Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies

Zagreb 3 March 2023

The importance of having the right policies and regulations in place to ensure patient safety – the case for nanomedicines

Mike Isles
Executive Director,
European Alliance for Access to Safe Medicines

European Alliance for Access to Safe Medicines

Independent pan-European NFP organisation dedicated to protecting patient safety by ensuring access to safe medicines - falsified medicines awareness & legislation/safer use of off label medicines/medication errors/nanomedicine regulatory clarity

ASOP EU
Alliance for Safe Online Pharmacy

Multisectoral, coalition of organisations dedicated to making the internet a safer place to buy medicines where it is legal to do so

International Health Partners

Charity whose Queen's Award for Innovation 2011 recognises the work sourcing quality donated medicines from the pharma industry and delivery via secure supply chains to disaster-struck areas in close liaison with NGOs

ECAMET

European Collaborative Action on Medication Errors and Traceability

View reports on reduction of medication errors and interactive dashboard

Click here to read the ECAMET White Paper and Call to Action

Click here to read the White Paper 'Digital Medication Management in Healthcare Settings'

NEWS

NEWS · 13th September 2022

PRESS RELEASE: Medication Errors – the Most Common Adverse Event in Hospitals Threatens Patient Safety and Causes 160,000 Deaths per Year

Read more

NEWS · 26th March 2022

EVENT SUMMARY: Event summary of the roundtable event on "Preventing Medication Errors across European Hospitals to protect Patient Safety" held on 22nd March 2022 11:30-13:30 CET

Read more

BREAKING NEWS · 22nd March 2022

Launch and publication of WHITE PAPER ECAMET – THE URGENT NEED TO REDUCE MEDICATION ERRORS IN HOSPITALS TO PREVENT PATIENT AND SECOND VICTIM HARM

Read more

NEWS · 18th February 2022

EVENT: Preventing Medication errors across European hospitals to protect patient safety: Launch of the White Paper on Medication Errors and Traceability – 22 March 2022

Read more

PUBLICATION · 9th July 2021

Working Against Cancer: Giving Professionals the Right Tools for the Job

Read more

View Latest News

Join us - We need your support

ECAMET

NAVIGATION

Dashboard

Results

Data

Absolute

Hospital Type

- [x] General Hospitals
- [x] University
- [x] Private Hospital
- [x] Oncology
- [x] Other

Hospital Size

- [x] Small
- [x] Medium
- [x] Large

Medication errors survey - dashboard to compare and contrast results across Europe

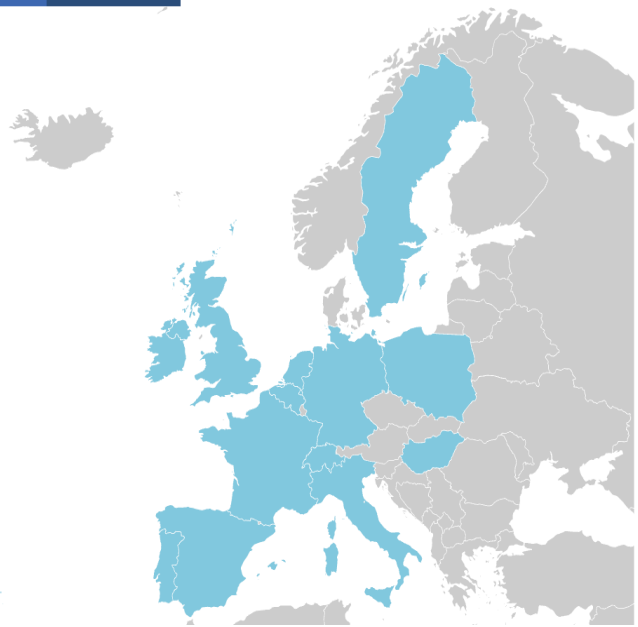
Home › Interactive Dashboard

Question: Q4 - Is your hospital accredited (has it a quality certification or passed a recognised inspection)?

Answer (Please select one of the options below to colour the answers)	EU	BE	FR	DE	HU	IT	NL	PL	ES	SE	CH	PT	UK	IE	Priv.H.
Yes	260	7	41	39	6	25	10	19	31	4	10	24	36	1	7
No	57	3	1	1	0	17	0	1	10	1	2	12	4	3	2
Base	317	10	42	40	6	42	10	20	41	5	12	36	40	4	9

MAP

0-25% 26-50% 51-75% 76-100%



The Issue - one

- Nanomedicines and follow-on nanosimilars have complex manufacturing processes and heteromolecular structures
- The question is being raised in ever increasing frequency, whether the current European regulation of medicines for human use is robust enough to authorise these medicines and their nanosimilar follow-ons
- Until this can be achieved then there is the potential for patient safety to be compromised

The Issue - two

- Currently nanomedicines can be assessed under four different types of procedures:
  - National, decentralised, mutual recognition, centralised procedure
- 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 S, Halamoda-Kenzaoui B, Borgos SE, Journal of Interdisciplinary Nanomedicine vol 3,issue 1 March 2018

- This gives rise to major safety monitoring issues as the same nanosimilar can be registered under different brand names in different countries making adverse event monitoring linkage difficult.

