Department of Health (NI)

EU Exit Operational Readiness Guidance

Version 2.0

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Contents

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Purpose

This Department of Health (DoH), Northern Ireland, EU Exit Operational Readiness Guidance, supplements the guidance already issued by the Department of Health and Social Care (DHSC) in London. It lists the actions that health and social care organisations in Northern Ireland 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 social care organisations, including independent providers, to ensure that the health and care system as a whole is prepared. All providers are advised to use this guidance as a prompt to test their own contingency plans.

Overview

This Operational Readiness Guidance summarises the Department's contingency plans and covers actions that all health and social care organisations and independent providers should take in preparation in the event of a 'no deal' EU Exit.

All organisations/providers receiving this guidance are required to undertake local EU Exit readiness planning, local risk assessments and plan for wider potential impacts.

The actions in this guidance cover three areas of activity in the health and social care system that the Department is focusing on in its 'no deal' exit contingency planning:

- Healthcare supply chain including
    - supply of medicines and vaccines;
    - supply of medical devices and clinical consumables;
    - supply of non-clinical consumables, goods and services;
- Cross Border movement and/or free movement of people; and,
- Data transfer risks.

The potential impact of a ‘no deal’ exit on the health and social care sector would not be 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 Northern Ireland Blood Transfusion Service and NHS Blood and Transport to co-ordinate ‘no deal’ planning for blood, blood components, organs, tissues and cells.

This guidance and the planning assumptions within it represents the most up to date information available. If required, further operational guidance will be issued and updated to support the health and social care system to prepare for the UK leaving the EU without a deal prior to Exit day.

Emergency Preparedness

In preparation for a ‘no deal’ exit, the Department of Health (NI) has set up a Departmental Operations Centre (DOC). This DOC will sit within the Northern Ireland C3 (Command, Control & Co-ordination) structure and will deal with any disruption to the population’s health and social care and the delivery of health and social care services in Northern Ireland, which may be caused or affected by EU Exit.

The C3 model is derived from existing civil contingencies emergency management frameworks across UK government and the devolved administrations and will not replace or bypass local and regional reporting structures. An NI Hub has been established by The Executive Office (TEO) to coordinate reporting from the individual DOCs through to Civil Contingencies Group (CCG) and ultimately to the Secretary of State.

Existing arrangements are well-tested for dealing with emergencies whether that emergency is triggered by EU Exit or not.

The main responsibility of the DOC will be to co-ordinate, collate and disseminate Departmental information upwards (via Situation Report (SitRep)) to the NI Hub on health and social care related matters; in collaboration with Departmental policy leads and the wider Health and Social Care (HSC) Arm’s Length Bodies (ALBs). The Department will be supported by the Public Health Agency (PHA), the Health and

Social Care Board (HSCB) and Business Services Organisation (BSO), collectively known as HSC Silver Command and HSC Trusts at operational level, known as Bronze Command.

This three tiered approach enables DoH in conjunction with HSC partners, Silver and Bronze to manage any disruption to critical health and social care services and assist the return to normality for the DoH and HSC organisations when pragmatic and safe to do so.

Summary

This section summarises the DoH contingency plan in the areas of activity in the health and social care system on which the Department is focusing 'no deal' exit contingency planning, and where local action is required. Detailed actions for HSC organisations are listed in **Annex A** (pages 17 to 31). Please read the summary and the action card that is applicable to your organisation.

The Department of Health has been engaging with the Department for Infrastructure (DfI), the Department of Health & Social Care (DHSC) (London) and Department for Transport (DfT) (London) 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 cross-government 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 crossings of Dover and Folkestone, for up to six months.

Healthcare Supply Chain

Supply of medicines and vaccines

- The Department recognises the vital importance of medicines and vaccines, and is working closely with the DHSC on development of a UK-wide

contingency plan to ensure the flow of these products into the UK in a ‘no deal’ exit.

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

- DHSC previously undertook an analysis using Medicines and Healthcare Products Regulatory Agency (MHRA) and European Medicines Agency (EMA) 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, DHSC communicated with 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.

- There continues to be good engagement from industry with the DHSC to ensure the supply of medicines is maintained in a ‘no deal’ exit.

- DHSC is supporting manufacturers in contingency planning and has provided funding for the provision of additional capacity for the storage of medicines where needed.

- In October 2018, DHSC invited wholesalers and pre-wholesalers of pharmaceutical warehouse space to bid for UK 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 DHSC 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 UK Government's updated planning assumptions.

- Whilst the six-week medicines stockpiling activities remain a critical part of the UK-wide contingency plan, it is now being supplemented by additional national actions.

- DHSC 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.

- DHSC has 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 EU Exit day. This includes all medicines, including general sales list medicines.

- DHSC is also planning to set up an 'express freight service' to deliver medicines and medical products into the country to deliver small parcels of medicines or medical products on a 24-hour basis, with additional provision to move larger pallet quantities on a two-to-four-day basis.Even though longer border delays are now expected on some crossings from EU to UK, the Department will continue to work with DHSC and other UK Government departments on contingencies to mitigate the risk of delays and maintain business as usual flow within supply chains across the UK.

- Health and social care providers – including hospitals, care homes, dentists, 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 health service prescriptions and the public should be discouraged from stockpiling.

- Heads of Pharmacy at HSC Trusts and the HSC Board are responsible for ensuring their organisations and the providers that they commission do not stockpile medicines unnecessarily.

