Nanomedicines – ensuring patient safety through regulatory clarity

A poster by the European Alliance for Access to Safe Medicines (EAASM).

An independent non-profit patient safety organisation.

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ADVANCING HEALTH PRIORITIES

Objective

- To raise awareness of the need for scientific consensus on definitions for nanomedicines and nanosimilars across Europe

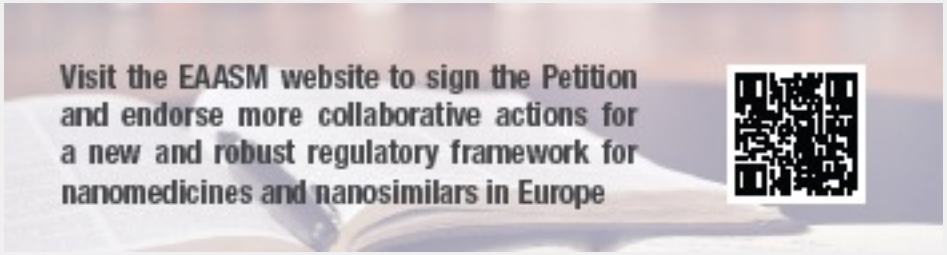
- Develop a robust fit for purpose centralised regulatory procedure for both new innovative nanomedicines as well a nanosimilars (“follow-on” copy products).

- To be achieved through an advocacy programme to include:
  - Forming an Alliance with outreach to the EU Institutions
  - A scientific report
  - A summary briefing document
  - Mobilise MEPs and hold EU Parliament and national round table discussions
  - Campaign to the EMA and DG SANTE

Methods and background

- Nanomedicines and nanosimilars ("follow-on" copy products) are **complex molecules**
- **Strong regional differences** in the regulation of nanomedicines
- Protocols used in clinical **trials need standardising**
- There is evidence that "follow-on" copy products **do not deliver the same efficacy and safety**
- **More scientific, policy and practice knowledge** on the quality, safety, and efficacy of nanomedicines and nanosimilars is needed among all stakeholders including payors, health authorities and health care professionals.
- **A centralised regulatory procedure** to ensure a harmonised approach by Member States' regulatory authorities with a separate framework for "follow-on" copy products – like biosimilars.

Please sign the petition and join the call to action



Conclusions

- **Nanomedicines and nanosimilars need regulatory clarity**
- Only by a **concerted campaign** will we be able to drive awareness of the need for a centralized EMA regulatory process
- **Join the growing Alliance and sign the petition**

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International Alliance of Patients' Organizations

ESN
EUROPEAN SPECIALIST NURSES ORGANISATIONS

ELPA

EPDA
European Parkinson's Disease Association

European Cancer Patient Coalition

European Alliance for Access to Safe Medicines

Thank you

- Please make contact

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