Klein et al., European Journal of Pharmaceutical Science Volume 133, 15 May 2019, pages 228-235

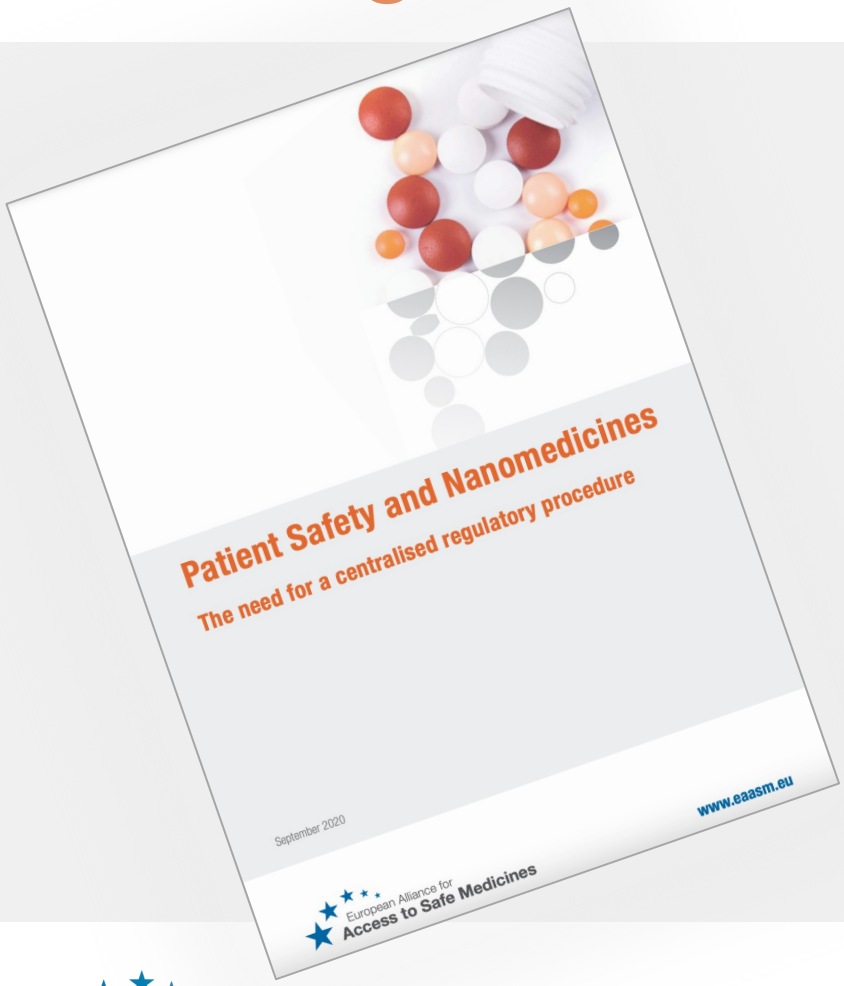
Objective of EAASM and the Nanomedicine Coalition Patient Safety Project

1. To raise awareness amongst policymakers, prescribers, payers, patient organisations and patients of the need for scientific consensus on definitions for nanomedicines across Europe
2. To develop a robust fit-for-purpose centralised regulatory procedure for both new innovative nanomedicines as well as nanosimilars follow-on products.

Methodology

1. Through an extensive advocacy programme comprising:
   - A scientific report
   - A summary briefing document
   - A coalition of influential like-minded organisations
   - A coalition website
   - Scientific paper in Frontiers in Pharmacology
   - EU Parliament round table discussions that aim to bring to the attention key influencers and especially MEPs, EMA and DG SANTE
   - Inclusion into the European Parliament INI report on the Pharmaceutical Strategy for Europe

Scientific report & summary briefing document



Sign the Petition and join the Coalition

Nanomedicines Petition: Ensuring patient safety through regulatory clarity – sign the petition

In collaboration with other European associations, the EAASM has produced a leaflet calling upon DG SANTE, the EMA, Member States' health authorities and regulatory bodies to address unmet medical needs and enhance quality, safety and efficacy of nanomedicines and nanosimilars by addressing patient safety issues due to significant regulatory challenges across Europe.

Title

Mr

First Name

Last Name

Email Address

Organisation

I support the petition to endorse more collaborative actions for a new robust regulatory framework for nanomedicines and nanosimilars.

Would you like to be contacted to hear about updates with our campaign?

Yes No

Submit

Screenshot

The Nanomedicines Regulatory Coalition

THE REGULATORY NANOMEDICINES COALITION

ERA LEADING EUROPEAN NEPHROLOGY

International Alliance of Patients' Organizations
A global voice for patients

ESN EUROPEAN SPECIALIST NURSES ORGANISATION

ELPA European Liver Patients' Association

EPDA European Parkinson's Disease Association

European Cancer Patient Coalition

European Alliance for Access to Safe Medicines

The Coalition Website

https://eunanomedicinescoalition.eu

OPINION article

Front. Pharmacol., 24 February 2022
Sec. Drugs Outcomes Research and Policies
Volume 12 - 2021 |
https://doi.org/10.3389/fphar.2021.787239

This article is part of the Research Topic
Prevention, Diagnosis and Treatment of Rare Disorders
View all 20 Articles >

Nanomedicines and Nanosimilars—Why a Robust Centralised Regulatory Framework Is Essential to Enhance Patient Safety

Michael P. Isles*

European Parliament

MEP Endorsement

European Alliance for Access to Safe Medicines

European Parliament

"Nanomedicines and their follow-on products, nanosimilars, are complex innovative molecules offering solutions for many treatment challenges. Hence, a centralised fit for purpose regulatory framework is urgently needed. The regulatory journey that biosimilars took achieved remarkable outcomes. With strong collaboration by DG Sante, the EMA, the industry and patient organisations, I am confident that nanomedicines will share a similar successful pathway in Europe."

