NEWSLETTER

SUMMER 2022

17 September

World Health Organization

World Health Organization
World Patient Safety Day

20-23 September

International Society of Pharmacovigilance
21ST ANNUAL MEETING
20 - 23 September 2022 - Verona, Italy
A New Era of Pharmacovigilance: Challenges and Opportunities

International Society of Pharmacovigilance
21st Annual Meeting, Verona, Italy

15 November

EU HEALTH COALITION
EU HEALTH SUMMIT 2022: TOWARDS AN EU HEALTH UNION

EU Health Coalition
EU Health Summit, Flemish Parliament, Brussels

European Alliance for
Access to Safe Medicines

ASOP EU
Alliance for Safe Online Pharmacy

SUMMER 2022 CONTENTS

European Alliance for
Access to Safe Medicines

ASOP EU
Alliance for Safe Online Pharmacy

MIKE ISLES - CHAIR OF EAASM

Despite the last year being partially eclipsed by the aftermath of the pandemic, I am happy to report that the EAASM (and also ASOP EU) has had a most productive period.

Of real significance have been two vital patient safety projects. In last year's opening remarks, I spoke about a new initiative to enhance patient safety by reducing medication errors through digitalisation and the use of traceability systems. At that time we were about to embark on a major pan European survey using IPSOS Mori. This is now complete and revealed some astonishing results. Variability across the countries is pronounced. We have published the results on the **ECAMET website** and we have constructed a unique interactive dashboard to compare and contrast between Member States (and the UK) results. I would encourage you to view this important piece of work. This study forms the bedrock of the **White Paper Call to Action** "The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm". We are now campaigning on many fronts to raise awareness and as far as possible, enable this topic to be addressed via a number of EU Institutional instruments. A full write-up of these important initiatives can be found on **page 5**.

The second vital patient safety project concerns nanomedicines and our strong advocacy outreach to MEPs which resulted in two significant political amendments to the INI Impact Assessment report (a key institutional instrument used by the Parliament to progress legislative thinking), where these amendments called for a centralised regulatory process. This is because we firmly believe that the complexity of the originator medicines requires a more robust regulatory pathway for follow-on nanosimilars. There is a direct parallel here to the evolution of the biologics and biosimilars.

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

Our request is a simple one: nanomedicines and nanosimilars should go through a European Medicines Agency (EMA) centralised process to ensure absolute similarity and thus avoid interchangeability issues which in the past have led to patient safety issues. **Pages 7-8** will give you all of the details.

We have also supported the Good Off Label Practice initiative, contributing with a presentation and emphasising the need for patients to be fully consulted and to receive their written consent.

In addition, we have been active members of the EU Health Coalition, the PACT initiatives as well as being an active Civil Society member of the EUIPO Observatory, attending and contributing to their many initiatives.

STEFAN FELTENS - NEW DIRECTOR OF ASOP EU

Since joining ASOP EU as a fellow-Director*, I have been impressed with the urgency and enthusiasm shown by Mike and those he works with to combat online illegal websites peddling sub-standard and/or falsified medicines. This is a highly challenging issue and requires not just one silver bullet but many. This is because the nature of the world wide web is highly complex and involves a huge number of players. As CEO of a leading online pharmacy, we are committed to pharmaceutical drug safety and high quality pharmaceutical consulting services.

This is not just important for chronically ill patients but gives all patients freedom of choice when it comes to safe self-medication, which furthermore lessens the burden on healthcare systems. It is therefore essential that the public is made fully aware of the tools to recognise legally operating online pharmacies and avoid illegal ones – the stats show 35,000 illegal websites selling falsified medicines are operating worldwide on any given day. This is a wholly unacceptable situation, which both the EAEP and ASOP EU are prioritising. And only through collaboration and cooperation can we combat this rising scourge. ASOP EU, with its close affiliation with ASOP Global with its Canadian Chapter and strong connections with the Asia Pacific Economic Co-operation (APEC), is well placed to influence patient safety initiatives in this vitally important area. One example of this is the updating of the APEC Toolkit to Combat Illegal Internet Medical Product Sales. This provides governments, law enforcement, regulatory agencies and other interested parties with a footprint to enable countries to tackle this growing problem. ASOP EU has shown its influence in other ways too. By being invited to become an Observer of the Medicrime Convention and so contribute to the Committee of the Parties' initiatives, it can pass on practical learnings and accelerate thinking and make a real difference which in turn, will help make the Internet a safer place to buy medicines online.

