Nanomedicines – ensuring patient safety through regulatory clarity

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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.

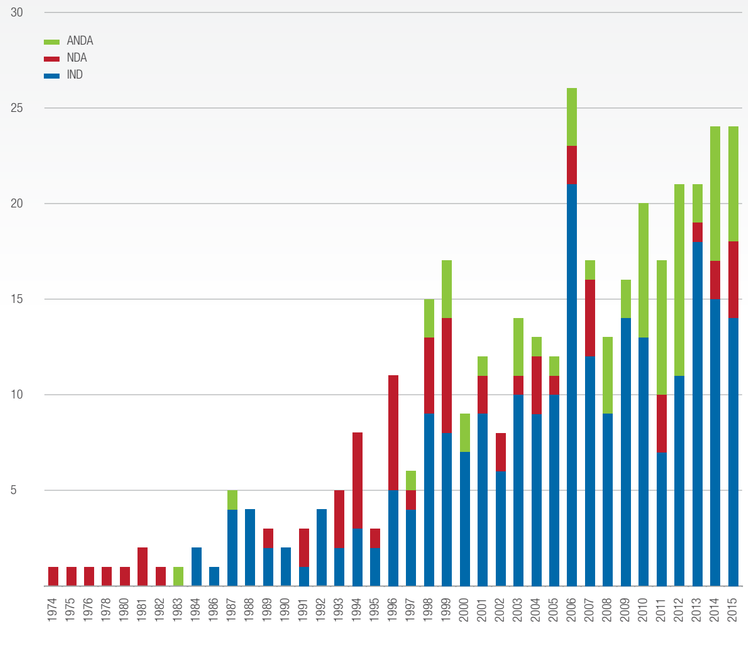


Figure 1 clearly shows the increasing number of nanomaterial product applications submitted to CDER by year. Applications are separated as INDs, NDAs and ANDAs.

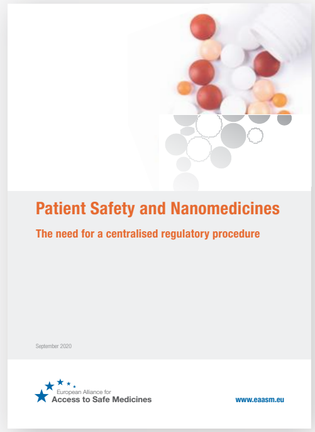
Conclusions

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

European Alliance for
Access to Safe Medicines

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