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European authorities working to avoid shortages of medicines due to Brexit – questions and answers

On 29 March 2017 the United Kingdom (UK) notified the European Union (EU) of its intention to withdraw from the EU ('Brexit').¹

The United Kingdom formally left the European Union on 31 January 2020 and became a third country to the EU. On 1 February 2020, a transition period started which is due to end on 31 December 2020. The relationship between the UK and the EU after this date is currently unknown and will be determined by future negotiations. During the transition period, Union law in its entirety will continue to apply to the UK, meaning that pharmaceutical companies can continue to carry out activities in the UK as before until the end of the transition period.

However, all interested parties should be mindful of legal repercussions when the transition period ends. To ensure that medicines can continue to be supplied in the EU after this period, companies carrying out certain activities in the UK will need to make changes to comply with EU law.

EMA, the European Commission (EC) and EU/EEA² Member States have worked closely together since May 2017 to advise companies on how to apply for the necessary changes and have encouraged industry to plan well in advance and to implement such changes before Brexit.³ The objective of this work is to minimise the impact on the supply of medicines after the transition period.

This Q&A applies to both human and veterinary medicines and will be updated as necessary.

What is the EU/EEA doing to avoid shortages of medicines after Brexit?

The single market is one of the EU's major achievements, allowing for seamless trade and supply of products, including medicines, between Member States. The current arrangements for this seamless trade and the supply of medicines between EU Member States and the UK will remain in place until the end of the transition period.

¹ According to Article 50 of the Treaty on the European Union, the UK was due to leave the EU by 29 March 2019. However, the withdrawal was postponed three times at the UK's request and with the European Council's agreement. The first extension was until 12 April 2019. On 10 April 2019, the European Council granted a further extension to 31 October 2019. On 29 October, the European Council agreed to another extension until 31 January 2020 requested by the UK to allow time to ratify a withdrawal agreement.

² Iceland, Liechtenstein and Norway

³<https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit>

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According to EU law, pharmaceutical companies are required to carry out certain essential operations within the EU/EEA to market their medicines in this area. If companies currently carry out some of these essential operations for marketing medicines in the UK, they must transfer them to an EU/EEA Member State before the end of the transition period to comply with EU law and be able to continue supplying the EU/EEA market with their medicines. For example, a UK-based company marketing a medicine in the EU/EEA must formally transfer its licence from the UK company to one that is based in an EU/EEA Member State.

Since May 2017, EU/EEA authorities have given guidance and urged companies to make these changes ahead of Brexit. As a consequence, the risk of disruptions in the supply of some medicines in the EU/EEA has been greatly reduced. EU/EEA authorities will continue to work with companies for the changes to be made in time.⁴

What happens if a company cannot make the regulatory changes in time?

If a company does not transfer relevant operations from the UK to one of the remaining EU/EEA Member States in time before the 31 December 2020, the company may no longer be able to put the medicine on the market until it has made the necessary changes. These changes have to occur within a certain timeframe.

Can the EU/EEA oblige companies to apply these regulatory changes to their medicines?

EU/EEA authorities cannot force companies to act but it is in the companies' interest to do so if they want to continue to serve the needs of patients and animals in the EU. EMA, the EC and EU/EEA Member States have been monitoring the situation and advising companies on the necessary steps to take and urging them to make these changes in time in order to allow continued availability of medicines after the transition period. However, ultimately the responsibility to transfer relevant activities and to continue marketing a medicine in the EU/EEA lies with the company holding the medicine's marketing authorisation.

If a company makes the necessary changes, does this guarantee the supply of the medicine after the transition period?

Even if companies take the necessary regulatory steps, there may still be issues outside the control of EMA, the EC or EU/EEA Member States that affect the supply of medicines. Companies have been asked to ensure that arrangements are in place to minimise the potential for supply disruptions after the transition period.

Is there a risk to the supply of medicines due to Brexit during the transition period?

No. During the transition period, EU pharmaceutical law will continue to apply to the UK, meaning that until the end of the transition period pharmaceutical companies can continue to carry out activities in the UK and supply their medicines as before. However, companies have to ensure that necessary

⁴ <https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies>

changes are in place before the end of the transition period to minimise the potential for supply disruptions after this period.

Which medicines are at risk of being in short supply in the EU/EEA after the transition period?

Companies are still making the necessary changes and it is difficult to indicate at the moment which medicines are at risk of a shortage.

Whenever a specific shortage is confirmed for a medicine, medicines authorities will make this information public according to their regular practices. This may include recommendations for patients, healthcare professionals, farmers and pet owners, including recommendations to switch to a suitable alternative. Such communication will be published on the websites of EMA and/or national authorities. The following link gives access to EMA's shortage catalogue and links to registers published by national authorities (medicinal products for human use only): <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages/shortages-catalogue>.

Does Brexit affect the safety of medicines in the EU/EEA?

Brexit will not impact the safety of medicines. EMA and the Member States will continue to monitor the safety and efficacy of medicines in the same way as before Brexit.

Does Brexit affect the way medicines are evaluated in the EU/EEA?

EMA and the Member States will continue to evaluate medicines in the same way as before Brexit. However, as the UK will no longer be part of the EU, the evaluation activities for EU medicines previously carried out by the UK are now being carried out by the remaining EU/EEA Member States.

During the transition period, any recommendations or decisions made by EMA's scientific committees in the context of regulatory procedures of medicines will also apply in the UK.

Does Brexit affect the way clinical trials are carried out for human medicines?

Companies producing investigational medicines to be used in clinical trials may also need to transfer certain operations from the UK into an EU/EEA Member State, before the end of the transition period, to comply with EU law.

For any concerns regarding your clinical trial, please consult your doctor.

Should I ask for more than my usual supply of medicine?

No. Medicine prescribers carefully adjust supplies of medicines to patients' needs. It is important that you only get your usual supply and that healthcare professionals do not prescribe or purchase additional supplies in order to prevent unnecessary strain on the supply system.

For the same reason, authorities also do not advise veterinarians to prescribe or farmers and pet owners to purchase more than their usual supply of medicines.

No Brexit-related shortages of human or veterinary medicines will occur during transition period.