians](#) to raise awareness on falsified medicines amongst the medical profession. [London University College of Pharmacy and Fight the Fakes](#) combined meeting. ASOP EU involved in the organisation, presentations and filming. Attendance at the [Patient Access partnership \(PACT\)](#) meeting Brussels. Involvement in developing Statement on the “Future of Health in the European Union” [EAASM Board meeting](#) Brussels to discuss 2018 activities and planning for 2019 strategy and tactics. Ongoing discussion with [senior NHS IT personnel](#) for presence at the February FMD EU Parliament meeting on implementation of safety features in the hospital environment. scheduled for 19 February 2019 in the EU Parliament.

JANUARY 2019

Planning of the Roundtable “Improving patient safety with the FMD in the hospital pharmacy”. ASOP EU presents at the [G2 Risk Summit Series](#) in Riga, Latvia.

FEBRUARY 2019

[ASOP Global Quarterly Meeting](#). A New [EAASM/ASOP EU](#) plan drawn up to increase contact with new MEPs following the May elections, Directorates-General (DG Connect, DG Grow, DG Trade, DG SANTE) to advocate for patient safety issues including a safer Internet and encourage appropriate legislation and voluntary actions. New [EUIPO Expert Group - ASOP EU](#) confirmed as an Expert Member of “Cooperation with Intermediaries”. Preparation of new educational materials to be used by in-country Youth Internet Governance Movement Ambassadors. Speaking engagement at the [G2 Risk Summit](#) in London. Speaking engagement at [12th Annual Parallel Trade Conference](#), London. Speaking engagement at [Royal Pharmaceutical Society Summit](#) meeting. EU Parliament Roundtable discussion “Improving patient safety with the FMD in the hospital pharmacy, status of implementation”. Participant at “EU collaboration in health for better access: Taking stock and looking to the future” European Parliament, hosted by PACT in collaboration with the MEP Interest Group on Access to Healthcare. Supporting the [European Specialist Nurses Organisation \(ESNO\)](#) congress “The Specialist Nurse in European Healthcare towards 2030”

MARCH 2019

EU Parliament round table meeting on “Handling innovation in NANOMEDICINES: regulatory challenges and opportunities in modern healthcare” Meeting with [European Association of Mail Service Pharmacies](#) to understand the operation and to meet new Chair of ASOP EU, Robert Hess.

APRIL 2019

Follow up meeting with Olivier Bringen Deputy and acting Head of Unit DG CONNECT - Unit E3 to discuss participation by ASOP EU of new Implementation Acts of .EU regulation. Meeting Tamas Király, Policy Officer, international aspects of intellectual property rights, Unit B.3 Intellectual Property and Public Procurement at the Directorate General for Trade of the European Commission.

May 2019

Attendance at the 3rd Forum Unique Codes, organised by Securikett, Vienna Meeting with head of IT and senior law enforcement official to discuss Internet issues relating to ccTLDs ASOP Global quarterly meeting - discussion on US importation issues and Global regional updates.

June 2019

ASOP EU invited to speak at the USP-APEC Center of Excellence: “Minimizing Quality Risks in the Upstream and Downstream Supply Chain – A Regulator Dialogue & Training” Santiago, Chile Santiago, Chile ASOP EU invited to speak at the International Forum on IP Enforcement Paris, France ASOP EU supporting partners at the [Pharmaceutical Anti-Counterfeiting Forum](#) Zurich, Switzerland

Our thanks...

Chair of EAASM



We would like to take this opportunity to sincerely thank the out-going Chair **Cathalijne van Doorne**. Her period of tenure has been marked by many successes and indeed, as of last year the EAASM patient safety organisation had been in existence for 10 years. Key projects such as work on off label usage of medicines, support of the Falsified Medicines Directive with best practice Common Logo Member State meetings, as well as public awareness raising campaigns all took place during her tenure as the Chairperson. Cathalijne will remain an active Board Member as well as continuing her patient safety responsibilities for EFNA where she is the Vice-President and is also looking forward to contributing her expertise as a patient representative to the Pharmacovigilance Risk Assessment Committee of the EMA. Mike Isles was voted in as the new EAASM Chair.

Director of ASOP EU

We would also like to thank **Klaus Gritschneider** for his truly supportive work as a **Director of ASOP EU**. Klaus played a very active role in many of the activities relating to ASOP EU's objectives and as a Board member of the European Association for Mail Service Pharmacies brought valuable expertise and insights in to all practices relating to the sales of medicines online. We are pleased to announce that he will be replaced by **Robert Hess** in his personal capacity. Robert brings a wealth of experience in all pharmaceutical matters. Having trained as a pharmacist and following a distinguished career in the pharmaceutical industry, he then co-founded the highly successful mail service pharmacy operation Europa Apotheek based on the Dutch border town of Venlo.



