



By email

30<sup>th</sup> March 2021

Dear colleague

I am writing to share with you an important update on our collective work to help ensure the continuity of the supply of medicines and medical products to the United Kingdom (UK). This follows the negotiated Withdrawal Agreement between the Government and the European Union (EU) and the UK-EU Trade and Cooperation Agreement (TCA) that came into force from the end of the transition period (EoTP).

### **Maintaining our working relationship**

Firstly, I would like to thank you for the continued, crucial, role you play in helping to ensure continuity of supplies for the health and care sector. The last year has been hugely challenging due to the global impact of Covid-19 and we know many of your supply chains were and remain under severe strain.

The ongoing pandemic and return of planned and elective care in the NHS mean that we must prepare thoroughly for the next phase of this process. Risks remain over the course of the next year, and we must ensure our supply chains are resilient to these short-term challenges and co-develop long-term strategies for enhancing supply resilience for the benefit of patients. Over the past 18 months, we have learned the importance of working together to build greater resilience into supply chains and will continue to do so.

### **Maintaining current levels of preparedness**

While there have been isolated, often complex incidents of disruption since 1 January, we have not seen the level of disruption to supply that underpinned our planning assumptions. Acknowledging that this is good news, the view of the Department is that **we must maintain current levels of preparedness for some months yet**, as part of our shared goal of ensuring patient safety through resilient supply chains.

There are existing challenges that must be recognised, not least of which is the ongoing response to the Covid-19 pandemic, the growing third wave in Europe and likely impact here in the UK. There remains a residual risk of Covid-19 impacting global borders and, as we have seen over the past 12 months, the impact of this is hard to anticipate and mitigate against, though we are doing so where possible. For these reasons, the Department has asked NHS Supply Chain to maintain contingency stock for medical devices and clinical consumables in the Centralised Stock Build (CSB) for the foreseeable future, and **we strongly encourage you to continue to hold your UK stockpiles**, where these have been built and remain.

The Department is committed to a review of these contingency measures and reporting back to industry again with recommendations after this review and during the summer. This review will include looking at the CSB and our advice to industry, taking into consideration the latest intelligence as well as the Covid-19 situation and outlook.

Some of you chose to make your own rerouting plans ahead of the EoTP. As part of ensuring your supply chains are resilient, **you may wish to continue to have alternative logistics routes built into your plans to support uninterrupted replenishment into the UK**. Government will maintain availability of Government-Secured Freight Capacity (GSFC) until the end of June. [See here for the list](#) of critical goods that can be transported on GSFC.

The **National Supply Disruption Response** (NSDR) remains operational and available to support instances of supply disruption. Please see here for [how to contact the NSDR](#).

### **Import controls coming into force on 1 October 2021 and 1 January 2022**

Phased border controls initially planned for 1 April and 1 July 2021 have now been delayed to 1 October 2021 and 1 January 2022 respectively. As the government has revised the timetable for introducing controls on imports from the EU into Great Britain (GB), it is crucial that you use this time to continue preparations to be ready for the introduction of these controls.

The import controls constitute a general update on the sanitary and phytosanitary (SPS) import requirements. SPS measures include the requirement for pre-notification to national authorities before goods are imported, health certification and goods need to enter through a Border Control Post (BCP) equipped to handle the specific goods imported. These changes will be taking place in two phases:

- **October 2021:**
  - From 1 October 2021, imports of all Products of Animal Origin (POAO), certain animal by-products (ABP), regulated plants and plant products will require pre-notification to the UK authorities via Imports of Products, Animals, Food and Feed System (IPAFFS) and must be accompanied by correct health documentation. However, if your product has a license under medicine legislation issued by the Medicines and Healthcare products Regulatory Agency (MHRA) or Veterinary Medicines Directorate (VMD), or a CE mark, then the product is exempt from sanitary and phytosanitary (SPS) controls. This applies to products that are not finished medicines, as finished medicines are not subject to SPS controls.
- **January 2022:**
  - Full UK import controls come into force from 1 January 2022. Products subject to SPS checks will need to transit through a designated BCP equipped to handle the goods in question and be subject to checks, with a list of [approved BCP available here](#). Goods will be subject to an increased rate of physical checks. This relates to applicable medicines, medical devices and any other in-scope category of healthcare supplies.

