Question for written answer E-003136/2020
to the Commission
Rule 138
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Subject: EU pharmaceutical strategy – specific provisions on nanomedicines and nanosimilars

Nanomedicines and their unique properties open up new and improved therapeutic opportunities. There is currently no specific regulatory framework for nanomedicines and their follow-on products, nanosimilars. At the moment, they can be approved through decentralised national procedures that risk creating uncertainty, confusion and ambiguity given the different interpretations and policies in place in each Member State.

Some years ago, the European Group on Ethics in Science and New Technologies outlined the importance of a dedicated robust safety framework on nanomedicines. Since then, the complexity and number of this new class of medicines have increased at a rapid pace, as has the number of questions regarding their quality, biological properties and therapeutic profiles.

A mandatory centralised procedure would in principle ensure better coordination and understanding, harmonise marketing procedures and ensure patient safety and awareness across the EU.

Given the Commission's intention to adopt a new framework for pharmaceuticals:

1. Does it plan to include specific references to nanomedicines in the EU Pharmaceutical Strategy?

2. Is it planning to review the authorisation procedure for these products?

3. Do its plans include a proposal for a centralised approval mechanism for nanomedicines and nanosimilars?