NEWSLETTER

SUMMER 2023

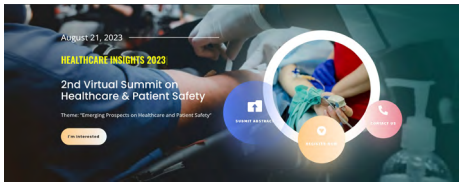
17 September

World Health Organization

World Patient Safety Day 17 September 2023

World Health Organization
World Patient Safety Day

21 August



2nd Virtual Summit on Healthcare & Patient Safety
Emerging Prospects on Healthcare and Patient Safety

2-3 October

ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES

ASOP All Hands Meeting
Washington DC and Virtual

European Alliance for
Access to Safe Medicines

ASOP EU
Alliance for Safe Online Pharmacy

SUMMER 2023 CONTENTS

European Alliance for
Access to Safe Medicines

ASOP EU
Alliance for Safe Online Pharmacy

MIKE ISLES - CHAIR OF EAASM

At the recently held EAASM Board meeting, it was my pleasure to run through the many achievements of the past year. Of particular note was the ECAMET Alliance (European Collaborative Action on Medication Errors and Traceability) project which was comprehensively covered in the last newsletter. Since then we have been working closely alongside the European Health Management Association and indeed our White Paper was quoted in their Call to Action to help ensure this topic is kept 'top of mind'.

We are planning to join the e-health network group which should give us a place at the table to further champion digitalisation and get a better understanding of how the EU Institutions plan to address the patient safety issues of medication errors. A recent statistic that was quoted brought this patient issue into stark contrast. Based on published work, 1 in 5 hospitalised patients suffer a medication error. And the WHO statistic of one death per million people is something that needs addressing urgently. In that regard, we contributed to last year's patient safety day, the topic of which was medication safety; this was highly successful in highlighting the subject.

"Moving on to the nanomedicines and nanosimilars, we enabled two significant amendments to be tabled by the EU Parliament which called for all nanomedicines or nanosimilars to be authorised via the centralised EMA body. Whilst the new legislation does not specifically mention nanomedicines/ nanosimilars, the new regulation states that all new innovative medicines now have to go through the centralised process.

In addition, the "hybrid" (10.3 regulatory pathway) must now be assessed centrally. So this will, to a large extent, include follow-on versions of complex drugs like nanomedicines. This will mean that clinical data on top of other data proving similarity will be required. Indeed we know of instances where a product authorisation was re-routed from a generic application to a hybrid one. The Commission has also stated that "*Training opportunities will be provided so that all Member States build expertise in new areas of science and technology, so they can actively contribute to the work of the regulatory network in assessing and monitoring medicinal products, including cutting edge innovative and complex medicinal products.*" This topic is covered further on page 6.

So a positive picture has been forming and we are in regular discussion on this topic with the Commission. With EU Parliament elections happening early in the New Year, we will continue to engage with the institutions.

In the fight against falsified medicines, the new Digital Services Act is welcomed and we shall follow all of its stages of introduction and take opportunities to influence its implementation where we can, e.g. instance the appointment in each Member State of a Digital Services Coordinator whose responsibilities will include the appointment of Trusted Flaggers. This is covered in more detail on page 7.

WHITE PAPER
Call to Action developed by
the ECAMET Alliance on

The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm

Read white paper

WALTER HESS, NEW CO-DIRECTOR OF ASOP EU SUMMARISES THE E-PHARMACY PATIENT SAFETY INITIATIVES

As I step into this role, I would like to take the opportunity to thank the out-going Director Stefan Feltens, a colleague who also holds the values and objectives of ASOP EU as a positive force in the fight against falsified medicines. Having reviewed the work of ASOP EU, it is clear that this patient safety organisation is an essential part of solving this rising problem.

"In particular the work that ASOP EU carries out to make the internet a safer place for patients to buy medicines online is to be commended. From EHDS to the EU Common Logo, the DSA and the principle of KYBC, we are working tirelessly to future-proof patient-centric legislation, and we will continue to do so.

