



By email

26th March 2019

EU Exit contingency planning: National Supply Disruption Response system

Dear Colleague,

Last Thursday, following agreement by the EU leaders, the European Council President Donald Tusk announced that if the Prime Minister's Withdrawal Agreement passes through Parliament next week, Article 50 would be extended from 29th March to 22nd May 2019. If the Withdrawal Agreement does not pass through Parliament, Article 50 will be extended to 11pm on 12th April 2019 and the UK Government will have to propose an alternative plan for Exiting the EU to the European Council for consideration.

The agreement with the EU means the UK will no longer leave the EU on 29th March 2019. However, the department is clear that we must continue to plan for a no deal outcome until a legally binding alternative is secured. At this stage, we therefore urge you to continue preparations that will protect patients in all possible outcomes.

The Government has put in place a range of contingency measures to support continuity of supply, including clinical trial supplies, to NHS and Adult Social Care providers in the event of the UK leaving the EU without a deal, and I want to thank the industry and sponsors of clinical trials for their positive engagement with our contingency planning programme.

While we have every confidence that these measures, coupled with your actions, will enable the continued supply of goods and services to health and social care providers once out of the EU, it is important that we are all fully prepared to respond to any supply disruption incidents that may arise.

As part of its Operational Response Centre, the Department of Health and Social Care has set up a National Supply Disruption Response (NSDR). The NSDR processes will monitor the supply situation and co-ordinate actions to address supply disruption incidents that occur after the UK has exited the EU where normal procedures are unable to provide a resolution.

The following table identifies what actions you should take should you experience supply disruption to products or services. The overall NSDR system incorporates existing reporting mechanisms, with an additional NSDR call centre to be used as outlined below. If an issue arises and it is unclear who to contact in those circumstances, please contact the NSDR call centre.

Industry sector	Actions
Medical Devices, Clinical Consumables and Non-Clinical Goods and Services	<ul style="list-style-type: none"> • If you experience disruption to your normal supply routes, or you feel that there is potential for disruption, regardless of the cause, you should do everything possible to remedy the issue within your normal supply arrangements. • you should notify NSDR immediately of any issues relating to your normal supply routes, or any potential risks that are likely to impact your ability to ship products in to the UK on schedule, including your proposed contingency resolution where possible. These issues may or may not be related to the UK's exit from the EU and may include problems such as component or raw material shortages, manufacturing outages, quality issues, regulatory challenges or delays, logistics or transportation problems, etc.; • if you are unable to resolve a disruption incident, you should contact the NSDR immediately to allow as much time as possible to assess the urgency and nature of the issue, and help to identify actions with you to mitigate impact on care provision and patients; • You should also notify the NSDR of any direct communication to care providers or patients that are planned or that have been issued in relation to emerging supply disruption issues. Where possible, the NSDR teams will look to work with you to coordinate communications to ensure clear, consistent and timely messaging;
Medicines	<p>You should continue to use existing medicines reporting arrangements, and alert the DHSC 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.</p> <p>Guidance about the information that should be reported to the Medicine Supply team and how to report via the routes below can be found at the</p>

	<p>following link: https://www.gov.uk/government/publications/reporting-requirements-for-medicine-shortages-and-discontinuations</p> <p>The NSDR call centre can provide additional advice regarding transport issues, including access to the new Government-secured freight capacity, so companies should contact NSDR directly for queries of a logistical nature.</p> <p>The Medicines Contingency Planning team will continue to support companies with their stockpiling plans for EU exit and companies are encouraged to continue to report any changes or issues relating to their stockpiling plans to this team.</p> <p>In summary:</p> <ul style="list-style-type: none"> • For queries or issues relating to EU exit logistical or transport issues, including the new Government-secured freight capacity, please contact NSDR • For queries or to report issues relating to the EU exit stockpile for medicines, please continue to use medicinescontingencyplanning@dhsc.gov.uk • For all other issues that may affect the supply of medicines into the UK, please continue to report these through the business as usual route to the DHSC Medicines Supply team. <p>Please be assured that we will work across the NSDR system to ensure that medicines supply issues are reported to all relevant teams however they are initially reported.</p>
<p>Vaccines</p>	<ul style="list-style-type: none"> • Centrally procured: For vaccines and other products which are supplied to Public Health England (PHE) under contract, please continue to liaise with PHE directly

	<ul style="list-style-type: none"> • Locally procured: For vaccines which are not supplied to PHE under contract, please refer to the medicines section above
<p>Clinical Trials</p>	<ul style="list-style-type: none"> • If you are a sponsor or an organisation running a clinical trials/clinical investigation experiencing disruption to your normal supply chain regardless of the cause, you should use your existing processes to resolve the issue. • If you are a trial site, you should contact the clinical trial/ investigation sponsor or the organisation running the clinical trials/clinical investigation using established processes to resolve the issue. • Sponsors/organisations running the clinical trial/investigation should notify NSDR immediately of any issues relating to your normal supply routes, or any potential risks that are likely to impact your ability to ship clinical trials/ investigation supplies in to the UK on schedule, including your proposed contingency resolution where possible. These issues may or may not be related to the UK's exit from the EU and may include problems such as component or raw material shortages, regulatory challenges or delays, logistics or transportation problems, etc.; • you should contact the NSDR immediately to allow as much time as possible to assess the urgency and nature of the issue, and help to identify actions with you to mitigate impact on care provision and patients;

