NEWSLETTER

JULY 2021

European Alliance for
Access to Safe Medicines

ASOP EU
Alliance for Safe Online Pharmacy

JULY 2021 CONTENTS

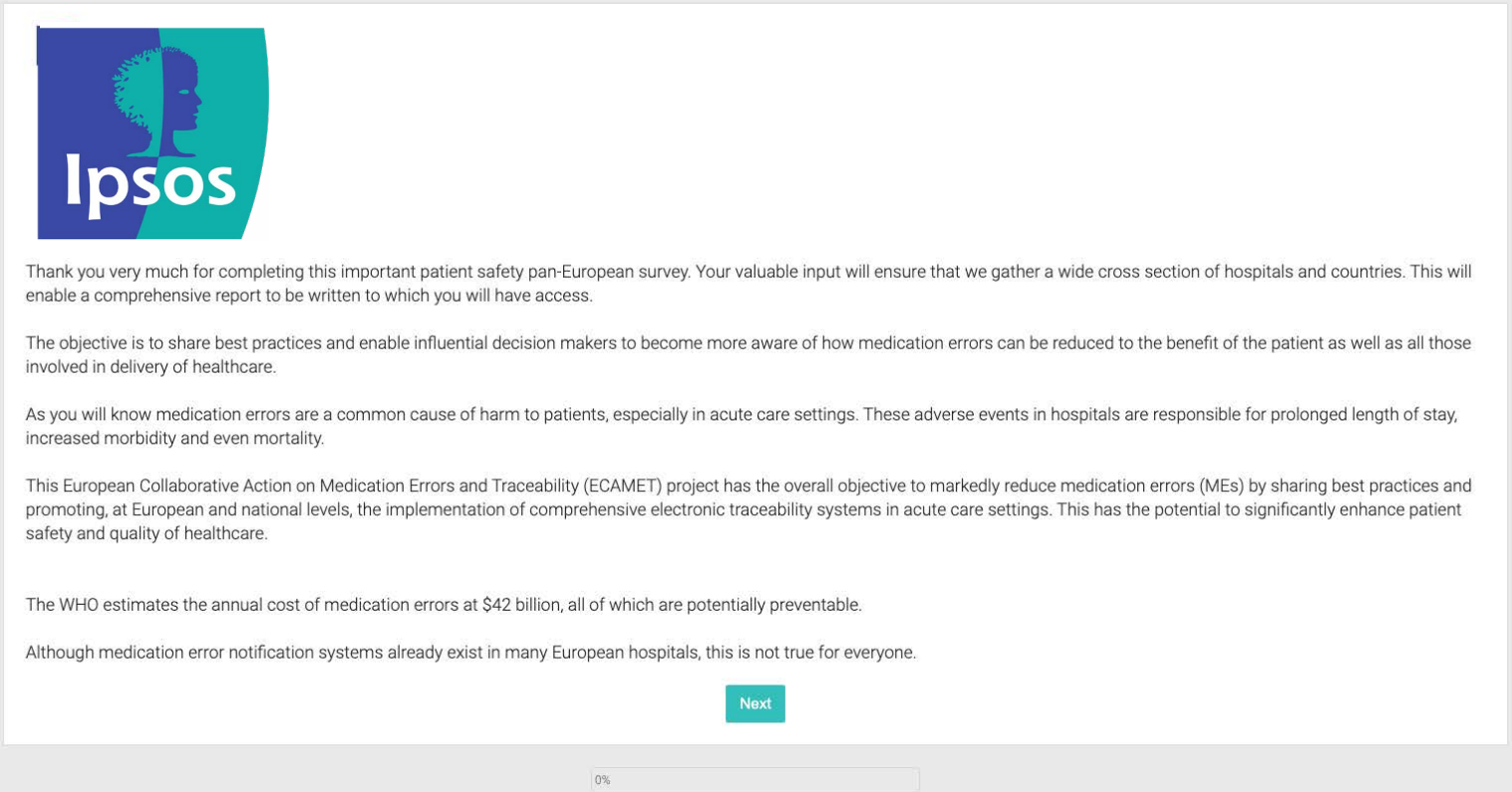
THE ECAMET PAN-EUROPEAN SURVEY LAUNCHED

ECAMET

European Collaborative Action on Medication Errors and Traceability

Ipsos Mori International research company will oversee the hospital survey. The survey will capture information from 12 European countries (Belgium, France, Germany, Holland, Hungary, Italy, Poland, Portugal, Spain, Sweden, Switzerland, UK) and also the European Union of Private Hospitals (UEHP).

The survey covers important areas to understand how medication errors are monitored and acted upon, what infra-structure exists to automate this process and what plans hospitals have to enhance their current capabilities.



The website displays useful information around research into medication errors. The Scientific Committee as well as the growing number of Alliance members can also be viewed.

Plans to disseminate the survey findings.

