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30 December 2020

Dear colleague,

## Outcome of UK negotiations with the EU

The <u>Government has announced</u> that they have reached an agreement on the UK's future relationship with the EU ahead of the end of the transition period. The Minister for Health, and EU Exit lead, has <u>written to the NHS</u> explaining some of the details of the deal.

The Future Relationship Bill will be introduced into Parliament on 30 December so that the Agreement can be in place on 1 January 2021.

Signing of the deal means that we can provide further detail for the NHS on its impact, including the approach to preparations and mitigations that have been put into place.

It is important to note that the continuity of supply preparations undertaken by DHSC will remain in place as they are required to help mitigate against potential disruptions caused by new customs and border processes, regardless of the agreement reached between the UK and the EU. This will help to ensure that the NHS, and the patients we serve, will continue to be able to access medicines and medical products as needed. Since the risk of disruption at the border remains when the UK leaves the Single Market and Customs Union at the end of the year, we ask that you keep in place the plans and mitigations stood up for the end of the Transition Period until further notice.

For some areas of policy which were included in the deal, such as reciprocal healthcare, items such as EHIC, will continue. Further details are in the attachments, and more information will be shared when we have it as to what this means for the NHS. More generally I will provide updates on key developments and next steps via my system webinars and I strongly encourage each NHS organisation to join.

The agreement also includes a provision to provide for the continued free flow of personal data from the EU and EEA EFTA States to the UK until adequacy decisions are adopted, and for no longer than six months. The UK has, on a transitional basis, deemed the EU and EEA EFTA States to be adequate to allow for data flows from the UK.

Thank you for your continued support in the weeks and months ahead.

Yours sincerely,

## **Professor Keith Willett**

Strategic Incident Director for COVID-19
Strategic Incident Director for EU Exit
National Director for Emergency Planning and Incident Response

Annex A: Reporting a supply disruption issue

| Product Category  |  |
|---|--|
| Medical Devices, Clinical<br>Consumables (MDCC)<br>and<br>Non-Clinical Goods and<br>Services (NCGS) | ACTION  In the first instance, please follow your BAU processes to resolve the issue.  Should you be unable to resolve, please escalate the issue to your Regional Coordination Centre who will look to support you.  Should you still be unable to obtain a satisfactory resolution, please escalate to the NSDR.  Considerations/Notes   |
| Medicines   | ACTION   |
|   | Report via your Pharmacy Department to the Regional Pharmacy Procurement Specialist.   |
|   | Considerations / Notes   |
|   | You should continue to manage medicines supply issues as per current processes. Any medicines supply issues (regardless of whether or not they are considered to be related to the end of the transition period) that you are concerned about, or for which you require further assistance, should continue to be reported via your Pharmacy Department to the Regional Pharmacy Procurement Specialist. |
| Vaccines  | ACTION   |
|   | Report locally procured vaccines via your Pharmacy Department to the Regional Pharmacy Procurement Specialist.   |
|   | For vaccines that are ordered through the ImmForm website (and centrally procured by PHE), you should continue to use existing channels when you need to replenish stock.  |
| Clinical Trials   | ACTION   |
|   | Report to the chief investigator of the trial or investigation.  |

|                   | Considerations / Notes   |  |
|-------------------|--|--|
|                   |  |  |
|                   | For clinical trials and clinical investigations supplies, you should seek to resolve the issue through the chief investigator of the trial or investigation.   |  |
|                   | If needed, the Trial Sponsor/organisation running the trial will be able to escalate supply issues through the National Supply Disruption Response unit.   |  |
|                   | If it relates to supplies being provided as part of treatment as usual and/or through normal NHS supply routes, then you should follow relevant procedures for the relevant supplies – please see above for Medical Devices and Clinical Consumables, and for Medicines. |  |
| Blood and Organs  | ACTION   |  |
|                   | Report issues involving blood and blood products using existing channels via your blood service.   |  |
|                   | Report issues involving organs via the usual routes through NHS Blood and Transplant.  |  |
| Tissues and Cells | ACTION   |  |
|                   | Report via existing channels to the Human<br>Tissue Authority (HTA) or the Human<br>Fertilisation and Embryology Authority (HFEA)  |  |
|                   |  |  |

## Annex B: Information you will need when contacting the National Supply and Disruption Response

Any escalation to the National Supply and Disruption Response (NSDR) should be made by the head of procurement to ensure BAU measures have been followed in the first instance. The NSDR service remains operational in order to assist with the response to COVID-19. NSDR will be stood up for the end of the transition period from 21 December, regardless of the COVID-19 situation.

In addition, please ensure you also notify your regional EU Exit lead of issues you have escalated to NSDR. The contact details are as follows:

| North East & Yorkshire | england.eprrney@nhs.net       |
|------------------------|-------------------------------|
| North West             | England.eprrnw@nhs.net        |
| Midlands               | england.midsroc@nhs.net       |
| East of England        | england.eastofengland-        |
| _                      | covid19@nhs.net               |
| London                 | England.london-euexit@nhs.net |
| South East             | england.se-incident@nhs.net   |
| South West             | england.sw-incident1@nhs.net  |

If the 'business as usual' actions in Annex A have not resolved the supply disruption. You should contact the NSDR on:

Freephone number in the UK: 0800 915 9964

Direct line from abroad: 0044 (0) 191 283 6543

On reporting supply disruption issues into the NSDR, please provide as much of the following information as possible:

- i) Product description, product name, generic name and product code(s) such as MPC or NPC;
- ii) Supplier(s) that normally supply the products(s) and the supply route used (i.e. whether this is supplied through NHS Supply Chain, E-direct etc or direct from the supplier):
- iii) Quantity of product currently available and how long this will last without resupply (e.g. days of current stock cover; time to next delivery; rate of use);
- iv) The quantity of products required, and regularity of deliveries;
- v) Assessment of the potential impact on care provisions and patients of any delay:
- vi) Whether the product is part of a clinical trial or clinical investigation
- vii) The phone number(s) and email addresses (for a named individual or a generic email address) that the NSDR unit should use to follow up on the issue and provide updates. This should include out of hours contact details.