



Department
of Health &
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Lord Jay of Ewelme
Chairman of the House of Lords EU Home Affairs Sub-Committee
House of Lords
London SW1A 0PW

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Dear Lord Jay,

Thank you for your letter of 24 January to Matt Hancock raising further concerns the Committee has regarding access to medicines in the event of a 'no deal' EU exit. I would like to extend my apologies for missing the deadline you set in your letter for a response; this was due to an administrative error at the Department. In response to the issues you raise, please see the information provided below.

- ***When will the Government contact suppliers of medicines and medical products to give them notice and guidance on rerouting their supplies?***

In December 2018, the Department of Health and Social Care (DHSC) wrote to pharmaceutical companies that supply licensed medicines to the UK from or via the EU/European Economic Area (EEA), and/or manufacture medicines in the UK, and suppliers of medical devices, providing an update on the latest cross-Government reasonable worst-case scenario border disruption planning assumptions. We asked them about their current transportation routes and ability to reroute their supply chains if they currently rely on the short strait crossings via Dover and/or Folkestone, which may be subject to a significantly reduced flow of goods for at least six months rather than the previous estimate of six weeks of disruption.

The Department is preparing further communication to suppliers on re-routing their medicines and other medical products in a no-deal scenario that will be disseminated imminently; these will set out how to engage with Government about accessing this additional roll-on, roll-off ferry capacity, and detail the process for accessing this capacity including a registration system.

- ***In the letter to UK-based manufacturers of medicines on 7 December, you warned that a ‘no deal’ scenario “may now affect you even if you do not supply prescription only or pharmacy medicines from or via the EU/EEA into the UK”. Can you please clarify what effect on the UK pharmaceutical manufacturers you were referring to?***

As a responsible Government, we have a duty to plan for all exit scenarios, including the possibility that the UK leaves the EU without a deal. As such, DHSC’s no deal contingency planning is based on the Government’s reasonable worst-case scenario border disruption planning assumptions, ensuring that the Department is ready for any scenario, including that with the worst possible impact on the flow of goods into the UK.

In a no-deal scenario, we would press EU Member States to introduce pragmatic arrangements to ensure the continued full flow of goods, which would be a mutual interest. Furthermore, in areas where we cannot tolerate significant risk to the flow of goods, such as with medicines and medical products, the Department is preparing detailed contingency plans and will implement these if ‘no deal’ is confirmed.

The possible border delays indicated in the updated planning assumptions would impact **any** import of medicines, including prescription-only and pharmacy medicines, critical to the continuity of patient care. It would also impact UK manufacturers of medicines that may rely on the import of raw materials from or via the EU. Therefore, we have asked **all** suppliers to consider their supply routes and whether any re-routing to avoid the short straits is necessary. At the point of writing, the Department have received very good engagement from industry who share our aims of ensuring the continuity of medicines, medical devices and clinical consumable supplies for patients is maintained, and that suppliers are able to cope with any potential delays at the border that may arise in the short term in a no-deal scenario.

- ***In the letter to health and care providers on 7 December you noted there is a separate programme to ensure the continuity of supply for centrally-procured vaccines and other products ...used for urgent public health use.” Can you please provide more information on this programme, including whether Public Health England is planning to stockpile these medicines and if there is a list of other products for urgent public health use***

Public Health England (PHE) already manages significant stockpiles of vaccines for the national immunisation programme as part of their business as usual planning; however, it is working closely with vaccine suppliers to ensure replenishment of

these existing stockpiles continues in the event of supply disruption in the UK, including increases in suppliers' own UK stockpiles. DHSC is also working to ensure that there are sufficient stockpiles of vaccines for other NHS and non-NHS uses outside of the national vaccination programmes, such as for travel and occupational health purposes. This forms part of the wider continuity of supply programme, which is aimed at ensuring a minimum of six weeks additional supply in the UK of prescription-only and pharmacy medicines including locally-procured vaccines, medical devices and clinical consumables entering the UK from or via the EU/EEA, over and above existing business-as-usual buffer stocks, by 29 March.

In addition, the UK Government stockpiles a range of medical countermeasures to respond to risks identified in the National Risk Register of Civil Emergencies. DHSC works with PHE, the NHS and other stakeholders to ensure arrangements are in place for the distribution of these stockpiles in emergencies. Stockpiled medical countermeasures include vaccines, drugs and consumable products (e.g. syringes).

