EAASM Chair’s welcome
Within the context of COVID-19 patient safety must be uppermost in our minds.

ASOP EU Director’s welcome
COVID-19 is an opportunity to make the Internet a safer place.

ASOP EU in Latin America
ASOP EU contributes to Latin America training session on medicines and the Internet.

When medication errors need traceability solutions
The EAASM has been working on a major project to raise awareness amongst policy makers and health institutions about the patient harm caused by medication errors.

Falsified Medicines Directive
EAASM plans a follow up EU Parliament meeting on the FMD in hospitals.

ASOP EU invited to comment on new EUIPO/OECD report
ASOP EU travelled to the OECD HQ in Paris to join a group of experts to comment on the draft of what is now a published report “Trade in Counterfeit Pharmaceutical Products”.

ASOP EU goes live on Instagram Indonesia
ASOP EU is interviewed live by the Youth Internet Governace Forum (YIGF) young Ambassador of Indonesia.

ASOP EU joins EUIPO Observatory Expert Group
ASOP EU inputs to the Expert Working Group “Cooperation with Intermediaries”.

Nanomedicines
Ensuring patient safety through regulatory clarity.

Live webinar with OECD
ASOP EU intervention as part of the OECD webinar on COVID-19 entitled “Illicit Trade at the time of crisis: current challenges and long-term impacts”.

Diary of events
June 2019 to April 2020.
We can reflect very favourably on the work of the EAASM since our last Newsletter. We hope that you like the new design and the addition of a contents page will help you to navigate to articles that are of interest.

We trust that you are all keeping safe in these very challenging times. Falsified medicines and other fake offerings that we are seeing more and more of do at least offer the opportunity to throw a focused light on such criminal activity; let us all hope that there is a sliver lining and that we come out of this period with new knowledge and actions that will benefit patient safety. We are beginning to contribute to this debate and to raise awareness about vendors selling fake coronavirus cures on the Internet. The Falsified Medicines Directive and the obligation of websites selling medicines to display a Common Logo on each page will help.

However, with a largely unwitting public whose fears and concerns are being stoked by these criminals, we need a multi-stakeholder approach and to urge all Member States to address this developing phenomenon that is adversely affecting patients across Europe and the globe.

This newsletter covers in particular two new and very important patient safety projects. First, an initiative to look closely at the issue of medication errors and how traceability, if enhanced, can dramatically reduce error rates.

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Our second major new project concerns the rapidly developing field of nanomedicines which requires regulatory reform to ensure patient safety and to realise the establishment of new treatment opportunities across Europe.

The EAASM will do all it can to catalyse these much needed reforms. There are also other issues tackled in this newsletter and we hope to have published a scientific paper on compounding practices in hospitals shortly.

“Our second major new project concerns the rapidly developing field of nanomedicines which requires regulatory reform to ensure patient safety”

I trust that you will remain safe as we go through this critical period and wish you and your families a healthy period ahead.

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that different parts of the world are at different stages of capability to combat falsified medicines online.

It is clear though that governments are becoming much more aware of the deleterious consequences to public health that this causes.

The report recently published by EUIPO/OECD entitled “Trade in Counterfeit Pharmaceutical Products”, where ASOP EU was invited amongst a select group of experts to critically analyse and contribute to the final version, is a clear recognition of the good work and standing of ASOP EU. Similarly their input into the EUIPO Observatory expert group “Cooperation with Intermediaries” is worthy of mention and is written up in this newsletter.

Since becoming a Director of ASOP EU, we have had conversations with Mike Isles and Laura Cigolot pertaining to the issues in hand and have offered advice from time to time.

I noted with particular interest the involvement of ASOP EU with the USP-APEC Centre of Excellence “Minimizing Quality Risks in the Upstream and Downstream Supply Chain” which brought together regulators from across Latin America to Santiago, Chile.

Two of the three days were given over to education about falsified medicines and the Internet. These initiatives can only help to spread the word and we should remember

“The letter to VP Mike Pence at the White House is backed by 43 companies and is a must read.”

The current COVID-19 pandemic is truly alarming and ASOP EU is playing its part in raising awareness about fake medicines and other illicit offerings. The recent intervention at the live webinar held by the OECD lays out two practical solutions. Based on the good work of ASOP Global, it signposts clearly the way forward and the letter to VP Mike Pence at the White House is backed by 43 companies and is a must read. In addition the recent live interview on the Instagram platform with the Indonesian YOUTH IGF Ambassador movement is to be commended and underlines the global nature of what we are facing. It is also encouraging to note that ASOP has secured funding to enable 10 Youth IGF Ambassadors to hold local events to educate their followers about fake medicines on the Internet.

