Department of Health & Social Care

[**Withdrawn.** This guidance document has been withdrawn from GOV.UK and replaced by How healthcare providers can prepare for Brexit and Actions for social care providers to prepare for Brexit.]

EU Exit Operational Readiness Guidance

Actions the health and care system in England should take to prepare for a 'no deal' scenario.

Published on 21 December 2018

Contents

Purpose

The EU Exit Operational Readiness Guidance, developed and agreed with NHS England and Improvement, lists the actions that providers and commissioners of health and care services in England should take if the UK leaves the EU without a ratified deal – a 'no deal' exit. This will ensure organisations are prepared for, and can manage, the risks in such a scenario.

This guidance has been sent to all health and care providers, including adult social care providers, to ensure the health and care system as a whole is prepared. Adult social care providers are advised to use this guidance as a prompt to test their own contingency plans. A further letter has also been sent in parallel to local authorities and adult social care providers to address specific adult social care issues.

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.

All organisations receiving this guidance are advised to undertake local EU Exit readiness planning, local risk assessments and plan for wider potential impacts. In addition, the actions in this guidance cover seven areas of activity in the health and care system that the Department of Health and Social Care is focussing on in its 'no deal' exit contingency planning:

- supply of medicines and vaccines;
- supply of medical devices and clinical consumables;
- supply of non-clinical consumables, goods and services;
- workforce;
- reciprocal healthcare;
- research and clinical trials; and
- data sharing, processing and access.

The impact of a 'no deal' exit on the health and adult social care sector is not limited to these areas, and the Department is also developing contingency plans to mitigate risks in other areas. For example, the Department is working closely with NHS Blood and Transplant to co-ordinate 'no deal' planning for blood, blood components, organs, tissues and cells (as detailed in the two technical notices on blood and organs, tissues and cells and the recent letter to the health and care system sent by the Secretary of State for Health and Social Care on 7 December 2018).

The actions in this guidance factor in the Government's revised border planning assumptions which were detailed in the Cabinet Office's guidance on 7 December 2018.

In preparation for a 'no deal' exit, the Department, with the support of NHS England and Improvement, and Public Health England, has set up a national Operational Response Centre. This will lead on responding to any disruption to the delivery of health and care services in England, that may be caused or affected by EU Exit. The Operational Response Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system. The Operational Response Centre will also work with the devolved administrations to respond to UK-wide incidents.

The Operational Response Centre has been established to support the health and care system to respond to any disruption, and will not bypass existing local and regional reporting structures.

Working closely with the Operational Response Centre, NHS England and Improvement will also establish an Operational Support Structure for EU Exit. This will operate at national, regional and local levels to enable rapid support on emerging local incidents and escalation of issues into the Operational Response Centre as required. Contact details for the regional EU Exit leads are below:

Region	Contact details for regional EU Exit lead
North East	England.euexitnortheast@nhs.net
North West	England.euexitnorthwest@nhs.net
Midlands	England.mids-euexit@nhs.net
East of England	England.eoe-euexit@nhs.net
London	England.london-euexit@nhs.net
South East	England.se-euexit@nhs.net
South West	England.sw-euexit@nhs.net

NHS providers and commissioners will be supported by local NHS teams to resolve issues caused or affected by EU Exit as close to the frontline as possible. These issues will be escalated to regional level, as required. Where issues are impacting across the health and care system at a national level, the Operational Response Centre will co-ordinate information flows and responses.

This guidance and the planning assumptions within it represent the most up to date information available. Further operational guidance will be issued and updated to support the health and care system to prepare for the UK leaving the EU prior to 29 March 2019.

Summary

This section summarises seven areas where the government is focussing ‘no deal’ exit contingency planning in the health and care system, and where local action is required. Detailed actions for providers, commissioners and NHS England and Improvement regional teams are listed in Annex A (pages 15 to 33). Please read the summary and the action card that is applicable to your organisation.

Common to all of the groups of medical products listed below, it should be noted that government departments have also been working to design customs and other control arrangements at the UK border to ensure goods, including medical supplies, can continue to flow into the UK without being delayed by additional controls and checks.

However, the EU Commission has made clear that, in a 'no deal' exit, it will impose full third country controls on people and goods entering the EU from the UK. The crossgovernment planning assumption has therefore been revised to prepare for the potential impacts that the imposition of third country controls by member states could have. The revised assumption shows that there will be significantly reduced access across the short straits, for up to six months.

Supply of medicines and vaccines

- The Government recognises the vital importance of medicines and vaccines, and has developed a UK-wide contingency plan to ensure the flow of these products into the UK in a 'no deal' scenario.

- The plan covers medicines used by patients and service users in all four nations of the UK, as well as the UK Crown Dependencies. The Department is working very closely with the devolved administrations, the Crown Dependencies and other government departments to explore specific issues related to the various supply chains for medicines in the UK, as well as potential mitigations. The plan covers medicines used by all types of providers, including private providers.

- Earlier this year, the Department undertook an analysis using Medicines and Healthcare Products Regulatory Agency and European Medicines Agency data, on the supply chain for all medicines (including vaccines and medical radioisotopes). This identified those products that have a manufacturing touch point in the EU or wider EEA countries.