- ***The letter to health providers also states that NHS Blood and Transplant are working to put written agreements in place with EU organisations to allow organ exchange to continue after 29 March 2019. Can you provide more detail on the agreements, including the provisions of the agreements and progress of concluding the agreements?***

NHS Blood and Transport (NHS BT) coordinates organ donation across the UK. It has well-established relationships with its counterparts in EU countries and has been reviewing current organ exchange arrangements with them to ensure that sharing of organs with EU countries can continue post-exit. The UK shares small numbers with EU countries; only 39 organs came into and 14 left the UK from deceased donors in 2016/17.

On exit day the UK and EU will consider each other as third countries. The EU directive 2010/53/EU allows for organ exchange between EU countries and third countries. In a no-deal scenario, the UK will meet the current EU safety and quality standards for organs, and these would be traceable from donor to recipient and from recipient to donor. Organisations that currently exchange organs can make written arrangements to ensure organs can still move between the UK and EU countries.

Further guidance is available at:

<https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexite-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexite-deal>.

NHS BT is currently in the process of formalising existing arrangements with their EU counterparts by putting in place written agreements, to ensure that the

arrangements are appropriate to satisfy the provisions relating to imports with third countries as set out in UK and EU legislation post exit.

- ***With regards to clinical trials, I note that your guidance published 4 January says the “EU’s current position is that where trials are pan-EU, sponsors or legal representatives must be based in the EU”. What impact will this have on clinical trials that are in progress on 29 March 2019? Has the Government assessed the impact on the UK of the EU’s policy position on clinical trials?***

The European Commission’s position will not impact the authorisation status of pan-EU trials ongoing in the UK on exit day, as the Government has confirmed the UK will continue to recognise existing approvals, and will accept the sponsor or legal representative of a clinical trial being established in a country on an approved country list (which would include EU/EEA countries from Day 1), as well as the UK. However, UK sponsors of trials running in the EU will need to establish a presence in the EU/EEA (either as sponsor or legal representative). We have been advising stakeholders of the need to prepare accordingly since the EU position was published in September 2018, as well as encouraging organisations to consider their supply chains ahead of exit day (to assure supplies of Investigational Medicinal Product in the event of any possible border delays) and provide assurance to trial participants. We will continue working closely with stakeholders to make sure they are prepared for running clinical trials in a no-deal scenario.

- ***In my previous letter I also referred to a news item that claimed a drug company was excluding UK patients from a pan-EU clinical trial due to uncertainty over whether the EMA would accept the data of the trial. What assurances can you provide to drug companies to encourage them to continue to make their trials open for UK patients?***

To be clear, the MHRA has not authorised any applications from Recardio, the drug company referenced in the aforementioned news item, for a clinical trial. On 3 January 2019, the MHRA published a guidance note on the regulation of medicines, medical devices and clinical trials in a no-deal scenario, which may be of interest to you.

- ***In the Minister’s response he cited commercial sensitivities as the reason for not providing the cost of flying in medical products for a six-week period nor the list of medicines that would be prioritised for air freight. We do not consider an estimate of this figure nor a list of medicines and medical***

products to have adverse commercial implications. Providing this information will assist the Committee in understanding the impact of no deal preparations and give assurances that the Government is prioritising medicines effectively.

As stated in my previous letter, the Department is not able to provide a published list of medicines prioritised for air freight as this is commercially sensitive. The Department is still reviewing what support it may provide to companies flying medicines to the UK. The cost of flying in medicines is a confidential commercial decision made between air-freight companies and the manufacturer.

We have, however, asked that for medicines with short shelf lives which could not be reasonably stockpiled, and where their continued import route to the UK from the EU/EEA is via road haulage and roll-on, roll-off sea, road and rail routes, suppliers ensure in advance plans to air freight these medicines from the EU if there is no deal.

Where companies wish to use alternatives to air freight to maintain the continuity of supply in the initial period following 29 March 2019, we will explore with suppliers the potential use of alternative roll-on, roll-off sea freight routes in light of the updated border planning assumptions.

I recognise and appreciate your concerns regarding the Department's 'no-deal' EU exit contingency plans as we approach exit day. I hope this information will allay the further concerns you have raised.

With all best wishes



STEPHEN HAMMOND