Klaus Gritschneider



Robert Hess

ASOP Global's Annual Internet Pharmacy Safety Award Presented to .DK Hostmaster



The DK Hostmaster Team

The Alliance for Safe Online Pharmacies (ASOP Global) together with ASOP EU presented its annual Internet Pharmacy Safety E-Commerce Leadership Award to .DK Hostmaster at the 2018 ICANN63 on 22 October. The domain name administrator for Denmark, DK Hostmaster, was selected for the award based on their commitment to ensuring citizen safety by maintaining transparent WHOIS data, proactively enforcing identity accuracy policies to increase consumer trust and safety online.

"ASOP Global is pleased to recognize DK Hostmaster for their outstanding efforts to prevent the illegal use of domain names for online drug sales and rapidly responding to any complaints," said Libby Baney, Principal at Faegre Baker Daniels Consulting and senior advisor to ASOP Global. All DK domain names belong to the sovereign state of Denmark and are managed by DK Hostmaster and its owner, nonprofit member association Dansk Internet Forum (DIFO). Nominations for ASOP Global's third Internet Pharmacy E-Commerce Safety Award are now open. Award recipients will be announced during ICANN66 in November 2019 in Montreal, Canada.

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ASOP Global is pleased to recognize DK Hostmaster for their outstanding effort to prevent the illegal use of domain names for online drug sales and rapidly responding to any complaints.

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ASOP EU and the Youth Internet Governance Forum Movement collaborates to raise awareness about fake medicines



Left to right: Laura Cigolot ASOP EU, Junior Saint Fleur - Youth IGF Haiti, Mirella Peronne - Sanofi, Maryam Jetha - UCL School of Pharmacy, Michel Chammas - Youth IGF Lebanon, Maria Kornits - Youth IGF Ukraine, Yuliya Morenets - Founder Youth IGF Global Movement, Mike Isles - ASOP EU, Agita Nindya Miesye Pasaribu - Youth IGF Indonesia, Geoffroy Bessaud - Sanofi, Bernardo Sequeiros - Youth IGF Portugal, Lucille Barbie - Sanofi

On 12th November 2018, the Alliance for Safe Online Pharmacy in the EU (ASOP EU) held the first meeting with the Youth Internet Governance Forum Movement (Youth IGFM)

ASOP EU and TaC-Together Against Cybercrime International, coordinator of the Youth IGF two non-profit organisations committed to work together to support the **Youth IGF Movement (YIGFM)**. The Movement was conceived during the First French Youth and Teenagers Internet governance Forum in France in 2011 at the Council of Europe to inspire young people across the world to discuss and take a lead on Internet-governance related issues. Youth IGFM Ambassadors from six different countries, Indonesia, Haiti, Lebanon, Portugal, UK and Ukraine, met to learn about the rising tide of fake online medicines. 35,000 websites advertise and sell prescription and OTC medicines on any given day around the world and with 96% operating illegally the seriousness of the situation was underlined. Furthermore, medicines

bought online may contain too much, too little or no active ingredients at all. Some even have dangerous or deadly substances like paint thinner, rat poison or fentanyl endangering life and health.

They also learnt that consumers risk economic, personal data or cybercrime threats when purchasing drugs from an illegal online pharmacy. The young ambassadors collectively brainstormed and shared thoughts on how best to educate and raise awareness amongst young citizens in their respective countries. The possibility of a unified worldwide annual awareness day to speak out against fake medicines which is killing one million people per year, was one of the concrete actionable ideas to come out of the meeting.



Yulia Morenets, Maryam Jetha, Mike Isles

To learn more about the Youth IGF, please go to the website www.youthigf.com

Development of a compounding survey to assess best practice in both the hospital and community

In collaboration with Professor Marc Dooms, Senior Orphan Drug Pharmacist at the University Hospitals in Leuven, Belgium, the EAASM embarked on a project to gain a greater understanding of compounding procedures and techniques across hospitals and community pharmacies throughout Europe.

The responses are still being received and will be kept confidential and the outcomes of the [questionnaire](#) will be shared by a future publication and communication via conferences. This survey aims to **highlight best practice and help to support increased quality of compounding practices which in turn will enhance patient safety.**



In order for us to disseminate this as widely as possible, we would kindly ask you to consider helping us to [circulate the survey within your network](#). The outcomes of the questionnaire will enable best practices to be revealed and will be shared across the hospital community in Europe to enhance patient safety. Please contact Laura Cigolot laura.cigolot@eaasm.eu for the survey - thank you.