Together with the European Association of E-Pharmacies (EAEP), ASOP EU has worked in the past months to ensure that EU legislation on the sharing of health data promoted a level playing field for healthcare providers, leaving no patients behind. The new European Health Data Space (EHDS) will fundamentally set the governance over the storage and transfer of patient health data, as such it is groundbreaking. However, although the European Commission's proposal rightfully identifies the critical role played by digital health in ensuring patients' access to healthcare, we regret that the latest proposed amendments in the European Parliament and compromise text in the Council of the EU indicate that co-legislators are leaning towards the opposite direction, which will create an uneven playing field between online pharmacies services and the pharmacy community at large. In this context, ASOP EU and EAEP promoted a joint statement on the topic, calling on relevant policymakers to take action.

ASOP EU and the EAEP are also working together on a survey amongst all Member States authorities that have the responsibility to manage the EU Common Logo. We look forward to seeing the outcome as this may well mean an acceleration of public facing campaigns around the scourge of falsified medicines.

I look forward to working with my co-director Mike Isles and a fruitful 2023.

European Health Data Space is groundbreaking but…

"…we regret that the latest proposed amendments in the European Parliament and compromise text in the Council of the EU indicate that co-legislators are leaning towards the opposite direction, which will create an uneven playing field between online pharmacies services and the pharmacy community at large."

SURVEYMONKEY – ARE MEMBER STATES INFORMING THE PUBLIC ABOUT FALSIFIED MEDICINES AND THE COMMON LOGO?

The survey aims to answer this question. ASOP EU and the EAEP are working collaboratively to make this happen. Both have been working hard to re-establish contacts in the various Member States' authorities charged with managing the registration of pharmacies that wish to sell medicines online.

Within the Falsified Medicines Directive under Article 85d there is a section relating to the legal obligation by Member States and the DG Health and Food Safety of the European Commission to inform the public about the purpose of the Common Logo and the dangers relating to falsified medicines:

Article 85D states…

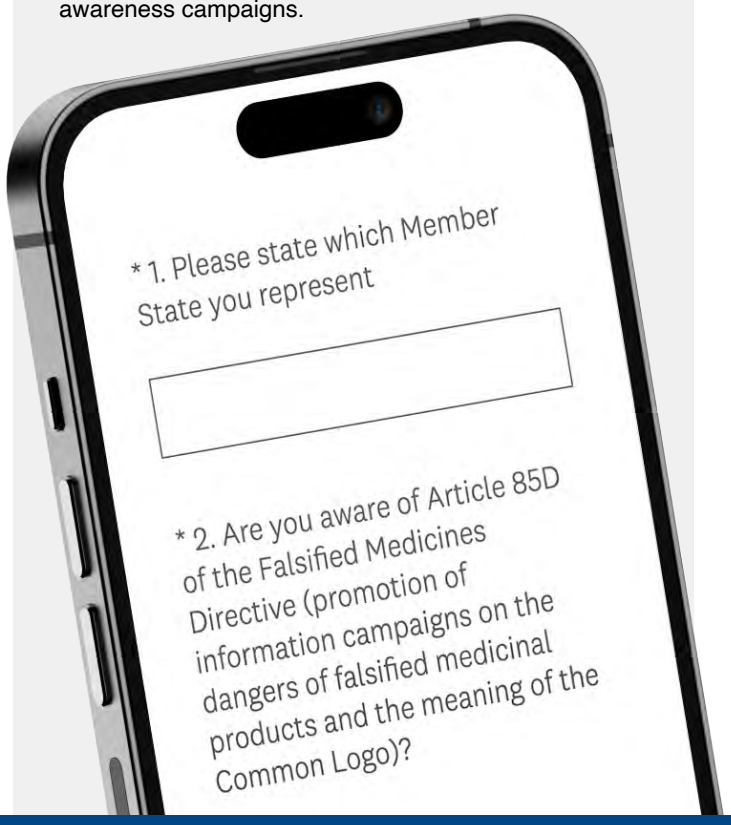
"Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.

The plan is then to follow up with Member States' authorities to arrange a sharing best practice webinar.

Introductory text to the survey...

