Department of Health & Social Care

Stephen Hammond MP
Minister of State for Health

39 Victoria Street
London
SW1H 0EU

020 7210 4850

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

10 January 2019

ACCESS TO MEDICINES AND MEDICAL PRODUCTS IN THE EVENT OF A 'NO DEAL' EU EXIT

Thank you for your letter of 22 November 2018 to the Secretary of State for Health and Social Care. I am replying in my capacity as the Minister responsible for EU Exit no deal planning at the Department.

I would like to apologise for an administrative error within the Department which means that I have been unable to reply before now. Officials in my Department have spoken to your Parliamentary Clerk to put in place measures to prevent a repeat.

I do understand, however, that replies to the thirteen questions within your letter will still be very helpful to your Committee's members as they prepare for the House of Lords debate in advance of the meaningful vote on the UK's exit from the European Union, due to commence on 9 January.

In the appendix that follows, I address each of those questions in the order they appeared in your letter. I trust that this information will be of help to your members.

STEPHEN HAMMOND MP

Appendix

DHSC replies to the Sub-Committee's questions

Do you consider that the contingency planning, however extensive, will remove all risk of disruption to the supply of medicines and medical products in the event of the UK leaving the EU without a deal?

I do not believe that it is ever possible to entirely remove all risk in situations like the one the country is now facing. However, I do have confidence that if everybody does what they need to do, continuity of medicines and medical products could continue unhindered in the unlikely event of a 'no deal' Brexit.

What percentage of NHS-purchased medicines and medical products are imported from or via the EU?

DHSC estimates that up to three-quarters of medicines, based on MHRA licensing data from early 2018, and over half of medical devices and clinical consumables used in the UK are imported from or via the EU.

What work have you undertaken to ensure the import of medicines and medical products is treated as a priority at the border in the event of no deal?

The Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely into the UK from 29 March in the unlikely event of a 'no deal' Brexit.

The Government has also agreed that all medicines and medical products are prioritised on these alternative routes – i.e. away from the short straits crossings to Dover and Folkestone - to ensure that the flow of all these products will continue unimpeded after 29 March 2019. The Department is working very closely with the Department for Transport on how the prioritisation and re-routing of these vital products will work in practice.

What did you mean by "other routes" and what plans have you made to secure these before 29 March 2019?

The Department for Transport has taken steps to secure additional roll-on, roll-off freight capacity on a variety of routes to ease pressure on the short straits crossing. This includes capacity on ferries into and out of Poole, Portsmouth, Plymouth, Ramsgate, Immingham and Felixstowe. The Government has agreed that medicines and medical products will be able to access capacity on these alternative routes and will be prioritised.

How confident are you that the contingency measures deployed as an immediate response to secure the supply of medicines and medical products can be sustained beyond the first six weeks after Brexit, should this be required?

Whilst the six-week stockpiling activity remains a critical part of our contingency plans, this has been supplemented with additional actions. The Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely in to the UK from 29 March in a 'no deal' scenario. DHSC is working closely with the Department for Transport to ensure all medicines and medical products are prioritised on these alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019.

***Can you provide more detail on the tender for additional storage capacity, including: the amount of funding awarded; the size of the storage obtained; and how much of that is for refrigerated storage*.**

As part of the Department's 'no deal' EU exit contingency planning, a tender process to procure additional warehouse space to store stockpiled medicines within the mainland UK, including ambient, refrigerated and controlled drug storage, was launched in October 2018. Contract agreements for storage have either recently been signed or are imminent. This is expected to cost the Government in the low tens of millions of pounds.

The contracts will cover additional capacity including: 53,000 pallets of ambient storage, 5,000 pallets of refrigerated storage and 850 pallets of controlled drug storage. We have agreed funding on the condition that the additional medicine warehousing capacity is in place in time to accommodate stockpiled medicines by the beginning of February 2019, lasting for a period of between twelve and 18 months.

We will publish the names of successful contractors when the tender process is complete and all contracts have been signed.

What plans has the Government made to secure and prioritise airborne routes for medical products?

The Government has secured an airborne route as a contingency measure to move medical products where there is an urgent transport requirement.

What is the expected cost of flying in medical products for a six-week period?

This information is commercially sensitive.

Can you list which medicines and medical products will be prioritised to be flown in? If no such list exists yet, how will you prepare it, and when?

The Department recognises that through our 'no deal' EU Exit medicines and medical supply contingency programmes we are requesting sensitive commercial information from pharmaceutical and medical device suppliers. To reassure participating companies, we have committed to treating all information received confidentially, securely and to using it only for the purposes of the Department's programme. That means not introducing information about a company or a specific medicine into the public domain or sharing with third parties. However, short-shelf life products such as medical radioisotopes will require air freight in many cases.

What analysis has the Government conducted on the impact to the UK economy and employment of companies shifting their licensing activities from the UK to the EU as a result of a unilateral recognition of EMA approvals by the UK? How many companies have already shifted their activities or have indicated their intention to do so?