ASOP EU presents at the British Medical journal and Royal College of Physicians Annual Global Conference

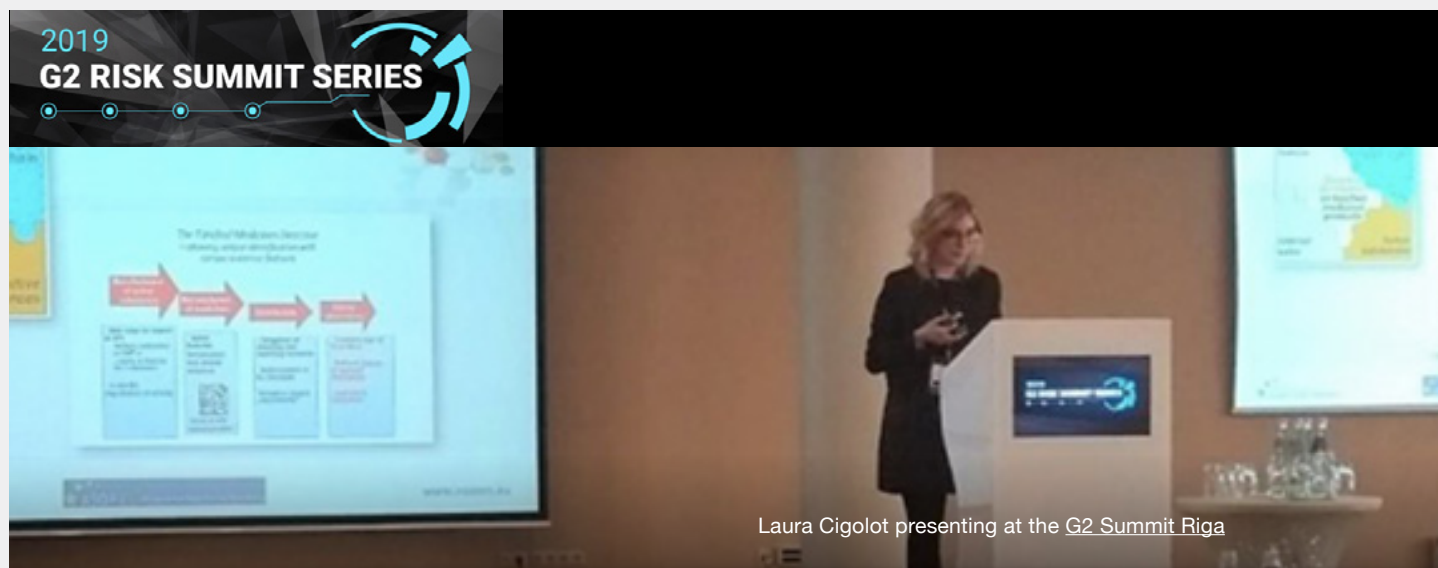
On 3 December, Mike Isles, Executive Director of ASOP EU and the EAASM, addressed doctors at the Global Health Horizons – “**Learning from the past, looking in to the future**” symposium held at the Royal College of Physicians, in London. Mike expressed his deep concern that the public and therefore patients were not being made aware of the rising tide of falsified medicines. He emphasised the need for all stakeholder engagement and stressed the role that doctors could play to help educate the public. Mike stated that most patients will have explored their health issues by searching the Internet. Doctors, community or hospital, have a clear duty of care to ascertain, as much as they can, if their patients have bought medicines from the Internet. With 35,000 illicit websites aimed at the European citizen and an estimated 130 million people in Europe buying medicines online, this underlines the importance of doctors taking a pro-active stance.



Mike Isles at RCOP meeting

Mike also took the opportunity to reveal ground breaking evidence collected from the ASOP EU/EAASM educational website. With over 2300 survey responses from would-be buyers of medicines online, the respondents revealed an overwhelming desire to change their behaviour and find a safe, genuine place to buy their medicines, once they understood that 96% of websites on the Internet in Europe are operating illegally.

ASOP EU presents at the G2 Risk Summit in Riga and London



Laura Cigolot presenting at the G2 Summit Riga

On both occasions, Director Mike Isles and the Secretariat run by Laura Cigolot addressed the rising tide of falsified medicines in Europe and related legislation, with a major focus on Article 85d of the Falsified Medicines Directive and the EU Common Logo. They presented ASOP EU activities to enhance Internet patient safety and raise awareness about falsified medicines. This included Parliamentary meetings, an educational campaign in five EU countries and the latest report which highlights what gaps still exist in consumer/patient education. They called upon relevant authorities to continue to build on the many initiatives that raise public awareness.

