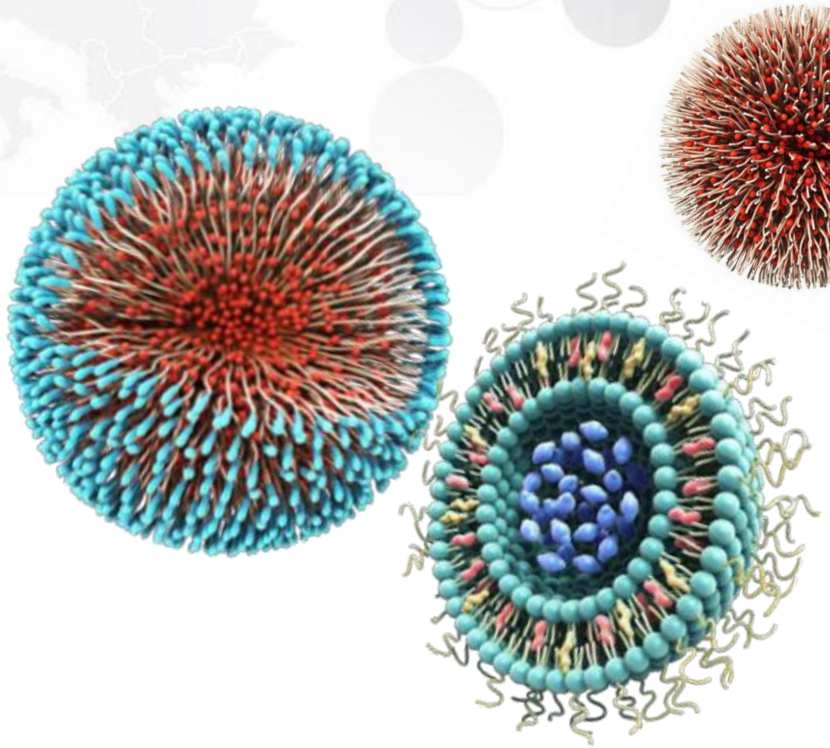
European Alliance for
Access to Safe Medicines

EDUCATIONAL WORKSHOP

Nanomedicines in the EU: Innovative Therapies and Regulatory Needs



7 DECEMBER 2022, 16:00 – 17:30 VIA ZOOM

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Housekeeping rules

- Please don’t forget to mute yourself and turn off your video.
- This meeting will be recorded.
- All participants have access to the chat.
- It is possible to send separate messages by clicking on the image of the person you want to talk to, so you will be able to start a private conversation with him/her.
- We will have a Q&A session at the end of the meeting, but feel free to write your questions down in the chat. We will share them with our speakers in due time.

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Agenda

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

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

Paola Minghetti, Universita' degli studi di Milano

Katherine Tyner, Food and Drug Administration Liaison Officer to the European Medicines Agency

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

Mike Isles, Results of the EAASM survey on Member States' knowledge on nanomedicines

Q&A session and closing remarks

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Access to Safe Medicines

Independent pan-European not for profit 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

* EU Transparency registry Identification number: 8613686111058-84

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Nanomedicines and Nanosimilars – mutual understanding

- Raising awareness around the rapidly developing of nano-medicinal products; history and future
- Understanding the knowledge and the position of the **National Competent Authorities (NCAs)** of the Member States responsible for human medicines, **Permanent Representations and Health Ministers** on nanomedicines and nanosimilars
- Pharmacovigilance issues
- **EU Parliament** position
- Proposal to **amend legislation**

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The EU Nanomedicines Regulatory 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

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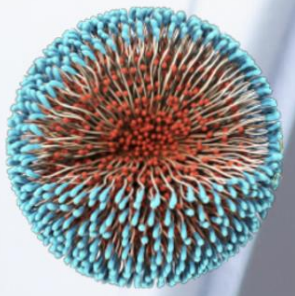

THE NANOMEDICINE REGULATORY COALITION

NANOTECHNOLOGY

Nanotechnology is a compelling and growing scientific field that provides numerous opportunities for life science organisations to develop innovative medicines to address unmet medical needs.