Finally, my personal wishes to you and your families to stay safe and healthy during this critical time.
ASOP EU contributes to Latin America training session on medicines and the Internet

ASOP Global and ASOP EU participated in a three-day conference with USP (United States Pharmacopeia) and the APEC (Asia Pacific Economic Cooperation) on “Minimizing Quality Risks in the Upstream and Downstream Supply Chain” Conference at the Center of Excellence. This conference brought together regulators from across the continent and was held in Santiago, Chile from 11-13 June 2020.

Libby Baney, Senior Advisor to ASOP Global, delivered a keynote speech on Global Internet Pharmacy Best Practices and facilitated a panel on Opportunities for Collaboration and Implementation of Best Practices. ASOP EU Executive Director Mike Isles provided a European perspective at the international session and ASOP Director Matt Rubin led a plenary session discussion. Lynda Scammell, senior law enforcer at the UK’s MHRA also contributed her knowledge and practical experiences on the topic of falsified medicines. The full agenda can be seen here.
"All medication errors are potentially preventable. They can be reduced or avoided by improving systems and practices in medication, including purchasing, prescribing, preparation, dispensing, administration and monitoring."

WHO 2017

The EAASM has been working on a major project to raise awareness amongst policy makers and health institutions about the patient harm caused by medication errors. The patient safety project is called “The European Collaborative Action on Medication Errors and Traceability”.

The European Medication Error and Traceability project (ECAMET) is now well under way. In some countries approximately 6-7% of hospital admissions appear to be medication related, with over two-thirds of these considered avoidable. These statistics are truly alarming and so the EAASM feels it has a responsibility to address this patient safety issue.

Such errors can lead to no harm, may be minor or range to major errors which can result in morbidity, mortality and poor quality of life for the patient. In turn, these may have significant health and economic consequences, including the increased use of health services, preventable medication-related hospital admissions and death.

The EAASM is currently establishing an Alliance and a Scientific Committee to drive this initiative forward.
The project has the overall objective to reduce medication errors and promote, at European and national levels, the implementation of comprehensive electronic traceability systems in acute care settings, thus enhancing patient safety and quality of healthcare.

Create awareness of the importance of medication patient safety in the hospital environment.

Call on European institutions and Member States’ authorities to promote regulations and guidelines on medication traceability to prevent medication errors.

Promote medication traceability in European Member States with a focus on acute care settings as the most efficient way to prevent medication errors.

The EAASM has been requesting European Scientific and Patients’ organisations to be part of the ECAMET project. The following associations have positively welcomed and endorsed the ECAMET project:

- UEHP - European Union of Private Hospitals
- EHMA - European Health Management Association
- ESNO - European Specialist Nurses Organisation
- ESOP - European Society of Oncology Pharmacists
- SEFH - Spanish Society of Hospital Pharmacists
- ESICM - European Society of Intensive Care Medicine
- EUPSF - European Patient Safety Foundation
- FEP - Spanish Patients’ Forum
- HFE - Health First Europe
- Melanoma Patient Network Europe
- ISMP - Institute for Safe Medication Practices and ECO - Fundación ECO para la Excelencia y Calidad de la Oncología

The EAASM is in the process of creating a Scientific Committee (SC) to oversee the project and ensure that each step is scrutinised to optimise the outcomes.

It is envisaged that the Scientific Committee would comprise:

1. A clinical oncologist
2. A hospital pharmacist
3. An oncology pharmacist
4. A clinical intensive care specialist for adults
5. A clinical intensive care specialist for paediatrics
6. Patient safety representatives
7. A specialist nurse
8. A private hospital representative
9. The EAASM Executive Director
10. A medication safety expert
Managed by an independent European market research company, the SC will be asked to guide and develop a comprehensive Pan-European survey among clinicians.

The survey will include questions about the size of the problem of medication errors, the level of awareness and education and the existing traceability systems in place in acute care settings. The survey will be delivered to the following groups of clinical experts: oncologists, pharmacists and intensive care specialists and nurses.

From the important research findings this will enable:

Creation of a White Paper
The Pan-European survey will act as the foundation for a White Paper which highlights the issues surrounding medication errors across several EU countries and puts forward solutions and opportunities for the future to prevent them.

Creation of a Joint Call to Action
Creation of a Joint Call to Action calling upon health authorities, policymakers, healthcare professionals and patients to join hands to prevent unnecessary harm in hospital settings by promoting medication traceability and innovative quality standards for patient safety across Europe.