MEP Dominique Riquet

Member of the European Parliament
France, Renew Europe

Visit the Nanomedicine Regulatory Coalition's website:
www.eunanomedicinescoalition.eu

MEP Endorsement

European Alliance for Access to Safe Medicines

Parlamentum Europaeum

"Nanomedicines are innovative products which enhance the way that medicines target and reach areas of disease, making treatments highly effective. However, even small changes in the manufacturing process can adversely affect the safety, efficacy and quality of the nanomedicine and the follow-on off patent nanosimilars. So it's critical that policy makers endorse a fit-for-purpose centralised regulatory framework which in turn, will ensure a resilient and sustainable Health Union for all citizens in the EU."

MEP Cyrus Engerer

Member of the European Parliament

Cyprus, S&D

Visit the Nanomedicine Regulatory Coalition's website:

w Screenshot medicinescoalition.eu

MEP Endorsement

European Alliance for Access to Safe Medicines

Parlamentum Europaeum

"The EU has the chance to lead the world in developing a centralised regulatory procedure for nanomedicines and nanosimilars. Together with the members of the Nanomedicines Regulatory Coalition, the hope is to address unmet medical needs so that regulatory weaknesses can be addressed through a robust regulatory pathway and thus provide medicines with the highest quality, safety and efficacy profiles for all European citizens and patients."

MEP Petar Vitanov

Member of the European Parliament
Bulgaria, S&D

Visit the N Screenshot ine Regulatory Coalition's website:

Letter to the EU Commissioner for Health and Food Safety

European Alliance for Access to Safe Medicines

Brussels, 30 June 2021

Re: Enabling a centralised regulatory system for nanomedicines through the Pharmaceutical Strategy for Europe

Dear Commissioner for Health and Food Safety, Ms. Stella Kyriakides,

On behalf of the European Alliance for Access to Safe Medicines (EAASM), the member organisations of the Nanomedicines Regulatory Coalition (NRC)[1] and a number of Members of the European Parliament, we would like to bring to your attention a regulatory issue which will have a major impact on the EU health sector in the upcoming years; namely the approval of innovative nanomedicines and their follow-on copy versions, nanosimilars.

What are nanomedicines?

Nanotechnology is an emerging innovative technology which has the potential to address unmet medical needs and will offer alternatives for several therapeutic areas. Nanomedicines offer potential solutions for a number of current treatment challenges, such as cancer, cardiovascular, neurodegenerative disorders, as well as other diseases; the innovative mRNA vaccines contain nanoparticles.

Nanomedicines are:

- **Innovative** – they enhance the way that medicines target and reach areas of disease within the body, as well as having inherent therapeutic activity, making treatments highly effective.
- **Complex** – they consist of multifaceted nanoparticles engineered to have favourable biological, chemical, pharmacological as well as immunological properties.
- **Manufacture dependant** – assembling different chemical parts into complex nanoparticles requires highly standardised and complex manufacturing processes to guarantee consistent quality and clinical effectives and safety.

Patient safety … needed

Currently, th… has potentia… surrounding nanomed…

In order to fully harness the potential of nanomedi… framework for this class of products is needed at EU level. Nan… through a centralised procedure to prevent different approaches by Membe… a separate regulatory framework for follow-on products is also required – as it has been… biosimilars over the past years – or as alternative, additional guidelines on how the centralised hybrid regulatory pathway should be used to approve these medicines.

3 key recommendations to ensure patient safety and enable the EU to fully harness the potential of these medicines:

1. Developing a **scientific consensus** on definitions for nanomedicines in Europe, improving education and fostering awareness on the complexity and sophistication of nanomedicines among policy makers, prescribers, payors and patients;
2. Adopting an **EMA centralised procedure** for all nanomedicines and nanosimilars which would ensure the correct scrutiny and assessment of these complex products. This is key to avoid diverging approaches between Member States and to ensure patient safety;
3. **Clarifying regulatory criteria** for the approval of follow-on/nanosimilar medicines. As manufacturing exact replicas of nanomedicines is not achievable, therapeutic similarity will need to be shown through clinical evidence. In addition, the highest possible manufacturing standards must be guaranteed and included in the licence application.

In the absence of clarity on nanomedicines and nanosimilar regulatory pathways and a… scientific, policy and practical knowledge on the quality, safety, and efficacy of nan… must be gained among all stakeholders, including payors and health care p…

Clarifying the regulatory system for nanomedicines th…

With the ongoing Pharmaceutical Strategy for E… slations, it is the right time to set the scene for b… tory weaknesses can be addressed through a … es with the highest quality, safety and efficacy … dicines but the many new nanomedicines tha…

chance to lead the world in developing a c… In doing so, it will contribute greatly to the … of legislation to **cutting-edge products, sc…**

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…ent these recommendations and str…

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…ice of Socialists and Democrats)
…sive Alliance of Socialists and Democrats)
…ark, Greens/European Free Alliance)

European Alliance for Access to Safe Medicines

EAASM Director Mike Isles and the Members of the Nanomedicines Regulatory Coalition (NRC)

ERA · 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

5 MEPS

European Alliance for Access to Safe Medicines

www.eaasm.eu

So where are we in the process?
The Own-Initiative Procedure

European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

DRAFT REPORT

on Pharmaceutical Strategy for Europe
(INI))</DocRef>.

