EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency - Science, medicines, health

Guidance for pharmaceutical companies to prepare for UK's withdrawal from EU

19/06/2018

Guidance for pharmaceutical companies to prepare for UK's withdrawal from EU

Publication of updated Q+As and practical guidance

The European Medicines Agency (EMA) and the European Commission have updated their guidance to help pharmaceutical companies prepare for the United Kingdom's (UK) withdrawal from the European Union (EU).

Updates to the questions-and-answers document are marked 'NEW' and include information on how the UK's withdrawal will affect the status of inspection outcomes by the UK national competent authority and batch release processes for medicines that are subject to Official Control Authority Batch Release (OCABR) and Official Batch Protocol Review (OBPR). The document also clarifies how scientific opinions of the Committee for Medicinal Products for Human Use (CHMP) for ancillary medicinal substances in medical devices requested by UK notified bodies will be affected. In addition, it includes new information on back-up arrangements for Qualified Persons for Pharmacovigilance (QPPVs) and on marketing multi-country packs of medicines, where one of the countries in which the packs will be sold includes the UK.

The Agency has also published an updated version of its practical guidance for industry which outlines the steps that companies should follow to make sure that necessary changes to their marketing authorisation are made by the end of March 2019, to allow for the continued marketing of their medicine in the Union after Brexit. The document should be read in conjunction with the updated questions-and-answers document. All updates are marked 'NEW'.

Companies are reminded to plan for the UK's withdrawal from the EU on 29 March 2019 in order to avoid any impact on the continuous supply of medicines for human and veterinary use within the EU and are advised to regularly check EMA's dedicated webpage on the consequences of the UK's withdrawal from the EU.

How helpful is this page?

Average rating:

on
on
on
on
on
on
on
on
on
Based on 4 ratings

Add your rating:

1
2
3
4
5

See all ratings

Share
Loading