- In August 2018, the Department for Health and Social Care wrote to pharmaceutical companies that supply the UK with prescription-only and pharmacy medicines from, or via, the EU or European Economic Area (EEA) to prepare for a no deal scenario.

  Companies were asked to ensure they have a minimum of six weeks' additional supply in the UK, over and above their business as usual operational buffer stocks, by 29 March 2019. Companies were also asked to make arrangements to air freight medicines with a short shelf life, such as medical radioisotopes.

- Since then, there has been very good engagement from industry to ensure the supply of medicines is maintained in a 'no deal' exit.

- The Department will support manufacturers taking part in the contingency planning and is already providing funding for the provision of additional capacity for the storage of medicines.

- In October, the Department invited wholesalers and pre-wholesalers of pharmaceutical warehouse space to bid for government funding to secure the additional capacity needed for stockpiled medicines, and funding for selected organisations has now been agreed.

- On 7 December 2018, the Department wrote to UK manufacturers of medicines currently using the short straits crossings of Dover and Folkestone as they will want to review supply arrangements in light of the Government's updated planning assumptions.

- Whilst the six-week medicines stockpiling activity remains a critical part of the Department's UK-wide contingency plan, it is now being supplemented by additional national actions.

- 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 agreed that medicines and medical products will be prioritised on these alternative routes to ensure the flow of all these products will continue unimpeded after 29 March 2019. This includes all medicines, including general sales list medicines.

- In the event of delays caused by increased checks at EU ports, the Department will continue to develop the UK-wide contingency plan for medicines and vaccines with pharmaceutical companies and other government departments.

- 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.

- Chief and Responsible Pharmacists are responsible for ensuring their organisation does not stockpile medicines unnecessarily. Any incidences involving the overordering of medicines will be investigated and followed up with the relevant Chief or Responsible Pharmacist directly.

- The Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines; arrangements are also likely to be put in place to monitor the unnecessary export of medicines.

- The Department is putting in place a “Serious Shortage Protocol”. This will involve changes to medicines legislation that will allow flexibility in primary care dispensing of medicines. Robust safeguards will be put in place to ensure this is operationalised safely, including making authoritative clinical advice available.

- Public Health England (PHE) is leading a separate UK-wide programme ensuring 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. In addition to the national stockpiles that PHE has in place to ensure continued supply to the NHS, PHE continues to work alongside contracted suppliers on their contingency plans to ensure that the flow of these products will continue unimpeded in to the UK after exit day.

Supply of medical devices and clinical consumables

- On 23 October 2018, the Secretary of State for Health and Social Care wrote to all suppliers of medical devices and clinical consumables updating them on the contingency measures the Department is taking to ensure the continuity of product supply.

- One of these measures is to increase stock levels of these products at a national level in England.

- The Department is working with the devolved nations and Crown Dependencies to ensure that national contingency arrangements are aligned and able to support specific preparedness measures necessary to meet the needs of their health and care systems.

- The Department is also developing contingency plans to ensure the continued movement of medical devices and clinical consumables that are supplied from the EU directly to organisations delivering NHS services in England.

- The Department has asked all suppliers that regularly source products from EU countries to review their supply chains and determine what measures they need to take to ensure the health and care system has access to the products it needs.

- NHS Supply Chain officials are also contacting suppliers who routinely import products from the EU to establish what measures are required to ensure they can continue to provide products in a ‘no deal’ scenario. Products are already being ordered.

- 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. This will help facilitate the flow of products to both NHS and private care providers.

- The Government has agreed that medicines and medical products will be prioritised on these alternative routes to ensure the flow of these products will continue unimpeded after 29 March 2019.

- There is no need for health and adult social care providers to stockpile additional medical devices and clinical consumables beyond business as usual stock levels. Officials in the Department will continually monitor the situation and, if the situation changes, will provide further guidance by the end of January 2019.

- The Department continues to engage directly with industry suppliers, trade associations, NHS providers and other government departments to develop its contingency planning approach and ensure the continued supply of medical devices and clinical consumables into the UK.

Supply of non-clinical consumables, goods and services

- The Department has identified categories of national suppliers for non-clinical consumables, goods and services that it is reviewing and managing at a national level. Examples of relevant categories include food and laundry services.

- For these categories, the Department is engaging with suppliers and industry experts to identify and plan for any supply disruption. Where necessary, there will be crossgovernment work to implement arrangements at the point of EU Exit to ensure continued supply.

- On food, for example, the Department is engaging with both suppliers and health experts to identify and plan for any food items that might suffer supply disruption in the event of a ‘no deal’. Standard guidelines will be developed for health and adult social care providers on suitable substitution arrangements for any food items identified as being at risk.

- The Department is also conducting supply chain reviews across the health and social care system to assess commercial risks. This includes reviews for high-risk nonclinical consumables, goods and services, and a self-assessment tool for NHS Trusts and Foundation Trusts. The results of these self-assessments were received at the end of November, and the Department is conducting analysis of the data, that will be used to provide additional guidance to Trusts and Foundation Trusts in January 2019.