Committee on the Environment, Public Health and Food

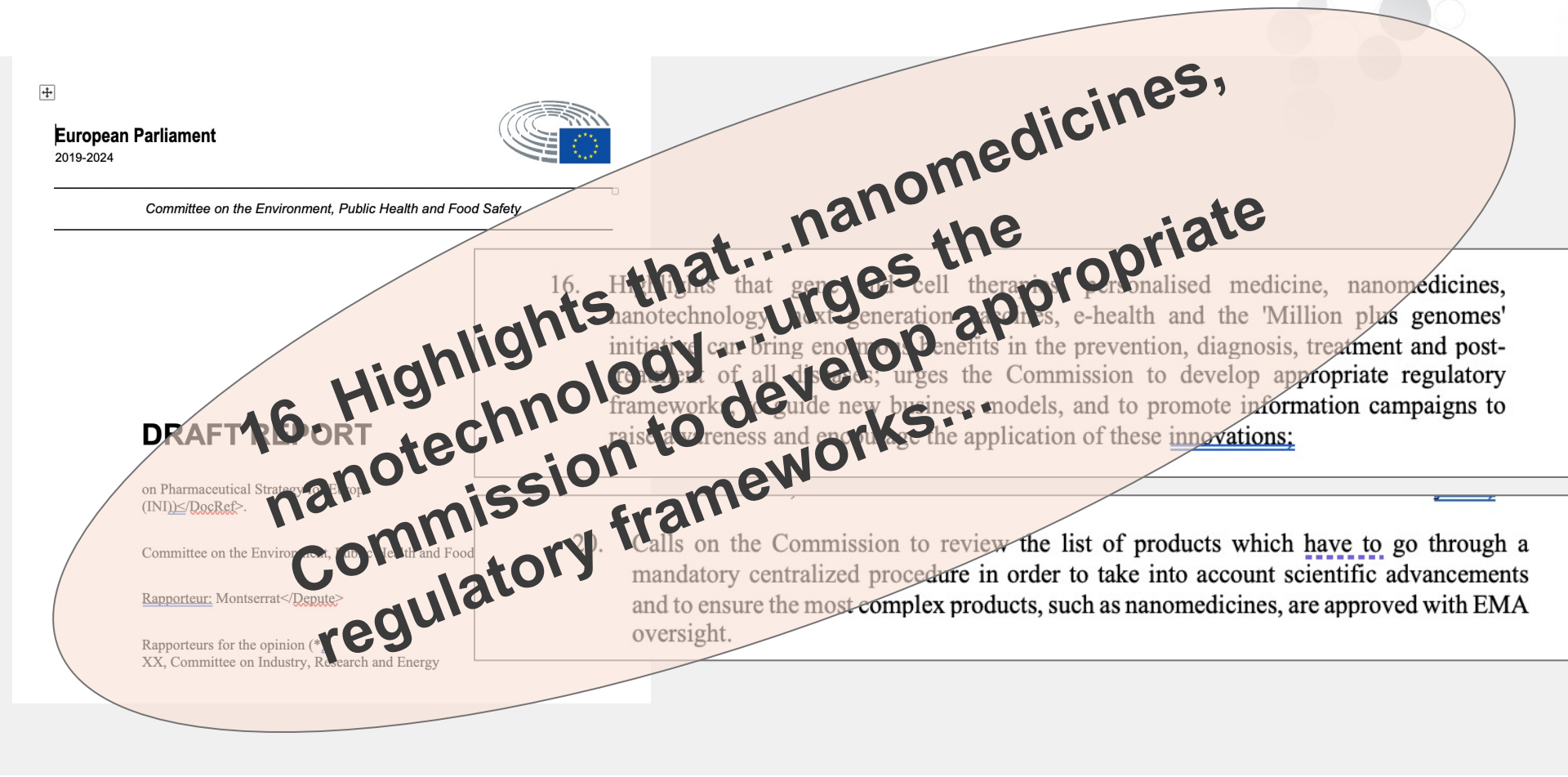
Rapporteur: Montserrat</Depute>

Rapporteurs for the opinion (*):
XX, Committee on Industry, Research and Energy

16. Highlights that gene and cell therapies, personalised medicine, nanomedicines, nanotechnology, next generation vaccines, e-health and the 'Million plus genomes' initiative can bring enormous benefits in the prevention, diagnosis, treatment and post-treatment of all diseases; urges the Commission to develop appropriate regulatory frameworks, to guide new business models, and to promote information campaigns to raise awareness and encourage the application of these innovations;

20. Calls on the Commission to review the list of products which have to go through a mandatory centralized procedure in order to take into account scientific advancements and to ensure the most complex products, such as nanomedicines, are approved with EMA oversight.

