



By email
26th June 2019

Dear Colleagues,

Continuity of supply of medicines and medical products in 31st October no-deal EU exit scenario

Further to my note of 26th April, I want to update you on the Government's approach to delivering our shared goal of ensuring the continued supply of medicines and medical products to patients in the UK in the event of a no-deal EU exit on 31st October; and to set out how we believe suppliers of those products to the UK can best prepare to achieve that objective. In compiling this guidance, we have listened carefully to industry feedback on our 29th March no-deal exit contingency programme, as well as building on latest insight into company preparedness from trade bodies and suppliers, and using the most recent borders planning assumptions (explained below).

Border assumptions and the need for a continued multi-layered approach

The main risk to the unhindered supply of medicines and medical products presented by the UK exiting the EU without a deal remains the predicted reduced traffic flow at the short straits crossings (i.e. between Calais/Dunkirk/Coquelles and Dover/Folkestone). Around three-quarters of medicines and over half the clinical consumables the UK uses come from (or via) the EU and the vast majority are reliant on those crossings.

Contingency planning for 29th March involved a multi-layered approach of stockpiling, regulatory flexibility, and putting in place a coordinated National Supply Disruption Response system to manage issues arising following the exit day. These were supported by buying additional warehouse space for medicines and securing freight capacity on routes away from the short straits.

That approach was a response to the reasonable worst-case (RWC) planning assumption regarding the short straits issued by central government at the time, and our approach for 31st October will be determined by the latest version of these. To that end, the Government's Border Delivery Group (BDG) has been reviewing the readiness of border infrastructures and of traders to comply with customs and borders processes in the UK and the EU.

While the predicted flow rate across the short straits has improved slightly since 29th March, significant disruption would be expected for six months following a no-deal exit, with the most severe period being the first three months. Given this, it remains necessary to maintain a multi-layered approach to contingency, in order to secure continuity of supply for medicines and medical products, ahead of a potential 31st October no-deal exit.

Guidance to suppliers: A flexible approach to stockpiling and re-routing

The Department and Ministers recognise, and are extremely grateful for, the work that suppliers of medicines and medical products did in advance of 29th March and would like to thank you once again for your collaboration and efforts. Many companies have put in place detailed rerouting and stock management plans, and we are aware that many of you are currently reviewing your position, and other contingency measures. Building on this, the Government's guidance to prepare for 31st October is set out below:

Medicines suppliers

Our aim is to achieve at least the same level of assurance as before, but to give suppliers greater flexibility in terms of the balance between their stockpiling and re-routing plans to ensure a continuity of supply of their products.

All no-deal preparedness plans should therefore contain a mix of the following, depending on each company's specific situation:

- Secured capacity for rerouting freight away from the short straits after no-deal exit day, in order to avoid the worst restrictions on flow outlined above.
- Stockpiling product above and beyond business-as-usual inventory levels; as a default, this is recommended as six weeks' stock above business as usual inventory, the same as last time.
- Assurance on the readiness of a company's logistics and supply chains to meet the new customs and border requirements for both import and export (sometimes referred to as "trader readiness").

Where companies have already made plans containing these three elements, we will continue to work with you on ensuring these are robust, and help you deal with any specific product issues by exception. Where companies have not yet done so, the Government asks that they build a plan which 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, for example, medical radioisotopes, we ask for alternative air freight plans to be made.

While we advocate the above approach, we do understand 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 us of their plans.

In the coming days, companies will be asked to provide information at product level, focused on the minimum key data set necessary for assurance of the programme. This will build on information from the 29th March exercise, including stock levels expected to be held on 31st October and plans for re-routing away from the short straits.

Following this data collection exercise, we will ask suppliers to notify us by exception of any subsequent changes to their plans. The assurance process underpinning the programme has been refined and streamlined following feedback.

While the above advice and guidance is primarily aimed at suppliers of prescription only medicines (POMs) and pharmacy medicines (Ps) with an EU touchpoint, we have also been considering the implications of the latest border planning assumptions on suppliers of other categories of medicinal product, including critical general sales list medicines, unlicensed medicines, 'specials', and parallel imports and exports, as well as on UK manufacturers of products where raw materials may come from/via the EU/EEA. While a combination of stockpiling and re-routing, together with trader readiness, would also be advisable for these products too, we will be engaging separately with companies on their contingency plans over the coming weeks.

Medical devices and clinical consumables suppliers

In advance of 29th March, the Department, 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 a 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.

Government measures to support suppliers

In addition to the above guidance to industry suppliers, the Government is also taking its own steps to ensure continuity of supply of medicines and medical products in a no-deal scenario on 31st October.

Measures spanning medicines and medical products

Securing freight capacity

As above, we strongly recommend that suppliers of medicines and medical products review their supply routes and, where necessary, put in place robust plans to re-route supply away from the disrupted short straits routes into the UK, especially during the first three months following 31st October when the most significant disruption is anticipated.

In addition, the Government has also taken steps towards delivering Government-led solutions to support product re-routing, to be used to address urgent need where suppliers' arrangements encounter difficulties:

- a. DHSC will commence a procurement exercise for 'Express Freight Services' to 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.
- b. The Government also intends to commence procurement of 'roll-on, roll-off' freight capacity on which medicines and medical products would be prioritised to ensure the flow of all these products may continue unimpeded.

The Department will continue to keep suppliers updated on developments on both procurement exercises once more information is available.

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 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 no deal. In August 2018, the Government also published a dedicated technical notice on the unilateral recognition of batch testing of medicines, if there is no deal. Both the guidance and the technical notice were made available in our Written Ministerial Statement to the House of Commons on 25th February.

National Supply and Disruption Response

As per arrangements put in place for March, the Department will also be operating a National Supply and Disruption Response (NSDR) unit. The contact details for the NSDR remain active and arrangements are in place to increase the capacity in this unit to support resolution of supply disruption incidents, should they arise. Full details of arrangements for alerting us to any anticipated disruption in supply across the UK will be issued closer to exit date.

Measures specific to medicines

Strengthening the processes and resources used to deal with medicines shortages

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>.

In addition to the normal medicine shortage management route, the Department has put in place legislation to enable Ministers to issue serious shortage protocols that, where appropriate, enables community pharmacists 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.

Procuring extra warehouse space

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.

Moving forward together

The multi-layered approach set out above is similar to the package of 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 exiting the EU without a deal.

We will continue to ask health and social care service providers to avoid local stockpiling over and above business as usual ahead of 31st October as it is unnecessary and could cause shortages in other areas, which could put patient care at risk. Nor do patients need to personally stockpile medicines.

We have reflected on the planning and approach we took in advance of 29th March. While we were prepared for the event of exiting the EU without a deal, there are elements of the planning we believe we can improve in advance of 31st October. We are committed to sharing information and guidance with you at the earliest possibility to enable you to plan properly but also to ensuring that we minimise the number, length and complexity of requests for information we send to you.

To that end, in addition to ensuring that all future written updates on our EU exit planning are as clear and timely as possible, the Department will also invite you to regular supplier webinars to provide you with further information and guidance and to answer your questions. These will cover, for example, further details on the rationale for the six-week stockpiling ask in light of the latest border assumptions and how, together, government and suppliers can maximise trader readiness for the potential new customs requirements.

I hope this information is useful and provides direction to inform your own preparedness planning and arrangements. I continue to be extremely grateful for your engagement and cooperation.

Yours sincerely,



Steve Oldfield
Chief Commercial Officer