Workforce

- The current expectation is that there will not be a significant degree of health and care staff leaving around exit day. Organisations can escalate concerns through existing reporting mechanisms to ensure there is regional and national oversight.

EU Settlement Scheme

- Through the EU Settlement Scheme, EU citizens will be able to register for settled status in the UK if they have been here for five years, or pre-settled status if they have been here for less than five years. This will ensure the rights of EU citizens are protected in the UK after EU Exit, and guarantee their status and right to work.

- Some EU citizens working in the health and care system would have been able to register for EU settled status under the pilot scheme that was open between the 3rd and 21st December 2018. People that did not register under the pilot scheme do not need to worry as the scheme will be fully open by March 2019 and remain open until 31 December 2020 in a 'no deal' scenario, so there will be plenty of time for EU staff to register.

- More information, including where to register, can be found on this website.

Professional regulation (recognition of professional qualifications)

- Health and care professionals (including UK citizens), whose qualification has been recognised and who are registered in the UK before 23:00 on 29 March 2019, will continue to be registered after this point.

- Health and care professionals (including UK citizens), who apply to have their qualification recognised in the UK before 23:00 on 29 March 2019, will have their application concluded under current arrangements.

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- Health and care professionals (including UK citizens) with an EU/EEA or Swiss qualification, who apply to have their qualification recognised in the UK from 23:00 on 29 March 2019 will be subject to future arrangements.

Reciprocal healthcare

- These plans are without prejudice to the rights and privileges available to Irish citizens in the UK, and UK citizens in Ireland, under the Common Travel Area arrangements.

- 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 transitional bilateral agreements with other member states.

- The Government has recently introduced the Healthcare (International Arrangements) Bill to ensure we have the legal powers to enter into such agreements in a 'no deal' scenario. The Bill could support a broad continuance of the existing reciprocal healthcare rights under current EU regulations (such as the European Health Insurance Card).

- The Government will issue advice via www.gov.uk and www.nhs.uk to UK nationals living in the EU, to UK residents travelling to the EU and to EU nationals living in the UK. It will explain how the UK is working to maintain reciprocal healthcare arrangements, but this will depend on decisions by member states. It will set out what options people might have to access healthcare under local laws in the member state they live in if we do not have bilateral agreements in place, and what people can do to prepare. These pages will be updated as more information becomes available.

- As is currently the case, if UK nationals living in the EU face changes in how they can access healthcare, and if they return permanently to the UK and take up ordinary residence here, they will be entitled to NHS-funded healthcare on the same basis as UK nationals already living here.

- It is not possible to quantify how many people might return due to changes in reciprocal healthcare, and it is important to note that people might return to the UK for many other reasons such as changes in legal status or costs of living.

Research and clinical trials

EU research and innovation funding schemes

- 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 EU Exit, until the end of 2020.

- This means that successful bids for EU programme funding until the end of 2020 will receive their full financial allocation for the lifetime of the project.

Clinical 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.

- The Department and NHS England are in contact with the ERNs and no action is required at this stage. Further information will be communicated to the NHS and professional bodies in due course.

Clinical trials and clinical investigations

- The Government has issued guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a ‘no deal’ scenario.

- The Department continues to engage with the life sciences industry regarding contract research and clinical trials of IMPs and medical devices. The Department is working closely with the NHS and is undertaking a comprehensive assessment of the potential impact of ‘no deal’ exit on clinical trials and investigations, to gain a greater understanding of those which might be affected by supply issues. This includes examining supply chains for IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables, used in clinical trials and investigations, which originate from, or travel through, the EU and EEA. This assessment aims to conclude in January 2019 and, if necessary, further guidance will be issued thereafter.

- All organisations participating in and/or recruiting patients to clinical trials or clinical investigations in the UK should contact their relevant trial sponsors for confirmation of plans for supply chains for IMPs and medical devices as soon as possible.

- The Department has communicated with Sponsors of trials to emphasise their responsibility for ensuring the continuity of IMP supplies for their trials. The Government will monitor for any clinical trials or clinical investigations impacted due to disruptions to clinical trial supplies. Organisations should therefore continue to participate in and/or recruit patients to clinical trials and clinical investigations from 29 March 2019, unless they receive information to the contrary from a trial sponsor, organisation managing the trial or investigation, or from formal communications.

Clinical Trial Regulation

- For EU-wide trials, the new EU Clinical Trial Regulation (CTR) will not be in force in the EU on 29 March 2019 and so will not be incorporated into UK law.

- However, the Government has stated the UK will align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals. This will provide certainty for organisations conducting trials in the UK.

- Those organisations carrying out clinical trials should follow the normal process for seeking regulatory approval.

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 Department for Digital, Culture, Media and Sport and the Information Commissioner's Office (ICO) have released guidance on data protection in a 'no deal' scenario, which can be viewed on gov.uk and the ICO website.

- 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 place. This is the case even if organisations are currently compliant with the GDPR.

