



THE FUTURE OF NANOMEDICINES IN EUROPE

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Nanomedicine uses state-of-the-art nanotechnology like nanoparticles, nanorobots or nanoelectronic biosensors for diagnosing or treating cancer, cardiovascular, and neurodegenerative diseases.

However, a number of issues related to the regulatory framework raise more questions than answers while critics suggest that without an EU-centralised approach, the potential of nanomedicines will remain untapped.



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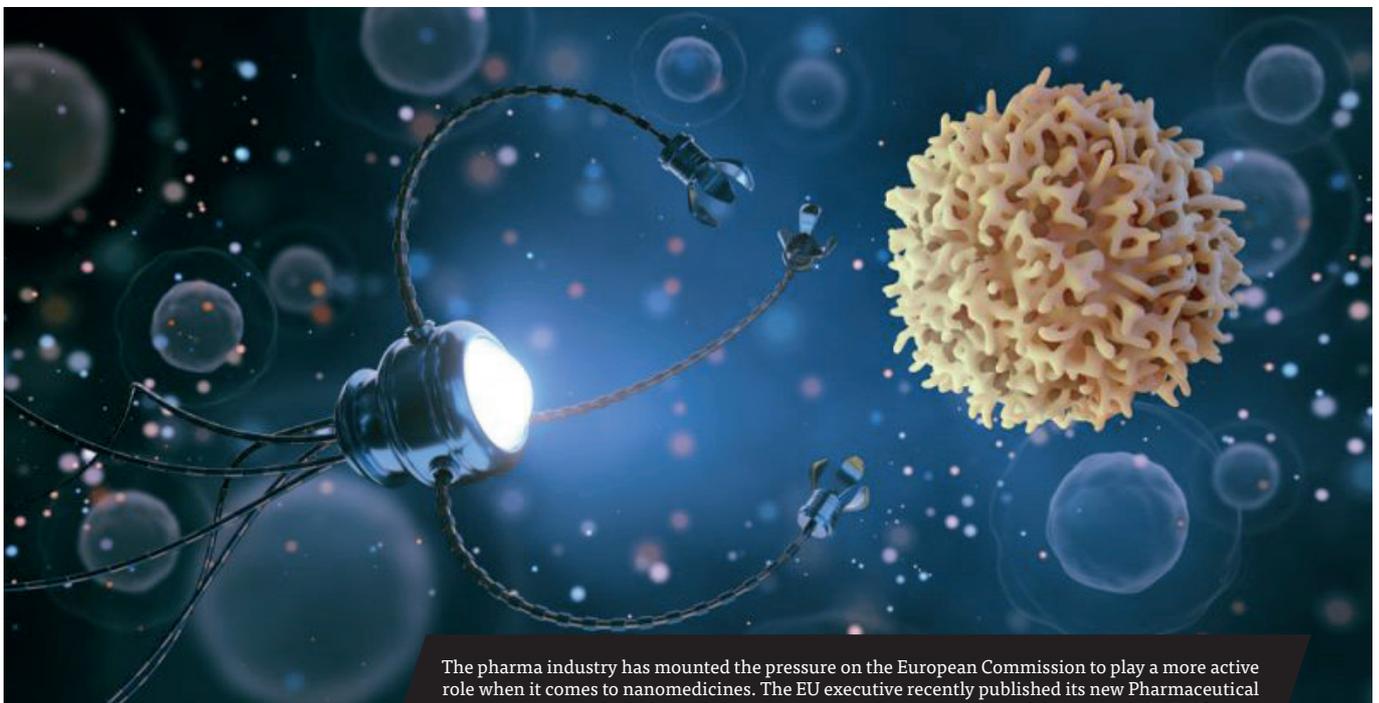
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Nanotechnology: Part of COVID-19 vaccines but potential still hindered in Europe

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By Sarantis Michalopoulos | EURACTIV.com



The pharma industry has mounted the pressure on the European Commission to play a more active role when it comes to nanomedicines. The EU executive recently published its new Pharmaceutical Strategy, in which the push for innovation is taking center stage. [Shutterstock/K_E_N]

Nanotechnology has contributed to the production of vaccines against the COVID-19 virus. However, in Europe, a de-centralised and vague regulatory framework prevents nanomedicines from harnessing their full potential to save lives.

At a recent event organised by the European Alliance for Access to Safe Medicines (EAASM), EU lawmakers and stakeholders focused on nanomedicines, which are emerging

as an innovative technology in the scientific field, as they help address unmet medical needs and offer alternatives for many therapeutic areas.

