

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 effectiveness and safety.

Patient safety is the main reason why a centralised regulatory framework for nanomedicines is needed

Currently, there is no fit for purpose regulatory framework specific to nanomedicines and nanosimilars, which has potential implications for patient safety. EU regulatory bodies are becoming more aware of the issues surrounding nanomedicines, and the need for regulatory clarity.

In order to fully harness the potential of nanomedicines and to protect patient safety, a fit for purpose regulatory framework for this class of products is needed at EU level. Nanomedicines and nanosimilars should be reviewed through a centralised procedure to prevent different approaches by Member States' regulatory authorities. and a separate regulatory framework for follow-on products is also required – as it has been for the development of biosimilars over the past years – or as alternative, additional guidelines on how the centralised hybrid regulatory pathway should be used to approve these medicines.

¹ European Renal Association – European Dialysis and Transplant Association (ERA – EDTA), International Alliance of Patients' Organizations (IAPO), European Specialist Nurses Association (ESN), European Liver Patient Association (ELPA), European Parkinson's Disease Association (EPDA), European Cancer Patient Coalition (ECPC).

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 legal definition, more scientific, policy and practical knowledge on the quality, safety, and efficacy of nanomedicines and nanosimilars must be gained among all stakeholders, including payors and health care professionals.

Clarifying the regulatory system for nanomedicines through the Pharmaceutical Strategy for Europe

With the ongoing Pharmaceutical Strategy for Europe and the revision of the EU general pharmaceutical legislations, it is the right time to set the scene for building a pan-European medical agency consensus so that regulatory weaknesses can be addressed through a robust centralised regulatory pathway and thus provide medicines with the highest quality, safety and efficacy profiles to European patients. This not only applies to existing medicines but the many new nanomedicines that are in a rich development pipeline.

The EU has the chance to lead the world in developing a centralised regulatory procedure for nanomedicines and nanosimilars. In doing so, it will contribute greatly to the EU Pharma Strategy of “Innovation” which has at its core the adoption of legislation to **cutting-edge products, scientific developments** and transformations.

This topic is being highlighted in the INI report of the European Parliament which is expected to be voted in plenary in Q4 2021.

We ask for your support to implement these recommendations and strengthen EU actions on health care.

We would welcome the chance to meet you to discuss the above-mentioned issues and how we could work together to make them a reality.

Yours sincerely,

The Members of the European Parliament

MEP Cyrus Engerer (Malta, Progressive Alliance of Socialists and Democrats)
MEP Romana Jerkovic (Croatia, Progressive Alliance of Socialists and Democrats)
MEP Petar Vitanov (Bulgaria, Progressive Alliance of Socialists and Democrats)
MEP Pietro Fiocchi (Italy, European Conservatives and Reformists Group)
MEP Margrete Auken (Denmark, Greens/European Free Alliance)

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