NANOMEDICINES

Nanomedicines may exhibit a complex mechanism of action combining mechanical, chemical, pharmacological as well as immunological properties.

NANOSIMILARS

Nanosimilars are follow-on products after the originator nanomedicine's patent has expired. A nanosimilar is a nanomedicine which should be highly similar to the originally approved product.

In spite of the opportunities they bring, nanomedicines are highly complex and their quality attributes are closely linked to their manufacturing process. Changes in quality, safety

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Main activities at EU level 2018-2022

- Annual **events** within the European Parliament and participation in **several conferences and seminars**
- Publication of a **Scientific Report** (September 2020)
- MEPs co-signed **letter to the European Commissioner** for Health and Food Safety, Ms Stella Kyriakides
- **Media coverage** (including the prestigious medical journal Frontiers)
- Meetings with **MEPs and DG SANTE**
- Outreach campaign to **National Competent Authorities, Permanent Representations, Health Ministers**

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The European Parliament has called for this to be addressed:

European Parliament's 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****"*

Amendments tabled by MEPs from:

epp group in the european parliament

S&D Group of the Progressive Alliance of Socialists & Democrats in the European Parliament

ECR GROUP EUROPEAN CONSERVATIVES AND REFORMISTS

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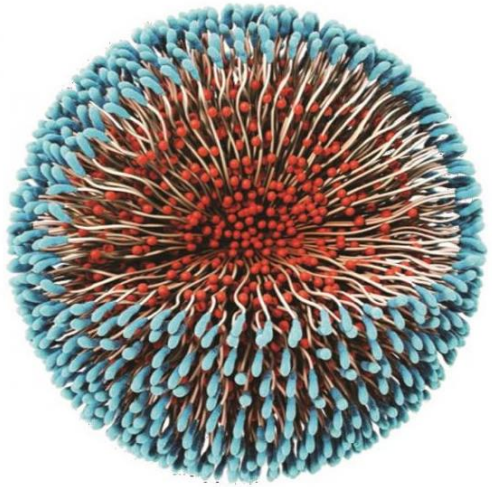

EAASM Survey Results

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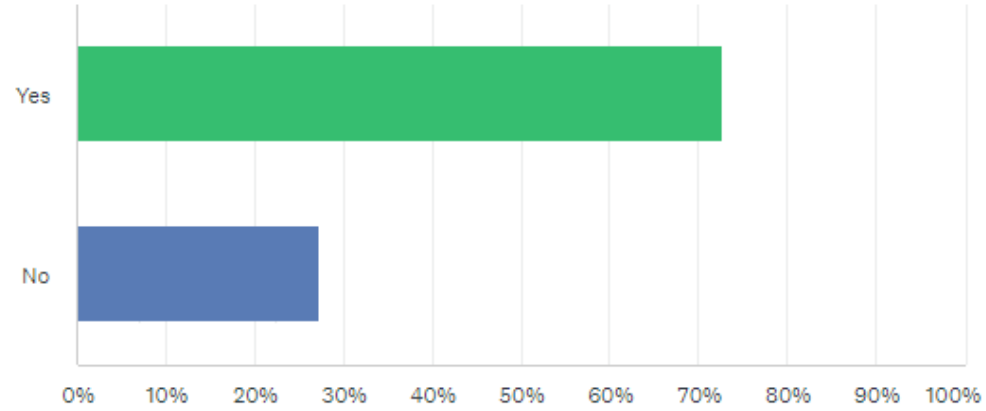
Do you believe there is a need of a legal definition of nanomedicine at European level?

Answered: 10



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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."