They outlined the patient safety initiative by the National association of Boards of Pharmacies (NABP) whose top-level domain initiative of .pharmacy is another important step to enable patients to go to a secure place on the Internet to buy medicines. In addition, ASOP Global Board Member John Hertig, PharmD, MS, CPPS Associate Professor at Butler University Indianapolis, Indiana, USA added his own expert knowledge to this important topic.

EUIPO Observatory – ASOP EU chosen to be part of new Expert Group “Collaboration with Intermediaries”

Following a screening process, ASOP EU and the EAASM are now part of a new EUIPO Observatory Expert Group (EG). The title of the group is “Cooperation with Intermediaries”. There are six EGs namely: Observatory Outreach, Legal, Impact of Technology, Cooperation with Intermediaries, International Cooperation and SME comprising the public, private and civil society sectors. ASOP EU/EAASM sits representing the civil society sector.

The first meeting was held at the Observatory premises in Alicante and took place from 8 to 11 April 2019. One particular presentation around the subject of “future site blocking” has generated a line of interest for a potential future project which may have relevance for the blocking of illegally operating websites selling medicines.



EU Parliament round table - Improving patient safety with the FMD in the hospital pharmacy



There has been much talk about the difficulties of implementing a robust process-driven verification system of prescription packs within the hospital settings across Europe. Depending on which hospital pharmacist you talk to, you still get a rainbow of opinions. This despite the legal implication, that as of 9th February 2019 all pharmacists should be ready to fulfil the final stage of the Falsified Medicines Directive's (FMD) safety features that will help ensure the patient is protected from falsified medicines. Opinions range from "We have implemented the Directive and can see great halo benefits" to those that feel "It adds no value, only extra work and cost".

The EU Parliament meeting on 19th February "Improving patient safety with the FMD in the hospital pharmacy, status of implementation – are we ready?" was initiated by the European Alliance for Access to Safe Medicines (EAASM) in collaboration with MEP José Inácio Faria to support the final elements of the FMD. The programme was designed to dispel some of these myths and establish a firmer base for the sharing of best practices by bringing together a team of experts to offer their advice and expertise.

From the technical perspective, Andreas Walter, head of the – European Medicines Verification Organisation (EMVO) whose repository captures all of the bar-coding data, stated "...the system had been built in all 28 Member States and that there is the need for a period of stabilisation and inspection measures. This is the largest verification system initiative in the world which is further complicated by the commitment for each Member State to construct a compatible subsidiary nationally based IT architecture."

The example of a very successful implementation was presented by Maija Gohlke-kokkonen, General Manager of the Finnish Medicines Verification Organisation. Despite 83% of transactions having been successful, there are still challenges faced by hospital pharmacies and four in-country views by experts as well, as the European Association of Hospital Pharmacists (EAHP) presented their practical solutions to the implementation of the FMD.

Challenges such as procurement of new IT systems, volume of packs, complexity of distribution pathways within the hospital, slow decommissioning, staffing resource issues, planning procedures for in-bound stock, identifying who can perform the decommissioning and the need for a standing buffer were all cited.

EU Parliament round table - Improving patient safety with the FMD in the hospital pharmacy



András SÜLE - European Association of Hospital Pharmacists, Maija GOHLKE-KOKKONEN - Finnish Medicines Verification Organisation, Andreas WALTER - European Medicines Verification Organization, Ana HERRANZ ALONSO [Spain]

Critical success factors a succesful implementation of the FMD in the hospital setting

- Support from national bodies to ensure alignment and financial support where possible across the national health system
- Communication between stakeholders (from hospital to hospital and allied services; ambulance services etc.) to standardise the processes to ensure that the technology platforms are compatible and fully integrated into existing workflow
- The relationship with third-party automation providers and their understanding and cooperation to work out the final optimal approach
- Definition and handling of false alerts
- A clear and understandable language within the system read outs
- The use of technology to overcome the manual burden placed on hospitals was required with robotics as a way to facilitate the implementation process.
- **It was stated that only 10 days after the implementation date of the FMD, the European Hub functions properly and no major issues have been identified so far. All databases are connected and connection to end-users is in progress. The Commission is an observer who facilitates the discussion between stakeholders as the level of awareness is still not sufficient and so there is a need for more outreach to actors. DG SANTE had set up a sub group of Member States to investigate possibilities of having a system of data files with suppliers instead of aggregation**

Read the full [report](#). More information on the event are available [here](#).

New report demonstrates significant resources required to implement FMD in the Hospital Setting

Resources needed to implement the Falsified Medicines Directive in hospitals across the EU and the EEA would cost more than 86 million euros, according to estimates.

The recently published [report](#) produced by the EAASM highlights the costs involved but also the significant added value that the final patient safety elements of the Falsified Medicines Directive will bring. The Directive requires that every single prescription pack is serialised and has a unique identifier in the form of a barcode and a tamper evident seal. Each pack will need to be verified and decommissioned before it can be dispensed thus confirming the pack is genuine and not falsified.

