



39 Victoria Street London SW1H 0EU

020 7210 4850

23 October 2018

Dear Colleague,

## Medical Devices and Clinical Consumables EU Exit contingency planning for a 'no deal' scenario –

As you will recall, I wrote to medical suppliers in August to provide an overview of the Department's preparations for EU exit. 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. Further to this, and in view of the important role your organisation plays in the supply of medical devices and clinical consumables in the UK, I am writing to update you on our contingency planning approach and to inform you of the measures we are now asking you to take in preparation for the unlikely event of a no deal scenario.

As part of our approach, the Department has undertaken an analysis of supply chains for medical devices and clinical consumables identifying those products routinely imported into the UK from countries in the EU.

As previously indicated, one of the contingency measures we will be taking is to increase stock levels at a national level. To facilitate this process, our NHS Supply Chain colleagues are now contacting suppliers who routinely import products from other EU countries to establish the action required to achieve this. In parallel with this, we would ask all suppliers that source products from other EU countries to review their supply chains and determine what measures they need to take so that they can continue to provide products in the event of a no deal exit.

Where companies have already put contingency plans in place, it is important that they share details of their arrangements with us at <a href="mailto:mdcc-contingencyplanning@dh.gsi.gov.uk">mdcc-contingencyplanning@dh.gsi.gov.uk</a>. This will aid our work in ensuring, in the

unlikely event of a no deal scenario, that the NHS has uninterrupted access to the full range of products that it relies on for delivering safe and effective patient care.

In addition, arrangements are being put in place to help ensure the continued movement of medical devices and clinical consumables that are routinely supplied from other European Union countries directly to NHS organisations. In conjunction with representatives from industry and trade associations, we have established an industry working group to test and refine our contingency plans, and the mechanisms by which suppliers will interact with these processes. It is planned to complete this process during October to support communications on the details of these arrangements in November.

Work is ongoing with our counterparts in Scotland, Wales and Northern Ireland to ensure that national contingency arrangements are aligned and support specific preparedness measures necessary to meet the needs of the healthcare systems in each country.

In August, the Department issued a technical notice to update businesses on the arrangements that will come into force for the regulation of medicines, medical devices and clinical trials currently subject to EU rules if we leave the EU on 29 March 2019 with no deal. In respect of medical devices, the notice explains that the UK will continue to recognise medical devices approved for the EU market, i.e. those that carry a CE mark and, where required, have appropriate certification from an EU notified body. Further details are available <a href="here">here</a>.

Ensuring the continued supply of medical devices and clinical consumables in any scenario is central to ensuring that patients can continue to receive the care they need and, to this end, we look forward to working with you over the coming months.

If you have any questions, please do not hesitate to get in touch with us at <a href="mailto:mdccontingencyplanning@dh.gsi.gov.uk">mdccontingencyplanning@dh.gsi.gov.uk</a>. You can view my letter of 23<sup>rd</sup> August, technical notices and other information relating to EU exit contingency planning here.

Yours ever,

MATT HANCOCK