To the attention of Marketing Authorisation Holders (MAHs) concerned

The National Agency for Medicines and Medical Devices (NAMMD) hereby informs on the document conveyed by the European Commission at the end of February 2019 to all human and veterinary medicines agencies of the 27 EU Member States on regulations for quality control of medicinal product batches in the context of Great Britain's (UK) withdrawal from the Union.

The document refers to provisions of Article 51(1)(b) of Directive 2001/83/EC (transposed into Article 769 1)(b) of Law no. 95/2006 on healthcare reform, republished as amended), stating mandatory quality control in the EU/EEA of human medicines batches imported into the EU.

However, the document states, objective grounds may exist, beyond MAH's control, to prevent timely transfer of such testing activities to the EU.

In such cases, pursuant to provisions of Article 20 (b) of Directive 2001/83/EC (transposed into Art. 729 b) of Law no. 95/2006 republished as amended), competent national authorities may for limited time and in justifiable cases exempt importers of medicinal products for human use coming from third countries from implementation of 51(1)(b) provisions and accordingly to have testing conducted by third parties.

In applying these provisions, EU competent authorities may allow MAHs, for limited time and in justifiable cases, to rely on quality control testing performed in the UK, under conditions specified in this document (https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf).

To be granted such exemption, concerned MAHs shall immediately notify competent national authorities that had granted the marketing authorisation (the NAMMD, in Romania) or the European Medicines Agency (EMA), for centrally authorised medicinal products.

The notification must be prepared according to the *Template for Notification of request for a time-limited exemption to continue batch control testing in the United Kingdom (UK) after UK's withdrawal from the Union for a nationally authorised medicinal product*, posted on the CMDh website (http://www.hma.eu/535.html) and submitted to the NAMMD at Brexit@anm.ro, by **29 March 2019**.