As a non-profit patient safety organisation committed to enable patients and consumers to buy their medicines safely online, the Alliance for Safe Online Pharmacy (ASOP) in the EU wishes to share best practices and cooperate with EU Member States regarding the EU Common Logo for the online sale of medicines. By contacting those who are responsible for the administration and good governance of the Common Logo which is described in the Falsified Medicines Directive under Article 85D and in light of the revision of EU Pharmaceutical legislation, it will help all Member States in their patient safety endeavours. By completing this survey, you will be sharing your country's initiative to help raise awareness of the issue of falsified medicines which is a growing online threat due to websites that are selling falsified, substandard, or unlicensed medicines to a largely unwitting public. The information from the survey can be used to foster cooperation between Member States and so enhance already proven communication platforms, be they via social media or website campaigns.

ASOP EU has supported the above patient safety initiative in the past and you will find here a previous report which usefully lists Member States public facing awareness campaigns.



THE NEW EU PHARMACEUTICAL LEGISLATION – WILL IT PROVIDE PATIENTS WITH SAFE NANOSIMILARS?

You will recall that there was a willingness by a number of MEPs to endorse the principle that Non Biological Complex Drugs (which a nanomedicine is) need exacting marketing authorisation criteria above and beyond that of a simple generic pathway, to ensure the safety, efficacy and quality of the product. This is because a nanosimilar medicine will only ever be similar as it is defined by its complex manufacturing process. This is why our campaign has included the essential requirement for clinical data within an application for a product licence.

This endorsement by MEPs was only made possible by the strong advocacy work of the EU Nanomedicines Regulatory Coalition (EUNRC).

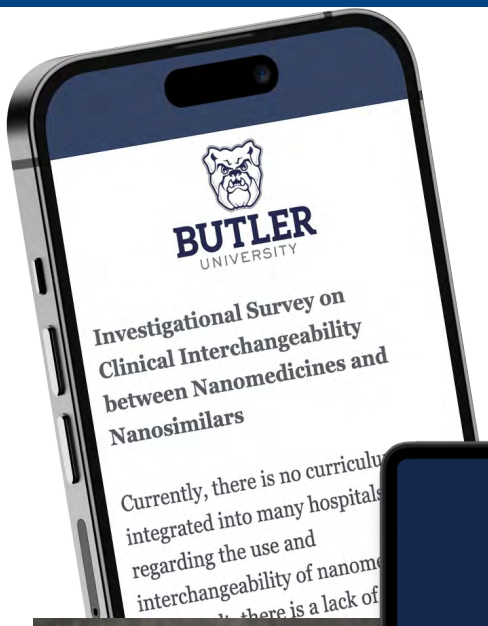
In creating this Parliamentary cooperation two important amendments were achieved in the "Own Initiative Report" (also referred to as the INI report). These amendments are summarised below:

