

## Event summary: Innovation in Nanomedicines: Enhancing Patient Safety Through Regulatory Clarity

EU Parliament virtual roundtable

30 November 2020

### Event summary

On Monday 30th November, the European Alliance for Access to Safe medicines (EAASM) organised an online event on “Innovation in nanomedicines: enhancing patient safety through regulatory clarity” bringing together high-level speakers from the European Parliament, the European Commission, academia and experts with the view to discuss current challenges and provide useful recommendations so that regulatory support and enhancements in the field of nanomedicines can be developed further and thus provide medicines with the highest quality, safety and efficacy profiles to European patients.



**MEP Maria Carvalho (EPP, Portugal)** opened the debate thanking the EAASM for its excellent work in the field of nanomedicines. She outlined that nanotechnology offers tremendous opportunities to address unmet medical needs. Its applications for clinical purposes have captured the attention of academia, researchers, governments, funding agencies and regulatory bodies. Nanomedicines have demonstrated significant therapeutic advantages for a multitude of applications. Notwithstanding this, their practical translation into treatments has not progressed as quickly as the positive preclinical results have suggested due to the absence of a fit for purpose regulatory framework within the European Union.

MEP Carvalho reminded us that in 2007, the European Group on Ethics in Science and New Technologies issued an Opinion on the ethical aspects of nanomedicine highlighting the opportunity for their use in diagnostic and treatment options but also pointing out the need to verify safety through proper assessment processes and a fit for purpose regulatory framework. Thirteen years later, the issue still remains. Legal certainty is needed for comprehensive and consistent product licences/market authorisations in the future. This will ensure the safety, efficacy and quality of future nanomedicines.

MEP Carvalho also stressed that patients, healthcare professionals and other stakeholders need to feel assured that nanomedicines have the same efficacy as originators. Hence, more awareness and transparency need to be created to gain public trust. **The recently published European Commission Pharmaceutical Strategy, expresses hope that it will create a stable and flexible regulatory environment that offers legal certainty for investment and accommodates technological trends.**

A robust regulatory framework will provide the grounds for the next generations of nanomedicines, which have the potential to revolutionise the way we detect and treat diseases.



Jon de Vlieger, Director Business Development and coordinator of the Working Group on non-biological complex drugs at Lygature, said that the rise of biotechnologies and nanotechnologies had accelerated the development of complex medicines. Due to the legal definition of nanomedicines, they are not classified as conventional drugs nor as biotechnology drugs, which prevents them from being categorised with the same rules and regulations. Jon interestingly highlighted that two recently announced Covid-19 vaccines, from Pfizer and Moderna, both included a nanotechnology approach. He underscored the fact that the use of nanotechnology has huge opportunities but still has a wide range of challenges.

Jon recommends an **appropriate, worldwide aligned, science-based approval process for nanomedicines**. This can be achieved by mapping the issues of patient safety, terminology, and characterisation, engaging in discussions with regulators and other stakeholders, and by informing on policy globally.

The current framework for approval of medicines in Europe has seen a growth in abridged hybrid applications, which suggests that regulators are becoming more aware of nanomedicines and that regulators may be steering manufacturers towards the hybrid applications. Each EU member state has its own authorisation process, which further highlights the need for a centralised procedure as companies may face different requirements if they are looking for marketing authorisation in several Member States.

Biotechnology products and Advanced Therapy Medicinal Products (ATMPs) currently follow a centralised procedure to obtain marketing authorization and a mandatory centralised procedure is the way forward for non-biological complex drugs (NBCDs), including nanomedicines. Jon noted that this will guarantee consistency in the scientific evaluation of products through having direct access to the collective scientific expertise of all associated Member States. The centralised procedure also arranges coordinated pharmacovigilance across the EU.



**Mr. Anthony Rodiadis, Policy Officer in the Unit B5 on Medicines-policy, authorisation and monitoring at the Health and Food Safety Directorate General (DG SANTE)** identified the need for a holistic approach covering the full life cycle of medicines and noted that the flagships of the EU Pharma Strategy ensure, among others, access to high quality, safe, efficacious and affordable medicines for patients. They also enable sustainable innovation as well as the availability of medicines. Moreover, working with the EMA and the network of national regulators will be key for these goals and to promote regulatory convergence at the international level.

The revision of the basic pharmaceutical legislation could pave the way for a future proof and crisis resistant regulatory landscape, through delegated acts or through a principles-based approach where regulators and agencies will assess products in a more flexible, dynamic way.

Also, one of the main goals to be achieved within the newly published Strategy of the EMA network to 2025 enables and leverages research and innovation in regulatory science. Hence, such innovations may facilitate the implementation of novel manufacturing technologies and delivery approaches including nanotechnology. The EU Pharma Strategy will be implemented next year and an analysis will be required to assess what areas may need to be changed by consulting with stakeholders to identify areas to review and policy options. Mr. Rodiadis said that DG SANTE welcomes the exchange views on how the revision of the pharmaceutical legislation can lead to a legal regime that makes the most of regulatory advancements in the field of nanomedicines.



**Professoressa Paola Minghetti from Milano University** highlighted the complexities of different nanomedicine products and the need to have a clear definition of what a nanomedicine is. She highlighted the need for biotechnological products to be assessed via a centralised regulatory procedure and so confirmed the view of Jon de Vlieger. She further highlighted the need to ensure the quality of nanomedicines through pharmaceutical development using in vitro and in vivo studies with post-marketing evaluation being key with the additional criteria to ensure that any follow-on/copy products are therapeutically equivalent. The complexity of monitoring the parameters affecting in vivo behaviour of nanomedicines was underlined and concluded "...non biologic complex drugs should be

firmly classified alongside biosimilars as they are very much complex medicines and as such deserve the same scientific rigour to ensure therapeutic equivalence".

## Summary

Overall, the scientific experts agreed that a centralised approval process is the logical scientific approach that needs to be taken to ensure a robust fit for purpose regulatory pathway. This was endorsed by the MEPs who suggested that a campaign to raise awareness amongst the Parliament is essential. This approach has the potential to accelerate regulatory development by providing the necessary political urgency so that the therapeutic benefits for patients can be realised within an optimum timeframe.

The speakers were also asked a question on how to improve regulatory systems and simplify the requirements for nanomedicines / nanosimilars in order to protect patient safety. All of the speakers were in agreement with equivalence when it comes to therapeutic safety and agreed that manufacturing criteria needs to be equally stringent during the approvals process. MEP Pietro Fiocchi noted that a large, centralised data collection could accelerate findings during the process.



In the closing remarks, **MEP Pietro Fiocchi (ECR, Italy) member of the BECA Committee**, pointed out that the situation is clear: the current nanomedicines framework in place is not fit for purpose. Nanomedicines are proving to be very important in oncology treatments and have reduced mortality in cancer patients and also have had a positive impact in therapies that target specific cells. The use of nanomedicines and nanotechnology can improve the quality of life for patients and should be treated as a priority in the healthcare industry.

Europe has the chance to become the technology centre for R&D excellence and that nanomedicines and nanotechnology are extremely important, given the benefits for both patients and the economy. He also suggested that the Parliament should become better informed of the potential for nanomedicines and gave assurances that he would support such an initiative.

We invite you to read the EAASM 2020 report “Patient Safety and Nanomedicines: the need for a centralised regulatory procedure” and its policy calls [here](#).

Please sign the Petition to endorse more collaborative actions for a new robust regulatory framework for nanomedicines and nanosimilars.