ASOP EU has also been highly active in advocating for a broader Digital Services Act. ASOP EU and the Know your Business Customer (KYBC) community - comprising no less than 85 companies and organisations including the EAEP - firmly believe that any entity that buys a domain name to transact business on the Internet should provide concrete proof of who they are – just like a bricks and mortar business. ASOP EU has written a number of letters to the EU institutions advocating for this.

Finally, I believe that the EAEP and ASOP EU with its members, can build on the momentum to create laws that will better govern the Internet. Paradoxically, the pandemic has actually brought to the attention of governments around the world, that organised crime is exploiting the consumer and selling falsified medicines, substandard PPE, medical devices and tests as well as vaccines. This is at least some sort of silver lining that we must capitalise on, and I for one, look forward to supporting further future efforts to combat this vital patient safety issue.

*Stefan Feltens is the President of the European Association of E-Pharmacies (EAEP) as well as the CEO of the online pharmacy Shop Apotheke Europe. He recently became a fellow-Director of ASOP EU, a non-profit Community Interest Company.

WHITE PAPER CALL TO ACTION LAUNCHED

The ECAMET Alliance launched a White Paper on March 22nd entitled "Call to Action - The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm" at an EU Parliament virtual round table that attracted over 150 participants.

The White Paper calls on European and national health authorities to commit to:

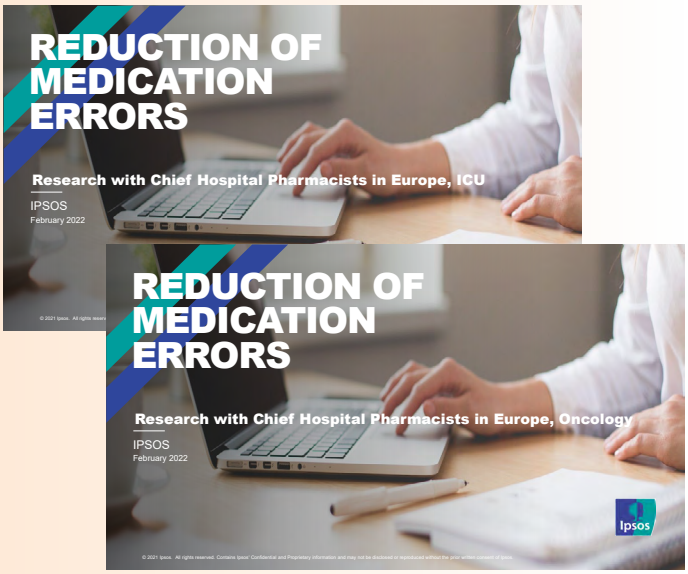
- Include medication safety in the Pharmaceutical Strategy for Europe, in the EU general pharmaceutical legislation and in Europe's Beating Cancer Plan through medication traceability systems in a healthcare setting to minimise medication errors.
- Prioritise strategic investments in medication traceability systems in the EU4Health programme to minimise medication errors.
- Foster the development and implementation of ECDC guidelines and key indicators on medication errors in EU healthcare settings.
- Facilitate the systematic exchange of best practices between healthcare providers both at European and national levels to reduce medication errors in healthcare setting.

The event was hosted by MEPs Tomislav Sokol (EPP party Croatia) and MEP Joëlle Mélin (ID France).

SURVEY REPORTS

Research conducted with hospital pharmacists who are department heads in European Countries.

Read consolidated report



This EU Parliament round table coincided with the launch of a pan European survey. Completed by 317 hospital pharmacists, it posed 37 questions which enabled a comprehensive picture on the state of digitalisation and management of medication errors to be to be realised. Questions around how medication errors are recorded and acted upon, the varying degrees of digitalisation amongst the hospitals and the current barriers and future needs to reduce medication errors revealed significant actionable insights as well.

In all, **25 reports were published** which included individual country reports, special reports on the private hospital sector, ICU and Oncology areas, as well as a consolidated report. To supplement these reports an **interactive dashboard** that allows comparisons across the countries with filters to enhance the analysis was also made available.

ASOP EU CONTRIBUTES TO AN INTERNATIONAL PHARMACY WEBINAR

fip International Pharmaceutical Federation

Falsified Medicine and Misinformation on the Internet: Public Risk and Solutions

Mike Isles Alliance for Safe Online Pharmacy in the EU - ASOP EU

12th July 2022

This worldwide event was part of The International Pharmaceutical Federation (FIP) educational programmes. FIP is the global body representing over 4 million pharmacists and pharmaceutical scientists.

