

**From:** [REDACTED] (SANTE)  
**Sent:** 30 November 2020 14:13  
**To:** [REDACTED] (EMA); [REDACTED] (EMA); [REDACTED] (SANTE);  
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);  
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);  
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);  
[REDACTED] (SANTE)  
**Cc:** SANTE CONSULT-B5  
**Subject:** BTO - INNOVATION IN NANOMEDICINES: ENHANCING PATIENT SAFETY THROUGH REGULATORY CLARITY - 30 Nov. 2020  
**Attachments:** NBCD JdV Nov 2020 EAASM - Read-Only.pptx; EAASM GENERAL slide deck intro F.ppt; Innovation in Nanomedicines\_v0.2.pptx

Dear colleagues,

Please find below a short BTO on the event in subject organised by the European Alliance for Access to Safe Medicines.

Kind regards,

BTO: INNOVATION IN NANOMEDICINES: ENHANCING PATIENT SAFETY THROUGH REGULATORY CLARITY - 30 Nov. 2020

**Speakers:** MEP [REDACTED] EPP Portugal, MEP [REDACTED] ECR Italy, [REDACTED] European Alliance [REDACTED] NBCD Working Group, [REDACTED] Unit B5 Medicines-policy, authorisation and monitoring, European Commission DG SANTE, [REDACTED] Università degli Studi di Milano Statale - [REDACTED]

PPTs of other speakers are attached.

#### **Main request**

The discussion focused on the necessity for a **comprehensive and clear EU Regulatory framework for Non Biological Complex Drugs and Nanomedicines**.

- The request from all speakers was to extend the mandatory scope of the centralised procedure to nanomedicines and nanosimilars. The revision of the basic pharma legislation under the EU Pharmaceutical Strategy is seen as a unique opportunity for this.
- Possibly with the adoption of a *nano* specific authorisation pathway and definition of nano-medicine in the legislation.
- The adoption of clear and appropriate, science-based approval and post-approval standards for NBCDs across Europe.

The most notable **arguments** raised were linked to:

- Variable standards of authorisation across MSs create differences in the way such products are authorised
- There are variable degrees of expertise across the EU
- Lack of legal clarity for companies
- Copies of products deriving of nanotechnology are not sufficiently covered by current authorisation standards and guidelines

- A mandatory centralised system would enhance the quality of assessment in terms of safety/efficacy and allow to apply the same parameters in authorisation (morphological, thermal, structural etc [REDACTED])
- Possibility to create centres of excellence in some regulatory authorities and in EMA for the authorisation of such products.

An interesting study published in the European Journal of Pharmaceutical Sciences on 15 May 2019 [REDACTED] shows that such products have traditionally been following MRP/DCP instead of CAP (with only 2 products authorised centrally) and a trend changing from Art. 10(1) authorisations to Art. 10(3) Hybrid authorisation most recently.

It was also mentioned that authorisations of copies of nano-medicines is especially challenging.

### **Comments by Commission**

In my intervention I made a presentation of the Pharmaceutical strategy focusing on the innovation aspects, notably the creation of a future proof framework. I mentioned that it is too early to say specifically which changes in the legislation will realise this objective, but any change will aim to create a framework that is open to such developments taking into account their specificities in terms on innovation but also safety, quality and efficacy; without necessarily creating specific regulatory pathways for each category of products (avoiding having proliferation of authorisation procedures). Perhaps the way forward would be to create a principle-based system, or a system which is easily adaptable in case of new developments through delegated or implementing acts, this would allow the legislation to be ready for other novel products and technologies once they arrive. We must first carefully assess the legislation and consider impacts of possible changes to the current marketing authorisation system, including the scope of the CAP. This assessment will be conducted during 2021 and beginning of 2022. A separate consultation process will be part of it.

I also made the link to the EMANS which mirrors the strategic goals of integrating science and technology in medicines development and ensure that the network has sufficient competences to support innovators incl. facilitating the implementation of novel manufacturing technologies and delivery approaches like nanotechnology.

Finally, I noted that according to the study mentioned by [REDACTED] there are only 2 products having used the CAP and inquired why such products cannot already today benefit from the optional scope of the CAP given their significant therapeutic scientific or technical innovation.

The interlocutors replied that the root causes for this phenomenon have not been sufficiently studied, however one can speculate this has to do with:

- Economic decisions by companies
- Authorization experience is available only in some MSs.
- The time of authorisation varies from MS to MS
- Some MS have more friendly approaches to the authorisation of such products compared to others.

END