So where are we in the process?
The Own-Initiative Procedure



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European Parliament
2019-2024

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DRAFT REPORT

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20. Calls on the Commission…to ensure the most complex products, such as nanomedicines, are approved with EMA oversight

The Coalition is pursuing two objectives in ongoing revision of EU Pharmaceutical Legislation

1a) Develop a new stand-alone application for non-biologic complex drugs/nanomedicines similar to what exists for biosimilars by changing Article 10 of Directive 2001/83/EC

Or

1b) Introduce additional requirements for abbreviated ("hybrid") applications for follow-on nanomedicines/NBCDs by Changing Part II of Annex I of Directive 2001/83/EC (new section similar complex non-biological medicinal products)

And

2) Mandatory centralised procedure for NBCDs (including follow-on NBCDs) by adding NBCDs/nanomedicine to Annex of Regulation 726/2004

Parliament meeting

- Tuesday 30th November 2021
- Virtual event entitled **“Nanomedicines and nanosimilars: the medical need for a centralised EMA regulatory process”**
- Via Teams, 1000 – 1130 CET
- Hosted by **MEP Petar Vitanov** (S&D, Bulgaria), with the participation of the **Dr Rys** Director for Health systems and products at DG SANTE, **Prof. Scott McNeil** and influential health stakeholders

AGENDA

FREE ONLINE EDUCATIONAL WORKSHOP

Nanomedicines in the EU: Innovative therapies and regulatory needs

Date: Wednesday, 7 December 2022 (16.00 - 17.30 CET)
Via ZOOM

EAASMeds

16.00 - 16.10

Welcoming remarks

Mr. Mike Isles, Executive Director, European Alliance for Access to Safe Medicines

16.10 - 16.20

Regulatory challenges for non-biological complex drugs products

Mr. Jon de Vlieger, phD, Coordinator NBCD Working Group and Strategy Director, Lygature

16.20 - 16.35

Academic perspective on the future of nanomedicines in Europe

Prof. Poala Minghetti, Universita' degli studi di Milano

16.35 - 16.50

Intervention from the U.S. Food and Drug Administration

Mrs. Katherine Tyner, FDA Liaison Officer to the European Medicines Agency

16.50 - 17.00

Results of the EAASM survey on Member States' knowledge on nanomedicines

Mr. Mike Isles, Executive Director, European Alliance for Access to Safe Medicines

17.00 - 17.10

Intervention from a National Competent Authority

Prof. Anthony Serracino-Inglott, Chief Executive Officer, Malta Medicines Authority

17.10 - 17.30

Q&A session and closing remarks

Mr. Mike Isles, Executive Director, European Alliance for Access to Safe Medicines

Parliament meeting

www.eaasm.eu

European Alliance for
Access to Safe Medicines

The revision of the general pharmaceuticals legislation is the perfect opportunity:

- Regulatory clarity in this area would allow the full benefits of nano-medicinal products to be realised.

Solutions:

1. **Introduce a regulatory framework** → Introduce new Article 10.5 of 2001/83 **OR** amend existing Article 10.3
2. **Introduce a centralised approval procedure** → Amend Annex I, 2001/83
3. **Introduce a nano-medicinal products definition** → Amend Annex I, 726/2004

As part of the EU pharmaceuticals strategy, and drawing lessons from the COVID-19 pandemic, the **Commission plans to evaluate and revise the EU's general legislation on medicines for human** use to ensure a future-proof and crisis-resistant medicines regulatory system.

The revision will aim to:

- ensure access to affordable medicines
- foster innovation, including in areas of unmet medical need
- improve security of supply
- adapt to new scientific and technological developments
- reduce red tape

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Revision of the general pharmaceutical legislation

4.3.2 Relevance of the general pharmaceutical legislation's objectives and required actions to current needs and problems and expected developments related to medicinal products in the EU

Overall, stakeholder groups agreed in interviews that the current legislative framework and obligations need to be adapted in light of scientific and technological developments. These new technologies are giving rise to new types of medicinal products that do not fit in with the existing paradigms of what a medicine is and how it should be evaluated. For example, ATMPs and medicine-device combination products find themselves at the borderline between the general pharmaceutical legislation and other legislations e.g. the ATMP and medical device regulations. Therefore, there is demand from stakeholders (civil society, healthcare professionals, industry and public authorities) for clarity with regard to requirements for borderline and combination products. Real-world evidence, big data and digitalisation have not been accommodated to their full potential according to industry and public authorities. Other areas noted include nanomedicines, microbiome-based products, nuclear medicine; the use of artificial intelligence (AI) and digitalisation are not adequately accommodated by the current legislation.

4.3.2 Relevance of the general pharmaceutical legislation's objectives and required actions to current needs and problems and expected developments related to medicinal products in the EU

Overall, stakeholder groups
need to be adapted
giving rise to
medici
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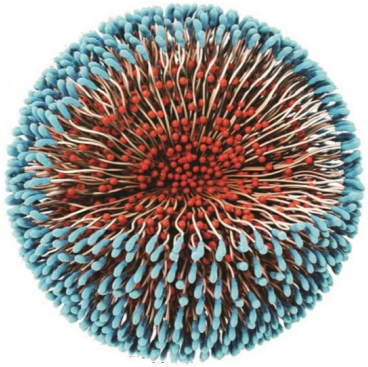
medicine; the use of artificial
ed by the current legislation.

However, academics and civil society organisations noted that in certain areas, such as nanomedicines and medical devices, the legislation has not responded as well.

Next steps - Pharmaceutical Legislation due to be published on 29th March 2023

- Question to EU Parliament by MEP regarding inclusion of the amendments
- Advocacy to EU Council – Permanent Health Attaches
- Re-connect with DG Sante asking pertinent questions
- Re-connect with MEPs who are supporting the amedments

European Alliance for
Access to Safe Medicines



EAASM Survey Results

We submitted a survey to the National Competent Authorities (NCAs) of the Member States responsible for human medicines to gather their knowledge and views on nanomedicines and nanosimilars (off patent follow-on medicines).