In order to address the complexities of such an operation in the hospital environment, the EAASM held a [meeting](#) in the European Parliament on 19 February 2019 to encourage and support best practice in hospitals by bringing together a group of experts.



In order to estimate the cost to implement this part of the FMD, the report extrapolated data compiled on the volume of prescriptions dispensed within the hospital environment from the German experience. Specifically, the data indicates a clear need for additional human resource capacity; up to 2-4 extra staff per large hospital. A map, by country, depicts the financial implications with a consolidated calculated cost of up to 86 million euros depending on the authentication process and anticipated time to scan a barcode on a prescription pack.

Opportunities for the future formed an important part of the meetings and emphasised the ways in which medicine's authentication systems (MAS) using artificial intelligence and automation can reduce the human resource required whilst delivering safer processes.

A medicine's authentication system, when utilised in combination with the FMD, has the potential to:

- Secure authenticity of all prescription packs across the EU and the EEA thus protecting patients
- Realise potential savings due to automated stock control and inventory management
- Reduce waste (expired medicines and medicine shortages)
- Increase opportunities for pharmacist engagement in patient care
- Achieve more rapid and lower cost of product recalls
- Reduce personnel time and costs assessing product due to tamper proof seals
- Identify improvements in pharmacy workflows
- Support the monitoring of inappropriate antimicrobial prescribing.

Read the [report](#) to get more insights

The EAASM calls upon all stakeholders in the hospital setting to build on the implementation of the FMD by:

- **Encouraging all national and regional medical authorities to become even more involved** to help ensure that any hospitals who need to support the implementation of the FMD do so;
- **Implementing a continuous improvement culture** that involves inclusive collaboration with all staff and parties involved to capitalise on the many opportunities to use the data collected for positive patient care
- **Encouraging hospitals when onboarding patients to carry out a thorough discussion on the patients' medication history** to include questions around whether medicines have been bought on the Internet and thus introduce education to safeguard against patients taking themselves outside of their national health systems
- **Procedural and system improvements by embracing technology such as Artificial Intelligence and IT infrastructure** to introduce automated dispensing solutions to save time and alleviate the manual actions that lead to mental burden
- **Introducing smart applications to help connected services (ambulance, satellite hospitals) and robotics to aid the verification process and enhance the security of the medication use process**

EU Parliament meeting - 'Handling Innovation in nanomedicines: regulatory changes needed to realise new treatment opportunities and ensure patient safety'



Nanomedicines are highly complex products. The complexity and number of this new class of medicines is increasing at a rapid pace and so are the questions around assessing their quality, biological properties and therapeutic profiles.



Nanomedicines are medicinal products that have a size in the nanoscale range with unique properties which allow them to distribute in the body in a way that was previously impossible. This is why nanomedicines have been gaining greater attention in academia and research, as they have the potential to open up new and improved therapeutic opportunities. A [roundtable meeting](#) in the **European Parliament co-hosted by the European Alliance for Access to Safe Medicines (EAASM) and MEP Jose Inacio Faria (PT, EPP)** took place on 20 March to discuss the appropriateness of the current regulatory approval process for nanomedicines and their follow-on products, also known as nanosimilars, and to analyse the potential implications for policymakers, regulators, physicians, pharmacists, healthcare workers and ultimately patients.

Nanomedicines are highly complex products. The complexity and number of this new class of medicines is increasing at a rapid pace and so are the questions around assessing their quality, biological properties and therapeutic profiles. Such assessments are exacerbated in the absence of a legal definition on nanomedicines. Harmonisation of terminology was one of the issues raised during the debate. Current regulatory approvals for nanomedicines and nanosimilars are decided on an ad-hoc basis by product category. **With the accelerating progress in the development of clinically significant nanosimilars and in the absence of a specific regulatory pathway for them, the EAASM believes that the time is right to set the scene for building a consensus so that this regulatory weakness can be addressed.**

The EAASM believes the regulatory framework should be urgently reviewed.