- One solution you could consider, which the ICO states that most businesses find to be a convenient safeguard, particularly when dealing with non-public organisations, is to use one of the standard contractual clauses (SCCs) approved by the EU Commission. Guidance on these SCCs can be found in the links to gov.uk and the ICO website

above. Further information will be issued in due course. For now, health and adult social care organisations should follow the instructions detailed in Annex A to identify data flows that may be at risk in a ‘no deal’ exit.

ANNEX A – Action cards

Card 1 – Action card for providers

Role

All providers of NHS services – including NHS Trusts and Foundation Trusts, primary care organisations and independent sector organisations who provide NHS services – must consider and plan for the risks that may arise due to a ‘no deal’ exit.

All providers should continue with their business continuity planning, taking into account the instructions in this national guidance, incorporating local risk assessments, and escalating any points of concern on specific issues to regional NHS EU Exit or departmental mailboxes listed in this guidance. Officials monitor these mailboxes and will respond to queries. Contact details for the regional NHS EU Exit Teams are included in the overview on page 5.

Clinical Commissioning Groups and NHS England should agree the handling of communications with general practice in line with existing delegation arrangements.

Actions for providers

Local EU Exit readiness preparations

Risk assessment and business continuity planning

- Undertake an assessment of risks associated with EU Exit by the end of January 2019, covering, but not limited to:
- The seven key areas identified nationally and detailed below.
- Potential increases in demand associated with wider impacts of a ‘no deal’ exit.
- Locally specific risks resulting from EU Exit.
- Continue business continuity planning in line with your legal requirements under the Health and Social Care Act 2012, taking into account this guidance and working with wider system partners to ensure plans across the health and care system are robust. These organisational and system-wide plans should be completed at the latest by the end of January 2019.
- Test existing business continuity and incident management plans against EU Exit risk assessment scenarios by the end of February to ensure these are fit for purpose.

Communications and escalation

All providers to:

- Ensure your board is sighted on EU Exit preparation and take steps to raise awareness amongst staff.

- Ensure Local Health Resilience Partnerships, Local Resilience Forums and Local A&E Delivery Boards are sighted on EU Exit preparation in your local health economy.

- Review capacity and activity plans, as well as annual leave, on call and command and control arrangements around the 29 March 2019, but at this point there is no ask to reduce capacity or activity around this time.

- Be ready for further operational guidance from NHS England and Improvement as contingency planning work progresses.

NHS providers to:

- Confirm escalation routes for different types of issues potentially arising from or affected by EU Exit into the regional NHS EU Exit teams listed in this document.

- Note your nominated regional NHS lead for EU Exit and their contact details (included in the overview on page 5).

- Escalate any issues you have identified as having a potentially widespread impact immediately to your regional EU Exit team.

- Confirm your organisation's Senior Responsible Officer for EU Exit preparation and identify them to your regional EU Exit team as soon as possible. This role should be held by a board level member and will entail providing information returns to NHS England and Improvement, reporting emerging EU Exit-related problems, and ensuring your organisation has updated its business continuity plan to factor in all potential ‘no deal’ exit impacts. Organisations should also identify named staff to work in a team with the Senior Responsible Officer to support EU Exit preparation, implementation and incident response.

Reporting, assurance and information

NHS providers to:

- Be aware that if additional reporting is required, NHS England and Improvement will provide further guidance on requirements. However, existing reporting from NHS

organisations will be used to develop a baseline assessment of the EU Exit impact on the health and care system.

- Note that regional NHS EU Exit teams will be in contact shortly to confirm your progress on these actions.

- For queries relating to specific topic areas in this guidance, please contact the relevant departmental mailboxes. Any immediate risks or concerns about provision of NHS service continuity should be escalated to the relevant regional NHS EU Exit mailbox

Supply of medicines and vaccines

All health and adult social care providers to:

- Follow the Secretary of State's message not to stockpile additional medicines beyond their business as usual stock levels. No clinician should write longer prescriptions for patients. The Department's UK-wide contingency plan for the continued supply of medicines and vaccines from the moment we leave the EU is being developed alongside pharmaceutical companies and other government departments.

- Note that there is no need to contact suppliers of medicines directly.

- Direct staff to promote messages of continuity and reassurance to people who use health and care services, including that they should not store additional medicines at home.

- Note that 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.

- Note that the Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines.

- Be aware that UK-wide contingency plans for medicines supply are kept under review, and the Department will communicate further guidance as and when necessary.

- Continue to report current shortage issues and escalate queries for medicine supply issues unrelated to current shortages through existing regional communication channels.

Regional pharmacists and emergency planning staff to:

- Meet at a local level to discuss and agree local contingency and collaboration arrangements. The Chief Pharmaceutical Officer will hold a meeting with the chairs of regional hospital and CCG Chief Pharmacist networks (and representatives of private hospital Chief Pharmacists) in January 2019 to help inform local plans.

Supply of medical devices and clinical consumables

- Note that there is no need for health and adult social care providers to stockpile additional medical devices and clinical consumables beyond business as usual stock levels. Officials in the Department will continually monitor the situation and if the situation changes, will provide further guidance by the end of January 2019.

- Send queries about medical devices and clinical consumables provided by NHS Supply Chain to your usual contact. If you receive medical devices and clinical consumables from other suppliers, you should contact them directly with any queries as you would normally do.