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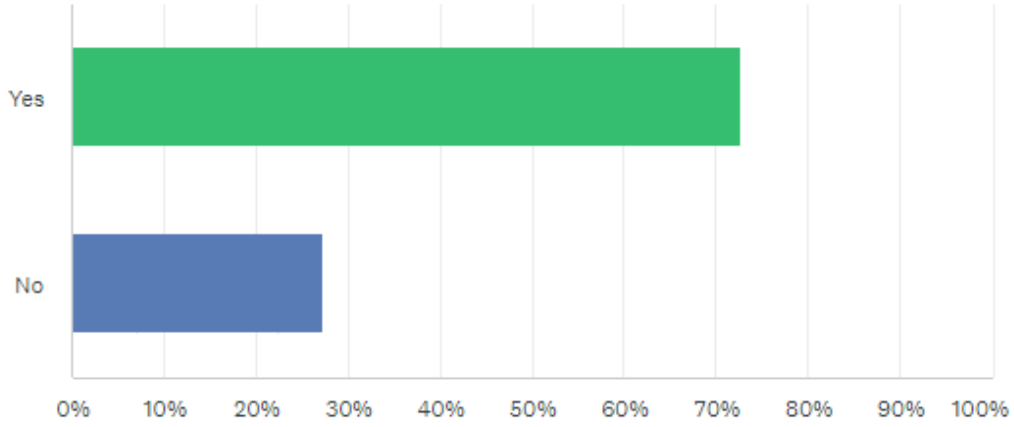
Do you believe there is a need of a legal definition of nanomedicine at European level?

Answered: 11 Skipped: 0



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Access to Safe Medicines

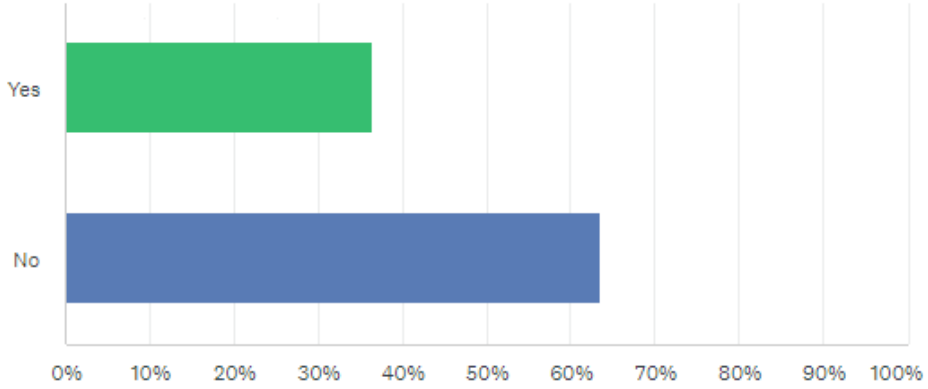
Proposed definition of nanomedicines:

“Nano-medicinal product shall mean medicinal products that are purposely designed, engineered or manufactured to contain nanoparticles of at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm), which are presumed to affect the physiological or pharmacological effect as a result of the size; OR Particles with at least one external dimension, or an internal or surface structure, up to one micrometer (1,000 nm), where such medicinal products are designed, engineered or manufactured to exhibit physical or chemical properties or biological effects, that are attributable to their dimensions.”

European Alliance for
Access to Safe Medicines

Have you had direct experience of assessing a nanomedicine or nanosimilar dossier? Please add any comments in relation to challenges you may have identified in the assessment

Answered: 11 Skipped: 0



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Access to Safe Medicines

Challenges during the assessment

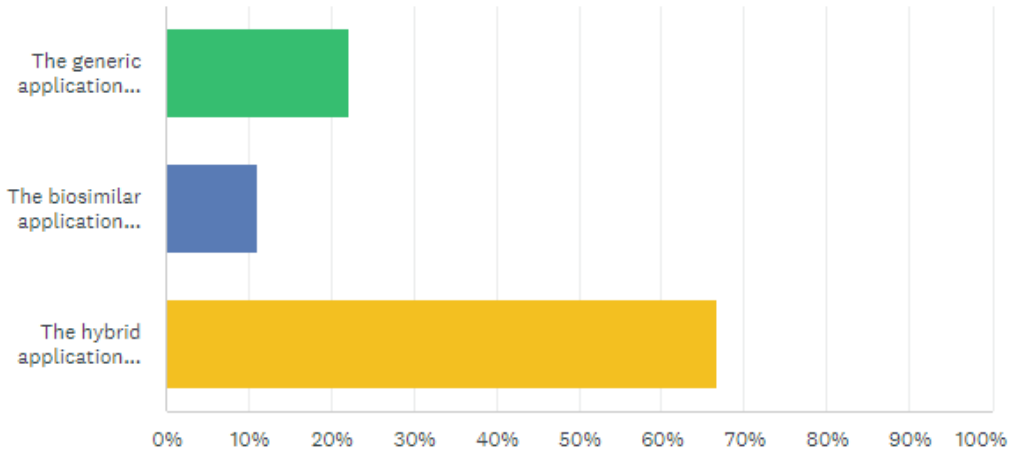
- **According to some National Competent Authorities, among the most challenging aspects, is the complex manufacturing process and the lack of harmonised criteria for their assessment, together with the lack of experience and expertise within the National Competent Authorities.**

- It should be noted that one of the authorities did not participate in the survey, reporting a lack of expertise and limited resources to be able to devote to collecting the information needed to answer the questionnaire.