A full consolidated report and separate country reports will be made available via an interactive dashboard. The report will be launched at an EU Parliament meeting in the Autumn. The Alliance will advocate via a White Paper to influence policy to raise awareness of medication errors in hospitals with a view to sharing best practice and thus enhance patient safety in this vital area.

The ECAMET Alliance

EU PARLIAMENT WEBINAR TO LAUNCH WHITE PAPER ON MEDICATION ERRORS

The survey findings will be presented and the Autumn 2021 webinar aims to create debate and awareness. The agenda will broadly comprise:

SETTING THE SCENE

- Welcoming remarks by MEP Dolors Montserrat (Spain, lead rapporteur of the INI report on the pharma strategy). TBC
- EAASM Mike Isles – Chair & Moderator
  Presentation of the ECAMET Alliance, mission and survey.

1 PANEL - The size of the problem and the main victims: patients and healthcare professionals.

- EU policy landscape to eliminate avoidable harm in health care
- Victims: patients and their families
- Victims: second victims, healthcare professionals

2 PANEL - Preventing Medication Errors in Hospitals: clinical solutions and policy recommendations

- ICUs
- Hospital Pharmacists
- European Organizations

European Commission DG SANTE
The Pharmaceutical Strategy for Europe

CONCLUSIONS

- Next steps to prevent medication errors in EU: Open debate
- Final remarks by the moderator/ new MEP endorsing our Call to Action/ White Paper

If you would like to attend please contact **mike.isles@eaasm.eu**

EU WEBINAR TO SUPPORT IMPLEMENTATION OF THE FMD IN HOSPITALS

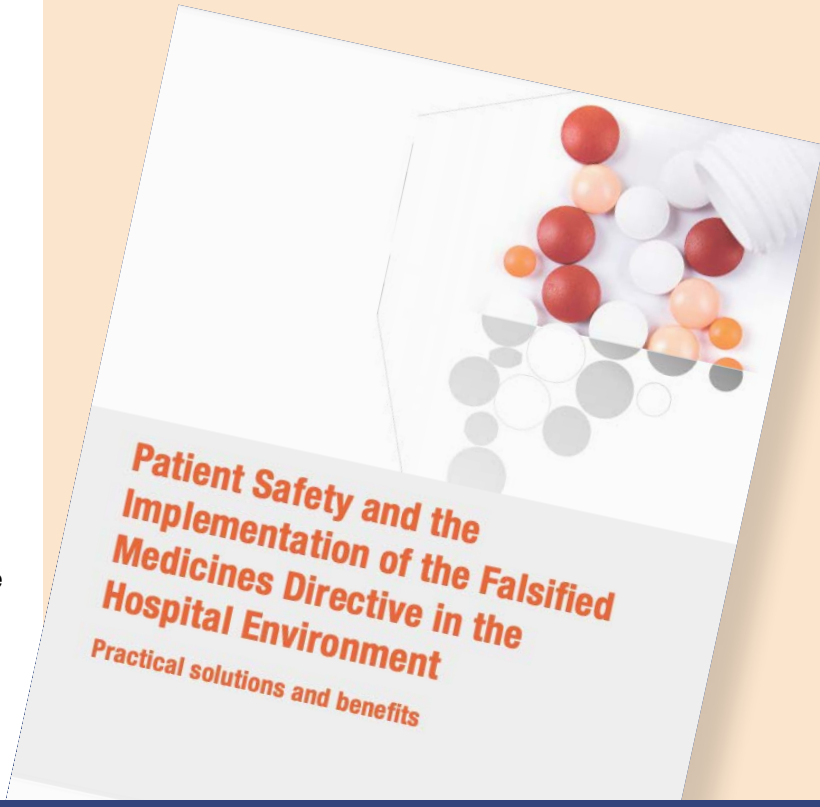
The EAASM supports the implementation of the Falsified Medicines Directive (FMD) in hospitals and a sharing best practice report was recently published following a widely attended webinar on 30th September 2020.

This report made 5 key recommendations to stakeholders to ensure good implementation of the FMD:

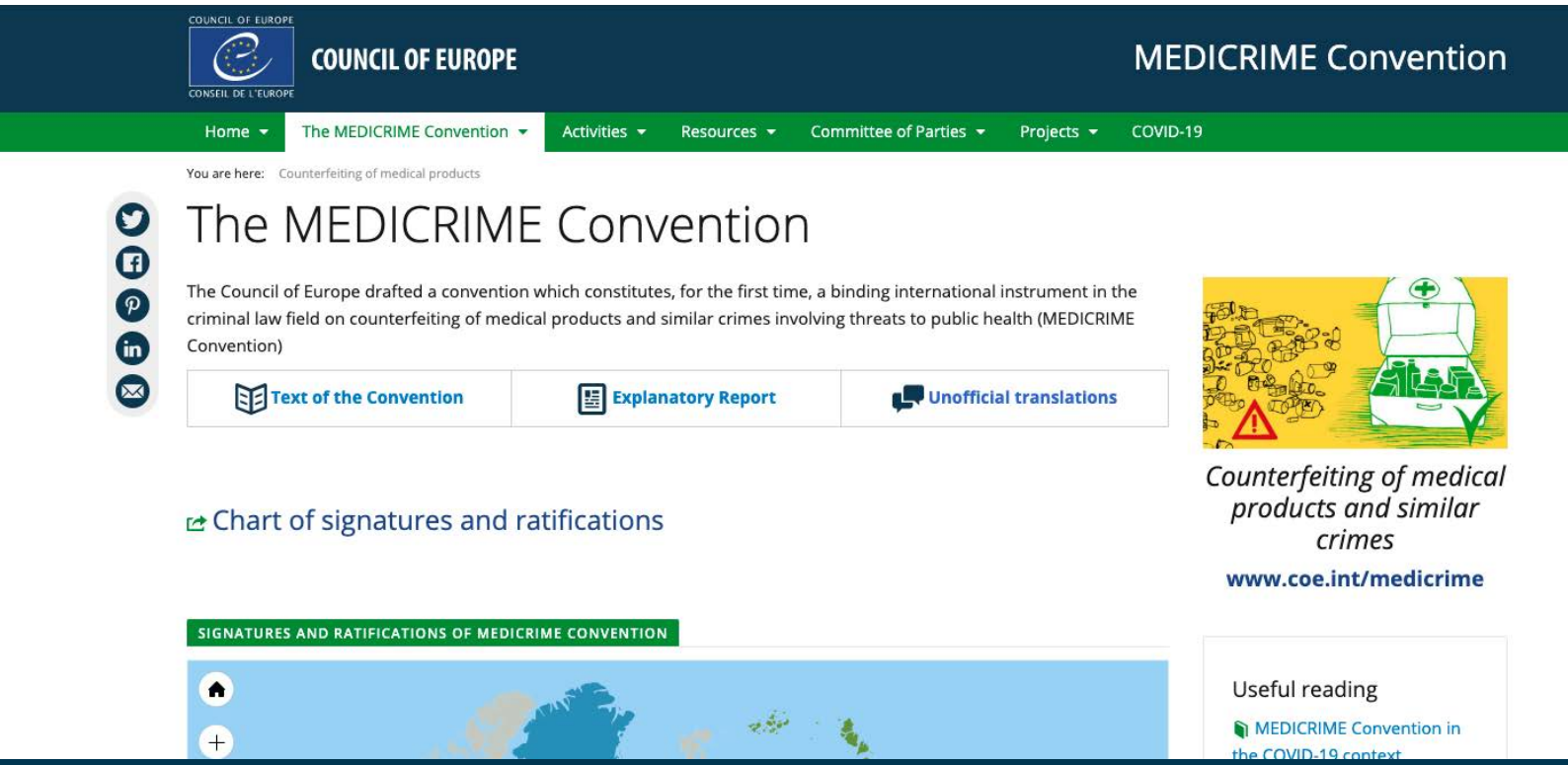
- Encouraging all national and regional medical authorities to help ensure that any hospitals that need to support the implementation of the FMD do so.
- Implementing a continuous improvement culture that involves inclusive collaboration with all staff and parties involved.
- Making procedural and system improvements by embracing technology such as Artificial Intelligence IT infrastructure to introduce automated dispensing solutions to save time and to alleviate manual actions.
- Introducing smart applications to help connected services (ambulance, satellite hospitals) and robotics to aid the verification process and enhance the safety of medication use.
- Encouraging hospitals when admitting 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.

Mike Isles EAASM, who moderated the meeting, said:

"Implementing the FMD in hospitals comes with definite challenges. However, two case studies were presented which clearly showed it was well worth the effort and clearly sets out the practical steps and timelines to achieve it. Also of particular importance was a presentation that analysed the clear benefits, most notable of which was a massive inventory saving due to the much better management of stocks and product flows through the hospital"



ASOP EU GAINS MEDICRIME CONVENTION OBSERVER STATUS



STRASBOURG, FRANCE – MAY 26, 2021

At the 4th plenary session of the Medicrime Committee of the Parties (CoP), ASOP EU was granted official status as an Observer within this important and growing group of countries that have ratified the MEDICRIME Convention treaty. There are currently 18 countries that have ratified this treaty, and many more that are about to sign.

This followed a comprehensive application submission combined with an intervention at the plenary meeting on May 26th, 2021 from which the vote was taken.

ASOP EU joins four other NGOs: OPALS, PSI, Brazzaville Foundation and IFPMA.
The Medicrime Convention, under the guidance of the Council of Europe, 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.

"We have been working hard to gain this acceptance and it was due to the fact that we demonstrated the achievement of many concrete and collaborative actions to combat falsified medicines that we were accepted as an Observer in this important multi-country convention to fight falsified medicines..."