These new medicines benefit from new modes of action and innovative drug delivery properties that were only made possible by the use of nanotechnology. As recently stated in a response from Commissioner Andriukaitis to a Written Question posed by MEP Faria (EPP, PT), efforts are however being made to better understand their specific properties and to continuously improve the available scientific guidance. For example, the Nanotechnology can offer opportunities to address unmet medical needs and hence regulatory changes are needed to realise new treatment opportunities that will help ensure patient safety and wellbeing. This is the reason why training a new generation of experts through working groups is vital to tackle the lack of consistent standards, address side-effect issues and develop relevant analytical methods for pharmacovigilance. The paramount issue of patient safety was emphasised by Mike Isles, EAASM Director. He stated that "...clearly nanomedicines and nanosimilars are complex and patients must not be put in harm's way from products that are copies of the original without absolute scientific assurance that their therapeutic profile has been tested as rigorously as the originator's. It is somewhat alarming to read in the scientific press that this may not always be the case. Patient safety must always be the most important criteria when assessing the granting of a new product licence. That is why we need to create a robust and totally fit for purpose regulatory framework which is clearly needed in this new, exciting and developing field of medicine".

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Nanomedicines in health can offer opportunities to address unmet medical needs and hence regulatory changes are needed to realise new treatment opportunities that will help ensure patient safety and wellbeing.

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Luis Rhodes Baiao - Parliamentary Assistant to MEP Jose Inacio Faria, Stefaan De Smedt - Ghent University, EU Commission, MEP Jose Inacio Faria, Susanne Bremer Hoffman - Joint Research Centre, EU Commission, Jon De Vleiger - Lygature, Mike Isles and Laura Cigolot - EAASM

In the absence of a specific regulatory pathway and a legal definition, **more scientific, policy and practice knowledge on the quality, safety, and efficacy of nanomedicines and nanosimilars must be gained** and there is a need to build a consensus dialogue as well as alignment between all players in Europe and beyond to further explore the field of nanomedicines at EU and national level. Awareness as well as **a well-controlled robust manufacturing process are indeed fundamental to ensure quality, safety and efficacy.**

Read more about speakers' presentation [here](#).

ASOP EU meets DG SANTE to discuss Article 85d of the Falsified Medicines Directive and the legal obligation to publicise the meaning of the Common Logo and a falsified medicine

ASOP EU has championed the need to raise public awareness about falsified medicines. In doing so it has strenuously supported Member States and encouraged them to fulfil Article 85d of the FMD by holding no less than 6 large meetings with Member States and other specific meetings with DG Sante.

At the Member States' meetings public facing campaigns are shared. The ASOP EU/EASM report published last year on the status of Article 85d showed a woeful lack of such campaigns. ASOP EU has written to the Commissioner for health about this and so this meeting with DG Sante was to brief them on the state of play and to encourage the Commission to encourage greater participation by Member States.



Mike Isles EAASM, MEP Jose Inacio Faria, Agnès Mathieu-Mendes - DG SANTE EU Commission

ASOP EU meets the Directorate-General for Communications Networks, Content and Technology (DG CONNECT) and the Directorate General for Trade of the European Commission

In April 2019, Mike Isles and Laura Cigolot had meetings with EU policymakers in Brussels.

They met Olivier Bringer, Deputy and acting Head of Unit of Unit E3 Next Generation Internet, to discuss the upcoming approval of the [Regulation \(EU\) 2019/517](#) of the European Parliament and of the Council of 19 March 2019 on the implementation and functioning of the .eu top-level domain name, and potential engagement in the process by ASOP EU. The purpose of the meeting was to catalyse a process of greater collaboration and cooperation to address the issue of infringing websites to arrive at an optimum set of Implementing Acts within the new regulation for .eu top-level domain name. What emerged was the idea to organise a meeting amongst interested parties in the near future



Laura Cigolot ASOP EU, Olivier Bringer and Fulvia Menin DG CONNECT EU Commission, Mike Isles ASOP EU

Mike Isles and Laura Cigolot also met with Tamas Király, Policy Officer - Desk Officer for international aspects of intellectual property rights, in the Unit B3 Intellectual Property and Public Procurement at the Directorate General for Trade of the European Commission to discuss the [Counterfeit and Piracy Watch List](#). Here ASOP EU agreed to support the production of a best practice document for registrars with a view to influencing the behavior of those identified on the "Watch list" involved in selling medicines over the Internet. The Watch List aims to encourage the operators of websites and physical marketplaces, local enforcement authorities and governments to take action to crack down on intellectual property abuse. It also aims at making EU citizens aware of the environmental, product safety and other risks of purchasing from problematic markets.

ASOP EU will be involved during the creation of this important document to be hopefully created by the end of Summer.

ASOP EU/EAASM speaks at first ever International conference on Medicine Quality and Public Health

Over 200 delegates travelled from more than 50 countries to attend the first ever conference on **Medicine Quality and Public Health (MQPH 2018)** in Oxford from 23-28 September 2018. The conference, at Keble College, Oxford University brought together experts in pharmacy, public health, chemistry, law, sociology, governance and ethics, from medicines regulatory authorities, academia, pharmaceutical industry, NGOs, and international organisations. The many conference partners included the **US Pharmacopeia (USP)**, **WHO**, **Wellcome and the Concept Foundation**. The latest evidence on the prevention, detection and response to substandard, falsified and unregulated medicines was discussed along with inspiring collaborations and strategies to tackle this global challenge.



