EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET).[2] The United Kingdom will then become a 'third country'.[3]

Preparing for the withdrawal is therefore not just a matter for EU and national authorities, but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of medicinal products for human and veterinary use no longer apply to the United Kingdom. This has, in particular, the following consequences in the different areas of EU law on medicinal products:

- EU law requires that marketing authorisation holders are established in the EU (or EEA);
- Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, batch release etc.

Marketing authorisation holders may be required to adapt processes and to consider changes to the terms of the marketing authorisation in order to ensure its continuous validity and exploitation, once the United Kingdom has left the Union.

Marketing authorisation holders will need to act sufficiently in advance to avoid any impact on the continuous supply of medicines for human and veterinary use within the European Union.

In particular, the Commission and the European Medicines Agency expect marketing authorisation holders to prepare and proactively screen authorisations they hold for the

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1 Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

2 Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

3 A third country is a country not member of the EU.

need for any changes. The necessary transfer or variation requests will need to be submitted in due time, considering the procedural timelines foreseen in the regulatory framework.

The Commission and the European Medicines Agency stand ready to support marketing authorisation holders and will provide a series of Q&As. A dedicated page of the Agency's website already contains general information pertaining to the outcome of the UK referendum. This page will be updated with further practical information and relevant Q&As and will be subsequently expanded, where necessary.

For products authorised in decentralised or mutual recognition procedures, the information will be provided through the websites of the Coordination Groups.

European Commission *European Medicines Agency*