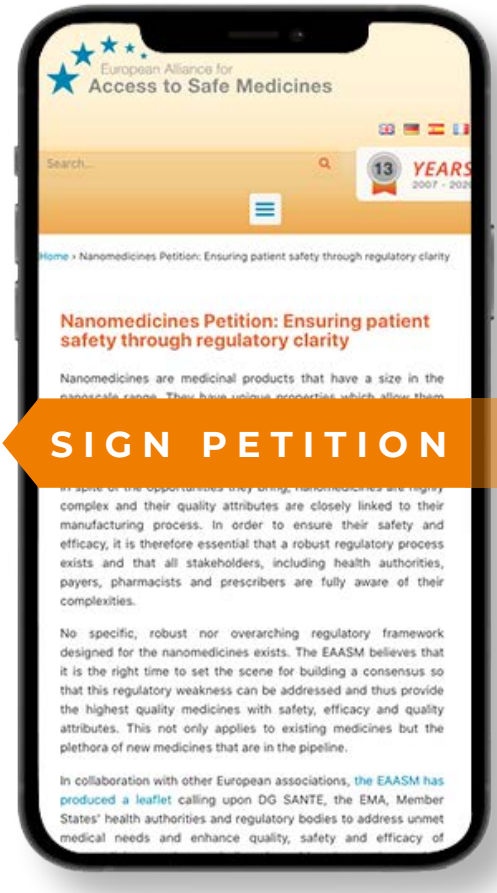
"We look forward to contributing to the many initiatives that need establishing within this convention."

Mike Isles, Executive Director of ASOP EU

NEW EAASM NANOMEDICINES WEBSITE

The new website will enable the growing list of collaborators to raise awareness about the need for regulatory clarity when nanomedicines and nanosimilars are being assessed by Medical agencies. At the moment there is no centralised process, unlike the Biologics and the Biosimilars.

If you would like to join the growing number of supporters please sign the petition here – thank you.



SIGN PETITION

MEP OUTREACH ON RAISING AWARENESS OF NANOMEDICINES' REGULATORY ISSUES SUCCESSFUL

Outreach to MEPs and EU Commissioner for Health and Food Safety, Ms Stella Kyriakides, Commissioner to raise awareness about nanomedicines and to incorporate the need for regulatory clarity within the context of the EU Pharmaceutical Strategy.

A concerted effort to inform a number of the ENVI Committee MEPs (this committee is made up of MEPs with a direct interest in health topics and legislation to improve health outcomes) resulted in a unanimous positive response around the objective to gain greater regulatory clarity. This enabled the EAASM to co-sign a letter with the support of the Coalition and MEPs requesting that the all important INI* report contains references to nanomedicines. The information sent to brief the MEPs and their Assistants included the EAASM published report entitled "Patient safety and Nanomedicines – the need for a centralised regulatory procedure".

*** Own-initiative (INI) reports are one of the working tools and political instruments of the European Parliament and offer MEPs the opportunity to explore a diverse range of topics of interest. One of the aims of INI reports is to shape the early phase of the legislative cycle and shape the agenda of the European Union.**

MEP Cyrus Engerer (Malta, Progressive Alliance of Socialists and Democrats)

MEP Romana Jerkovic (Croatia, Progressive Alliance of Socialists and Democrats)

MEP Petar Vitanov (Bulgaria, Progressive Alliance of Socialists and Democrats)

MEP Pietro Fiocchi (Italy, European Conservatives and Reformists Group)

MEP Margrete Auken (Denmark, Greens/European Free Alliance)

