

**Report to the Meeting of the**

BOD 02(ii)/2018

(Agenda item: 4)

# Oxford Health NHS Foundation Trust

# Board of Directors

**31 January 2019**

**Appendix: Chief Executive’s Report**

**- EU Exit Operational Readiness**

**For Discussion**

**Background**

This report is an update on the Trust’s work with regard to its operational readiness for a no-deal EU Exit which we will continue to assess as the situation develops but much of the planning centres around the required national response.

The Government has published a number of guidance documents for the NHS on what providers and commissioners of health and care services in England need to know and should do now to prepare for the possibility that the UK leaves the EU without a ratified deal – a ‘"no deal" exit.

The actions outlined cover seven key areas of activity likely to be impacted by such a no-deal scenario, and we are advised to prepare for a no-deal as part of existing local business continuity planning.

**Summary**

The Department for Health and Social Care (DHSC) have established a national Operational Response Centre supported by an Operational Support Structure for EU Exit, coordinated by NHS England and NHS Improvement. The national centre will deal with any disruption to the population’s health and care, and the delivery of health and care services in England, that may be caused or affected by EU Exit. The Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system and will also work with the devolved nations to respond to UK-wide incidents.

The guidance which factors in the revised border planning assumptions, shows that there will be significantly reduced access across the short straits, for up to six months. This reflects the EU’s confirmation that in the event of ‘no deal’, it will impose full third country controls on people and goods entering the EU from the UK.

Despite the revised assumptions, the guidance emphasises that UK health providers – including hospitals, care homes, GPs and community pharmacies – should not stockpile additional medicines beyond their business as usual stock levels. There is also no need for clinicians to write longer NHS prescriptions and the public should be discouraged from stockpiling. Each Clinical Commissioning Group has been asked to agree a EU Exit medicines, prescribing and supply plan by 31 January 2019.

On 18th January 2019, following a rapid consultation, an amendment was published to The Human Medicines (Amendment) Regulations 2019 to include a Serious Shortage Protocol for potential shortages of medicines that could occur in scenarios such as a no-deal Brexit. The Protocol makes provisions for pharmacists to supply a different strength, quantity or pharmaceutical form of certain medicines in particular situations.

EU nationals working in the health and care system have been able to register for EU settled status under the pilot scheme that was open between 3-21 December. People who did not register under the pilot scheme do not need to worry, as the scheme will open by March 2019 and remain open until at least the end of 2020, so there will be plenty of time for EU staff to register

In a "no deal" scenario, UK nationals resident in the EU, EEA and Switzerland may experience limitations to their access to healthcare services. The Government is therefore seeking to protect current reciprocal healthcare rights through bilateral agreements with other member states.

In a "no deal" scenario, UK clinicians would be required to leave European Reference Networks (ERNs) on 29 March 2019. However, the UK will seek to strengthen and build new bilateral and multilateral relationships – including with the EU – to ensure clinical expertise is maintained in the UK.

**Overview**

The EU Exit Operational Readiness Guidance summarises the Government’s contingency plans and covers actions that all health and adult social care organisations should take in preparation for EU Exit. We are required to undertake local EU Exit readiness planning, local risk assessments and plan for wider potential impacts. The actions cover the following seven areas and the Trust’s risk assessment developed as part of system discussion across Thames Valley is appended to this report:

1. **Supply of medicines and vaccines**
* In a no-deal scenario, the default position will be for member states to impose full third country controls on people and goods entering the EU from the UK, meaning that we could see delays to the movement of goods between the UK and EU. In light of this, it is anticipated that the flow of goods between the UK and EU could be reduced for a period of up to six months.
* The six-week stockpiling activities remain a critical part of the DHSC's UK-wide contingency plan for medicines and vaccines. Now that the assumption has been revised, the DHSC will continue to work with pharmaceutical companies to develop this plan. In addition to stockpiling, the Government is working to ensure there is sufficient roll-on, roll-off freight capacity to enable medicines and medical products to continue to move freely into the UK. The Government has also agreed that medicines and medical products will be prioritised on these alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019. This includes all medicines, together with general sales list medicines.
* Officials in Public Health England are leading a separate programme to ensure the continuity of supply for centrally-procured vaccines and other products that are distributed to the NHS for the UK National Immunisation Programme or used for urgent public health use.
* UK health providers, including hospitals, care homes, GPs and community pharmacies, have been instructed not to stockpile additional medicines beyond their business as usual stock levels. We’ve been advised there is no need for clinicians to write longer NHS prescriptions.
* Chief and Responsible Pharmacists are responsible for ensuring their organisation does not stockpile medicines unnecessarily. Any incidences involving the over-ordering of medicines will be investigated and followed up with the relevant Chief or Responsible Pharmacist directly. **Michael Marvin is clear about the guidance and has supported the risk assessment attached and is part of hospital and CCG Chief Pharmacists meetings at a local level to discuss and agree further local contingency and collaboration arrangements.** Each CCG is required to agree a “EU Exit medicines, prescribing and supply plan” by 31 January 2019. Regional pharmacists and regional emergency planning staff will agree such plans.
1. **Supply of medical devices and clinical consumables**
* The DHSC is developing national plans to ensure the continued movement of medical devices and clinical consumables supplied from the EU. Work is being undertaken at local and national levels to identify suppliers who source products from EU countries and to review their supply chains to determine what measures they need to take to ensure that healthcare providers have access to the products they need.
* Despite the planning assumption being revised, there is currently no need to stockpile additional medical devices and clinical consumables beyond business as usual stock levels.
1. **Supply of non-clinical consumables, goods and services**
* NHS Trusts’ procurement leads have been asked to undertake internal reviews of purchased goods and services to understand any risks to operations if there is disruption in supply. This excludes goods and services that are being reviewed centrally, such as food, on which the Department has written to procurement leads previously. Our risk assessment has however included food given our reliance for our patients on cook chill. We have been assured by our providers own resilience plans.
* Trusts are advised to continue commercial preparation for EU Exit as part of usual resilience planning. **Our self-assessment on non-clinical consumables, goods and services is appended to this report** and further guidance to be issued by the Department early 2019. This will be based on an analysis of trusts’ self-assessments.
1. **Workforce**
* EU nationals working in the health and care system have been able to register for EU settled status under the pilot scheme that was open between 3-21 December. People who did not register under the pilot scheme do not need to worry, as the scheme will open by March 2019 and remain open until at least the end of 2020, so there will be plenty of time for EU staff to register.
* **We have publicised the EU Settlement Scheme to our health and care staff who are EU nationals** and agreed to pay the fee, which was in advance of the recent decision of government to not charge fees.
1. **Reciprocal healthcare**
* In a "no deal" scenario, UK nationals resident in the EU, EEA and Switzerland may experience limitations to their access to healthcare services. The Government is therefore seeking to protect current reciprocal healthcare rights through bilateral agreements with other member states.
* The Government is seeking to put in place transitional bilateral agreements with EU, EEA member states and Switzerland to continue reciprocal healthcare arrangements, broadly, on the same terms as today. However, this will depend on decisions made by other EU and EEA member states.
* The current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until 29 March 2019. NHS organisations should maintain a strong focus on correctly charging those who should be charged directly for NHS care.
* The Government will issue advice to explain how the UK is working to maintain reciprocal healthcare arrangements, but this will depend on decisions by member states.
1. **Research and clinical networks**
* **Funding**: The Government has guaranteed funding committed to UK organisations for certain EU funded projects in the event of a "no deal" scenario. This includes the payment of awards where UK organisations successfully bid directly to the EU while we remain in the EU, and the payment of awards where UK organisations are able to successfully bid to participate as a third country after Exit, until the end of 2020.
* **Clinical trials**: Organisations running investigator-initiated trials, other industry collaborative trials or non-commercially funded trials of investigational medicinal products (IMPs), or clinical trials or investigations using medical devices in the UK, should liaise with trial and study sponsors to understand their arrangements for ensuring continuity of supply of IMPs and medical devices which come from or via the EU or EEA.
* **European Reference Networks**: In a "no deal" scenario, UK clinicians would be required to leave European Reference Networks (ERNs) on 29 March 2019. However, the UK will seek to strengthen and build new bilateral and multilateral relationships – including with the EU – to ensure clinical expertise is maintained in the UK.
1. **Data sharing, processing and access**
* It is imperative that personal data continues to flow between the UK, EU and EEA member states, following our departure from the EU. The European Commission is unlikely to have made a data protection adequacy decision regarding the UK before EU Exit. An adequacy decision is where the European Commission is satisfied that a transfer of personal data from the EU/EEA to a country outside the EU/EEA would be adequately protected.
* Transfers of personal data from the UK to the EU/EEA should not be affected in a ‘no-deal’ scenario. This is because it would continue to be lawful under domestic legislation for health and adult social care organisations to transfer personal data to the EU/EEA and adequate third countries in the same way we do currently.
* At the point of exit, EU/EEA organisations will consider the UK a third country. This will mean the transfer of personal data from the EU/EEA to the UK will be restricted unless appropriate safeguards are put in place.
* In order to ensure that personal data can continue to be transferred from organisations in the EU/EEA to the UK in the event there is no adequacy decision alternative mechanisms for transfer may need to be put in pace. This is the case even if organisations are currently compliant with the GDPR. **The IT Department is contributing to the assessment of risk in this area and any associated mitigations necessary.**