Advocacy work
At institutional level (Europe and country state members), including bilateral meetings with relevant policymakers of the European Parliament and European Commission to build momentum and gather consensus, along with an awareness-raising campaign at European level. Advocacy work will include:

a. A round table meeting in the EU Parliament to launch the White Paper and a Joint Call to Action.
b. Dissemination of the Joint Call to Action at country level through round tables and awareness campaigns.

**PROJECT’S TIMELINE**

Summer 2019/Spring 2020: Mapping and creation of the ECAMET Alliance
Spring 2020/Summer 2020: Creation of the Scientific Committee and kick off meeting
Autumn 2020/Winter 2020: Pan-European survey
Winter 2020/Spring 2021: White paper and Joint Call to Action on Medication Errors and Traceability
Spring 2021: Awareness campaign and evidence building
Autumn 2021: Parliament meeting and advocacy work at institutional level
Winter 2021: Dissemination of the Joint Call to Action at national level
2022: Dissemination of best practices in Europe

The EAASM is looking for further support from patient safety organisations and other institutions so please do contact us if you would like to endorse the project. Please contact Mike Isles (mike.isles@eaasm.eu).
From 9 February 2019, every prescription pack in all 28 Member States was legally obliged to be uniquely serialised by way of a data matrix bar code and to have a tamper-evident device attached to where the pack is opened.

The EAASM supported this by holding a EU Parliament meeting entitled “The Falsified Medicines Directive (FMD) – implementing Practical Solutions in the Hospital Arena”. A follow up meeting was planned for 18 March 2020 which has now had to be postponed until this Autumn due to the COVID-19 pandemic.

The draft agenda follows; please do consider joining this important meeting when the new date and invitation is set.

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**Event Programme**

**Patient safety and the implementation of the Falsified Medicines Directive in the hospital environment - one year on**

18 MARCH 2020, from 14.30 to 16.30

EU Parliament Brussels, Room: A3H1

Hosted by MEP Manuel Pizarro (S&D, PT)

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14.30 – 14.40

- Welcoming remarks
  - MEP Manuel Pizarro (S&D, PT)

14.40 – 14.45

- Introduction and how the FMD will help patient safety
  - Mike Isles, European Alliance for Access to Safe Medicines

14.45 – 15.25

- Status of implementation of the FMD
  - Andreas Walter, European Medicines Verification Organisation
  - Andrea Sule, European Association of Hospital Pharmacists
  - Isabel Holmquist, Unit B4 DG SANTE, European Commission

15.25 – 15.55

- Practical solutions to a successful implementation of the safety features and future developments
  - Julie Appleby, East and North Hertfordshire NHS Trust, UK
  - Valérie Pelletier, CHU-Hôpitaux de Rouen - Pôle Pharmacie, France
  - Grant Courtney, Be4ward on behalf of EFPIA

15.50 – 16.30

- Debate and conclusion
  - MEP Manuel Pizarro (S&D, PT)
  - Mike Isles, European Alliance for Access to Safe Medicines & all
In 2019 the Observatory formed a series of new Expert Groups (EG). ASOP EU was put forward to contribute to the Expert Working Group “Cooperation with Intermediaries.” This EG was sub-divided in 4 areas: Payers, Online Platforms, Social Media and Domain Names. ASOP EU joined the Domain Names group. A series of draft scoping documents for all four areas is being created. Current concrete suggestions include classification and research into “good practices” and to scope out the domain name registration cycle and determine proactive and reactive measures. Similarly, discussions around the roles and responsibilities of registries and registrars depending on their jurisdiction are also under discussion.

ASOP EU has also suggested the creation of an expert group to look into search engine good practices and this may follow in the near future.

In December 2019 ASOP EU travelled to the OECD HQ in Paris to join a group of experts to comment on the draft of what is now a published report "Illicit Trade in Counterfeit Pharmaceutical Products." According to the report, the value of falsified medicines is an astonishing USD 4.4 billion worldwide.

The impact of the global illicit drug trade on national health systems is considerable and incidents of patient harm are well recorded. The harm to individuals is covered comprehensively and reveals the high mortality rate due to falsified antibiotics and anti-malarials to name but two therapeutic areas. ASOP EU followed up with a press release “Many silver bullets needed to cure the Internet of falsified medicines and fake Covid-19 treatments.” Mike Isles of ASOP EU commented:

“There is no one silver bullet so it requires many silver bullets and coordination amongst a myriad of public and private sector partners. And with an estimated 130 million people potentially buying medicines across Europe, urgent action is needed. This is especially important as we see false and predatory promises and misguided advertisements around potential treatments or “cures” for COVID-19.”

The video intervention that Mike made can be viewed here.