Patient Safety and Nanomedicines

The need for a centralised regulatory procedure

www.eaasm.eu

The Nanomedicines Coalition

era edta

International Alliance of Patients' Organizations

ESN EUROPEAN SPECIALIST NURSES ORGANISATIONS

ELPA European Liver Patients' Association

EPDA European Parkinson's Disease Association

European Cancer Patient Coalition

European Alliance for Access to Safe Medicines

EAASM INTERVIEWED BY EURACTIV

EURACTIV The Capitals The Brief

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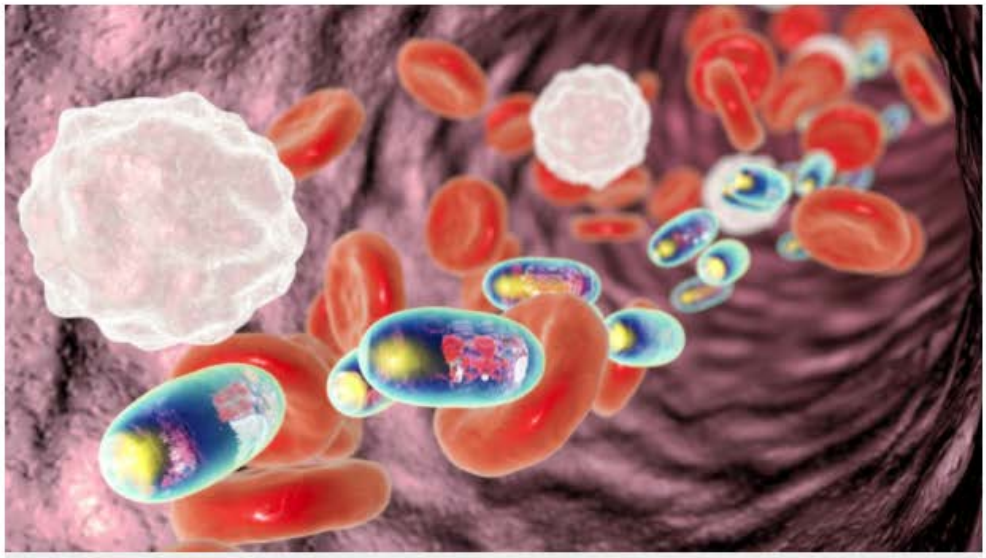
Home / News / Health / Innovation in pharma / Commission urged to consider common regulatory framework for nanomedicines

Commission urged to consider common regulatory framework for nanomedicines

By Sarantis Michalopoulos | EURACTIV.com 17 Sept 2020



Nanomedicine uses state-of-the-art nanotechnology like nanoparticles, nanorobots or nanoelectronic biosensors for diagnosing or treating diseases. [Kateryna Kon/Shutterstock]

Comments Print

EURACTIV Members

Acumen public affairs
Association of European Cancer Leagu...
BSEF - The International Bromine Cou...
Cosmetics Europe - The Personal Care ...
ECPC - European Cancer Patient Coaliti...
EHFG - European Health Forum Gastein
EHPM - The European Federation of A...
ESA - European Sunlight Association
EuropaBio
Medicines for Europe - Better Access. ...
MedTech Europe - from diagnosis to c...

Popular articles

The EAASM was interviewed by the widely read Euractiv journal on the topic of nanomedicines and the need for regulatory clarity.

The Commission was urged to consider a common regulatory framework for nanomedicines and to support the EAASM goals to achieve regulatory clarity for nanomedicines and nanosimilars for regulatory clarity.

Mike Isles, EAASM, stated:

"...the lack of a fit-for-purpose regulatory framework on nanomedicines and their "generics" poses risks for the safety of EU patients and the European Commission should urgently look to address this."

MEP CALLS FOR A ROBUST REGULATORY FRAMEWORK FOR NANOMEDICINES

THE PARLIAMENT
POLITICS, POLICY AND PEOPLE MAGAZINE

NEWS | OPINION | MEP AWARDS | INTERVIEWS | PM+ | POLICY | MAGAZINE

By **Petar Vitanov**

Petar Vitanov (BG, S&D) is a member of the European Parliament's Environment, Public Health and Food Safety Committee

26 Jul 2021

Nanomedicines and Nanosimilars: Building a robust legislative framework

The EU has the chance to lead the world in developing a centralised regulatory procedure for nanomedicines and nanosimilars, argues Petar Vitanov

The EAASM has been influential in raising awareness amongst the EU Parliament to the extent that a leading MEP felt strongly enough to write:

"It is now time to scale up concrete actions to build a robust, legislative framework for nanomedicines and nanosimilars for the benefits of all European patients."

The clear message from MEP Petar Vitanov

Nanotechnology is an emerging innovative technology with the potential to address unmet medical needs and offers alternatives for several therapeutic areas.

Nanomedicines offer potential solutions for a number of current treatment challenges, including cancer, cardiovascular and neurodegenerative disorders, as well as other diseases. It is also important to note that the innovative mRNA vaccines contain nanoparticles.

Nanomedicines and their follow-on products, also referred to as nanosimilars, are complex molecules and so regulatory oversight must be scientifically fit for purpose.

They are proving to be very important in oncology treatments and have reduced mortality in cancer patients and also have had a positive impact in therapies that target specific cells.

The fact that the European Alliance for Access to Safe Medicines along with several patient safety member organisations of the Nanomedicines Regulatory Coalition are calling on the European Commission to accelerate actions in the field of nanomedicines was also reported in this powerful article in this widely read political magazine.

YOUTH IGF MOVEMENT EDUCATIONAL WEBINARS USING FACEBOOK LIVE STREAMING

ASOP EU collaborated with the Youth IGF Movement and three pharmaceutical companies to raise awareness across 12 countries worldwide to Combat COVID-19 scams and fake medicines' website posts.

In June 2020, after much planning, the Youth IGF Movement, created by Yuliya Morenets, teamed up with the ASOP EU supported by three French global healthcare companies (Ipsen, Sanofi and Servier) to educate young people about buying fake medicines online, in particular COVID-19 scams. Announced in a press release, the campaign is called...