European Alliance for
Access to Safe Medicines

Do you believe that, of the currently abbreviated pathways there is one which is most appropriate for the application of follow-on nanomedicines/nanosimilars?

Answered: 9 Skipped: 2



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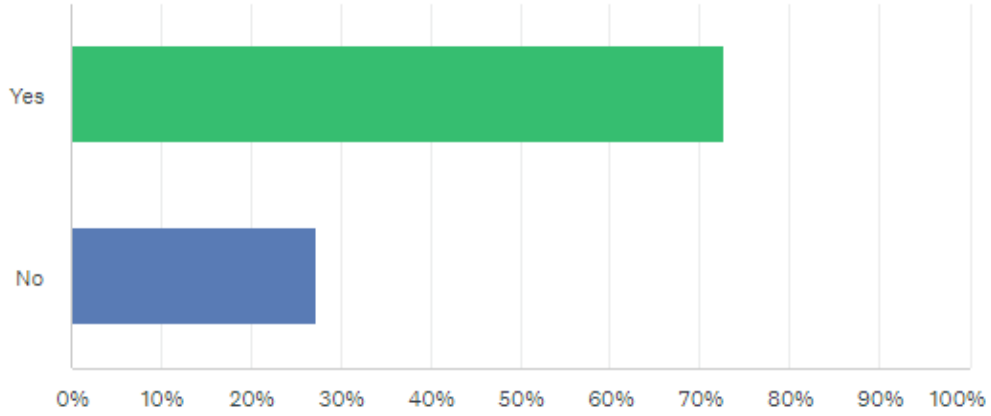
Access to Safe Medicines

Are you aware of the EMA 2013 Liposomal Products reflection paper and the EMA 2015 reflection paper on iron sucrose similar?

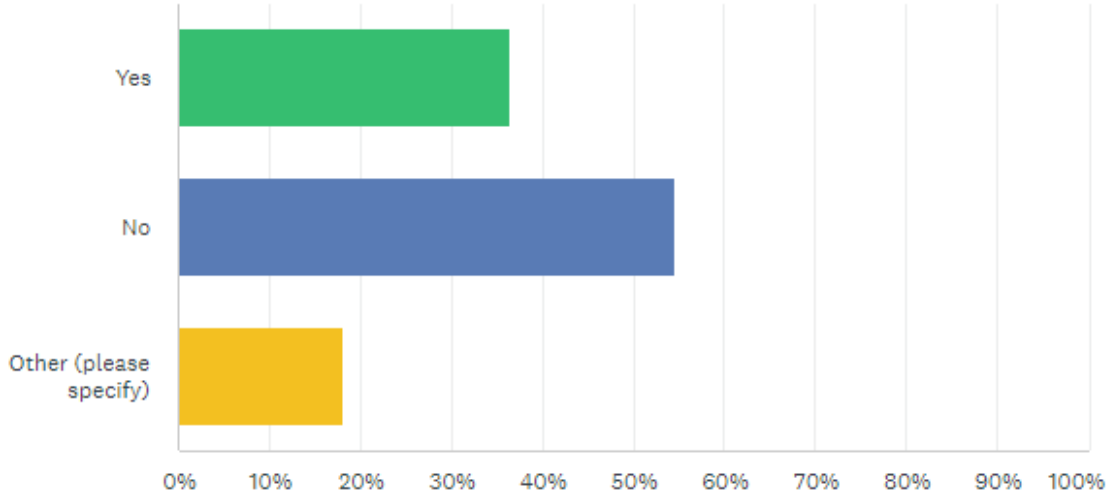
Answered: 11 Skipped: 0



European Alliance for
Access to Safe Medicines

In light of their complexities, do you believe that the 10.1 simple generic pathway is appropriate for the approval of nanosimilars and follow-ons of the broader category of NBCD (Non-Biological Complex Drugs)?

Answered: 11 Skipped: 0



European Alliance for
Access to Safe Medicines

National Competent Authorities' considerations

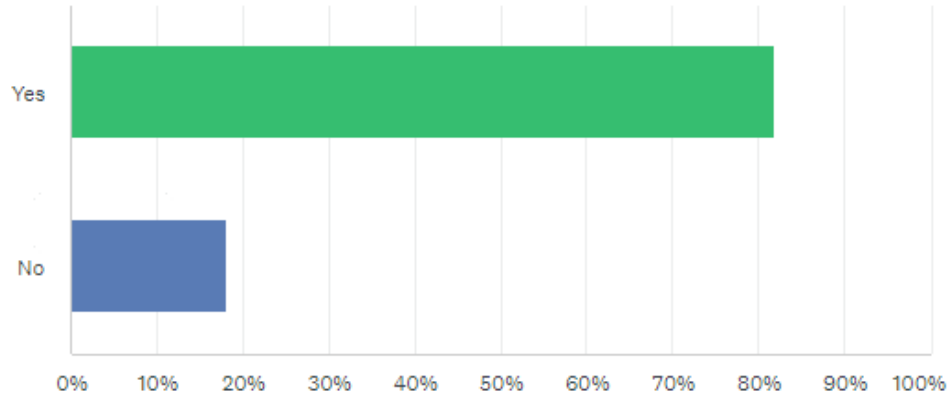
- According to one National Competent Authority, the product and type of nanoformulation have to be considered in selecting the most appropriate process pathway.

