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Press release

EMA identifies gaps in industry preparedness for Brexit

Survey indicates that some companies need to step up efforts to ensure medicine supply in the EU

A recent European Medicines Agency (EMA) survey shows that marketing authorisation holders for more than half (58%) of the 694 centrally authorised products (CAPs) with an important step in their regulatory processes in the United Kingdom (UK), are on track with their regulatory planning to ensure that their marketing authorisation remains valid once the UK leaves the European Union (EU).

Regulatory authorities and marketing authorisation holders both play an important part in preparing for the consequences of Brexit to safeguard the continuous supply of human and veterinary medicines after the withdrawal of the UK from EU. Since May 2017, the European Commission and EMA have informed companies and raised their awareness of the need to put the necessary measures in motion. Information notices on legal issues and guidance on practical and simplified requirements for companies have been published and regularly updated.

For marketing authorisation holders of CAPs, this may imply changes to the marketing authorisation itself, including, for example, a transfer of the marketing authorisation to a legal entity established in the European Economic Area (EEA), or a change of the qualified person for pharmacovigilance (QPPV) or pharmacovigilance system master file (PSMF) to a location in the EEA, as well as adaptations to their logistics, manufacturing sites, supply chains and contracts.

However, for 108 (88 human products and 20 veterinary products), or 16%, of these medicines with manufacturing sites located in the UK only, there are serious concerns that the necessary actions will not be carried out in time.

For 10% of the products included in the survey, EMA received no feedback from companies.

The aim of the survey, which was launched in January 2018, was to identify CAPS that are potentially at risk of supply shortages and to obtain information on the timelines for submission of the necessary regulatory changes. The survey was sent to marketing authorisation holders of the 694 CAPs (661 human and 33 veterinary products) who are located in the UK or who have quality control, batch release and/or import or manufacturing sites, or a QPPV or PSMF in the UK.

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According to EU law, the marketing authorisation holder, the QPPV, the PSMF and certain manufacturing sites need to be based in the EEA for a company to be able to market a medicine in the EU.

EMA is liaising directly with the marketing authorisation holders who either did not reply to the survey or have indicated in the survey that they do not plan to submit the changes required by 30 March 2019 and have manufacturing sites in the UK only, as this could potentially lead to supply disruptions.

EMA has analysed feedback from the survey and is now looking in detail at those medicines where there are risks of supply shortages and will assess how critical these are. As a regulator, EMA's role is to ensure that it has a complete overiew of the potential risks, and to work together with the relevant marketing authorisation holders to address these risks as early as possible and discuss relevant mitigation measures.

EMA will also regularly monitor the submission of changes to marketing authorisations for all 694 products to check if the relevant variations/notifications are being submitted. Figures are likely to change as regulatory changes are submitted.

EMA urges those companies who have not yet informed EMA of their Brexit preparedness plans to do so as soon as possible to mitigate any risks to the continuous supply of medicines for human and veterinary use within the EU.

Companies are reminded to plan for the UK's withdrawal from the EU on 29 March 2019 and are advised to regularly check EMA's dedicated webpage on the consequences of the UK's withdrawal from the EU. In particular, EMA encourages companies to refer to the updated Q+As and practical guidance for industry published on 19 June 2018.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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