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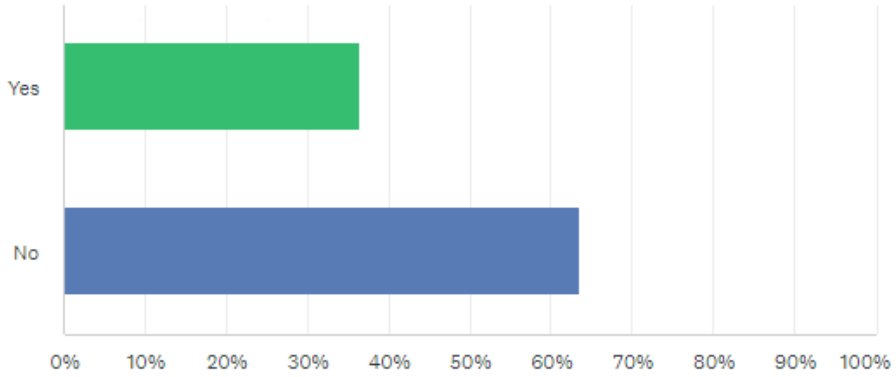
Have you had direct experience of assessing a nanomedicine or nanosimilar dossier? Please add any comments in relation to challenges you may have identified in the assessment

Answered: 10



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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.

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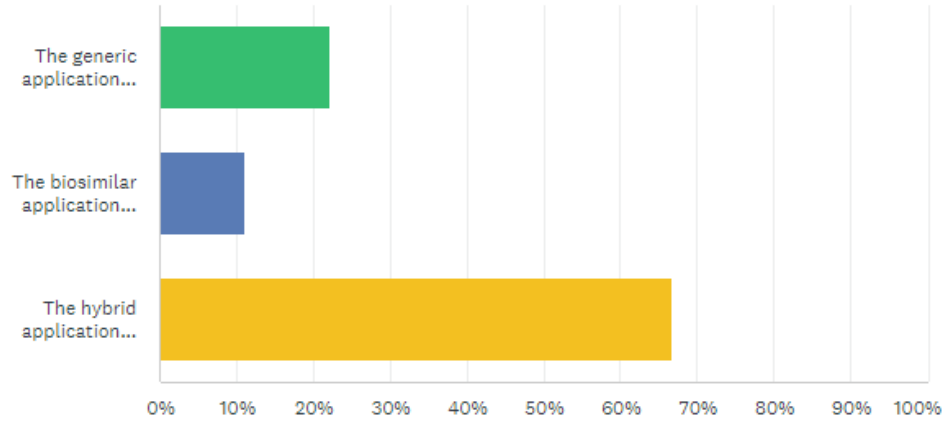
Do you believe that, of the currently abbreviated pathways there is one which is most appropriate for the application of follow-on nanomedicines/nanosimilars?

Answered: 10



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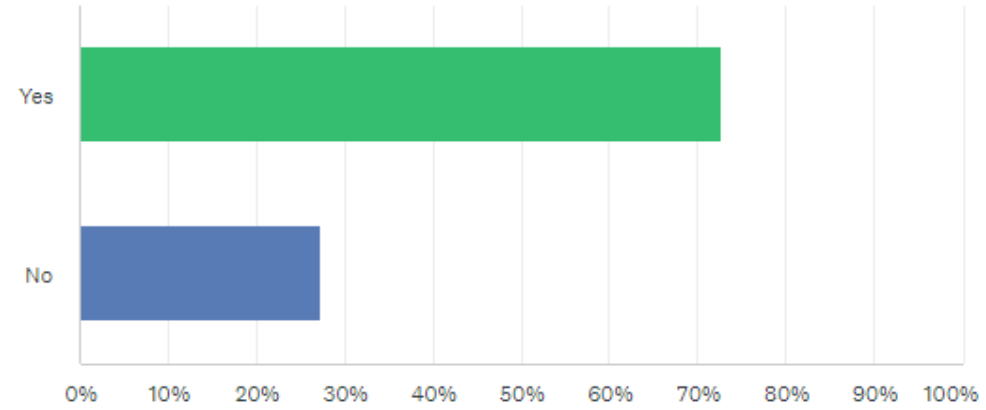
Are you aware of the EMA 2013 Liposomal Products reflection paper and the EMA 2015 reflection paper on iron sucrose similar?

