EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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'). 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 has now been postponed following the European Council's agreement with the UK's request for an extension.[1]

The conditions under which the UK will leave the EU are currently unclear.

If a withdrawal agreement is endorsed and enters into force, there will be a transition period during which EU law will continue to apply in the UK. This means that access to medicines will not be affected.

If instead, the UK leaves without a withdrawal agreement or deal ('no-deal scenario'), EU law will cease to apply in the UK.

In this case, in order to be able to continue to supply some medicines in the EU, companies carrying out certain activities in the UK will need to make changes to comply with EU law.

EMA, the European Commission and EU/EEA [2]Member States have been working 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, if the UK leaves the EU without a withdrawal agreement.

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 due to 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. If a withdrawal agreement is endorsed and enters into force, the current arrangements for this seamless trade and the supply of medicines in the EU/EEA will remain in place for a transition period.

[1] Under the European Council decision, in the event that the withdrawal agreement is approved by the House of Commons by 29 March 2019 at the latest, the extension will be until 22 May 2019. In the event that the withdrawal agreement is not approved by the House of Commons by 29 March 2019, the extension will be until 12 April 2019. In that event, the UK will indicate a way forward before 12 April 2019, for consideration by the European Council.
[2] Iceland, Liechtenstein and Norway
[3] https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit

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However, in case no agreement is reached the UK will no longer be part of the single market. In this case some companies may have to make regulatory changes in order to continue to comply with EU law.

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. For example, 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 States after Brexit, to comply with EU law and therefore 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 States.

Since May 2017 EU/EEA authorities have given guidance and urged companies to make these changes ahead of the scheduled Brexit date. As a consequence, the risk of disruptions in the supply of some medicines in the EU/EEA, in the case of a no-deal, 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 there is no deal and 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 UK leaves the EU, 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. However, companies may obtain a temporary exemption for one of the required changes under certain conditions.

Further information on these conditions can be found here:
https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf

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 if they want to continue to serve the needs of patients and animals in the EU. EMA, 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 on time in order to allow continued availability of medicines once the UK has withdrawn from the EU. However, ultimately the responsibility to transfer relevant activities and to continue marketing a medicine in the EU/EEA lies with the company holding its licence.

If a company makes the necessary changes does this guarantee the supply of the medicine?

Despite companies taking the necessary regulatory steps, there may still be issues outside the control of EMA, EC or EU/EEA Member States that may affect the supply of medicines (e.g. delays at the border in the case of a no-deal). Companies have been asked to ensure that arrangements are in place to minimise the potential for supply disruptions.

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

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

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

If at any point in time a specific shortage is confirmed for a medicine, medicines authorities will make this information public according to their regular practice. 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 nor the way they work. 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 currently carried out by the UK will be carried out by the remaining EU/EEA Member States after Brexit.

Does Brexit affect the way clinical trials are carried out? (human medicines only)

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, as for approved medicines, 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. Medicines' prescribers carefully adjust supply 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 to the supply system.

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