



23 August 2018

## **EU Exit – Human medicines supply in a March 2019 ‘no deal’ scenario**

I am writing as part of the Government’s ongoing preparations for a March 2019 ‘no deal’ Brexit scenario and the potential impact on the supply of medicines.

The Government has made significant progress in negotiations with the EU and remains confident we will leave with a good deal for both sides, that supports existing and future healthcare collaboration. However, as a responsible government, we continue to prepare proportionately for all scenarios, including the unlikely outcome that we leave the EU without any deal in March 2019. Given the significant amount of work that has now been done, I am confident this gives a clear basis for the health and care sector and the life sciences industry to plan so that patients can continue to receive high quality care unhindered.

### **Contingency planning approach**

Earlier this year, the Department undertook an analysis of the supply chain for medicines, including radioisotopes and vaccines, which identified those products that are imported from the European Union and the European Economic Area. Without a deal, the supply chains for these products may be affected by changes to border processes and procedures.

To address this issue the Department is working with the relevant pharmaceutical companies to ensure that UK stockpiles of medicines are adequate to cope with any potential delays at the border that may arise in the short term. In the unlikely event we leave the EU without a deal in March 2019, based on the current cross-Government planning scenario we will ensure the UK has an additional six weeks supply of medicines in case imports from the EU through certain routes are affected. This is the current planning assumption but will of course be subject to revision in

light of future developments. By way of this letter we are therefore asking pharmaceutical companies that supply medicines for NHS patients from, or via, the European Union or EEA, to ensure they have a minimum of six weeks additional supply in the UK, over and above their business as usual operational buffer stocks, by 29<sup>th</sup> March 2019. The same risk exists in the EU. It is for them to prepare for any disruption to supplies in the EU, especially in France, Germany, Belgium and the Netherlands.

We are seeking evidence of contingency plans put in place in respect of medicines that meet the relevant criteria (as set out in the link below). You are requested to respond to this letter by 10<sup>th</sup> September via an email you will receive in the next 24 hours. This will ask you to indicate how you propose to ensure continuity of supply of your products to the NHS in the event of a no deal Brexit. While we recognise that many companies will already have made their own arrangements we are keen to receive a response from all companies to ensure we have a comprehensive picture. We will consider how the department may support suppliers in making arrangements to meet this expectation following receipt of this evidence.

Separately, we recognise that there are some products that have short shelf lives and cannot be stockpiled. Where such products are at present imported to the UK from the EU/EEA via road haulage and roll-on, roll-off sea, road and rail routes, the Department is asking suppliers to ensure they have plans in place to air freight those products to avoid any border delays that may arise at the end of March next year in the event of a no deal exit from the EU. We will consider here too how the department may support suppliers in making arrangements to meet this expectation.

Further details of this request are contained on the information page which can be found here <https://www.gov.uk/guidance/medicines-supply-contingency-planning-programme> .

We are asking suppliers to confirm their plans on a product-by-product basis. We have established a dedicated programme team to manage this exercise, and they will be able to deal with any queries you may have. They will be in contact with you directly and your response to this letter should be sent to them.

### **Approach to batch testing and Qualified Person (QP) release**

We recognise that companies need certainty on the future requirements for batch testing and QP release after Brexit. The Government's White Paper on the Future Relationship between the UK and the EU covers all of the compliance activity necessary for products to be sold in the UK and EU markets. I am today announcing that in a no deal Brexit scenario then the UK will continue to accept products that have been batch tested and released in accordance with EU rules. This means there will be no requirement for any further manufacturer led batch testing and release of

medicines in the UK. For full details see the technical notice on this issue published today.

### **Countermeasures and vaccines**

Countermeasures and those vaccines which form part of the national vaccination programme are also part of our planning on contingency. As these are centrally procured they will not form part of the approach outlined above. They will be subject to separate arrangements with relevant suppliers. Other vaccines are covered by the arrangements set out in this letter.

### **Medical devices and clinical consumables**

The Department is also developing contingency plans for medical devices and clinical consumables that are the subject of a separate letter issued to suppliers of medical devices and clinical consumables today. This letter can be viewed at

<https://www.gov.uk/government/news/dhsc-publishes-brex-it-guidance-for-pharmaceutical-industry-and-suppliers-of-medical-devices> .

### **Guidance to NHS Trusts, pharmacies and general practices on medicines supply**

Guidance is also being issued today to frontline organisations including NHS Trusts, pharmacies and general practices, informing them of these plans for ensuring continuity of supply of medicines and advising them that they can expect to be able to continue accessing medicines through their existing supply routes in the event of a no deal Brexit. The Department of Health and Social Care does not therefore expect to see any distortions to existing supply chains or capacity in the intervening period but we will be monitoring this carefully.

Thank you for your support with this important programme. We are confident that, with adequate preparation and your support, we can together safeguard patient care in the event of no deal. We look forward to receiving your response.

Yours ever,



**MATT HANCOCK**