Answered: 10



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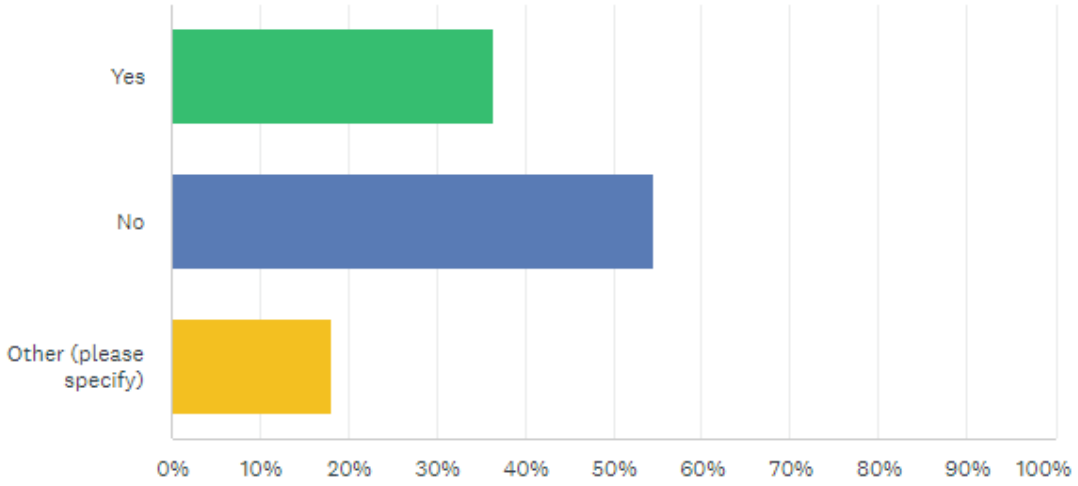
In light of their complexities, do you believe that the 10.1 simple generic pathway is appropriate for the approval of nanosimilars and follow-ons of the broader category of NBCD (Non-Biological Complex Drugs)?

Answered: 10



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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

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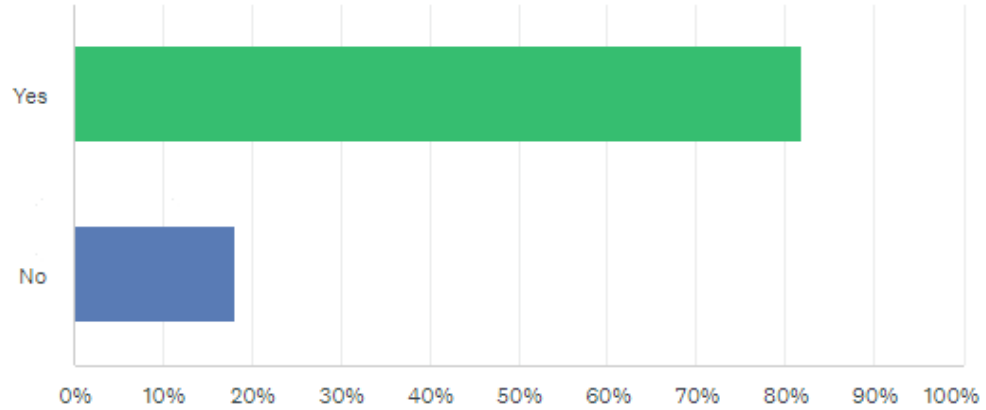
Are you aware that patient safety issues have arisen when biosimilars were first made available and that it took some time for clinical interchangeability best practice between the innovator and the biosimilars to become established?