The programme was spit in to three parts:

- The extent of the problem
- The devious ways in which criminals create websites to sell falsified medicines
- The ways the Internet can be better governed and solutions to the problem

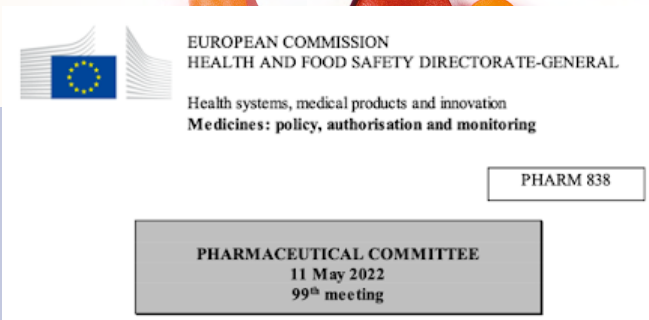
THE EU NANOMEDICINES REGULATORY COALITION ACHIEVES TWO SIGNIFICANT POLITICAL AMENDMENTS TO INFLUENCE NEW LEGISLATION VIA THE PARLIAMENTARY OWN INITIATIVE REPORT

This report which is one of the main tools that Members of the European Parliament use to voice their judgements on potential new legislation, in this case pertaining to the new EU Pharmaceutical Strategy, tabled Nanomedicines coalition's objective to centralise the regulatory process for nanomedicines and nanosimilars (the follow-on copies of the originator medicine once the patent has expired).

THE EUROPEAN PARLIAMENT HAS CALLED FOR THIS TO BE ADDRESSED:

European Parliament's own initiative (INI report) on the Pharmaceutical Strategy for Europe:

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**."



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 838

PHARMACEUTICAL COMMITTEE
11 May 2022
99th meeting

A recent meeting by the Pharmaceutical Committee provided useful commentary on this evolving topic.

> **Even though Member States thought that a definition and harmonised criteria for assessing such products can be useful (including via guidelines) there is currently no apparent need for a special pathway or to include them in the mandatory scope of the CAP. Members of the Committee maintained that the current rules sufficiently guarantee the main principles of the assessment process including for these medicinal products.**

These amendments were made possible by the strong advocacy work of the **EU Nanomedicines Regulatory Coalition** (EUNRC). Their activities included a webinar held in November 2021, hosted by MEP Vitanov who has been a committed supporter and has an important article published in **THE PARLIAMENT MAGAZINE**. The webinar covered the scientific reasons why a centralised procedure was needed from a patient safety perspective, the science behind these complex non biological drugs, as well as potential future challenges relating to clinical interchangeability issues. It was encouraging to note the European Commission's DG SANTE **Dr Andrzej Rys**, Director on Health systems, medical products and innovation, pointed out that we are at a crucial moment in shaping the European pharmaceuticals legislation, and that patient safety should be the central point of the European Union's pharmaceutical policy.

Since the webinar the EAASM has had a number of meetings with DG Sante, using a slide presentation to explain the EUNRC's position and recommendations. The recommendation includes suggested approaches for a new regulatory pathway as well as providing definitions for the relevant Annexes of the legislation involved.

However, the Committee also recorded:

"The first question examined was the possibility of exclusion of generic applications from the centralised procedure to allow the EMA Committee for Medicinal Products for Human Use (CHMP) to focus on more complex and innovative applications. While some Member States maintain that applicants should have the choice between the national and centralised procedures and some other Member States agree to the transfer to national level, other Member States agreed to a more nuanced approach e.g. transferring the simple generics to the Member States (MRP/DCP procedures) and keep the complex generics with the centralised procedure.

The discussion does therefore move the thought process along and clearly, as nanomedicines and nanosimilars are complex, it would be logical to ensure these products are assessed centrally.

The EUNRC is currently contacting all country health attachés as well as the National Regulatory Authorities to understand the level of knowledge and understanding of nanomedicines and nanosimilars. In particular we are gaining an understanding of the awareness of a reflection paper on the data requirements for intravenous iron-based nano-colloidal products. The EUNRC welcomes this reflection paper and would encourage the European medical agency to publish more guideline papers.

Reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product

Executive Summary

For the comparison of intravenous iron-based nano-sized colloidal products developed with reference to an innovator medicinal product, current scientific knowledge and regulatory experience for characterisation of nano-sized colloidal preparations indicate that quality characterisation on its own, would not provide sufficient assurance of the similarity between the two products, even if the quality tests performed show similarity. In the context of such iron based preparations, a "weight of evidence approach" including data from quality, non-clinical and human pharmacokinetic studies is required.