"We rely on you. We rely on youth"

One year after this important event, which reached many young people around the world, the pandemic scams makes it even more important for the youth of today to be educated about fake medicines.

Learn more about fake medicines online and how you can stay safe, please see explanatory leaflets.

- English
- French

We Rely On Youth: Youth IGF Movement + ASOP EU Join Hands To Combat Fake Medicines:

- We Rely On Youth: Youth IGF Movement + ASOP EU Join Hands To Combat Fake Medicines
- We Rely On You, We Rely On Youth – Sanofi
- We Rely On You, We Rely On Youth – Ipsen
- We Rely On You, We Rely On Youth – Servier
- We Rely On You, We Rely On Youth TikTok Video
- Youth IGF Video

Campaign results to be presented at the World Intellectual Property Organization (WIPO) Advisory Committee on Enforcement (ACE) in September 2021.

Facebook stats

June 10 global launch event 11600 views
June 10 Romania 491 views
June 11 Nigeria 5600 views
June 12 Kenya 11400 views
June 15 Lebanon 6100 views
June 16 Poland 4019 views
June 16 Côte d'Ivoire 8700 views
June 17 India 10600 views
June 18 Ukraine 4600 views
June 19 Philippines 7100 views
June 20 Russia 2000
June 23 Indonesia 7300
Promotional videos >22,220
Leaflet read > 46,646

ASOP EU JOINS THE KYBC COMMUNITY

This community now comprises over 85 companies and is campaigning strongly by writing to MEPs and EU Council members to have the Digital Services Act (DSA) expanded to include ALL INTERMEDIARIES and not just Online Marketplaces. In addition, ASOP EU sent a separate health focused letter which was co-signed by a number of other companies shown here.

European Alliance for Access to Safe Medicines

EPDA European Parkinson's Disease Association

COMMONWEALTH PHARMACISTS ASSOCIATION

Irish Patients' Association

Ketotic Hypoglycemia INTERNATIONAL

SCiE

THE KYBC POSITION

The Issue

1 The DSA could rectify the situation that allows bad actors to ignore Article 5 of the European Commerce Directive (ECD) with impunity.

2 A business cannot go online without a domain name, without being hosted, or without advertisement, payment services or online marketplaces.

3 These intermediary services, having a direct relationship with the business, are therefore best placed to make sure that only businesses that are willing to comply with the law have access to their services.

4 For decades, fraudulent businesses have been exploiting the lack of enforcement of the information requirements under Article 5 of the ECD.

5 This has been to the detriment of a safe and trustworthy online environment and has facilitated the use of infrastructure by completely anonymous commercial entities that intentionally make available or distribute illegal content.

The Solution

1 KYBC obligations are an ideal tool to give Article 5 ECD greater effect.

2 Requiring commercial entities to reveal their true identity on the internet would automatically reduce illegal content online and would greatly facilitate consumers' and business customers' efforts to seek redress. After all if you set up a shop in the high street, everybody knows who you are – why is it different for online businesses?

3 **The DSA Proposal should include ALL INTERMEDIARIES and not just online marketplaces, not to include these entities will leave much of the Internet free for criminals to pursue their illicit activities.**