- Be aware that the contingency plan is kept under review, and the Department will communicate further guidance as and when necessary.

- Send queries regarding medical devices and clinical consumables to mdcccontingencyplanning@dhsc.gov.uk.

Supply of non-clinical consumables, goods and services

All providers to:

- Be aware that NHS Trust and Foundation Trust 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.

- Continue commercial preparation for EU Exit as part of your usual resilience planning, addressing any risks and issues identified through your own risk assessments that need to be managed locally.

- Continue to update local business continuity plans to ensure continuity of supply in a ‘no deal’ scenario. Where appropriate, these plans should be developed in conjunction with your Local Health Resilience Partnership. All health organisations should be

engaged in their relevant Local Health Resilience Partnership, which should inform Local Resilience Forum(s) of local EU Exit plans for health and care.

- Be aware that the Department is conducting supply chain reviews across the health and care system, and work is in progress to identify risk areas specific to primary care.

- Await further advice from the Department on what actions should be taken locally.

NHS Trusts and Foundation Trusts to:

- Submit the results of their self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk, if not done so already.

- Act upon further guidance to be issued by the Department in January 2019. This will be based on analysis of NHS Trusts and Foundation Trusts' self-assessments.

Workforce

- Assess whether your organisation has incurred a reduction in the number of EU nationals in your workforce before the UK leaves the EU.

- Publicise the EU Settlement Scheme to your health and care staff who are EU citizens. The scheme will open fully by March 2019 and remain open until 31 December 2020 in a 'no deal' scenario, so there will be plenty of time for EU staff to register. Further information can be viewed here.

- Monitor the impact of EU Exit on your workforce regularly and develop contingency plans to mitigate a shortfall of EU nationals in your organisation, in addition to existing plans to mitigate workforce shortages. These plans should be developed with your Local Health Resilience Partnership, feed into your Local Resilience Forum(s) and be shared with your local commissioner(s). Consider the implications of further staff shortages caused by EU Exit across the health and care system, such as in adult social care, and the impact that would have on your organisation.

- Undertake local risk assessments to identify any staff groups or services that may be vulnerable or unsustainable if there is a shortfall of EU nationals.

- Ensure your board has approved business continuity plans that include EU Exit workforce planning, including the supply of staff needed to deliver services.

- Notify your local commissioner and regional NHS EU Exit Team at the earliest opportunity if there is a risk to the delivery of your contracted services.

- Escalate concerns through existing reporting mechanisms.

- Send queries on workforce to WorkforceEUExit@dhsc.gov.uk.

Professional regulation (recognition of professional qualifications)

- Inform your staff that health and care professionals (including UK citizens), whose qualification has been recognised and who are registered in the UK before 23:00 on 29 March 2019, will continue to be registered after this point.

- Inform your staff that health and care professionals (including UK citizens), who apply to have their qualification recognised in the UK before 23:00 on 29 March 2019, will have their application concluded under current arrangements.

- Await further information from the Government on the future arrangements for health and care professionals (including UK citizens) with an EU/EEA or Swiss qualification, who apply to have their qualification recognised in the UK from 23:00 on 29 March 2019.

Reciprocal healthcare

All providers to:

- Note that, in a no deal scenario, the current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until 29 March 2019, depending on the reciprocal agreements that are concluded.

- Continue to support individuals who apply for NHS authorised treatment or maternity care in another member state (the S2 and cross-border healthcare processes).

- Note that the Department will provide updates and further information on reciprocal healthcare arrangements prior to 29 March 2019.

NHS Trusts and Foundation Trusts to:

- Maintain a strong focus on correctly charging those who should be charged directly for NHS care. Information on implementing the current charging regulations can be viewed on the webpage here.

- Ensure there is capacity available for any further training that may be required if there are changes to the reciprocal healthcare arrangements. This should be undertaken by the Overseas Visitor Management team, and guidance and support materials will be made available to support this training.

- Note that the Department will provide updates and further information in due course. This information will cover migrant cost recovery charging after 29 March 2019 to

enable NHS Trusts and Foundation Trusts to amend processes and train staff if reciprocal healthcare arrangements change.

GP practices to:

- Promote completion of the supplementary questions section of the GMS1 form, and then, as appropriate, send the form to NHS Digital (NHSDigital-EHIC@nhs.net) or the Department for Work and Pensions' Overseas Healthcare Team (overseas.healthcare@dwp.gsi.gov.uk). The response on a person's non-UK EHIC/S1 helps the Department seek reimbursements from EU member states for those who are covered by the reciprocal healthcare arrangements. More information on the GMS1 form can be found here. Further information for primary care staff on providing healthcare for overseas visitors from the EU/EEA can be found here.

Research and clinical trials

EU research and innovation funding schemes

- Note that 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.

- Provide information about your Horizon 2020 grant here. This should be actioned as soon as possible. Further guidance can be found here and all queries should be sent to EUGrantsFunding@ukri.org.

- Contact officials at EU-Health-Programme@dhsc.gov.uk with information regarding your Third Health Programme grant, and any queries that you have, as soon as possible.

