Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

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Dear Colleague,

25 February 2019

I am writing to highlight recent developments in the Government's no deal planning work that are of relevance to your business.

Leaving the EU with a deal remains the Government's top priority. However, the government must plan for every possible outcome including no deal. The Department has published guidance to industry and the health and care system to allow them to make informed plans and preparations.

As part of this, I would like to take this opportunity to highlight three areas that businesses in the life sciences sector should be aware of as part of their preparations for our withdrawal in March: continuity of supply, the rights of EU citizens in the UK and plans for the licensing of medicines in a no-deal Brexit.

Continuity of Supply

While we never give guarantees, we are confident that, if everyone – including suppliers, freight companies and the NHS - does what they should do, the supply of medicines and other medical supplies should be uninterrupted in the event of exiting the EU without a deal.

Over the past twelve months, the Department of Health and Social Care, working closely with trade bodies, product suppliers, the NHS, and the Devolved Administrations, has been making detailed plans to ensure the continuation of the supply of medical products to the whole of the UK in the event of a no deal EU Exit.

This includes:

- medicines (prescription, pharmacy only and general sales medicines);
- medical devices and clinical consumables (such as needles and syringes);
- supplies for clinical trials;
- vaccines and countermeasures (such as anti-venoms, particular antibiotics and HazMat suits); and
- blood, tissue and transplant materials.

We have also assessed contract risks associated with potential EU Exit in the broader NHS and within the Devolved Administrations, and as many of you may be aware are working with suppliers to ensure adequate mitigations are in place for non-clinical goods and services (e.g. hospital food, laundry, IT contracts etc.).

Around three quarters of the medicines and over half the clinical consumables we use come from (or via) the EU.

Medicines shortages are a regular and ongoing issue that the Department has been managing for many years. The production of medicines is complex and highly regulated, and materials and processes must meet rigorous safety and quality standards.

Supply problems can arise for various reasons such manufacturing issues, problems with the raw ingredients and batch failures.

The Department's Medicine Supply Team has well established procedures to deal with medicine shortages and works closely with the MHRA, the pharmaceutical industry, NHS England and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do arise. There is no hard evidence to date to suggest current issues are increasing as a result of EU Exit.

The Department has overall responsibility on behalf of the devolved administrations for ensuring the continuity of supply of medicines, and they have opted in to our offer to manage supply of medical devices and clinical consumables (MDCCs) on their behalf.

Therefore, all supply arrangements take into account the volumes required and transportation to the whole of the UK.

The key risk to supply is reduced traffic flow at the short straits crossing (i.e. between Calais and Dover or Folkstone), which is where the majority of medicines and other medical products imported from the EU come through.

Government estimates show, in a reasonable worst-case scenario, that there will be significantly reduced access cross the short straits to and from Dover and Folkestone, for up to six months.

In addition, we're managing the risk that transportation to Northern Ireland and the Channel Islands suffers from reduced traffic flow and we are working with DfT on mitigations.

Together with industry and the NHS, the Department for Health and Social Care has analysed the supply chains of 12,300 medicines, close to half a million medical devices and clinical consumables, vaccines used in national and local programmes, and essential non-clinical goods on which the NHS relies, such as linen, scrubs and food.

This has been a very large undertaking but we are grateful for the excellent engagement from industry. Our plans are well advanced as a result.

As a result of this analysis, the DHSC has put in place a comprehensive approach with multiple lines of defence to minimise any supply disruption, consisting of:

- securing, via DfT, additional roll on roll off freight capacity (away from the short straits) for goods to continue to come into the UK from 29 March;
- building buffer stocks and stockpiling (where this is practical) or asking industry or the NHS Supply Chain to build up buffer stocks in the UK before 29 March;
- buying extra warehouse space, including refrigerated storage for the additional stock to be held in;
- booking space on airplanes for products which require an immediate shipment due to short shelf-life or specific storage conditions;
- consulting on ways of avoiding excessive exportation of goods away from the EU.
- making changes to, or clarifications of, regulatory requirements so that companies can continue to sell their products in the UK even if we have no deal;
- strengthening the processes and resources used to deal with shortages in the event that they do occur despite everyone's efforts.

No one of these measures will work on their own. A combination of securing freight, buffer stocks, stockpiling and warehousing, regulatory flexibility, and clinical assessment and decision making will be required help to ensure the continuation of medical supplies.

EU citizens in the UK

The NHS and wider care system is blessed to have many staff of EU origin working in it. They are very welcome to stay, in all EU Exit scenarios, and their rights will be protected. You may have seen that the Government reopened its pilot EU Settlement

Scheme on 21 January 2019; it is once again accepting applications, so EU staff can register to settle.