EAASM SUPPORTS THE GOLUP DECLARATION WITH AN INTERVENTION

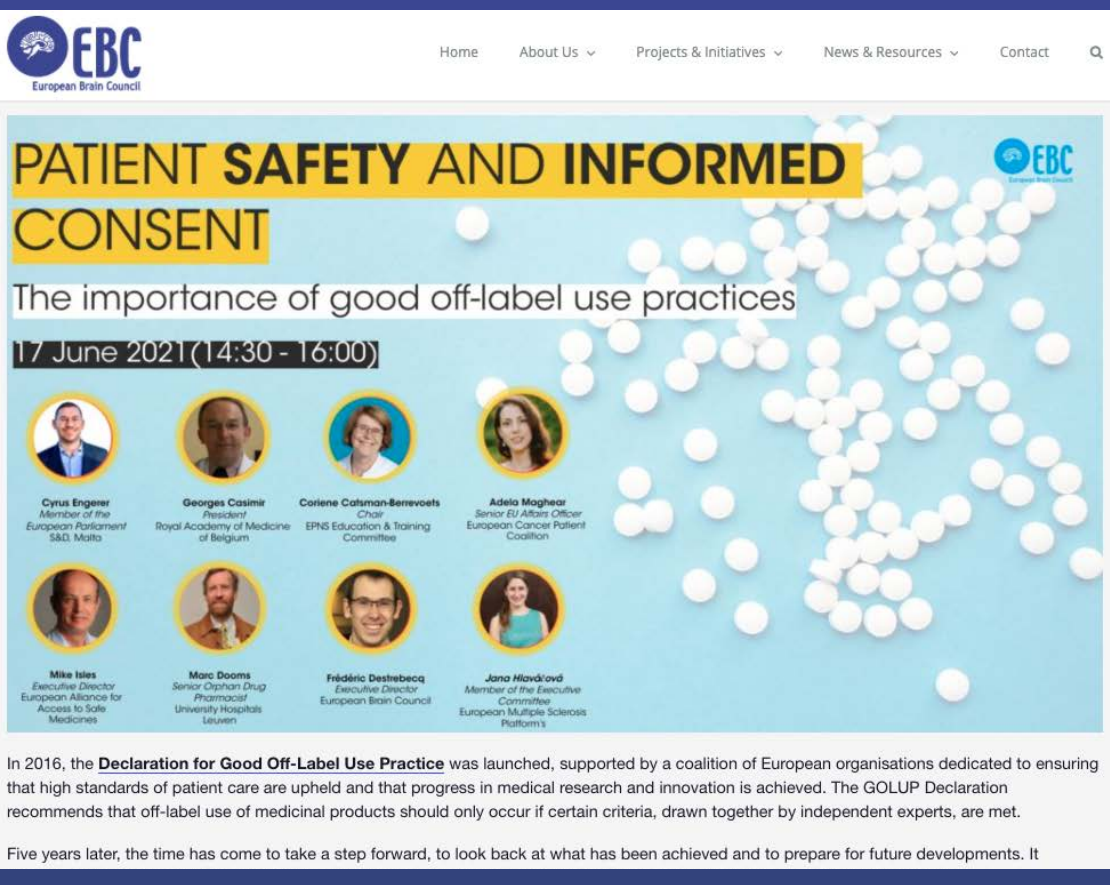
Mike Isles's intervention at the GOLUP webinar on 17th June 2021, supported the GOLUP Declaration and highlighted the fact that since 2015, the EAASM has been in communication with the then Commissioner Vytenis Andruikaitis.
These letters underlined a number of patient safety issues and asked for a proper review and subsequent recommendations for, at least, the setting down of centralised guidelines to begin to harmonise across Member States an understanding and approach and to raise awareness of this significant patient safety issue.

In particular, the EAASM highlighted those patients who had suffered serious eye infections during a procedure in the ophthalmology department of the hospital of Careggi (Florence).

These tragic incidences were brought to the attention of the Italian Medicines Agency (AIFA) by journalists. It is doubtful whether AIFA would ever have been aware of them without the intervention of the media. This fundamentally calls into question the reporting (or indeed the lack of it) of adverse events following off-label use in the EU. It can therefore be postulated that this also means that an unknown number of adverse events are, in all likelihood, occurring within the EU due to inappropriate off-label use and will remaining unreported, without corrective measures being taken. This is even more concerning knowing that in a Canadian scientific study, prescribing drugs off-label was associated with a 50% increased risk of adverse events.

The EAASM firmly believes in advocating for the following actions:

- Establish the number of Adverse Events relating to unlicensed/off-label use of medicines.
- Introduce a professional Code of Practice for mandatory reporting by healthcare professionals of AEs involving unlicensed/off-label medicines.
- Improve public awareness so that patients are aware of when unlicensed/off-label medicines are being used and these decisions have to be taken in conjunction with the patient and the patient has to give consent.



In 2016, the **Declaration for Good Off-Label Use Practice** was launched, supported by a coalition of European organisations dedicated to ensuring that high standards of patient care are upheld and that progress in medical research and innovation is achieved. The GOLUP Declaration recommends that off-label use of medicinal products should only occur if certain criteria, drawn together by independent experts, are met.

Five years later, the time has come to take a step forward, to look back at what has been achieved and to prepare for future developments. It

EAASM PARTICIPATES IN DIA EUROPE 2021 ADVANCING HEALTHCARE PRIORITIES

The poster session was designed to raise awareness of the need for scientific consensus on definitions for nanomedicines and nanosimilars across Europe by developing a robust fit for purpose centralised regulatory procedure for both new and innovative nanomedicines as well a nanosimilars ("follow-on" copy products).

This would be achieved through an advocacy programme which includes:

- Forming an Alliance with outreach to the EU Institutions
- A scientific report
- A summary briefing document
- Mobilising MEPs and holding EU Parliament and national round table discussions
- Campaigning to the EMA and DG SANTE

Nanomedicines – ensuring patient safety through regulatory clarity

Michael Isles Laura Cigolot
European Alliance for Access to Safe Medicines (EAASM)

Objective

To raise awareness amongst all interested parties of the need for scientific consensus on definitions for nanomedicines across Europe and to develop a robust fit for purpose centralised regulatory procedure for both new innovative nanomedicines as well a nanosimilars/ follow-on products.

Through an advocacy programme comprising a scientific report, summary briefing document and EU Parliament round table discussions; we will campaign for the EMA and DG SANTE to accelerate the development of a specific regulatory framework for nanomedicines and nanosimilars.

