



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH
AND FOOD SAFETY



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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 the withdrawal agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'.

In this regard, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of certain legal repercussions, which need to be considered:

- 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.

Preparing for the withdrawal is therefore not just a matter for European and national administrations, but also for private parties. 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 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, from May 2017 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.