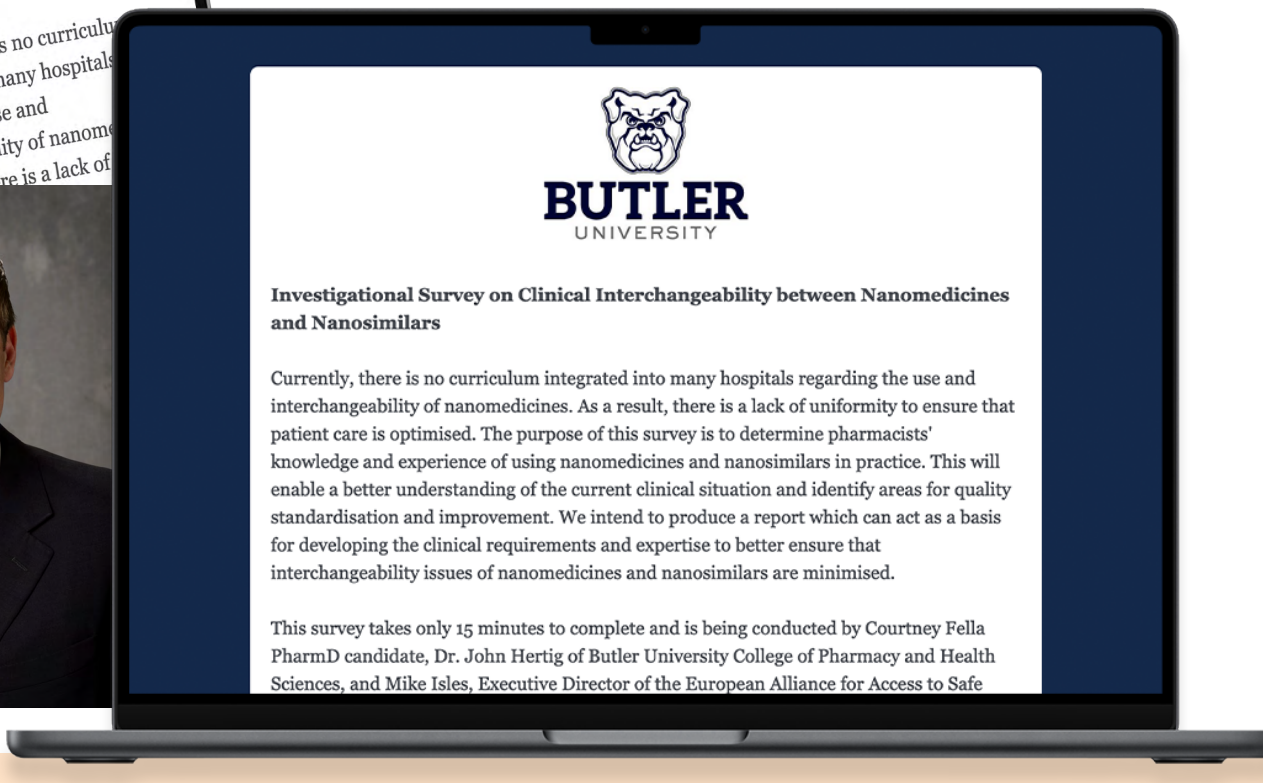
25. "...underlines that state-of-the-art technologies, **such as nanomedicines**, stand to provide solutions to current treatment challenges in areas such as cancer and cardiovascular diseases; **highlights that these innovative fields of medicine should be authorised by the centralised approval framework for nanomedicines**."
101. "...calls on the Commission to **establish a regulatory framework** for nanomedicines and nanosimilar medicines, and calls for these products to be approved through a **compulsory centralised procedure**."

However following further correspondence it is the expert view of Jon de Vlieger, who works at Foundation Lygature, that…

> **"The answer to the question posed in the title is that it should but we are still concerned, as companies wishing to register a follow-on nanosimilar may still have the choice to apply for a Marketing Authorisation via the 10.1 Generic route. However, we have been given assurance by the Commission that our concerns have been taken into account and our DG Sante point of contact acknowledged the need to ensure a harmonised interpretation by national authorities to ensure coherent decisions on whether to examine an application under the generic or the hybrid pathway."**

