



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH  
AND FOOD SAFETY



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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REV2 - replaces the Notice to  
stakeholders (REV1) published on 23  
January 2018

## NOTICE TO STAKEHOLDERS

### WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES FOR MEDICINAL PRODUCTS FOR HUMAN USE AND VETERINARY MEDICINAL PRODUCTS

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 as from 30 March 2019, 00:00h (CET) ('the withdrawal date')<sup>1</sup> the United Kingdom will be a 'third country'.<sup>2</sup>

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

In view of the uncertainties surrounding the ratification of the Withdrawal Agreement, all interested parties, and especially economic operators, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to the transition period provided for in the draft Withdrawal Agreement,<sup>3</sup> 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);

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<sup>1</sup> 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.

<sup>2</sup> A third country is a country not member of the EU.

<sup>3</sup> Cf. Part four of the draft *Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community*, as agreed at negotiator's level on 14 November 2018 ([https://ec.europa.eu/commission/publications/draft-agreement-withdrawal-uk-eu-agreed-negotiators-level-14-november-2018-including-text-article-132\\_en](https://ec.europa.eu/commission/publications/draft-agreement-withdrawal-uk-eu-agreed-negotiators-level-14-november-2018-including-text-article-132_en))

- 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 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 have provided detailed Q&As, which are continuously updated.

The websites of the Commission ([https://ec.europa.eu/health/human-use\\_en](https://ec.europa.eu/health/human-use_en)) and of the European Medicines Agency (<https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexid>) provide additional information. For products authorised in decentralised or mutual recognition procedures, additional information will be provided through the websites of the Coordination Groups. These pages will be updated with further information, where necessary.

European Commission  
Directorate-General Health and Food Safety

European Medicines Agency