Nanomedicine uses state-of-the-art nanotechnology like nanoparticles, nanorobots or nanoelectronic biosensors for diagnosing or treating cancer, cardiovascular, and neurodegenerative diseases.

The pharma industry has mounted

the pressure on the European Commission to play a more active role when it comes to nanomedicines. The EU executive recently published its [new Pharmaceutical Strategy](#), in which the push for innovation is taking centre stage.

“Under affordability and access to medicines, there is a quite a big push for boosting medicines that basically respond to unmet needs,” Anthony Rodiadis from the European Commission’s DG SANTE commented.

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However, a number of issues related to the regulatory framework raise more questions than answers while critics suggest that without an EU-centralised approach, the potential of nanomedicines will remain untapped.

In addition, at present, there is no specific regulatory pathway for follow-on nanosimilars. Given their highly complex manufacturing process, it is possible that even the slightest change from the original nanomedicine would result in a different level of efficacy.

Maria da Graça Carvalho, a Portuguese MEP from the European People's Party (EPP), emphasised the potential of nanomedicines in delivering unmet medical needs but noted that the current regulatory framework puts severe obstacles on the process.

"We may conclude that the practical translation into treatments has not progressed as quickly as we would like to and as the enormous positive preclinical results have suggested. We are convinced that the reason for this is that we do not have a strong fit-for-purpose regulatory framework," the centre-right EU lawmaker said.

NANOTECHNOLOGY AND COVID-19

Jon De Vlieger, director of business development at Lygature, a not-for-profit partnership management provider bringing together academia, industry and society, said nanomedicines are already being provided to patients saving lives every day.

He added that two of the front runner vaccines for COVID-19, Pfizer and Moderna, which the European Medicines Agency is expected to approve on 29 December and 12 January respectively, do include nanotechnology-based approaches.

"Both vaccines are based on lipid-based nanoparticles. So, it's important to realise that it has a huge opportunity, it's already established, but there are still some challenges that we need to solve," he said.

There are different procedures to authorise a medicine in Europe: mainly the centralised and the de-centralised processes. In the centralised procedure, the European Medicines Agency (EMA) conducts its own scientific studies, and then the European Commission gives the green light for market authorisation. The Commission's decision is valid in all EU member states.

On the other hand, the de-centralised procedure is used for authorising medicines in more than one EU member states in parallel. According to EMA, it can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any member state.

Nanomedicines are by nature complex and things become even more complicated due to the lack of a centralised approach: currently, regulatory authorities at the member state level assess them differently.

De Vlieger presented a study on 85 different nanomedicines applications. Just two of these products were approved through the centralised procedure.

He explained that a centralised process should be the best route for nanomedicines as "it guarantees consistency in the scientific evaluation of these products," and centralised safety monitoring.

MEP: Parliament will pressure Commission to focus on nanomedicines

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By Sarantis Michalopoulos | EURACTIV.com



MEP Pietro Fiocchi: "The advantage for the quality of life of patients is huge; a lot of pathologies could be cured without surgery and chemotherapy. A strong support and regulatory framework in this field is the desired outcome of the report of the special committee on Beating Cancer". [European Parliament]

The European Parliament will put pressure on the Commission and the member states to provide the necessary regulatory framework for nanomedicines in order to better make use of their potential for patients, EU lawmaker Pietro Fiocchi told EURACTIV in an interview.

"We are currently discussing the need to give the necessary regulatory framework not only for nanomedicines but also for a wide range of incredible technologies in the health system. I expect some results by April 2021," the Italian MEP said.

Nanomedicines are emerging as an innovative technology in the scientific

field, as they help address unmet medical needs and offer alternatives for many therapeutic areas.

Nanomedicines use state-of-the-art nanotechnology, like nanoparticles, nanorobots or nanoelectronic biosensors, for diagnosing or treating cancer, cardiovascular, and neurodegenerative diseases.

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Fiocchi, who also represents the European Conservatives and Reformists Group in the Special Committee on Beating Cancer, said nanomedicines provide huge advantages in both screening (detecting cancer earlier) and therapies (acting only on the cancerous cells and not on the healthy ones).

“The advantage for the quality of life of patients is huge; a lot of pathologies could be cured without surgery and chemotherapy. Strong support and a regulatory framework in this field is the desired outcome of the report of the Special Committee on Beating Cancer,” he said.