If you experience disruption to any part of your normal supply routes, with no immediate resolution available, you should report it to the NSDR unit on:

Freephone number in the UK: 0800 915 9964

Direct line: 0044 (0) 191 283 6543

Email: supplydisruption@nhsbsa.nhs.uk (available from 27 March)

How will the NSDR work?

- The NSDR provides a 24/7 call centre to record supplies disruption concerns from any source, and route them correctly;
- The NSDR will offer logistics trouble-shooting to suppliers/sponsors whose consignments are stuck in border disruption which includes supporting access to the Department of Health and Social Care Dedicated Shipment Channel for eligible products.
- Supply disruption issues that are not purely logistical will be immediately passed to teams that can resolve them, using scaled up existing business as usual processes.

I recognise some of the difficulties in identifying when issues in the supply chain will result in disruption to the continuity of supply, however, I would urge all suppliers/sponsors to report emerging supply issues at the earliest opportunity to the NSDR so that we maximise the time available to identify solutions with you; often 'early warning signs' are vital in preventing disruption in the future.

Please be assured that we will respect the commercial sensitivity of any information reported to the NSDR and will seek to work with you in the event that wider communication with care providers, patients or the public is required. Early notification will assist in this regard, but in all cases the overriding duty will be to safeguard patient wellbeing and safety.

It should be noted that the NSDR arrangements have been put in place to support effective response to issues that arise, but all efforts should continue to ensure that we are all as prepared as we can be to prevent supply disruptions occurring.

Guidance on reporting supply disruption issues to the NSDR

- In reporting issues to the NSDR, you will be asked for detailed information to help our teams determine the most appropriate response, for example;
 - details of the disruption and causes or anticipated duration of disruption,
 - products affected (including product description, product name and product code) and product characteristics e.g. storage conditions, short shelf life,
 - criticality of products for patient care,
 - potential alternative products within your range or available from other suppliers,
 - the likely impact of the disruption,
 - how many healthcare providers and/or patients that could be affected (for the whole of the UK and/or by region/country as applicable).
 - The phone number and email address that the NSDR should use to follow up on an issue, this should include out of hours contact details.
- Note that if you have reported a supply disruption issue to officials in Scotland, Wales or Northern Ireland, you should also report this to the NSDR. Close working arrangements have been put in place between the four countries and the Crown Dependencies of Jersey, Guernsey and the Isle of Man as well as Gibraltar, however, early notification to the NSDR will help to facilitate these processes;
- You will need to provide contact details of the key responders within your organisations that the NSDR teams can engage with. This should include office and mobile telephone numbers and e-mail details, including out of hours / on call arrangements, that provide a 24/7 coverage; in general, it would be helpful to have a clinical/medical contact as well as supply chain or commercial ones.

- In addition, you should provide details of customer service contacts that care providers or patients can contact for support in the event that supply issues start to manifest themselves ahead of mitigation actions taking effect;
- Note that guidance has been issued to all care providers on the steps that they should take in response to any supply disruption issues that they experience. In the first instance, providers and patients are directed to try and resolve supply issues through their normal supply routes.

So that you can promptly identify and manage supply issues, it is important that you take the following actions –

Suppliers are asked to:

- continue to mobilise your own plans for EU Exit operational readiness;
- have systems in place for monitoring stock positions and supply chain performance that allow for developing issues to be identified at the earliest opportunity and report any unusual movements;
- have in place effective procedures for monitoring and managing demand to detect and challenge excessive ordering, and control stock despatches and report any unusual movements;
- have put in place the necessary governance structures and approvals processes to allow for rapid response and collaboration with the NSDR on supply disruption incidents;
- ensure that customer service functions are adequately resourced and equipped to manage an increase in enquiries, in the event that supply disruption events do start to impact care providers and patients;
- ensure you have processes in place for the rapid reporting of all supply disruption incidents (including potential incidents) through the NSDR – the sooner the NSDR is informed of an incident or potential incident, the sooner it can take action to ensure providers and patients receive the products they need on time.

The Department will continue to work closely with industry, through trade bodies and industry representatives, to ensure that our contingency plans work effectively for patients and care providers across the UK, and that we can be as prepared as possible in advance of the UK's exit from the EU.

I am confident that, with adequate preparation and your continued support, we can together safeguard patient care after we have left the EU.

Kind regards,



Steve Oldfield
Chief Commercial Officer
Department of Health and Social Care