Mike Isles shared a session entitled **Internet Sector and Medicine Quality**. He presented on **Fighting Fakes by Raising Consumer Awareness**, stressing the new research results on behaviours that drive would-be buyers of medicines on the Internet. **The session was shared** with Professor Tim Mackey whose title was 'Digital Danger: A Landscape View of the Challenges and Potential Solutions Needed to Combat Illegal Online Pharmacies'.



Tim is the Director of the Global Health Policy Institute, an Associate Professor of Anaesthesiology and Global Public Health at UC San Diego School of Medicine, and the Director of Healthcare Research and Policy at UC San Diego – Extension and is a strong supporter of ASOP Global.

ASOP EU Joins European Specialist Nurses Organisation Congress in Brussels

ESNO became members of ASOP EU in 2018 and since then good collaboration has taken place including input in a new position statement. [The ESNO Congress](#) titled "The Specialist Nurse in European Healthcare Towards 2030" highlighted the need for a concerted effort to introduce an overall plan to build a robust framework to enable the Specialist nurse to be properly recognised across Europe. This will support the need to address the requirement for nursing quality assurance, capacity building and the current huge current shortage of nurses.



Mike Isles – ASOP EU, Annette Kennedy – President International Council of Nurses (ICN), Adriano Friganovic – President ESNO, Pascal Rod – Past President ESNO

ASOP EU announces Google AdWord finding – consumers willing to change their Online behaviour

The growing threat of illegal online pharmacies coupled with the ongoing opioid crisis makes robust research and education more critical than ever for health professionals, patient safety organisations, law enforcement, and policymakers as they work to help patients stay safe online.



On November 14 at the National Press Club, the Alliance for Safe Online Pharmacies Foundation convened its inaugural Research Symposium. The event featured leading academic research presentations and thoughtful dialogue on timely topics, including patient safety and medication quality online, internet intermediary responsibility, law enforcement best practices, and consumer behaviour online.

The Food and Drug Administration's Office of Compliance Director Donald Ashley and Office of Pharmaceutical Quality Director Michael Kopcha delivered the Symposium's keynote addresses about the role the FDA plays in combatting illegal online pharmacies. Caitlin Owens, healthcare reporter at Axios, moderated the Symposium's closing roundtable discussion about emerging research questions and strategies for leveraging research to guide policy, educate stakeholders, and improve patient care.

ASOP Global Foundation and its members will use learnings from the Symposium to develop a new research agenda to inform future efforts aimed at protecting patients online.

The full Symposium agenda, speaker bios and graphic discussion takeaways can be found [here](#).



Mike Isles - ASOP EU, Louise Shelley - George Mason University, Tim Mackey - UC San Diego School of Medicine, Marty Allain, John Hertig - Butler University College of Pharmacy and Health Sciences, Beena Patel, Libby Baney, Matt Rubin - ASOP Global

At this symposium, ASOP EU took the opportunity to announce significant research findings. Throughout the ASOP EU Google AdWords campaign, which ran for a number of years, over 2300 surveys were completed which asked important questions about the type of medicines being bought, the knowledge of illicit websites, age, gender, etc. One question was asked as follows "After visiting this website, where will you buy your medicines in the future?" A resounding 91% said that, armed with the knowledge about the risks, they would rethink their behaviour either by searching out a legitimate website or going to their local pharmacy.

ASOP EU chairs important networking session with Internet Intermediary stakeholders



ASOP EU/EAASM are Civil Society members of the EUIPO's Observatory and attends all of the meetings. Mike Isles was asked to chair a networking session to help catalyse the evolving concept of a new Observatory initiative - that of new expert groups. The stakeholders included Amazon and the session served to highlight how greater collaboration can enhance safer Internet behaviour to garner ideas on how Intermediaries on the Internet can collaborate more. The results of the workshop were presented in the Plenary session.

ASOP EU supports the European Medical Association (EMA) Acute at the General Medicines Annual conference in London

The EMA became members of ASOP EU and now have a presence on the [EMA website](#). This encourages doctors throughout the EMA membership to understand more about the rising tide of falsified medicines so that they can be more aware of patient behaviour and the Internet.



ASOP EU supports Fight the Fakes campaign

ASOP EU took the opportunity to pose for a photo to publicise the [Fight the Fakes](#) campaign immediately after the EU Parliament event entitled

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“Improving patient safety with the FMD in the hospital pharmacy, status of implementation.