The lack of a fit-for-purpose EU regulatory framework on nanomedicines and their generics” poses risks for the safety of EU patients, the director of the European Alliance for Access to Safer Medicines (EAASM), Mike Isles, recently told EURACTIV in [an interview](#).

Nanomedicines are complex by nature and their use is made even more complicated by the fact that EU member states’ regulatory authorities assess them differently.

Fiocchi defended a “centralised approach”, especially following the COVID-19 pandemic, which exposed Europe’s weaknesses and fragmented health systems.

“Even now, there are difficulties in collecting the data and coordinate the reactions. A centralised European approach could solve a lot of these problems, but it could also be a strategic move to make Europe

the centre of excellence worldwide on the health sector, with huge benefits for the economy and all the EU citizens,” he said.

For the conservative MEP, a key challenge will be how the EU member states will approach the issue.

“They generally do not like a strong EU centralised approach and interference in their health system. This problem will take a lot of political mediation and a lot of patience,” he warned.

He added that the European Parliament is currently collecting the “success stories” on different pathologies from across member states. “Then the Commission has to analyse all this data and devise an action plan. With the support and the pressure from the Parliament, of course,” he said.

A recent study has found that of the 85 nanomedicines applications, just two products were approved through the centralised procedure.

Jon De Vlieger, director of business development at Lygature, a not-for-profit partnership management provider bringing together academia, industry and society, emphasised that a centralised process should be the best route for nanomedicines as it “guarantees consistency in the scientific evaluation of these products” and centralised safety monitoring.

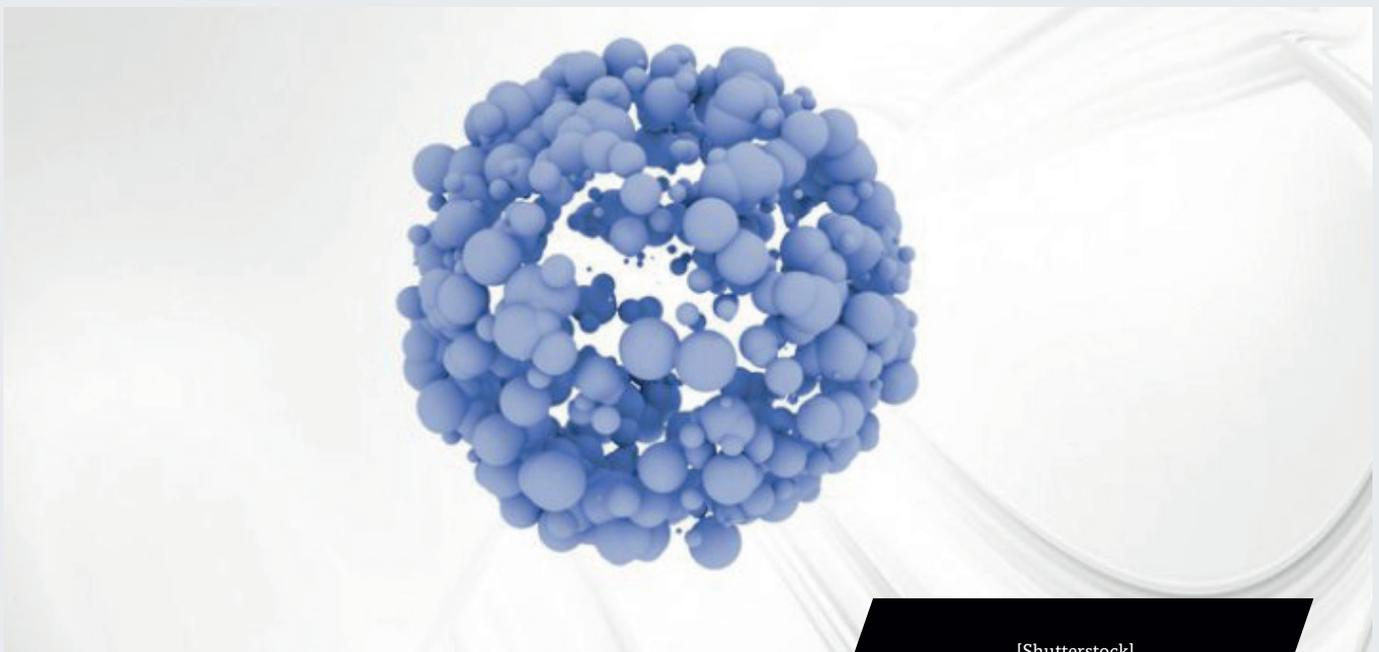
PROMOTED CONTENT

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Pharmaceutical Strategy must do more to support nanomedicines

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By Mike Isles | European Alliance for Access to Safe Medicines (EAASM)



[Shutterstock]

The EU's Pharmaceutical Strategy must do more to support nanomedicines and protect patient safety. Here's why.