EAASM IN COLLABORATION WITH THE BUTLER UNIVERSITY OF INDIANAPOLIS ON PATIENT SAFETY NANOMEDICINES PROJECT





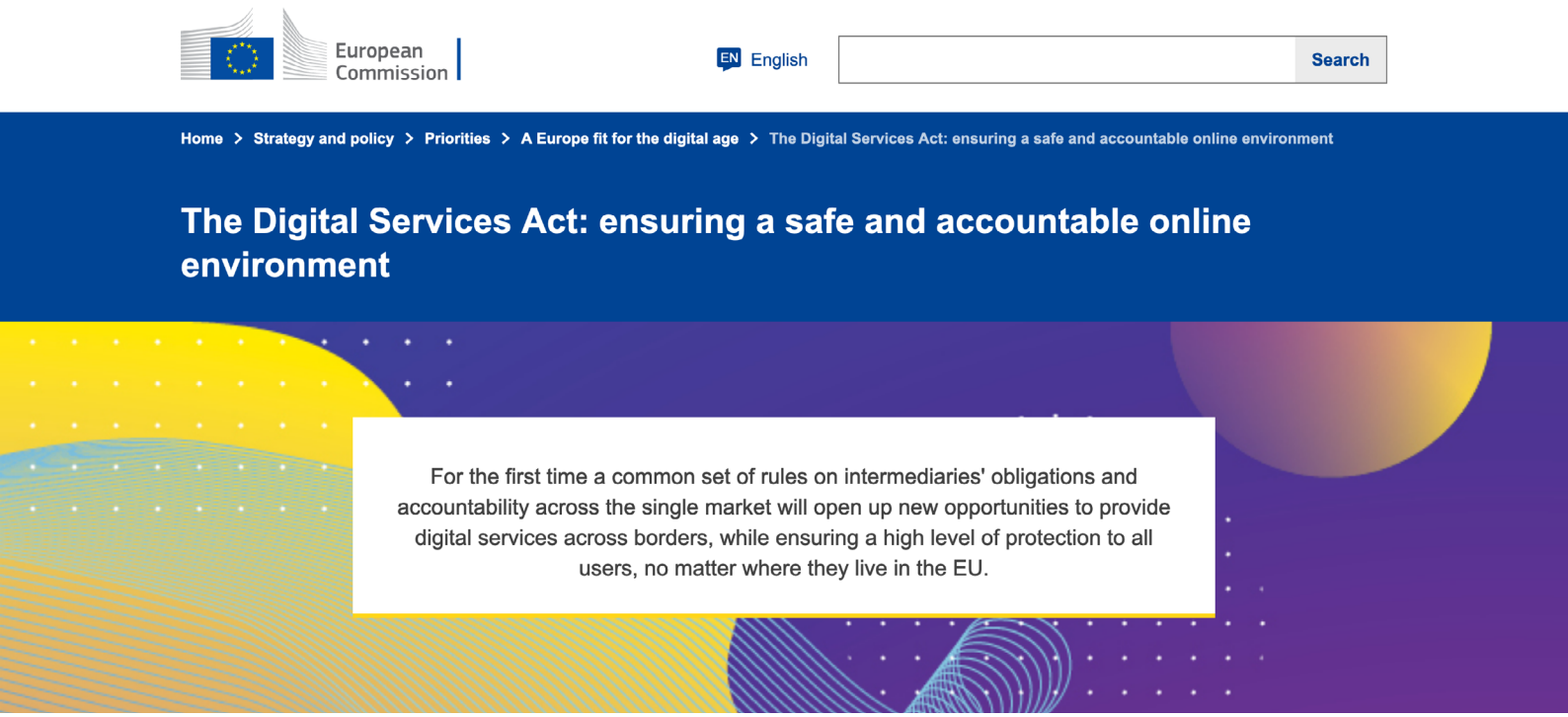
In close collaboration with the Butler University, Indianapolis, USA, the EAASM is the co-sponsor of an Investigational Survey on Clinical Interchangeability between Nanomedicines and Nanosimilars.

Working closely with John Hertig, Associate Professor in the College of Pharmacy and Health Sciences and Courtney Fella, Doctor of Pharmacy 2024/Spanish Major 2022 of Butler University, through the EAASM EU contacts, the plan is to conduct the survey in as many Member States as possible with translations to aid completion.

“Currently, there is no curriculum integrated into many hospitals regarding the use and interchangeability of nanomedicines. As a result, there is a lack of uniformity to ensure that patient care is optimised. The purpose of this survey is to determine pharmacists’ knowledge and experience of using nanomedicines and nanosimilars in practice. This will enable a better understanding of the current clinical situation and identify areas for quality standardisation and improvement. We intend to produce a report which can act as a basis for developing the clinical requirements and expertise to better ensure that interchangeability issues of nanomedicines and nanosimilars are minimised.”

says John Hertig, Associate Professor in the College of Pharmacy and Health Sciences

ASOP EU COLLABORATE WITH EUIPO-OBSERVATORY AND BIG PHARMA TO DISCUSS DIGITAL SERVICES ACT OPPORTUNITIES



On 9th June ASOP EU convened a meeting between EUIPO-Observatory and a number of major pharmaceutical companies. The Observatory constructed a very succinct but extremely useful presentation of the DSA. This was followed up by minutes which helped identify the opportunities for further advocacy.

The opportunities are summarised below.