From 30 March 2019 onwards, applicants won't have to pay to submit an application. Any fees paid for an application made before that date will be reimbursed (details of the refunds process will be published shortly). We want our EU workforce to remain in the UK after we leave and now, with these changes to the application fee, it is easier than ever for them to stay.

Following a successful testing phase in December 2018, the scheme is being rolled out to all EU citizens living in the UK who have a valid biometric passport. This is part of the public testing phase. It will also be open to non-EU family members who have a valid biometric residence card. We want to make sure as many of the UK biopharmaceutical industry's EU workforce apply as possible and so please share the link to the application with as many of your EU staff as you can.

The link to the Settled Status application form can be found here: https://apply-for-eu-settled-status.homeoffice.gov.uk/start/eu-settlement For this phase of the roll-out the application remains in digital format only, but alternative application routes will open in the Spring.

We know that, as employers, you want to be able to support your staff in making their applications. We have created an employers' toolkit which contains all of the information that you will need to promote the Settlement Scheme and help your staff complete an application. Documents can be found here: https://www.gov.uk/government/collections/eu-settlement-scheme-applicant-information.

The toolkit contains information about who is eligible to apply. To confirm: the next phase of testing now extends to family members who were not eligible under the previous pilot. EEA and Swiss nationals are not eligible to apply during the pilot but will be able to once the scheme is fully live by 30 March 2019. Irish citizens do not need to apply to the EU Settlement Scheme.

We guarantee that EU citizens resident in the UK by 29 March 2019 will be able to stay and we will take the necessary steps to protect their rights even in a 'no deal' scenario. The basis for qualifying for status under the scheme will remain the same as proposed in a 'deal' scenario and will be focused on residence in the UK. Further information is available at https://www.gov.uk/government/publications/policy-paper-on-citizens-rights-in-the-event-of-a-no-deal-brexit

If you have any further questions about eligibility or support in completing an application, you can contact the EU Settlement Scheme Resolution Centre by calling 0300 123 7379 (inside the UK) or +44 (0) 203 080 0010 (outside the UK). Find out about call charges on https://www.gov.uk/call-charges. You can also ask a question using the online submissions form https://eu-settled-status-enquiries.service.gov.uk/start

Further information and guidance is available on GOV.UK. You may find the following link useful: https://www.gov.uk/settled-status-eu-citizens-families.

Licensing medicines in the UK

In the event of a no deal, the UK's participation in the European regulatory network will cease. The Medicines and Healthcare products Regulatory Authority (MHRA) will take on the functions currently undertaken by the EU for medicines and devices on the UK market.

To maintain continuity of supply of medicines to UK patients, all Centrally Authorised Product (CAP) Marketing Authorisations (MA) will automatically be converted into UK MAs on 29 March 2019. The MHRA wrote to Marketing Authorisation holders on 2 January 2019 to outline this 'grandfathering' process and set out the actions that companies are requested to take concerning relevant products. The letter can be found here: https://www.gov.uk/government/publications/conversion-of-community-marketing-authorisations-to-uk-marketing-authorisations-letter-to-industry.

After EU Exit, to market a new product in the UK, an initial MA application will need to be submitted to the MHRA and will go through a national assessment. Medicines which proceed through the Centrally Authorised Product route in the EMA will be able to apply to the MHRA for a 'targeted assessment' whereby the MHRA will grant a UK licence based on a fully disclosed judgment from the EMA's Committee for Medicinal Products for Human Use (CHMP), unless they have exceptional evidence of a risk to public health and safety from doing so. A Market Authorisation Holder and Qualified Person for Pharmacovigilance should be established in the UK by the end of 2020. Guidance on licence routes and a possible no deal scenario more generally can be found here: https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario.

The UK will continue to accept batch testing of human medicines carried out in countries named on a list set out by the MHRA. On exit day, this list will include EU countries, other EEA countries and those third countries with which the EU has an

MRA. The UK will also continue to accept QP certification from the EU, with wholesalers importing these medicines required to put in place an assurance system to ensure any medicines they import have been QP certified.

The UK will also continue to accept batch testing of Investigational Medicinal Products (IMPs) manufactured in EU and EEA states. There will be no change to the present arrangements for batch testing of IMPs manufactured in third countries. Please consult Batch testing medicines if there's no Brexit deal for more information on manufacturing human medicines in the UK and EU.

We will also consider how we can go further, to introduce a direct UK licencing route to support innovation and accelerated access. Work on this proposal is ongoing, and we would value your input.

Please consult the further guidance note on the regulation of medicines, medical devices and clinical trials would be regulated if there's no Brexit deal for more information on manufacturing human medicines in the UK and EU:https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

I hope this update is useful.

Yours ever,

MATT HANCOCK