

Stephen Hammond
Minister of State for Health (Department of Health and Social Care)

Dear colleague,

Further to the Written Ministerial Statement made in the House today by the Chancellor of the Duchy of Lancaster, David Lidington MP, I am writing to provide more detail on plans from the Department for Health and Social Care (DHSC) to support the continuity of supply of medicines and medical products into the UK in the event we exit the EU without a deal on 31st October.

On 25th February, I made a statement to the House on the Department's planning in advance of 29th March. The plans I outline below are set out to ensure that we are at least as prepared for a no-deal EU exit in October as we were in March. These plans endeavour to ensure patients in England, the devolved nations and Crown Dependencies of the UK continue to have access to the medicines and medical products they need.

As in preparation for 29th March, our contingency plans for 31st October will cover NHS, social care and the independent sector and covers medicines (prescription-only medicines, pharmacy medicines and general sales list medicines); medical devices and clinical consumables (such as needles and syringes); supplies for clinical trials; vaccines and countermeasures; and organs and tissues for transplants.

Before setting out the detail of our plans I want to put on record my thanks for the valued collaboration and shared endeavour in putting patients first from industry trade bodies, all those involved in manufacture and distribution, charities and many other stakeholders, as well as, of course the NHS. I understand the complexity of preparing for 'no deal' but am confident that with the same collective commitment we can again put in place the necessary contingency plans.

In light of the agreed extension to Article 50, Government has been reviewing its 'reasonable worst-case' (RWC) scenario planning assumption regarding disruption at the Channel short straits, issued by the Cross-Government Border Delivery Group. These assumptions have been revised to reflect latest intelligence on both infrastructure (such as border inspection posts, holding bays and IT systems) and trader readiness (having all necessary paperwork in place at the border). At this stage, there is no material change in these assumptions that lead us to move away from our previous multi-layered approach.

My Department has continued to work closely with the Devolved Administrations (DAs), industry trade bodies and suppliers, the NHS and other key stakeholders. Prior to 29th March, my Department analysed the supply chains of 12,300 medicines, close to half a million product lines of medical devices and clinical consumables, vaccines used in national and local programmes, and essential non-clinical goods on which the health and care system relies, such as linen, scrubs and food.

We also assessed contract risks associated with potential no-deal EU exit in the broader NHS and social care sector in England and within the DAs and are continuing to work with suppliers to ensure suitable mitigations are in place for non-clinical goods and services (e.g. hospital food, laundry, IT contracts, etc).

These analyses and assessments have been updated where necessary - and will continue to be refined while a no-deal exit remains a possibility - and have informed the plans I set out below.

This has been, and continues to be, a very large undertaking, but we are grateful for the excellent engagement from all parties. The plans I set out today are robust and well advanced largely due to this engagement. We note that this is a difficult period for industry and that our ask is not always easy, particularly in relation to stockpiling. However, the planning and the successful execution of these plans in the event of exiting without a deal, rely on a positive response from colleagues in industry. We remain thankful for their continued constructive collaboration.

As per our planning in the run up to a potential 29th March no-deal EU exit, we are asking suppliers to analyse their supply chains and to make alternative plans if they anticipate disruption, including rerouting to alternative ports or using airfreight where necessary. The Government's contingency measures to address continuity of supply of medicines and medical products aim to support industry-led measures and, in places, act as a 'last resort' to be used only when a supplier's alternative arrangements to ensure uninterrupted supply.

My Department is maintaining some layers of contingency implemented previously, whilst adapting others to meet a potential 31st October no-deal EU exit date.

1. Improving trader readiness for new border arrangements

Working with colleagues across Government, we are addressing the issue of trader readiness for the new customs procedures that will come into force on Day One of Exiting the EU without a deal. This remains an area for improvement and we continue to work with industry to mitigate against its impact.

2. Building up buffer stocks

This approach is being taken across the following sectors:

- a) Medicines - Informed by the latest border assumptions, the Government asks suppliers of prescription-only medicines and pharmacy medicines with an EU or European Economic Area touchpoint to put in place plans to secure supply for the expected six-month period of disruption. We ask that this includes a stockpile of an additional six weeks' supply in the UK, on top of operational buffer stocks, in addition to developing a robust re-routing plan away from the short straits. As before, for products with a short shelf life or where production constraints mean stockpiling is not possible, e.g. medical radioisotopes, we ask for alternative air freight plans to be made. While we would advocate the above approach to suppliers, we do understand, however, that some companies may wish to adopt a different balance between stockpiling and re-routing to achieve the most effective and robust mitigation plan. In all cases, the Department will be asking companies to notify the Department of their plans.
- b) Medical Devices and Clinical Consumables – My department is working closely with procurement and logistics services in the Devolved Administrations, developed a central stockpile of fast-moving medical devices and clinical consumables. It is intended that this stockpile will remain in place in readiness for 31st October, with some small adjustments being made to reflect changes in demand and the time of year. As for March, this stockpile does not cover all product lines and, therefore, there will be requirement for suppliers to implement their own preparedness arrangements, considering the balance between stockpiling and re-routing to achieve the most effective and robust mitigation plan in the context of the anticipated disruption at the short straits. In all cases, the Department will be asking companies to notify the Department of their plans.