1

Article 18 – hosting providers should take action (promptly report to authorities) if they are suspicious of information that involves threats to life or safety. **Could this be an opportunity to inform hosting providers of the life-threatening aspects of selling falsified medicines and thus increase their vigilance and pro-activeness?**

2

Article 22 – Trusted flaggers (TFs) – only for medium to very large online platforms. **This is an opportunity to raise awareness amongst the individual Member States' Digital Services Co-ordinators as they will decide who the certified TFs will be. The notifications from these entities to services hosting websites selling medicines illegally, will have to be treated as a matter of priority for such websites to be taken down.**

3

Enforcement of the DSA – The Medicrime Convention is now fully operational again (12 countries within the EU have ratified the Convention). ASOP EU, as an official Observer of the MC Committee of the Parties, has tabled three initiatives for consideration and implementation, namely: **a. gTLD DotPharmacy in different languages b. longitudinal market research and c. alignment with the DSA. The Digital Services Coordinators should also be appraised of this and EFPIA may wish to support the above, especially as the IFPMA is also an official Observer of the MC Committee of the Parties.**

HOW CAN ASOP EU INFLUENCE THE MEDICRIME CONVENTION?

WWW.COE.INT HUMAN RIGHTS DEMOCRACY RULE OF LAW EXPLORE English Connect

COUNCIL OF EUROPE / CONSEIL DE L'EUROPE — COUNCIL OF EUROPE — MEDICRIME Convention

Home | The MEDICRIME Convention | Activities | Resources | Committee of Parties | Projects | COVID-19 | 10th Anniversary

You are here: MEDICRIME Convention > The MEDICRIME Convention

The MEDICRIME Convention

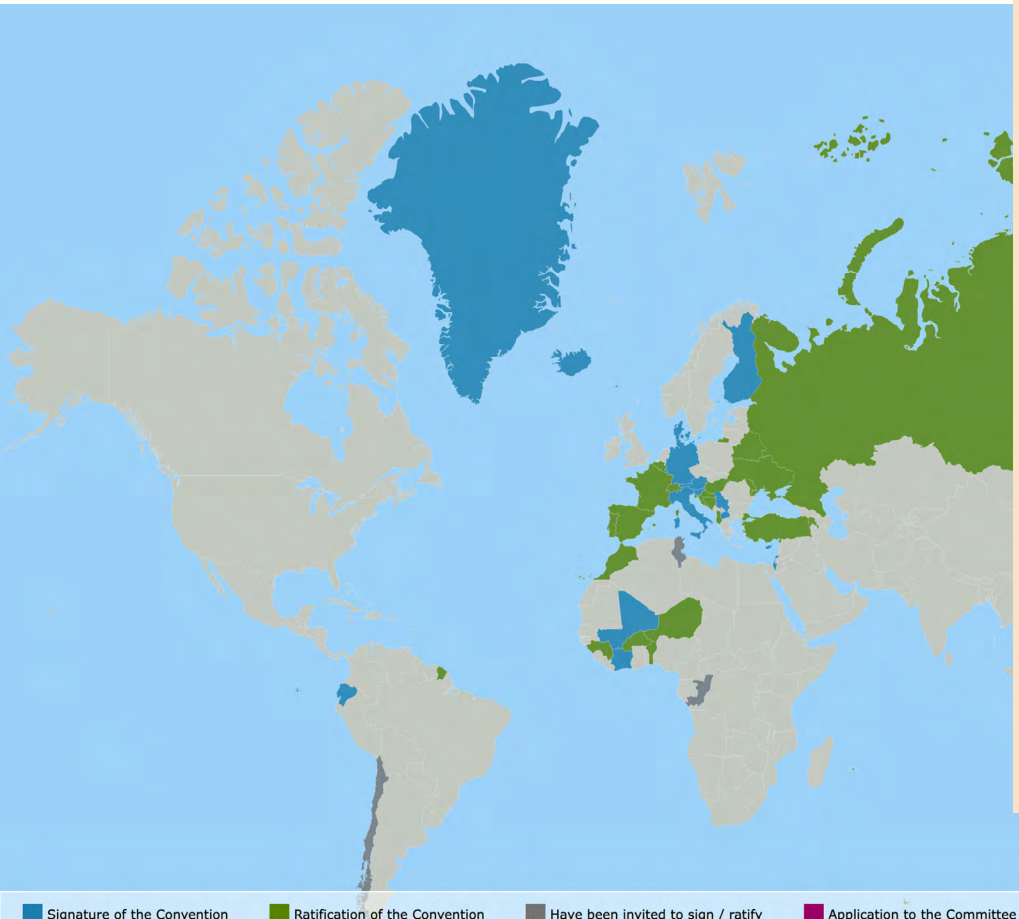
The Council of Europe drafted a convention which constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)