- One of the respondents envisaged the need to develop a specific validated pathway for nanomedicines

European Alliance for
Access to Safe Medicines

Are you aware that patient safety issues have arisen when biosimilars were first made available and that it took some time for clinical interchangeability best practice between the innovator and the biosimilars to become established?

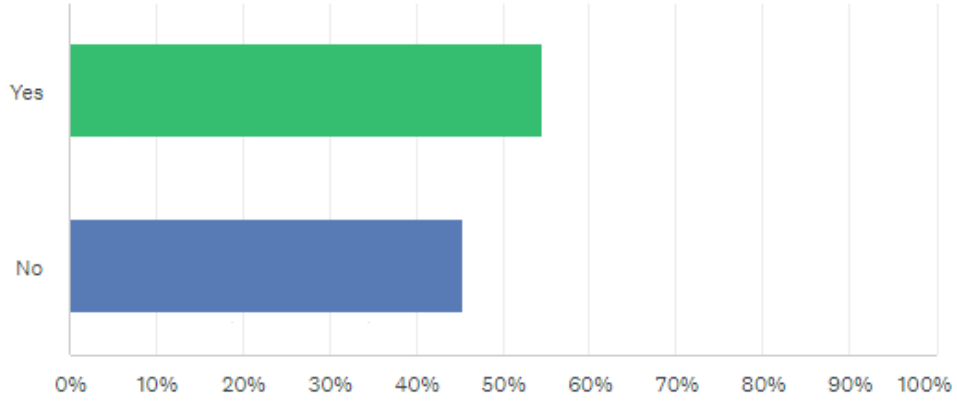
Answered: 11 Skipped: 0



European Alliance for
Access to Safe Medicines

Given the known and reported difficulties of linking pharmacovigilance due to different regulatory approvals occurring with different brand names, should this be addressed in the Revision of the EU general pharmaceuticals legislation?

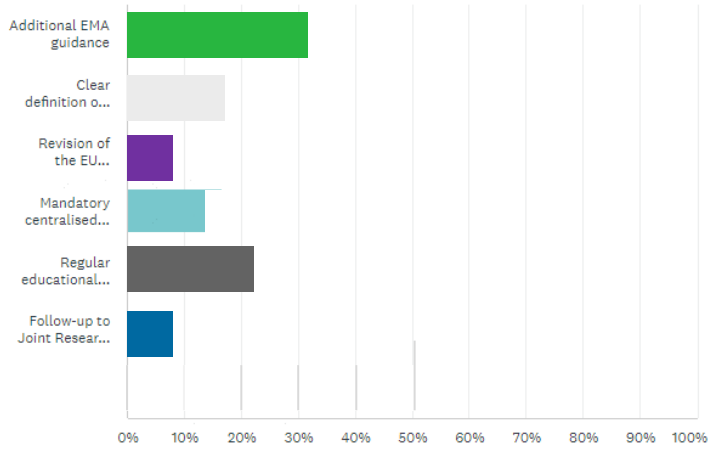
Answered: 11 Skipped: 0



European Alliance for
Access to Safe Medicines

What initiative would you find most useful to help you better assess nanomedicines and their follow-ons? Please choose top three

Answered: 23 preferences in total



European Alliance for
Access to Safe Medicines

Initiatives selected by the Member States

- Three National Competent Authorities did not choose three initiatives but only one. They preferences were:
  - *Additional EMA guidance*
  - *Mandatory centralised procedure for all nanomedicines*
  - *Regular educational workshops on the topic*

- The remaining National Competent Authorities selected three preferences. Their answers are:

6 *Additional EMA guidance with harmonised criteria for assessing such products*

4 *Clear definition of nanomedicines*

4 *Regular educational workshops on the topic*

2 *Mandatory centralised procedure for all nanomedicines*

2 *Revision of the EU Pharmaceutical Legislation (which may include an extended scope of mandatory centralised procedure for defined nanomedicines)*

2 *Follow-up to Joint Research Centre work on nanomedicines*

4.3.1 The extent to which the general pharmaceutical legislation responded to the needs and problems

The legislation has direct relevance to and responded well to the need of approving innovative medicines in Europe. According to public authority stakeholders, the legislation has a "fairly wide scope that is adaptable and can deal with new products through guidelines". This view was also shared by several industry stakeholders. However, academics and civil society organisations noted that in certain areas, such as nanomedicine and medical devices, the legislation has not responded as well.

Medicine shortage has been recognised as an important problem in Europe and the legislation has direct relevance to identifying and acting on shortages through obligation for MAHs to keep sufficient stocks of medicinal products and report potential future shortages. Nevertheless, civil society and healthcare professionals felt that the problem is not adequately addressed in the current legislation.

Within the survey, stakeholders identified areas where the current legislation has addressed stakeholder needs to the greatest and least extent. Some of these areas are listed in the table below:

European Alliance for Access to Safe Medicines

BUTLER UNIVERSITY

Investigational Survey on Clinical Interchangeability between Nanomedicines and Nanosimilars

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 and areas to improve patient care. The purpose of this survey is to determine clinical 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.

If you would like to take part in this short survey
Please complete your email contact details here……

Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies

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Thank you

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