

Brexit: Protecting medicines supply in Europe in a “no deal” scenario The need for urgent action by the European Union



1. The pharmaceutical industry in Europe has worked to support the EU27 and UK reach an agreement that will allow patients throughout the EU to receive medicines and medical technologies without disruption after the UK leaves the EU and provide long term co-operation in areas such as research, clinical trials, pharmacovigilance and access to talent.
 2. The current political situation in the UK means that the likelihood of the UK leaving the EU in a disorderly manner on 30 March 2019 without a deal remains. Respecting guidance from the European Medicines Agency and European Commission, companies have been preparing for a “no deal” scenario that removes the UK from the EU medicines regulatory framework and does not provide a transition period for any new arrangements or agreements to come into effect.
 3. Despite this preparation, a “no deal” scenario presents a clear threat of disruption to the supply of medicines throughout the EU, including from transport delays at the border with the UK and where the development, manufacture, packaging, safety testing and regulation of the medicine involves the UK in a manner that is no longer recognized by the EU.
 4. This paper sets out measures that would need to be put in place immediately by the EU in the eventuality of a ‘no deal’ Brexit to ensure that medicines can continue to reach patients.
- A. Measures to avoid delays at the EU/UK border for medicines, clinical trial materials and Active Pharmaceutical Ingredients (APIs);**
5. Should the UK leave the EU without a deal in March 2019, the biggest single area outside of the industry’s control remains what happens at the borders between the UK and EU. In the event of ‘no deal’, customs and other checks at ports and borders causing delays and the possible suspension of air flights, would cause very real disruption to the availability of medicines and time critical clinical trial materials to patients.
 6. Every month, 82 million packs of medicines move between the UK and the EU, many of which move between Dover and Calais. Companies are planning to use different routes to and from the UK where capacity exists, but this is limited. There are also difficulties with geographic location, suitable secure and refrigerated storage facilities for medicines, and customs checking arrangements. Some companies have considered moving essential medicines by air freight, but this will depend on the UK and EU having an agreement for planes to continue to fly should the UK leave without a deal.
 7. We ask that the European Commission and Member States consider every possible measure they can take collectively and with the UK to avoid disruption in the movement of medicines and clinical trial materials across the UK and EU borders to protect their supply to patients in Europe, and that they provide clarity as soon as possible to companies for them to be able to take the right measures.

8. Measures should include:

- Discussions between relevant authorities and the sector to co-ordinate contingency plans such as putting fast track lanes or priority routes for medicines into ports
- Medicines and clinical trial materials should be temporarily exempted from any new customs and borders checks
- Enable paperwork and regulatory checks to be completed away from the physical border
- The European Air Safety Authority (EASA) should recognise certificates issued in the UK to ensure that planes can continue to fly.
- Exploring the possibility of also exempting active pharmaceutical ingredients (API) and raw materials for medicines from border checks to ensure manufacturing of medicines continues with limited disruption

B. Measures for the EU recognition of medicines batch testing and release conducted in the UK

9. The European Commission and the European Medicines Agency have advised companies to prepare for the UK becoming a third country as of 30 March 2019 by that date and relocate batch testing from the UK to an EU Member State
10. Despite their best endeavors, not all companies will manage to relocate batch release testing to the EU by 30 March 2019. The EMA has reported that there are currently 18 centrally authorized human medicines that are at risk of supply issues after 30 March and the Heads of Medicines Agencies has said that “many more” medicines authorized through national procedures are at risk.
11. In many cases, the 30 March deadline will not be met for reasons outside of companies’ control. For example, there may not be enough clinical testing laboratory facilities to carry out the necessary quality control testing in EU jurisdictions or a shortage of qualified persons (QPs) in the EU able to perform batch release onto the EU market. In other instances, the physical replication of the complex testing equipment, processes and technology transfers cannot be completed by the deadline.
12. **It is critical that, in the event of a ‘no deal’, the EU introduces a measure that will continue to recognise UK based testing at least until it can be transferred to the EU.**

C. Measures to enable the continued UK participation in key data sharing platforms that protect public health and medicines safety in Europe

The EU has direct competence in public health with a range of agencies tasked with protecting public health. Proximity to Europe and high levels of cross-border travel means cases of infectious disease in the UK are regularly imported from Europe, and vice versa. In the event of a ‘no deal’ Brexit, there are several critical areas where the EU should agree urgent measures to ensure continued cooperation with the UK that protects public health.

13. **The European Centre for Disease Prevention and Control (ECDC)** protects EU citizens against infectious diseases, including through the the **Early Warning Response System (EWRS)**, the **European Surveillance System (TESSy)**, the **Epidemic Intelligence Information System (EPIS)**, and the **Threat Tracking Tool (TTT)** is a database of verified events is used to detect and assess emerging communicable disease threats.

The UK and EU also cooperate as part of the EU’s information technology public health network, including **EudraVigilance**, a centralized European database that supports stronger safety monitoring of medicines by reporting and analyzing suspected adverse reactions to medicines that are authorized or being studied in clinical trials in the European Economic Area.

14. With the UK removed from these platforms there is a threat to the detection and sharing of new warning signals detected in both the UK and EU27. To ensure that the public health in the UK and EU continues to be protected in the event of a ‘no deal’ Brexit in March 2019, we urge the **EU to introduce a mechanism (similar to that with Switzerland) which allows for the continued cooperation between the EU and UK on systems designed to protect public health.**

15. **The Falsified Medicines Directive (FMD)** is designed as a European wide measure to ensure that medicines are safe, authentic and do not contain counterfeit or poor quality ingredients. The FMD introduces a number of safety measures such as unique identifiers, anti-tampering devices, a common EU-wide logo to identify legal online pharmacies, etc.
16. These new requirements will apply from 9th February 2019. Pharmaceutical companies are well advanced with their preparations in meeting the requirements of this directive. As the implementation date for FMD lands in advance of any potential Brexit date, the UK will already be connected to the EU central data hub underpinning the FMD safety measures. As such, stakeholders would continue to upload, verify or decommission the unique identifier on packs of medicines in the UK until a time when that connection was cut. However, the legal obligation to comply with the FMD would be removed for actors in the UK supply chain if the relating legislation was proactively revoked.
17. Removing the UK from the FMD data base will put UK patients at a significantly higher risk of exposure to falsified medicines, and the integrity of the pan-European system may be weakened by:
 - The UK could be a future target country for counterfeit medicines.
 - The security of the European Medicines Verification System (EMVS) may be compromised. If the legislation is revoked in the UK, packs of medicines already on the UK market before 29 March 2019 will not subsequently be decommissioned and will therefore introduce a security risk to all other national systems, especially those sharing multi-market packs, which have already been released to the market.
18. In line with cooperation terms for Interpol and other security systems, the **EU should agree with the UK that the Falsified Medicines Directive will continue to apply in the UK, and that the UK can continue to access and input into the central data hub which underpins the FMD safety features.**