Question for written answer E-002496/2021
to the Commission
Rule 138
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Subject: Research on diagnostic radiopharmaceuticals

Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use provides that procedures for the reconstitution and labelling of diagnostic radiopharmaceuticals may be performed in hospitals with no good manufacturing practice (GMP) requirements. The regulation, in its relevant passages, allows for a simplified procedure for the use of radiopharmaceuticals produced in establishments already following GMP, and hence places the requirements incumbent on hospital pharmacies, in the case of sponsored research, on the same footing as those applicable to independent clinical trials (with no need for GMP authorisation).

Implementation of the regulation is currently at a standstill owing to the EMA's failure to set up an EU portal and database (Article 80 of Regulation (EU) No. 536/2014) on clinical trials.

Pending the implementation of the IT infrastructure, some European countries have made advance provision for applying the regulation, recognising that time is of the essence when it comes to research.

1. When will the EMA portal and database go operational?

2. Will the Commission issue an authentic interpretation of the regulation propitious to research into diagnostic radiopharmaceuticals, including in those countries where trials are in practice blocked due to the continuing requirement for hospital pharmacies to have GMP authorisation when conducting sponsored trials, which perpetuates a form of discrimination abolished on paper in 2014?