26 March 2015
EMA/CHMP/SWP/620008/2012
Committee for Medicinal Products for Human Use (CHMP)

THE DIGITAL SERVICES ACT (DSA)

KYBC
Know Your Business Customer

In the last newsletter the KYBC community, comprising no less than 85 companies and organisations, advocated for the recognition within the Act of the KYBC principles. ASOP EU sent letters advocating for the inclusion of the KYBC principle to Members of the EU Parliament, the EU Council, the EU Commision and also the President Ursula von der Leyen.

This letter by the KYBC Community summarises the position and this excerpt explains our position very clearly:

"We welcome the European Commission's proposal for a Digital Services Act (DSA). As this letter focuses on the "Know Your Business Customer" (KYBC) obligations of the proposal, the signatories of this letter may also be in touch with you independently on this and other important elements of the DSA. With regard to KYBC obligations, we welcome the inclusion of a provision ensuring the traceability of traders in Article 22.

We acknowledge that this represents a step forward.

November 2021

KYBC Letter to the European Parliament

"Digital Services Act: Know Your Business Customer obligations must meet the ambition set by the European Parliament to provide a meaningful tool for tackling illegal activities and products online..."

However, the Commission's proposed Article 22 only introduces KYBC obligations in the context of online marketplaces. Such a limited approach is a missed opportunity to address the broad range of illegal content and counterfeit, unsafe, non-compliant and substandard products online.

However, on July 5th 2022, the European Parliament formally endorsed the DSA. Unfortunately, the request that the KYBC principle, whereby any intermediary who has the capacity to sell domain names and thus allow business to be transacted, would be legally obliged to request and store identity information, was not included. Although this is disappointing, the KYBC Community has together built up a tremendous awareness of the need for a broader governance of the Internet. ASOP EU will continue to support in any way, the expansion of the DSA so that a more holistic approach to Internet governance is taken and thus enhance the safety and security of the EU citizen.

ARTICLE PUBLISHED IN THE LEADING JOURNAL FRONTIERS IN PHARMACOLOGY

frontiers | Frontiers in Pharmacology

OPINION article

Front. Pharmacol., 24 February 2022
Sec. Drugs Outcomes Research and Policies
https://doi.org/10.3389/fphar.2021.787239

This article is part of the Research Topic
Prevention, Diagnosis and Treatment of Rare Disorders
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Nanomedicines and Nanosimilars—Why a Robust Centralised Regulatory Framework Is Essential to Enhance Patient Safety

940
total views

1

View Article Impact

18%
Views Rank

To help raise the profile of nanomedicines and nanosimilars the EAASM published an article in the prestigious journal Frontiers in Pharmacology. Currently, as of 1st August 2022 the article has been viewed 940 times which is more than 18% of all Frontier's articles.

In demographic terms it has been viewed from many different countries.

Demographics

The article's abstract is shown below:

Given that nanomedicines and follow-on nanosimilars have complex manufacturing processes and heteromolecular structures, the question is being raised in ever increasing frequency, as to whether the current European regulation of medicines for human use is robust enough to authorise these medicinal products and their follow-ons. Until this can be achieved, there is a potential for patient safety to be compromised.

The current situation is that nanomedicines have the potential for being assessed under four different types of procedures: the national procedure, the decentralised procedure, the mutual recognition procedure, and the centralised procedure. In this context, it is important to note that a survey published 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" (**Bremer-Hoffmann et al., 2018**). Given their complex nature and the fact that each nanomedicine will have unique features, there is currently a lack of guidelines or protocols so that these medicines can be appropriately processed, which will provide a marketing authorisation (MA) that meets the demanding standards of today and thus ensure patient safety (**Nanomedicines and Nanosimilars, 2021**).

The EU Nanomedicines Regulatory Coalition (**Nanomedicines Regulatory Coalition, 2021**) currently comprising seven pan-European organisations is therefore advocating for all nanomedicines to be assessed by the EMA Centralised regulatory procedure (**Patient Safety and Nanomedicines, 2020**).

This is equally true of the off-patent follow-on copy products, or nanosimilars, as they are also called. Within this context, a centralised regulatory process that addresses this is needed at the EU level, and in the absence of a tailored regulatory pathway similar to that of the biosimilars, the European Alliance for Access to Safe Medicines (EAASM) strongly believes that all future nanosimilars should go through the Hybrid Application process (10.3) and not the Generics Application process (10.1). This pathway, if consistently applied and aligned to the draft guidance (**European Medicines Agency, 2015**) which the EMA has produced for specific types of nanomedicines, would ensure that follow-on copies are therapeutically similar to their originator and therefore improve patient safety.