Text of the Convention | Explanatory Report | Unofficial translations

Counterfeiting of medical products and similar crimes
www.coe.int/medicrime

As the Russian Federation was the incumbent Chair when Ukraine was invaded this created a hiatus in the management group (Committee of the Parties) which has taken a year to resolve, as it required article change across all of the Conventions to expel and re-appoint a Chair. This is now completed and the first plenary of 2023 took place on May 10-12 in Strasbourg.

This now means that the Medicrime Convention (MC) is now fully operational. It is important to note that 12 of the 18 countries who have ratified the Convention are within the EU. ASOP EU, as an official Observer of the MC Committee of the Parties, has tabled three initiatives for consideration and implementation by the MC Bureau sub-group, namely:



- ★ The creation of generic top level domain names such as the National Association Of Boards of Pharmacy (NABP) TLD DotPharmacy programme. To be understood, the suffix would need to be translated. So for Germany it would be DotApothek, for France DotFarmacie etc. This would serve as a safe go-to place **that could not be corrupted** (the Common Logo has been used on websites selling medicines illegally)
- ★ Longitudinal market research to track the current awareness levels of knowledge relating to falsified medicines by healthcare providers and the public
- ★ Ensure that any new laws are aligned with the new EU Digital Services Act. A key aspect of the DSA is the appointment by each Member State of a Digital Services Coordinator. Their responsibility would include the appointment of Trusted Flagger organisations which would have the power to fast-track take-downs of rogue websites.

THE ECAMET ALLIANCE - HOW CAN WE RAISE AWARENESS OF THE HARM CAUSED BY MEDICATION ERRORS

ECAMET

European Collaborative Action on Medication Errors and Traceability

Home | Patient Safety | White Papers | Scoping Document | Alliance | Scientific Committee | Publications & Newsroom | Contact | Join Us

It is an undisputed fact that great harm is caused by medication errors (MEs) especially in hospital environments. Reports have shown that 1 in 5 people experience medication related harm during hospitalisation (OECD region, 2022). Extrapolation from Member Sate evidence reveals that there are over 160,000 deaths per year in the EU alone. And the WHO estimates that there is one death daily per 1 million people. One also has to take into account the psychological harm to those healthcare workers involved in an incident often referred to as the "second victim". With national health systems struggling to achieve pre-pandemic standards of service, one might pessimistically assume that MEs will continue to rise.

This is the reason why the ECAMET Alliance was formed and a comprehensive survey was carried out in 13 countries plus the Private hospitals association. This provided the foundation for a strong call to action White Paper that was presented to DG Sante with a view to this patient safety topic being addressed within the new EU institution initiatives.

The ECAMET Alliance report formed part of the evidence of the European Hospital Management Association's White Paper. Both the ECAMET and the EHMA Alliance (EPACT) have been working hard to see where medication errors can be best placed within the new EU instruments that are being developed. We are therefore entering into a period of consultation and will be making further recommendations around traceability systems which have a proven track record of significantly reducing the incidence of medication errors.

> **"The number of people harmed by a medication error exceeds deaths from road traffic accidents. Harm from medication errors has a lasting effect on patients, their families, healthcare professionals and healthcare systems. Opportunity costs from one medication error is estimated to reach €15,000. Medication errors are not unfortunate occupational hazards. Policy makers must seize opportunities to reduce them by investing in digital tools and ensuring leadership training includes modules on how to build cultures of safety in hospital settings.**

HOW ASOP EU AND THE EAASM ARE INFLUENCING OUTCOMES

1

MEDICRIME Convention, Council of Europe

ASOP EU to present to the bureau subgroup of the Medicrime Convention in the Autumn - Committee of the Parties. The topics and recommendations for action will include alignment with the Digital Services Act, the DOTPharmacy verification programme, longitudinal research projects to monitor and measure the anti-counterfeiting activities and to understand the levels of understanding by the public and the healthcare profession.