Clinical trials and clinical investigations

- Follow the Government's guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a 'no deal' scenario, if you sponsor or lead clinical trials or clinical investigations in the UK.

- Consider your supply chains for those IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables, used in clinical trials and investigations, which originate from, or travel through, the EU and EEA as soon as possible if you sponsor or lead clinical trials or investigations in the UK.

- Liaise with trial and study Sponsors to understand their arrangements to ensure that clinical trials and investigations using IMPs, medical devices, IVDs, advanced therapy medicinal products, radioisotopes and other clinical consumables which come from, or via, the EU or EEA, are guaranteed in the event of any possible border delays. If multiple sites are involved within the UK, then co-ordinate with the lead site or Chief Investigator in the UK, or organisation managing the clinical trial/investigation, e.g. Clinical Research Organisation, to ensure a single approach to the Sponsor.

- Respond to any enquires to support the Department's comprehensive assessment of the expected impact of a ‘no deal’ exit on clinical trials and investigations. The Department is working closely with the NHS to gain a greater understanding of who might be affected by supply issues.

- Continue participating in and/or recruiting patients to clinical trials and investigations up to and from 29 March 2019. This should occur unless you receive information to the contrary from a trial Sponsor, organisation managing the trial or clinical investigation, or from formal communications that a clinical trial or clinical investigation is being impacted due to trial supplies.

- Send queries concerning IMPs or medical devices to imp@dhsc.gov.uk

Data sharing, processing and access

- Investigate your organisation’s reliance on transfers of personal data from the EU/EEA to the UK, especially those that are critical to patient care and/or would have a serious impact upon the system if they were disrupted.

- Note that many organisations tend not to disaggregate personal and non-personal data. As such, please be aware that restrictions on personal data may have knock-on effects on data more generally.

- Follow the advice from The Department for Digital, Culture, Media and Sport and the ICO on data protection in a ‘no deal’ scenario, which can be viewed on gov.uk and on the ICO website, in particular to determine where to use and how to implement standard contractual clauses.

- Ensure that your data and digital assets are adequately protected by completing your annual Data Security and Protection Toolkit assessment. This self-audit of compliance

  with the 10 Data Security Standards is mandatory to complete by the end of March 2019, but completing it early will enable health and adult social care providers to more quickly identify and address any vulnerabilities.

- Await further guidance, which will be issued to health and care providers in due course. Assistance will also be available through webinars in early 2019.

Finance

- Record costs (both revenue and capital) incurred in complying with this guidance. Costs with a direct financial impact should be recorded separately to opportunity costs. Providers should discuss these costs with their regional NHS EU Exit support team. Feedback from providers will inform decisions on whether further guidance on cost collection is required.

Queries

For queries relating to specific topics areas, providers should contact the departmental mailboxes listed in this guidance:

- Medicine shortage queries should be raised by business as usual routes
- Medical devices and clinical consumables to mdcccontingencyplanning@dhsc.gov.uk.
- NHS Trusts and Foundation Trusts' self-assessment on non-clinical consumables, goods and services to contractreview@dhsc.gov.uk.
- Workforce to WorkforceEUExit@dhsc.gov.uk.
- Third Health Programme grants to EU-Health-Programme@dhsc.gov.uk.
- Horizon 2020 grants to EUGrantsFunding@ukri.org
- IMPs or clinical devices to imp@dhsc.gov.uk.

Any immediate risks or concerns relating to continuity of NHS service provision should be escalated to the relevant regional NHS EU Exit mailbox.

Card 2 – Action card for commissioners

Role

In addition to current responsibilities, commissioners – including Clinical Commissioning Groups, Primary Care Commissioning and specialised commissioning – should ensure

that their contracted health and care services are ready to manage the risks arising in a ‘no deal’ exit.

Commissioners should continue with their business continuity planning, taking into account the instructions in this national guidance, incorporating local risk assessments and escalating any points of concern on specific issues to the relevant mailboxes.

Commissioners should also liaise with providers of services that they commission, to ensure they are taking account of the actions for providers outlined in this guidance. EU Exit and its implications on health and care services should be discussed at commissioner board level on a regular basis to ensure sufficient oversight.

Actions for commissioners

Local EU Exit readiness preparations

Risk assessment and business continuity planning

- Undertake an assessment of risks associated with EU Exit by the end of January 2019, covering, but not limited to:
- The seven key areas identified nationally and detailed below.
- Potential increases in demand associated with the wider impacts of a ‘no deal’ exit.
- Locally specific risks resulting from EU Exit.
- Continue business continuity planning in line with your legal requirements under the Health and Social Care Act 2012, including taking into account this guidance and working with wider system partners to ensure plans across the health and care system are robust. These organisational and system-wide plans should be completed at the latest by the end of January 2019.
- Support providers to test existing business continuity and incident management plans against EU Exit risk assessment scenarios by the end of February to ensure these are fit for purpose.

Communications and escalation

All commissioners to:

- Ensure your board is sighted on EU Exit preparation and take steps to raise awareness amongst staff.

