

NANOMEDICINES

ENSURING PATIENT SAFETY THROUGH REGULATORY CLARITY

A call to action on DG SANTE, the EMA, Member State Health Authorities and Regulatory Bodies to address patient safety issues due to significant regulatory challenges across Europe



**Please sign the Petition for more collaborative
actions for a new and robust regulatory framework**

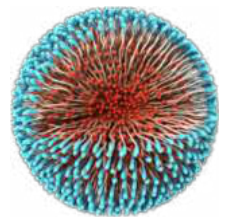


The European Alliance for Access to Safe Medicines (EAASM)¹ is an independent, non-profit pan-European Community Interest Company dedicated to protecting patient safety. The Alliance champions many patient safety issues to enhance medical practices. It especially believes that the rapidly developing field of nanomedicines requires regulatory clarity to ensure patient safety and to realise new treatment opportunities across Europe in a harmonised way.

- 1 **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.
- 2 **Nanomedicines** may exhibit a complex mechanism of action combining mechanical, chemical, pharmacological as well as immunological properties. This combined with a complex set of physical properties, calls for nanomedicines to have a modern fit for purpose regulatory appraisal process. Nanomedicines offer potential solutions for current treatment challenges, such as cancer, cardiovascular and neurodegenerative diseases, as well as other illnesses.²
- 3 **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. There is currently no specific regulatory pathway in Europe for the approval of these products. Recognising their complexities, they are increasingly approved through the hybrid application (Article 10.3 of Directive 2001/83/EC) by the European Medicines Agency or national regulatory bodies.³

Changes in quality, safety, efficacy, size distribution, surface properties, drug loading and release profile, aggregation status and stability – can alter how a nanomedicine acts within the body with a significant impact on patient safety and efficacy.⁴

NANOMEDICINES ARE



INNOVATIVE

Nanomedicines 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.⁵



COMPLEX

Nanomedicines consist of complex nanoparticles engineered to have favourable biological, chemical, pharmacological as well as immunological properties.⁶



MANUFACTURE DEPENDANT

Assembling different chemical parts into complex nanoparticles requires highly standardised and sophisticated manufacturing processes to guarantee consistent quality.

REGULATORY REFORM REQUIRED IN EUROPE – EAASM CALL TO ACTION



1) Need for a scientific consensus on definitions for nanomedicines in Europe, improving education and fostering awareness on the complexity and sophistication of nanomedicines among policymakers, prescribers, payers and patients

2) Need to harmonise information requirements of regulators for the characterisation of nanomedicines⁷

Develop a clearly defined regulatory pathway by adopting an EMA centralised procedure for all nanomedicines and nanosimilars. This is key to avoid diverging approaches between Member States. It will minimise post marketing adverse events and guarantee the safety of future personalised, innovative treatments for all patients. Robust scientific methodology that defines the process and criteria for the assessment of a nanomedicine is critical to ensure long-term safety and risk management. The definition of the quality attributes of a nanomedicine using strict criteria will be essential to ensure consistent manufacturing and therefore quality control of nanomedicines.

3) Need for clear regulatory criteria for the approval of follow-on nanosimilar medicines

The assessment criteria for the licensing of these medicines requires an equally robust regulatory process. Nanomedicines as nanosimilar/follow-on medicines have been proven not to be equivalent with patient safety issues arising.⁸

Manufacturing exact replicas of nanomedicines is not achievable, therefore the highest possible standard of manufacturing control must be guaranteed and included in the licence application. Minor changes in manufacturing may lead to unknown changes of composition, which can affect the clinical performance. In Europe, licence applications of follow-on/nanosimilar products are infrequent and so greater knowledge and sharing of expertise is called for urgent attention.

Without clinical evidence on the therapeutic equivalence of follow-on products/nanosimilars, national authorities should warn against their interchangeability and substitution to avoid putting patients in harm due to differing safety profiles of the follow-on products.

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 Joint Research Centre (European Commission) summarises the major challenges associated with the regulation of the nano-enabled health products.

“The increasing complexity of innovative nanomedicinal products and their sophisticated manufacturing processes often require additional physicochemical characterisation steps or safety assessment in order to ensure the quality and safety of the products. However, existing characterisation methods are often not suitable to assess different types of nanomedicines or are not sufficiently standardised to be employed for the generation of the regulatory information. For certain specific areas no suitable methods are available at all, generating methodological gaps.

Follow-on nanomedicines or “nanosimilars” are receiving more and more attention since patents of reference products are expiring but their complexity often does not allow a full comparability of physicochemical characteristics demonstrating the equivalence of the products. This group of products might require a new initiative that develops a regulatory framework allowing a demonstration of the equivalence of the innovator products and the nanosimilars. The framework for assessing biosimilars could serve here as an example”⁹.

SUPPORTERS



To find out more about the EAASM, visit www.eaasm.eu

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