Mike Isles is the Executive Director of the European Alliance for Access to Safe Medicines (EAASM).

If Europe is to make its world-leading pharmaceutical sector fit for the future, a regulatory framework that supports innovative types of treatments and protects patient

safety is imperative. The European Commission's new Pharmaceutical Strategy, published in the midst of a pandemic consuming all our attention, could provide a great opportunity for a step in the right direction.

Here we focus on a highly significant innovative technology in the medical field: nanomedicine. Nanomedicine is an exciting and growing field, offering potential solutions to several treatment challenges, notably in key areas such as cancer, cardiovascular

and neurodegenerative diseases.

Nanomedicines are medicinal products with at least one dimension in the nanoscale range – from 1nm to 100nm. They enhance the way that medicines target and reach areas of disease within the body, opening up new therapeutic options. However, nanomedicines and their follow-on products, nanosimilars, are complex molecules and so it is essential that their regulatory oversight is scientifically appropriate.

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A RISK TO PATIENT SAFETY

Despite these opportunities, the current regulatory framework of nanomedicines within the EU-27 is not fit-for-purpose. As of now, nanomedicines can be approved through a decentralised procedure, allowing for different policies and interpretations in each member state and creating uncertainty, confusion and ambiguity. To better protect patient safety, EAASM is campaigning for the introduction of a single and specific regulatory framework at EU level.

We are particularly concerned about the potential implications for patient safety in **three areas**. There is no unambiguous, legal definition of nanomedicines, leading to problems in how to classify these products. In addition, due to their elaborate nature, the regulatory tools available to fully characterise them are not fully developed. Finally, nanomedicines are extremely difficult to copy given their highly complex manufacturing process and even the slightest variation from the original product can bring different levels of efficacy – this is why they would benefit from a tailored regulatory pathway for their approval similar to the one which has been developed for biosimilars. Patient safety must always be the most important criterion when approving a new product. This principle is of particular importance for nanomedicines.

A FRESH APPROACH?

The Pharmaceutical Strategy allows the Commission to introduce a fit-for-purpose regulatory framework

and ensure that the full potential of nanomedicines and nanosimilars is realised. But there is, regrettably, no mention of nanomedicines within it, despite the pressing need for the Commission to address the topic – and that the EU already recognises it as a Key Enabling Technology. This is an oversight that must be remedied.

The Commission has stated that two key aims of the Pharmaceutical Strategy are to respond to unmet medical needs and ensure that the legislative framework for pharmaceuticals is future-proofed so it can adapt to cutting edge developments. Nanomedicine is a prime example of this. The pace of scientific change is moving at tremendous speed, and the new strategy can and must serve as the catalyst for adopting the proper regulatory framework on nanomedicines.

The overarching priority for the European Alliance for Access to Safe Medicines (EAASM) is to protect patient safety by ensuring access to safe and legitimate medicines. Our recent report, *“Patient Safety and Nanomedicines: the need for a centralised regulatory procedure”*, calls on DG SANTE, the EMA and member states to address unmet medical needs as well as tackle patient safety issues. We see the need for the EU to develop a scientific consensus on definitions of nanomedicines, adopt an EMA-centric procedure for all nanomedicines and nanosimilars and clarify the criteria for approving nanosimilars.

A PAN-EUROPEAN CONSENSUS

On 30th November, we held a

stakeholder event, *Innovation in nanomedicines: enhancing patient safety through regulatory clarity*. This included contributions from MEPs, the Commission and academic experts, with a strong focus on how nanomedicines can address unmet medical needs. The success of this event demonstrates that there is growing political appetite for regulatory solutions to be brought forward by the EU. What we need now, then, is a consensus on the way forward.

Nanomedicine has already proven its worth in the development of the new COVID-19 vaccines the world needs if it is to beat the pandemic and we know it can help treat diseases such as cancer in a more targeted manner. Patients stand to gain hugely in terms of quality of life and survival prospects – but only if we get the right regulatory framework and that must be pan-European.



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