- Ensure Local Health Resilience Partnerships, Local Resilience Forums and Local A&E Delivery Boards are sighted on EU Exit preparation in your local health economy.

- Be ready for further operational guidance from NHS England and Improvement as contingency planning work progresses.

- Review capacity and activity plans, as well as annual leave, on call and command and control arrangements around the 29 March 2019.

NHS commissioners to:

- Confirm escalation routes for different types of issues potentially arising from or affected by EU Exit, into the regional NHS EU Exit teams listed in this document.

- Note your nominated regional NHS lead for EU Exit and their contact details (included in the overview at page 5).

- Escalate any issues you have identified as having a potentially widespread impact immediately to your regional EU Exit team.

- Confirm your organisation's Senior Responsible Officer for EU Exit preparation and identify them to your regional EU Exit team as soon as possible. This role should be held by a board level member and will entail providing information returns to NHS England and Improvement, reporting emerging EU Exit-related problems, and ensuring your organisation has updated its business continuity plan to factor in all potential ‘no deal’ exit impacts. Organisations should also identify named staff to work in a team with the Senior Responsible Officer to support EU Exit preparation, implementation and incident response.

Reporting, assurance and information

NHS commissioners to:

- Be aware that if additional reporting is required, NHS England and Improvement will provide further guidance on requirements. However, existing reporting from NHS organisations will be used to develop a baseline assessment of the EU Exit impact on the health and care system.

- Note that regional NHS EU Exit teams will be in contact shortly to confirm your progress on these actions.

- For queries relating to specific topics areas in this guidance, please contact the relevant departmental mailboxes. Any immediate risks or concerns about provision of

NHS service continuity should be escalated to the relevant regional NHS EU Exit mailbox.

Supply of medicines and vaccines

- Promote the Secretary of State's message: healthcare providers should not stockpile medicines beyond their business as usual stock levels, and no clinician should write longer prescriptions for patients. The Department's UK-wide contingency plan for the supply of medicines and vaccines is being developed alongside pharmaceutical companies and other government departments.

- Advise providers that there is no need to contact suppliers of medicines directly.

- Ensure providers are encouraging staff to reassure patients that they should not store additional medicines at home as the Government is working with industry to ensure a continued supply of medicines from the moment we leave the EU.

- Inform providers that 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.

- Inform providers that the Department and NHS England and Improvement are developing arrangements to allow local and regional monitoring of stock levels of medicines.

- Be aware that the UK-wide contingency plan for medicines and vaccines is kept under review, and the Department will communicate further guidance as and when necessary.

- Share letters from the Department aimed at an NHS and wider health and care provider audience (such as the third sector, private sector and home care).

- Note that the Department has engaged directly with specialist commissioning leaders about prisons and defence. This is to address their specific needs and concerns relating to medicine supply.

- Continue to report current shortage issues and escalate queries for medicine supply issues unrelated to current shortages through existing regional communication channels.

Regional pharmacists and emergency planning staff to:

- Meet at a local level to discuss and agree local contingency and collaboration arrangements. The Chief Pharmaceutical Officer will hold a meeting with the chairs of regional hospital and CCG Chief Pharmacist networks (and representatives of private hospital Chief Pharmacists) in January 2019 to help inform local plans.

Supply of medical devices and clinical consumables

- Note that there is no need for health and adult social care providers to stockpile additional medical devices and clinical consumables beyond business as usual stock levels. Officials in the Department will continually monitor the situation and if the situation changes, we will provide further guidance by the end of January 2019.

- Send queries about medical devices and clinical consumables provided by NHS Supply Chain to your usual contact. If you receive medical devices and clinical consumables from other suppliers, you should contact them directly with any queries as you would normally do.

- Be aware that the contingency plan is kept under review, and the Department will communicate further guidance as and when necessary.

- Send queries regarding medical devices and clinical consumables to mdcccontingencyplanning@dhsc.gov.uk.

Supply of non-clinical consumables, goods and services

- Be aware that the Department is conducting supply chain reviews across the health and care system, and work is in progress to identify risk areas specific to primary care, adult social care and public health services.

- Continue commercial preparation for EU Exit as part of your usual resilience planning, addressing any risks and issues identified through your own risk assessments that need to be managed locally.

- Check your providers continue to update their local business continuity plans to ensure continuity of supply in a ‘no deal’ scenario.

- Await further advice from the Department on where actions should be taken locally by commissioners and providers of NHS-commissioned services.

Workforce

- Ensure healthcare providers that deliver your commissioned services publicise the EU Settlement Scheme to their health and care staff who are EU citizens, and support them to apply for the scheme.

- Monitor the workforce impacts of EU Exit in your primary and secondary care providers’ business continuity plans and highlight risks to WorkforceEUExit@dhsc.gov.uk.

- Ensure your providers’ board-approved business continuity plans include workforce planning.

- Assess whether your organisation has incurred a reduction in the number of EU nationals in your workforce before the UK leaves the EU.

- Publicise the EU Settlement Scheme to your staff who are EU nationals and actively support them to apply for the scheme when it opens in March 2019. Further information can be viewed here.