- c) Blood and Transplants – NHS Blood and Transplant (NHSBT) manages the blood supply in England and is putting in place stockpiles and other contingency measures to ensure a continuous supply of blood, including frozen plasma, and is working with the other UK blood services as required. NHSBT manages organ donation across the UK and is working with its EU counterparts to ensure that the current organ exchange arrangements can continue post exit. The UK regulators, the Human Tissue Authority and the Human Fertilisation and Embryology Authority, are working with licensed UK establishments so the import of tissues and cells from EU countries can continue after Exit day.
- d) Vaccines and countermeasures – My Department is taking the same approach to vaccines as to medicines (stockpiling, where possible, and replenishment), as well as working with Public Health England (PHE) which is responsible for managing existing stockpiles in the course of their business as usual planning. PHE is working with vaccine suppliers to ensure replenishment of these existing stockpiles continues in the event of supply disruption in the UK. In the case of seasonal flu vaccine, which cannot be stockpiled, manufacturers have robust contingencies in place for example rerouting away from the short straits, if necessary.
- e) Supplies for Clinical Trials – Supplies for clinical trials are transported in small quantities and often via airfreight. As per our planning in advance of a potential 29th March no-deal EU Exit, we are asking clinical trials sponsors to consider their supply chains and put in place contingency measures.
- f) Non-Clinical Goods and Services – My Department has continued to work closely with a range of NHS and social care providers to ensure mitigation plans are in place for supplies of non-clinical goods and services, such as hospital food and laundry.

3. Procuring extra warehouse space for stockpiled medicines

To ensure sufficient space to store stockpiled medicines ahead of a possible 29th March no-deal EU exit, my Department agreed contracts for additional warehouse space, including ambient, refrigerated and controlled drug storage. We will continue to provide warehousing capacity and will keep industry updated on how they can access this additional storage in advance of 31st October.

4. Securing freight capacity

As per the information provided by the Chancellor of the Duchy of Lancaster, across Government, it is planned to provide contingency freight capacity in two ways:

- a. Procuring 'roll-on, roll-off' freight capacity – the Department for Transport, acting on behalf of government, will be starting a procurement exercise to put in place a framework to provide suppliers, including those of medicines and medical products, with the opportunity to use freight capacity along routes that operate away from the Channel short straits. There is a cross government agreement that all medicines and medical products, and other 'category 1' goods, will be prioritised on these routes to ensure the flow of all these products may continue unimpeded.
- b. Procuring an 'Express Freight Service' – my Department will be procuring and managing a health-only freight solution. This 'Express Freight Service' will provide access to an end-to-end solution able to deliver small consignments on a 24-hour basis and a two-to-four-day pallet delivery service.

The procurement exercises for both above freight services are launching today, and we will provide updates to industry on how they can access this service in advance of 31st October.

In addition to the above four measures, the following two were put in place in advance of 29th March and remain relevant and applicable in the event of exiting the EU without a deal on 31st October.

5. Changing or clarifying regulatory requirements

So that companies can continue to sell their products in the UK even if we have no-deal, the Government has made changes to, or clarifications of, certain regulatory requirements.

The Medicines and Healthcare products Regulatory Agency (MHRA) has for this scenario consulted on, and published, further guidance on how medicines, medical devices and clinical trials will be regulated. Following the consultation, three statutory instruments, covering the regulation of human medicines, medical devices and clinical trials were considered and approved by Parliament in February and March 2019. This legislation will take effect on “exit day” in the event of a no-deal exit. In August 2018, the Government also published a dedicated technical notice on the unilateral recognition of batch testing of medicines, if there is a no-deal exit. Both the guidance and the technical notice were made available in my Statement of 25th February.

The Department’s Medicine Supply Team has well-established procedures to deal with medicine shortages and works closely with MHRA, the pharmaceutical industry, NHS England, the Devolved Administrations 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.

Medicines suppliers should continue to use existing medicines reporting arrangements and alert the Department’s Medicine Supply Team of any supply issues at the earliest point possible, so the team can undertake a risk assessment and implement a management plan where required to help mitigate any potential impacts affecting patients. Guidance about the information that should be reported to the Medicine supply team and how to report can be found at the following link: <https://www.gov.uk/government/publications/reporting-requirements-for-medicine-shortages-and-discontinuations>.

6. Strengthening the processes and resources used to deal with shortages

In addition to the normal shortage management routes, my Department has also put in place legislation to enable Ministers to issue serious shortage protocols that, where appropriate, enables community pharmacies to supply against a protocol, i.e. to issue a substitute medication instead of the medication indicated on the prescription without going back to the prescriber first.

The above multi-layered approach is similar to the measures put in place in advance of 29th March and remains essential to help ensure the continuation of medicines and medical supplies in the event of the UK exiting the EU without a deal.

Local stockpiling over and above business as usual ahead of 31st October is unnecessary and could cause shortages in other areas, which could put patient care at risk. It is also important that patients keep taking their medicines and order their repeat prescriptions as normal.