The experts which included ASOP EU, who contributed to the report, were officially acknowledged and thanked in the report.

Image: Morgane Gaudiau (Economist, OECD), Florence Mouradian (Economist, OECD), Peter Avery (Senior Consultant, OECD), Michal Kazimierczak (Economist, EUIPO), Cecilia Fant (PSI), Piotr Stryszowski (Senior Economist, OECD), Michael Morantz (Policy Analyst, FATF), and Mike Isles (ASOP EU).
In 2019, ASOP EU signed an MOU with the Youth Internet Governance Forum (YIGF) to support the education of the young about issues of falsified medicines on the Internet. In 2020, we obtained a educational grant from Ipsen, Sanofi and Servier to enable 10 country Youth IGF Ambassadors to hold local meetings and to use their social media reach to spread the word.

Recent examples of this were two live interviews by the Indonesian Ambassador Agita Pasaribu which took place on consecutive Saturdays in April. The first was an interview with Dr Olga Staroseltseva, a dynamic young Russian doctor talking about all aspects of the COVID-19 outbreak and the second was with Mike Isles who talked about the Internet and the fact that 95% of websites are selling medicines unlawfully and that other platforms are also hosting criminal activities to enable falsified medicines to be sold illicitly. In addition, Mike stressed that there is at present no cure available so there is little point going on the Internet to try to purchase a “cure” anyway.
EAASM COLLABORATION WITH THE EUROPEAN PARKINSON’S ASSOCIATION

The EPDA has been a long standing supporter of the EAASM and ASOP EU. We recently updated information on their website about falsified medicines. In addition, Mike was recently interviewed by an independent reporter and the results of that were published here.

NANOMEDICINES: ENSURING PATIENT SAFETY THROUGH REGULATORY CLARITY

Science and technology have never moved as fast as today. With personalised medicines and the advent of gene therapy, the standard rule book is clearly coming under pressure. It would appear that the same is true of the understanding and definitions behind the technology of nanomedicines.

Modern nanotechnology is focused on developing nanoparticles (NPs) for prophylactic, diagnostic, and therapeutic applications. Nanomedicines offer potential solutions for a number of the current treatment challenges such as:

- Neurodegenerative diseases
- Cancer
- Cardiovascular diseases

Nanomedicines and their follow-on products, also referred to as nanosimilars, are complex molecules and so regulatory oversight must be scientifically fit for
purpose. It is important to note that a survey carried out in 2018 reported “…strong regional differences in the regulation of nanomedicines and confirmed the need for a harmonisation of information requirements on nano-specific properties”. Therefore, experts believe that the level of data for market authorisation is not sufficient or consistent across EU countries.

In addition, protocols used in clinical trials are not of a level of detail to allow a full and consistent interpretation of clinical trial results and outcomes. Even with existing licensed nanosimilars, there is a question mark over the capability of the regulatory framework to adequately assess copies once the patent of the originator medicine has expired. There is evidence that such “follow-on” copy products do not deliver the same efficacy and safety. Clearly this was an issue that needed to be taken up by a patient safety organisation such as the EAASM. We believe that it is the right time to set the scene for building a consensus so that this regulatory weakness can be addressed and thus provide the highest quality medicines with safety, efficacy and quality attributes.

“…strong regional differences in the regulation of nanomedicines and confirmed the need for a harmonisation of information requirements on nano-specific properties”

This not only applies to existing medicines but the plethora of new medicines that are in the pipeline.

To spearhead this patient safety initiative, the EAASM is now drafting a comprehensive report which is under scrutiny by experts in the field of nanomedicines. In addition, the EAASM has produced a summary booklet to enable MEPs, institutions and interested parties to quickly understand the issues behind these new and exciting molecules.
On April 23rd 2020 the Organisation for Economic Cooperation and Development Task force on countering illicit Trade (OECD TF-CIT) invited ASOP EU to provide a 10 minute intervention as part of their webinar entitled “Illicit Trade at the time of crisis: current challenges and long-term impacts.”

The rising tide of illicit trade via the Internet formed an important part of the debate. The ASOP EU intervention outlined clearly two specific and achievable solutions which, if implemented, would drastically improve the governance of trade transacted over the Internet and thus drastically reduce criminal activity. These solutions are based on the good work that is being carried out by ASOP Global which is being highly influential in campaigning for change within Congress as well as writing to the VP Mike Pence with the clear message that issues relating to systemic, structural Internet policy problems that enable COVID-19 scams need to be urgently addressed.