Answered: 10



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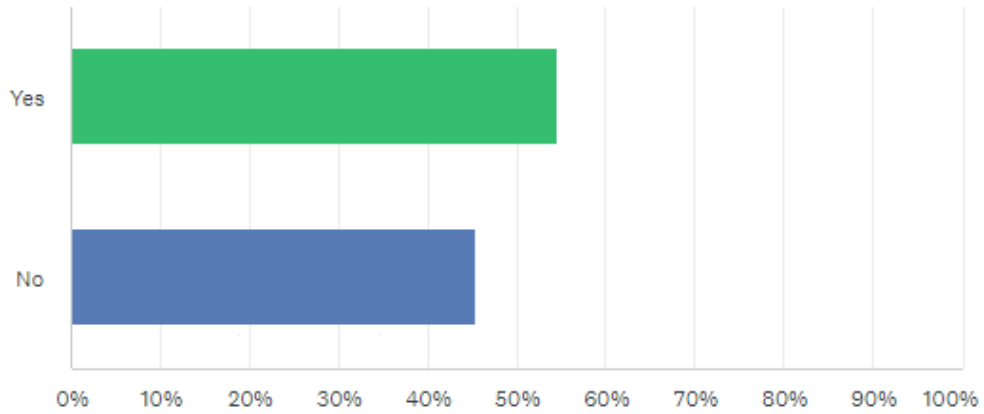
Given the known and reported difficulties of linking pharmacovigilance due to different regulatory approvals occurring with different brand names, should this be addressed in the Revision of the EU general pharmaceuticals legislation?

Answered: 10



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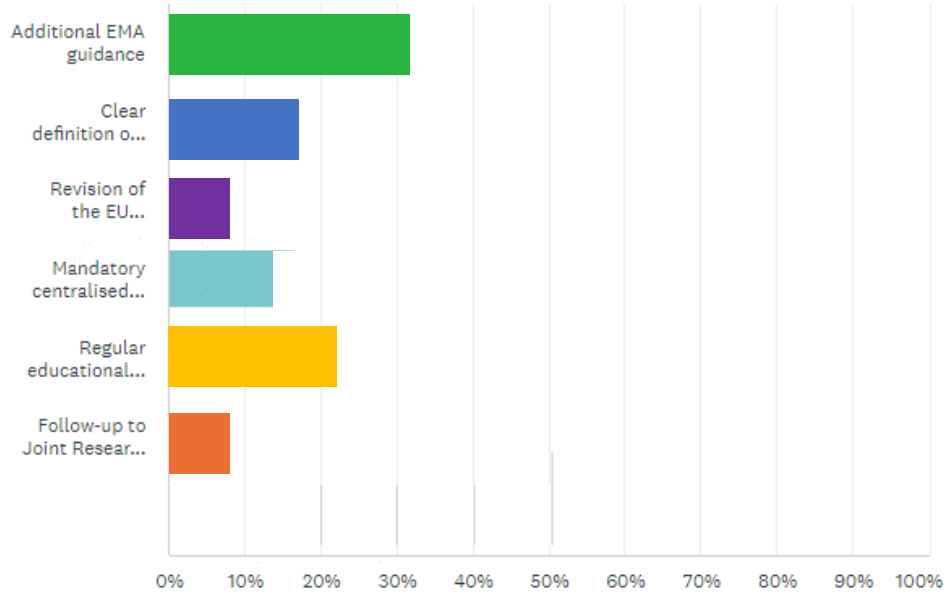
What initiative would you find most useful to help you better assess nanomedicines and their follow-ons? Please choose top three

Answered: 23 preferences in total



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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*

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Two live questions for you to answer now. Link is now in the chat

https://app.sli.do/event/92JujaUe9vNTgs6R4A3eBN

Slido.com
#2992730

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Open debate

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THANK YOU!

Do not hesitate to stay in touch with us:

Mike Isles (mike.isles@eaasm.eu)

Laura Cigolot (laura.cigolot@eaasm.eu)

https://eaasm.eu/ - @EAASMeds

https://eunanomedicinescoalition.eu/