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London University College of Pharmacy and Fight the Fakes combined meeting

A week of educational lecture and presentations on falsified medicines, presentations and filming

ASOP EU was heavily involved in the first “Fight The Fakes Week” and used its members and connections to contribute to important parts of the agenda. A session chaired by Professor Gino Martini - chief scientist of the Royal Pharmaceutical Society entitled “Internet & Illegal Pharmacies” coupled with a session on “Pharma Industry Response to Falsified Medicines” tackled the issues around the rising tide of falsified medicines. Geoffroy Bessaud spoke about the many activities that Sanofi undertakes to combat falsified medicines. Professor Martini gave a detailed account to the students present on how the implementation of the Falsified Medicines Directive will beneficially impact the pharmaceutical supply chain. Mike Isles spoke about the various activities to raise awareness which he believed to be paramount in tackling the demand side. He also said that the increased knowledge and curricula coverage amongst pharmacy schools will be an important strategic goal stretching in to the future and congratulated the collaborative efforts of the UCL School of Pharmacy and the Fight the Fakes teams to help bring this about.



Professor Gino Martini - Royal Pharmaceutical Society, Geoffroy Beasaud - Sanofi, Dr Oksana Pyzik - UCL School of Pharmacy, Mike Isles - ASOP EU



Dr Oksana Pyzik - UCL School of Pharmacy, with her pharmacy students

EAASM contributes to the BD patient safety medication conference – Milan

Following on from the highly successful EU Parliament meeting of February 19 2019 entitled EU Parliament round table “Improving patient safety with the FMD in the hospital arena” (see page 9 newsletter), Becton Dickinson (BD) staged a full day of presentations by hospital pharmacists who had increased quality, efficiency and above all patient safety with the use of automation robotics within the various hospital pharmacy settings. Mike Isles spoke about the outputs from the EU roundtable which included an analysis of how robotics can reduce hospital implementation costs of the FMD whilst conferring significant medication safety improvements. The issue of fake pharmacy websites was also highlighted and how a multi-stakeholder



Dr. Valerie Pelletier-Pharmacist-Rouen University Hospital-France, Dr. Ana Herranz-Alonso-Pharmacist-University Hospital Gregorio Marañón-Madrid-Spain, Thomas Utech-VP-Strategic Innovation-BD, Kirsten Kolligs-CEO-Helios Hospital-Schwelm-Germany, Prof. Pascal Bonnabry-DOP-Geneva University Hospitals-Switzerland and Chair of meeting

approach is needed to combat the issue and that raising awareness amongst healthcare workers about falsified medicines in the hospital arena is vital.

ASOP EU joins “Forum Unique Codes” and The Internet of Things (IOT) into the world of uniquely identifying single item products

A further development that could enable even greater protection for medicines was revealed at the [3rd Forum Unique Codes](#) organized by SECURIKETT on 23 May 2019 at the Innovation & Conference Center Packworld, in Oberwaltersdorf, Austria. The programme with international speakers brought together over 70 delegates from 14 countries. SECURIKETT are long standing Members and supporters of both ASOP EU and the EAASM. The conference focused on digitization in product and brand protection and the innovative new approach utilising the entry of IoT into the world of single item products.

The Internet of Things, does not only take place in the field of electronic products. With the help of unique codes, i.e. unique letter and number combinations, it is possible to identify products at item level. This enables digital communication with the products.

In addition to proof of originality and the benefit of

direct communication/engagement with consumers, traceability throughout the distribution chain is a major concern for many companies. Data security and a secure storage environment were another focus of the conference. Securikett Managing Director Dr. Marietta Ulrich-Horn, and the project manager of ISO 22381, presented the principles of the ISO standards referring to product ID systems. She stated “...implementation, interoperability of several systems is critical, especially in the public sector – such as pharmaceutical products – and requires international robust guidelines.”

The conference highlighted the importance, security and benefits of unique codes and how they can be applied to a product without the possibility of duplication and thus transfer to another product. At the end of the conference, participants had the chance to take a factory tour into the production area at Securikett headquarters.

Upcoming Meetings

1

**USP-APEC Center of Excellence:
“Minimizing Quality Risks in the Upstream
and Downstream Supply Chain – A
Regulator Dialogue & Training”**

“ASOP Global was tasked with facilitating and leading the dialogue on downstream supply chain implications and the impact of illegal online pharmacies for international health regulators.”

Santiago, Chile 11-13 June 2019

2

**International Forum on IP Enforcement
12-13 June 2019
Paris, France**



3

**Pharmaceutical Anti-Counterfeiting Forum
18-20 June 2019**

**Crowne Plaza Zurich, Zurich, Switzerland
ASOP EU have supporter status for this event**



Your contacts at ASOP EU and EAASM

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