Methods

- Nanomedicines and their follow-on products, also referred to as nanosimilars, are complex molecules
- A report showed that there are strong regional differences in the regulation of nanomedicines which confirmed the need for a harmonisation of information requirements on nano-specific properties
- 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
- There is evidence that such "follow on copy" products do not deliver the same efficacy and safety
- The European Medicines Agency supports international harmonisation of regulatory science standards through initiatives such as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- In the absence of clarity on nanomedicines, regulatory pathways and a legal definition, more scientific, policy and practice knowledge on the quality, safety, and efficacy of nanomedicines and nanosimilars must be gained among all stakeholders including payors and health care professionals.
- Nanomedicines and nanosimilars should be reviewed through a centralised procedure to limit different approaches by Member States regulatory authorities and a separate regulatory framework for follow-on products would be beneficial – as it has been for the development of biosimilars over the past years – or as additional guidance on how the hybrid pathway could be used to approve these products.

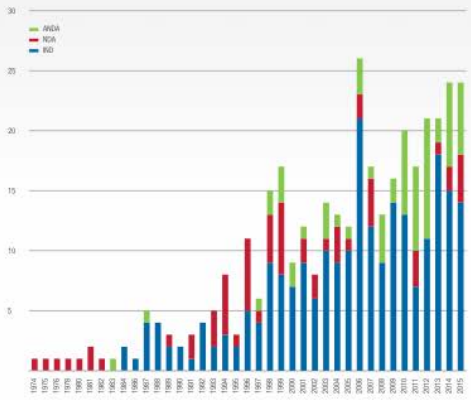


Figure 1 clearly shows the increasing number of nanomaterial product applications submitted to CDER by year. Applications are separated as INDs, NDAs and ANDAs.

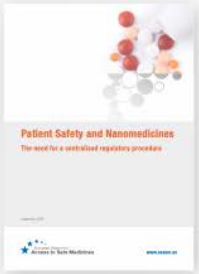
Conclusions

Nanotechnology is a compelling and growing scientific field that provides numerous opportunities to develop innovative medicines to address unmet medical needs and create alternatives for many therapeutic areas – from cancer to inflammation, neurological and cardiovascular disorders.

To fully harness their potential and protect patient safety, a fit for purpose regulatory framework for this class of product is needed at EU and International level. Nanomedicines and nanosimilars should be reviewed through a centralised procedure to limit different approaches by Member States regulatory authorities [5,6] and a separate regulatory framework for follow-on products would be beneficial – as it has been for the development of biosimilars over the past years – or as an alternative additional guideline on how the hybrid pathway could be used to approve these products.

Call to Action

The production of a comprehensive scientific report, a briefing brochure shown below so that all audiences can better understand nanomedicines and nanosimilars, combined with advocacy outreach to the EU institutions, is already achieving the objective of raising awareness. The launch of the scientific report was widely publicised and included articles in Euractiv and Politicow.



Visit the EAASM website to sign the Petition and endorse more collaborative actions for a new and robust regulatory framework for nanomedicines and nanosimilars in Europe

The campaign supporters are shown here

References – a comprehensive list of references is available within the scientific report https://eaasm.eu/wp-content/uploads/Patient-Safety-and-Nanomedicines-September-2020.pdf

HOW THE EAASM AND ASOP EU ARE INFLUENCING OUTCOMES

1 Speaker at the IP KEY SEA Enforcement series 2021 Conference on Combating Counterfeiting and Piracy in South-East Asia.

2 Speaker at the King's College London, Fight the Fakes "Let's talk about Fakes" seminar series entitled "Solutions for improved Internet Governance".

European Commission

Shaping Europe's digital future

3 Member of the growing Brussels advocacy community of Know your Business Customer (KYBC) to expand EU Commission's Digital Services Act to cover ALL INTERMEDIARIES not just online marketplaces as well as amending the revised Directive Security of Network and Information Systems (NIS2) which covers WHOIS Data and the Domain Name System (DNS).

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

4 ASOP EU gains official "Observer" status within the Medicrime Convention Committee of the Parties.

.eu Powered by EURid
NABP National Association of Boards of Pharmacy

5 Collaboration by ASOP EU and EURid in liaison with NABP to combat DNS abuse by identifying rogue pharmacy websites.

EU HIGH LEVEL GROUP ON INTERNET GOVERNANCE

6 ASOP EU invited as a participant of the EU High Level Group on Internet Governance HLIG.

Study on Domain Name System (DNS) abuse

7 The EU Commissioned DG Connect study on DNS abuse.

NABP NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

.pharmacy
Establish Your Legitimacy With Companies and Consumers
The .Pharmacy Verified Websites Program gives your organization a simple and straightforward way to stand apart as credible and safe.

8 Advisory Board member for the .Pharmacy Verified Websites NABP initiative.

Your contacts at ASOP EU and EAASM
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