**Business continuity planning**

As required, we have undertaken an assessment of risks associated with EU Exit by the requested end of January 2019, as appended, and covering, but not be limited to:

* + The seven key areas covered in this report
	+ Potential increases in demand associated with wider impacts of a "no deal" exit
	+ Locally specific risks resulting from EU Exit

We are continuing business continuity planning in line with our legal requirements under the Health and Social Care Act 2012, taking into account working with wider system partners to ensure plans across the health and care system are robust.

Having assessed the seven areas highlighted nationally, we are confident that our routine business continuity plans, annual reviews of same, and our ongoing testing already robustly cover the areas of risk, each being relevant for existing resilience and response planning purposes that are part of a trusted and embedded process across directorates and functions.

**Further information**

The Secretary of State will continue to issue guidance prior to 29 March 2019 to support the health and care system prepare for EU and so that we can be aware of ongoing preparation and actions to undertake.

**Lead Executive Director: Kerry Rogers, Director of Corporate Affairs & Company Secretary**

**Supported by Katie Cleaver: Emergency Planning Lead (Risk Assessment)**

**APPENDIX A**

**Oxford Health EU Exit Self-Assessment – 30th November, 2018 submission**

Background

Reference the letter of 12th October 2018 from Steve Oldfield, Chief Commercial Officer, concerning the EU Exit and NHS Trust Contract self-assessment review concerning the steps Trusts need to take to assess their remaining supply chains for a ‘no deal’ scenario. This included a self-assessment tool for Trusts to use to assess their supply chains that are not covered by the Department, such as ‘hotel services’, ‘office solutions’ and services carried out abroad.

The Trust’s Procurement team have reviewed the information provided to us by the Department of Health & Social Care (DHSC) in the context of a ‘no-deal’ EU Exit and the outcome of our initial review is summarised below.

Initial Findings and Mitigation

Our initial review indicates that we do not believe there will be a significant adverse impact to this Trust in terms of supply contracts in the event of a no-deal EU exit. As a mental health and community services Trust, we hold minimal stock levels unlike acute hospital Trusts.

The Trust procures a large proportion of its supplies (approximately 50% in value) through the NHS Supply Chain and most of the balance of supplies from well-known high-profile suppliers to the NHS.

We understand that the NHS Supply Chain has been working with all its suppliers for some time on planning for a no-deal EU exit and is in the process of building up a six-week buffer stock in the UK, prior to 29th March, to mitigate the possibility of customs hold-ups at the border.

Similarly, we understand that the DHSC has a team working with all the other major suppliers to the NHS, including pharmaceuticals, and has agreements with them to hold a six-week buffer stock. The DHSC has specifically asked NHS Trusts not to stock-pile as that would skew the demand figures and make the planning process even more difficult.

We have considered other purchases that the Trust makes through non-NHS Supply Chain suppliers and they are mostly UK based. However, we do make some purchases through a small number of non-UK based suppliers, mainly in relation to pharmaceutical products.

We have checked if these suppliers are one of the suppliers that the DHSC has identified and are already engaged with (as listed on Annex A of the letter dated 12th October) in which case no further action will be required.

Where we identified any suppliers that are not on the DHSC list, we have made contact directly with the supplier to ascertain their sources of supply in terms of country of origin and anything they source direct from the EU or outside side of UK.

If such a supply chain is identified, we will obtain assurances from the supplier that their supply will not be disrupted. We will also ascertain if the NHS Supply Chain is able to supply the items in question and additionally if any other alternative non-EU dependant supplier can be identified.