- Monitor the impact of EU Exit on your own workforce regularly, and update your local business continuity plans as necessary.

- Send workforce queries to WorkforceEUExit@dhsc.gov.uk

Professional regulation (recognition of professional qualifications)

- Inform your staff and healthcare providers that health and care professionals (including UK citizens), whose qualification has been recognised and who are registered in the UK before 23:00 on 29 March 2019, will continue to be registered after this point.

- Inform your staff and healthcare providers that health and care professionals (including UK citizens), who apply to have their qualification recognised in the UK before 23:00 on 29 March 2019, will have their application concluded under current arrangements.

- Await further information from the Government on the future arrangements for health and care professionals (including UK citizens) with an EU/EEA or Swiss qualification, who apply to have their qualification recognised in the UK from 23:00 on 29 March 2019.

Reciprocal healthcare

- Note that, in a 'no deal' scenario, the current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until 29 March 2019, depending on the reciprocal agreements that are concluded.

- Inform NHS Trusts and Foundation Trusts that they should continue to maintain a strong focus on correctly charging those who should be charged directly for NHS care.

- Note that the Department will provide updates and further information in due course. This information will cover migrant cost recovery charging after 29 March 2019 to enable NHS Trusts and Foundation Trusts to amend processes and train staff if reciprocal healthcare arrangements change.

Research and clinical trials

- Note that 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.

- Ensure your providers who receive Horizon 2020 grants input basic information about their awards into a portal, which can be accessed here, as soon as possible. Further guidance can be found here and all queries should be sent to EUGrantsFunding@ukri.org.

- Ensure your providers who receive Third Health Programme grants contact officials at EU-Health-Programme@dhsc.gov.uk with information regarding their awards and any queries that they have, as soon as possible.

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Clinical trials and clinical investigations

- Support your providers to respond to the Department's comprehensive assessment of the expected impact of a ‘no deal’ exit on clinical trials and investigations. The Department is working closely with the NHS to gain a greater understanding of who might be affected by supply issues.

- Support your providers who run clinical trials or investigations in the UK to consider their supply chains for those IMPs, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables which come from, or via, the EU or EEA as soon as possible. Providers should contact relevant trial Sponsors, and if multiple sites are involved within the UK, then coordinate with the lead site or Chief Investigator in the UK, or organisation managing the clinical trial/investigation, e.g. Clinical Research Organisation, to ensure a single approach to the Sponsor.

- Support your providers to participate in and/or recruit to clinical trials and investigations up to and from 29 March 2019. This should occur unless providers receive information to the contrary from a trial Sponsor, organisation managing the clinical trial or investigation, or from formal communications that a clinical trial or clinical investigation is being impacted due to trial supplies.

- Send queries concerning IMPs or medical devices to imp@dhsc.gov.uk.

Data sharing, processing and access

- Investigate your organisation’s reliance on transfers of personal data from the EU/EEA to the UK, especially those that are critical to patient care and/or would have a serious impact upon the system if they were disrupted.

- Note that many organisations tend not to disaggregate personal and non-personal data. As such, please be aware that restrictions on personal data may have knock-on effects on data more generally.

- Follow the advice from The Department for Digital, Culture, Media and Sport and the ICO on data protection in a ‘no deal’ scenario, which can be viewed on gov.uk and on the ICO website, in particular to determine where to use and how to implement standard contractual clauses.

- Ensure that your data and digital assets are adequately protected, by completing your annual Data Security and Protection Toolkit assessment. This self-audit of compliance with the 10 Data Security Standards is mandatory, to be completed by end March

2019, but early completion will enable health and adult social care organisations more time to identify and quickly address any vulnerabilities.

- Await further guidance, which will be issued to health and care providers in due course. Assistance will also be available through webinars in early 2019.

Finance

- Record costs (both revenue and capital) incurred in complying with this guidance. Costs with a direct financial impact should be recorded separately to opportunity costs. Commissioners should discuss these costs with their regional NHS EU Exit support team. Feedback from commissioners will inform decisions on whether further guidance on cost collection is required.

Queries

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Any immediate risks or concerns relating to continuity of NHS service provision should be escalated to the relevant regional NHS EU Exit mailbox.

Card 3 – Action card for NHS England and Improvement regional teams

Role

In addition to current responsibilities, NHS regional teams will be required to provide regional system oversight in a ‘no deal’ scenario. The forthcoming NHS EU Exit Operational Support Structure will operate at a national and regional level, and support existing regional teams. Its functions will include monitoring local preparations, responding to the escalation of issues, and co-ordinating assurance and reporting arrangements at regional level.

NHS regional teams should communicate the necessary actions to providers and commissioners, and ensure that these instructions are being followed. This assurance should be gained through reporting on resilience and business continuity plans, and through existing meetings with providers and commissioners in your area. Once the dedicated NHS EU Exit regional teams are established, they will undertake assurance of local business continuity plans in relation to EU Exit.

Regional NHS leads and mailboxes for EU Exit have been established. Further details of the structure and function of the regional operational support teams will be communicated as the functions are implemented.

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Global and Public Health Directorate / EU and International Health / EU Exit Preparedness

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