Solution number 2 – Access to and the acquisition of domain names. Specifically, these internet intermediaries are registries and the registrars who must now completely and comprehensively uphold DOMAIN INDUSTRY ACCOUNTABILITY. Efforts should be proactive and responsive to pervasive threats to user health and safety, not just for COVID-19 related frauds but the variety of other threats that are present online. This means that:

- Domain name registries and registrars (R/R) must act to stop online COVID-19 scams, and sales of illicit opioids and of counterfeit or unapproved prescription drugs.
- R/Rs have the power to stop massive amounts of public health harms and fraud online.
- R/Rs should immediately, upon notice from a credible party, lock and suspend any domain name that is used to facilitate the COVID-19 scams and the illegal online sales of medicines and illicit drugs.

Following the Intervention, the European Fraud Office, which is part of the European Commission, contacted ASOP EU as did DG Trade and discussions are under way for greater cooperation.

In addition, the Intervention will be developed into a policy document that ASOP EU will take to the EU Institutions to campaign for change.
11-13 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.


18-19 Speaker at Pharmaceutical Anti-Counterfeiting Forum.

Planning begins to establish a new alliance of experts to drive forward a medication error and traceability project (ECAMET) to enhance patient safety in the hospital environment. EAASM submits position on EMA consultation on future nanomedicines licensing requirements.

03 Planning meeting on Youth IGF Movement activities - Paris

04 Meeting with European Cancer Coalition Organisation (ECCO) to discuss medication safety and traceability project.

05 First meeting with POINTER a leading-edge digital company which identifies and investigates suspicious websites actors on the Internet – Amsterdam.

17 NABP Pharmacy Executive Board Members’ meeting to discuss progress to date and future plans for the top level domain name initiative .pharmacy.

26 Faculty-led Study Abroad training event - Spring 2020. Planning meeting with Professor John Hertig, PharmD. MS, CPPS for training visit by pharmacy students. Entitled “Healthcare Delivery in the UK: Lessons From the Past, Preparing Pharmacy for the Future” to be attended by students from the Butler University College of Pharmacy and Health Sciences.
Meeting with Chief Pharmacist, Pharmacy Department University Hospital of Heidelberg to discuss ECAMET patient safety project.

11-12 ASOP Global All Hands Strategy meeting Washington DC.
12 Meeting with Spanish Hospital Pharmacy Organisation Madrid to discuss ECAMET patient safety project.

Conference call with global major pharmacy chain about .pharmacy programme.
25-26 Attendance at EUIPO/Observatory meeting Alicante.

Meeting with MEP Manuel Pizarro.

Meeting with Malvika Vyas, Head of policy European Society for Medical Oncology (ESMO).

Pharmacy Executive Board Meeting to discuss progress and plans for .pharmacy top level domain name patient safety initiative.
15 Meeting with Manuel Ibarra Lorente Head of Department Pharmaceutical Inspection and Enforcement Department Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Spain.
**FEB 2020**

16 Meeting with the Spanish patients’ organisation - Gabinete del Consejero de Sanidad, la Subdirectora General de Farmacia Madrid.

16 Meeting with new President of the Spanish Hospital Pharmacy Association Madrid.

10 EUIPO Observatory Civil Society teleconference to discuss agenda items for upcoming EUIPO/Observatory meetings in Brussels.

14 Interview for article to be placed in the European Parkinson’s Disease Association (EPDA).

19 Meeting with MEP Joveva’s Assistant and with MEP Margrete Auken to discuss patient safety projects. Discussion with Isabel Holmquist, Policy Officer dealing with quality, safety and innovation of medicinal products - DG for Health and Food Safety at the European Commission.

**MAY NEWSLETTER 2020**

21 Attendance at launch of parallel trade organisation new name “Affordable Medicines for Europe” and the release of a new report.

22 Initial discussions with European Society of Oncology Pharmacy (ESOP) for the ECAMET patient safety project. Initial discussion with the European Liver Patients Association (ELPA) and the European Hematology Association (EHA) on a patient safety nanomedicines’ project to build a more robust regulatory framework.

27 Meetings with potential partners to support the worldwide Youth Internet Forum Group to formulate 2020 plans.

30 ASOP Global quarterly meeting.

**MAR 2020**

4 Speaker at the 8th Annual Pharma Anti-Counterfeiting & Serialisation 2019 London.

11 ASOP EU goes live on Instagram in Indonesia.

23 ASOP EU provides an intervention at OECD TF-CIT live webinar.

28 EAASM Board meeting.

**APRIL 2020**

20 Attendance at the European Specialist Nurses Organisation - Brussels.

20 Meeting with Olivier Bringer of DG CONNECT to discuss issues relating to registry good practices.

24-26 EUIPO/Observatory meetings Brussels – postponed.