More information on the [phased border controls in October this year and January 2022 can be found here](#). For information on [the continuation of the Scheme for Authorised Movements to Northern Ireland \(STAMNI\) arrangements, now extended until at least 1 October 2021, read here](#).

## **Medical Device Regulation**

On 26 May 2021, suppliers of medical devices into Northern Ireland (and the EU) will have to comply with the Medical Device Regulation (MDR).

MDR is not being implemented in GB, but, in line with the Northern Ireland Protocol, will be implemented in Northern Ireland (NI). [For more information on device regulation, please see here.](#)

## **Batch testing of medicines**

We have listened to industry concerns about the need for appropriate preparation time to implement our future medicines batch testing strategy. The TCA includes important facilitations in respect to medicines, including an agreement to recognise Good Manufacturing Practice (GMP) inspections and a medical product working group. The UK has previously agreed to a two-year period of unilateral recognition of EU batch testing for a time limited period, effective from 1 January 2021.

We have since introduced a two-year notice period of any change to the current position of unilateral recognition of EU/European Economic Area (EEA) batch testing and will conduct a comprehensive review of the future batch testing strategy for the UK, engaging with industry and other stakeholders throughout. The two-year notice period will be triggered once this review is complete, which will be no later than the end of December 2022.

This means that the continued recognition of EU/EEA batch testing will not be ending on 1 January 2023.

While the notice period allows the sector to continue to focus on the pandemic and to protect the supply of medicines to UK patients, the standstill policy on other areas has not changed. We continue to encourage and support industry partners to prepare for the end of standstill on all other areas later this year.

The MHRA has updated its [batch testing guidance](#) to reflect the addition of the two-year notice period.

## **Supply into NI from 1 January 2022**

The Department is aware of the challenges to supply into NI from 1 January 2022. We are currently working with all partners to address this.

## **Reporting changes in supply**

Please stay in close contact with the teams in the Department and raise any supply issues, shortages or discontinuations.

For medicines, this is through the Discontinuations and Shortages (DASH) portal. It is a legal requirement to notify the department about any perceived supply disruptions or shortages to all UK nations (English, Scottish, Welsh, and Northern Irish markets) through the DASH portal, although there remains a separate mailbox for EoTP related returns or queries.

For medicines, medical devices, substances of human origin, non-clinical goods and services and supplies for clinical trials, please notify the relevant teams in the Department via the mailboxes below.

- medicine contingency (for EoTP-related returns or queries): [medicinescontingencyplanning@dhsc.gov.uk](mailto:medicinescontingencyplanning@dhsc.gov.uk)
- medicine shortages or discontinuations reporting: [DASH@dhsc.gov.uk](mailto:DASH@dhsc.gov.uk)
- MDCC contingency team: [mdcc-contingencyplanning@dhsc.gov.uk](mailto:mdcc-contingencyplanning@dhsc.gov.uk)
- clinical trials: [ctcontingencyplanning@dhsc.gov.uk](mailto:ctcontingencyplanning@dhsc.gov.uk)
- vaccines and countermeasures: [immunisation-mb@dhsc.gov.uk](mailto:immunisation-mb@dhsc.gov.uk)
- blood and transplants: [transplants@dhsc.gov.uk](mailto:transplants@dhsc.gov.uk)
- non-clinical goods and services: [nhsi.eucpc@nhs.net](mailto:nhsi.eucpc@nhs.net)

### Further support

In addition to this letter and ongoing engagement through DHSC teams, we will be continuing to run webinars to which you will be invited. We also continue to encourage you to join our online DHSC eXchange platform, which now has a broad range of relevant government content for suppliers. If you are not yet a member, you can request an invite by emailing your usual contact or one of the teams at the email addresses above.

We continue to work hand in hand with the NHS, industry trade associations, the Devolved Administrations, the MHRA and other Government Departments on strengthening supply chains.

### Useful links

For more information on border and customs processes, visit [www.gov.uk/transition](http://www.gov.uk/transition). All guidance and advice on Covid-19 can be found at [www.gov.uk/coronavirus](http://www.gov.uk/coronavirus). For GSFC specific queries, please contact [cmc@dft.gov.uk](mailto:cmc@dft.gov.uk). You can follow these Twitter accounts to keep up to date:

- [Department of Health and Social Care](#) – @DHSCgovuk
- [NHS England and NHS Improvement](#) – @NHSEngland
- [Public Health England](#) – @PHE\_uk
- [MHRA](#) - @MHRAGovuk

Kind regards,



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