2

Ensuring the Digital Services Act implementation is as effective as it can be, by raising awareness with the 27 Member State Digital Services Coordinators so they are fully aware of the rising tide of falsified medicines and the harm that it causes to the EU population. This will help influence who and how they will appoint "Trusted Flaggers". These entities will have the power to demand immediate lock and suspend of websites selling medicines illegally. This system works well in the USA with bodies such as the FDA and the National Association of Boards of Pharmacy (NABP).

3

Speaker at 11th Annual Pharma Anti-Counterfeiting & Serialisation 2023 7-8 February London title of presentation Falsified medicines on the Internet – how close are we to achieving real solutions?

4

ASOP EU attended and participated in the event "vox pop". Read the summary here.

5

ASOP EU attending as an International Advisory Committee (IAC) member of HSRI e-pharmacy project International Advisory Committee meeting Monday 6 Feb 2023, 5pm Nairobi/8am CET/2pm UK. The role of the IAC member is: to contribute to the development of the overall research design and the methods to be employed with input into technical issues; to contribute to the broader research and policy landscape elsewhere whilst anticipating any risks to the project; to advise on the study communications strategy to maximise impact on policy and practice. Meetings - every 6 to 9 months by videoconference.

6

Speaking at the Pharma Supply Chain and Security World event, 28-29 March 2023 London, with the title **"How do we make the Internet a safer place to buy medicines – are we any closer to achieving real solutions?"**

7

Nano2Clinic
Cancer Nanomedicine - from the bench to the bedside

Guest speaker at the Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies Zagreb 3 March 2023. Title of talk "The importance of having the right policies and regulations in place to ensure patient safety – the case for nanomedicines."

8

Being a member of the EU Health Coalition and contributing to meetings and "Our Manifesto for a Healthier Europe".

9

Libby Baney of ASOP Global, speaking at the OECD ILLICIT TRADE Levelling the playing field for a resilient economy – OECD HQ Paris 16-17 March 2023.

10

Attending the High Level Group on Internet Governance Hybrid event. OECD/EUIPO reports on anti-counterfeiting which were highlighted as a track record of the good work carried out. High Level group on Internet Governance (HLIG). Next Hybrid webinar scheduled for 29 September 2023.

ASOP EU/EAASM are stakeholders of the High Level group on Internet Governance (HLIG). Agenda. The last event comprised: updates from the European Commission (such as the recently adopted Directive on measures for a high common level of cybersecurity across the Union - "NIS2 Directive" 2022/2555/EU, the Global Digital Compact – EU Contribution, recent and upcoming internet governance events (e.g. Youth IGF activities, a preview on IGF later this year 8-12 October 2023, Kyoto, Japan), a debrief from ICANN76 11-16 March 2023, Cancun Mexico, an update on EuroDIG event 19-21 June 2023, Tampere, Finland and a presentation of the first technical multi-stakeholder Internet shutdown report.

11

Informal Quality of Medicine Meeting - 23rd March 2023 Oxford University hosted by Professor Paul Newton. The topics covered the presentations by ITM, Antwerp, MSF Access, Tübingen University, University College Cork, QUAMED, Radboud University Medical Centre, MQRG. Paul is an infectious disease physician heading the Medicine Quality Research Group in Oxford, that is part of the Infectious Diseases Data Observatory (IDDO) in Oxford and the Mahidol University Oxford University Research Unit (MORU) in Bangkok. The main aims of the group are to improve our understanding of the epidemiology and impact of substandard and falsified (SF) medical products, the evaluation of devices for detecting SF medicines and vaccines in supply chains and development of innovative tools for pharmaceutical forensics.

12

European Commission

European Commission
DG Communications Networks, Content and Technology (CONNECT)

13

EUIPO
EUROPEAN UNION INTELLECTUAL PROPERTY OFFICE

ASOP EU/EAASM are Civil Society members of the EUIPO Observatory and have contributed to the Observatory Expert groups (EG). Active member of the expert group on Cooperation with intermediaries (the various reports can be found here), work continues on the EG looking at Search engines with a follow up meeting scheduled for 16th September 2023 to review the draft scoping paper.

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