In October 2018, the Medicines and Healthcare products Regulatory Authority (MHRA) held a consultation on the regulation of medicines, medical devices and clinical trials in the event of a 'no deal' Exit. There were many responses of varying detail on how the proposals will affect business and wider society, which have been taken into account when considering the overall impacts. A narrative impact assessment will be published alongside the 'no deal' secondary legislation in the coming weeks.

The Government published its response to the consultation on 3 January 2019, reiterating its commitment to patient safety and access to medicines, and setting out its plans for the treatment of medicines that are currently authorised by the European Medicines Agency (EMA). While most human medicines on the UK market already have a UK Marketing Authorisation (MA), and will be unaffected by our exit from the EU, most novel medicines and biosimilars, and some generics, come to market via the EMA's centralised MA route. Medicines approved via this route are known as centrally approved products (CAPs). To ensure such medicines will continue to be authorised for use in the UK, all CAP MAs will automatically be converted into UK MAs on 29 March 2019 (also known as "grandfathering").

The MHRA has already written to CAP MAHs to inform them of the UK's intention to grandfather the MAs, to explain what action they need to take and to provide information on how they will be able to opt out of receiving a UK MA, as well as providing guidance on data requirements related to grandfathering. MHRA will also write to MAHs for new CAPs approved before EU Exit.

The Government also published a series of 106 technical notices in the summer of 2018, setting out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario so they can make informed plans and preparations. One of the technical notices set out the Government's approach to the batch testing and the qualified person certification and release of medicines in the event of 'no deal'. In this, the Government committed to accept batch testing of human medicines carried out in EU countries, other EEA countries and those third countries with which the EU has a mutual recognition agreement. The UK will also maintain the arrangements for QP certification and

release for human medicines which apply at present. These arrangements will also apply to Investigational Medicinal Products – substances which are used in medical trials – and will continue until further notice. The technical notice can be found here.

The Government has held extensive engagement with individual companies and trade bodies right across the sector to discuss the impact of these changes. Industry has welcomed the clarity provided by the UK Government and the approach we have taken.

What are the Government's plans to encourage drug companies to prioritise introducing new products to market in the UK?

As the UK leaves the EU, the Life Sciences Industrial Strategy unites the whole sector – charities, academics and pharmaceutical companies – behind a vision that affirms the UK's place as a top tier global hub. The Strategy plays to our key strength, a strong science base, and focuses on areas where the UK has outstanding potential, such as in the areas of digital, genomics, AI and advanced therapy production.

In December 2017, the Government published the Life Sciences Sector Deal, which detailed our commitments to taking forward the ambition in the Industrial Strategy. This included the formation of the Accelerated Access Collaborative (AAC), which will bring together the key government, NHS and industry partners to form who will drive the uptake and adoption of innovation in the NHS, identifying and supporting the innovations that will be most transformative for patients. In December 2018, we published the second Life Sciences Sector Deal, which builds on our existing commitment to make the NHS one of the most innovative health systems in the world. This includes creating a stronger innovation ecosystem, through an enhanced and strengthened AAC.

Further to this, the NHS has world leading clinicians, researchers and scientists and the recently announced commercial agreements for CAR-T treatments are proof-positive that we are open to constructive and flexible partnerships with industry that rapidly bring life sciences innovation to NHS patients in a way that is also fair to British taxpayers. NHS England's commercial deal with the manufacturer Novartis for CAR-T (tisagenleucel) in leukaemia (followed quickly by Kite-Gilead) was the first in Europe, and came less than ten days after the treatment was granted its European marketing authorisation. It represents one of the fastest funding approvals in the 70-year history of the NHS.

What action is the Government taking to resolve uncertainty about data from clinical trials conducted in the UK being accepted by the EMA?

On 6 August 2018, the Government published on gov.uk (https://www.gov.uk/government/news/clinical-trials-regulation) an update on the Clinical Trial Regulation (CTR) during the implementation period, with a clear commitment to align where possible with the CTR without delay when it does come into force in the EU, subject

to usual parliamentary approvals. Equally, in the event of ‘no deal’ the Government will re-align with the parts of the EU’s CTR legislation that are within the UK’s control.

What consideration has the Government given to the reduced flexibility of manufacturers to move products from the EU to the UK in response to market needs, and how do you plan to mitigate this risk?

We have been working closely with industry since November 2017 to produce an analysis of supply chains for the pharmaceutical industry and medical devices and clinical consumables, identifying the proportion of product routinely imported into the UK from the EU. Since then, we have received very good engagement from industry who share our aims of ensuring continuity of medical product supply for patients is maintained.

The arrangements being put in place by the Department for Transport for additional ‘roll-on, roll-off’ ferry capacity – and to prioritise medicines and medical products – will help ensure that manufacturers can continue to move these vital products from the EU to the UK in response to market needs.