There will be different manufacturers producing these similar products from different sites with differing manufacturing processes, and so the production of identical replicas of the originator product cannot ever be achieved (**Ehmann et al., 2013; Marden et al., 2018**). It is for this reason that a thorough clinical valuation must be carried out before an Marketing Authorisation can be granted.

Patient harm has occurred when a nanosimilar has not had this rigorous safety and efficacy check established through a clinical trial (Rottembourg et al., 2011a) program.

This article endeavours to lay out the critical success factors that will enable a centralised procedure for nanomedicines and nanosimilars to be achieved.

HOW ASOP EU AND THE EAASM ARE INFLUENCING OUTCOMES

1 MEDICRIME Convention

Council of Europe

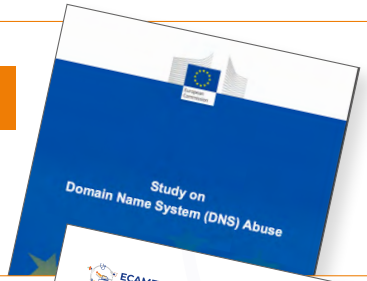
ASOP EU recommends to the Medicime Convention - Committee of the Parties the DOTPharmacy verification programme and longitudinal research methodology to monitor and measure the anti-counterfeiting activities.

2

ASOP EU recently wrote to the Executive Vice-President Vestager, Commissioner Breton and Commissioner Johansson following a very late tabled amendment which we believe will undermine the Directive.

"We are very alarmed with regard to a last-minute addition of completely new text--a new paragraph 5(a)-- that has been made to Article 23 in the Council's proposal for a final agreement on the proposed NIS2 Directive, after the conclusion of trilogue negotiations. This new language is not a procedural technical amendment. Rather, it is a substantive change that will create major obstacles to European law enforcement agencies (LEAs) and non-governmental organisations in their efforts to fight cybercrime and online abuse. If this language is permitted to remain in the final text, it will serve to diminish rather than increase the level of cybersecurity across the European Union."

3



Study on Domain Name System (DNS) Abuse

ASOP EU provided an intervention at the kick-off meeting during the commissioning of this important domain name system (DNS) abuse project. The report provides highly detailed information which can be used by all interested parties to support future patient safety initiatives.

4

The EAASM will continue to raise awareness about the need for traceability systems within hospitals to reduce the harm to patients and healthcare workers due to medication errors.

ECAMET
European Collaborative Action on Medication Errors and Traceability

5

KYBC
Know Your Business Customer

ASOP EU will continue to campaign for a strengthened Digital Services Act.

6

WATCH ON YOUTUBE

EUIPO
EUROPEAN UNION INTELLECTUAL PROPERTY OFFICE

ASOP EU and the EAASM will continue as a Civil Society member supporting all of the activities by contributing to the Expert groups and work streams of the EUIPO Observatory. Please watch this short video to show how its endeavours are protecting the EU Citizen and beyond.

7

nanomedicines
ThePowerofParticles

Mike Isles was invited to be part of the editorial board of this new educational website to raise awareness about the potential of nanotechnology and nanomedicines.

8

EUROPEAN COMMISSION
Directorate-General for Communications Networks, Content and Technology

Future Networks
Next-Generation Internet

Brussels, 27 June 2022

High Level Group on Internet Governance
Multi-stakeholder Open Session
29 June 2022 10:00 – 12:30
Virtual meeting (WebEx)

As a member of the High Level Group on Internet Governance ASOP EU will continue to provide support and advocacy.

9

ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES

The Domain Reform for Unlawful druG Sellers (DRUGS) Act
Lock and Suspend Websites that Illegally Sell Drugs and Endanger Public Health

ASOP EU will continue to follow and support US Congress activities to enact a new law to increase Internet governance.

10

THE REGULATORY NANOMEDICINES COALITION

EAASM will continue to campaign with all of the EU Institutions including Member States National Regulatory Authorities and Health Attachés to ensure Nanomedicines and their follow-on copy products are assessed by an EMA centralised process.

11

EU HEALTH COALITION

Supporting the EU Health Coalition activities.

12

Supporting the Patient Access Partnership activities.

13

World Health Organization

The EAASM will be supporting world patient safety day scheduled for 17th September 2022.

Your contacts at ASOP EU and EAASM

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