- National arrangements have been developed to allow monitoring of stock levels of medicines; arrangements are also likely to be put in place to monitor the unnecessary export of medicines.

- Legislation has been amended to enable the issue of “Serious Shortage Protocols” that will allow flexibility in primary care dispensing of medicines. Robust safeguards will be put in place to ensure this is managed safely, including making authoritative clinical advice available in line with advice from a national Medicine Shortages Response Group.

- The Public Health Agency is working with Public Health England on a UK-wide programme ensuring the continuity of supply for centrally-procured vaccines, including those used in Northern Ireland, and other products that are distributed to the health service for the UK National Immunisation Programme or used for urgent public health use.

- The Department continues to engage with key stakeholders including wholesalers, community pharmacy and GP representatives etc. to ensure that they are kept informed of planned contingency measures.

Supply of medical devices and clinical consumables

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

- One of these measures was to increase stock levels of these products at a national level.

- The Department is working with DHSC and the other devolved administrations to ensure that national contingency arrangements are aligned and able to support specific preparedness measures necessary to meet the needs of their respective health and social care systems.

- The Department has requested that HSC bodies undertake appropriate actions to ensure the continued movement of medical devices and clinical

consumables that are supplied from the EU directly to organisations delivering HSC services in Northern Ireland.

- The Department in conjunction with HSC bodies 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 social care system has access to the products it needs.

- NHS Supply Chain and Business Services Organisation's Procurement and Logistics Service (BSO PaLS) 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.

- The UK Government (UKG) is working to ensure that 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/HSC and private care providers.

- The UKG has 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 EU Exit.

- There is no need for health and social care organisations 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.

- The UKG continues to engage directly with industry suppliers, trade associations and other UK Government departments to develop its contingency planning approach and ensure the supply of medical devices and clinical consumables into all regions of the UK.

Supply of non-clinical consumables, goods and services

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

laundry services. The Department is also ensuring that there is appropriate engagement with key external suppliers of services, such as care homes, to confirm they have appropriate measures in place.

- The Department, through BSO PaLS, is engaging with suppliers and industry experts to identify and plan for any supply disruption. Where necessary, there will be cross-government work to implement arrangements at the point of EU Exit to ensure continued supply.

- On food, for example, the Department through BSO PaLS 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 social care providers on suitable substitutions arrangements for any food items identified as being at risk.

Workforce

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

- DoH has been advised by The Executive Office (TEO) and Cabinet Office (CO) that any border disruption is "not within their reasonable worst-case scenario" so we do not anticipate disruption to health and social care services as a result of this. Normal business continuity plans will apply and the Department's assessment is that these should be sufficient to cope with any unforeseen incidents that arise. The Department will keep this position under review.

Common Travel Area

- After EU Exit day Irish citizens in the UK and British citizens in the Republic of Ireland, who are living and working there, will continue to have the same associated rights and entitlements to public services, including access to

employment, healthcare, education, social welfare and benefits, as well as the right to vote in certain elections.

EU Settlement Scheme

- Through the EU Settlement Scheme, EU nationals 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 nationals are protected in the UK after EU Exit, and guarantee their status and right to work. The scheme will remain open until the end of 2020, so there will be plenty of time for EU staff to register.

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

Professional regulation (recognition of professional qualifications)

- Health and social care professionals (including UK citizens), whose qualification has been recognised and who are registered in the UK before Exit day, will continue to be registered after this point.

- Health and social care professionals (including UK citizens), who apply to have their qualification recognised in the UK before Exit day, will have their application concluded under current arrangements.

- Health and social care professionals (including UK citizens) with an EU/EEA or Swiss qualification, who apply to have their qualification recognised in the UK after Exit day 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 the Republic of Ireland, under the Common Travel Area (CTA) arrangements.

- In a ‘no deal’ scenario, UK nationals resident in the EU may experience limitations to their access to healthcare services. The UKG is therefore

seeking to protect current reciprocal healthcare rights through bilateral agreements with other member states.

- The Healthcare (EEA and Switzerland Arrangements) Act 2019 ensures we have the legal powers to enter into such agreements in a 'no deal' scenario. The Act could also be used to support a broad continuance of the existing reciprocal healthcare rights under current EU regulations (such as the European Health Insurance Card).

- The UKG is also 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 until 31 December 2020. However, this will depend on decisions made by other EU and EEA member states.

- The UKG will issue advice via www.gov.uk and www.nhs.uk to UK nationals living in the EU, and to UK residents travelling to the EU as well as 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, and what people can do to prepare. These pages will be updated as more information becomes available.

- UK nationals living in the EU may face changes in how they can access healthcare. If they return to the UK and take up ordinary residence here, they will be entitled to HSC services on the same basis as any person ordinarily resident in Northern Ireland.

- 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.

- Cross border services, arranged between Northern Ireland and the Republic of Ireland are not EU arrangements and they will continue to operate irrespective of EU Exit.

Data Transfer Risks

- 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 (DCMS) 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 on 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 social care organisations to transfer personal data to the EU/EEA and adequate third countries in the same way that 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 the flow of personal data from the EU/EEA to the UK continues uninterrupted in the event there is no adequacy decision, EU countries wishing to transfer data to the Department or HSC organisations will need to ensure that they meet the requirements of Chapter V of GDPR. This is the case even if organisations are currently compliant with the GDPR.

- In most cases transfers will take place through the updating of current contracts and MOUs with Standard Contractual Clauses and provisions within

administrative agreements. Guidance on SCCs can be found in the links to gov.uk and the ICO website contained in the attached action cards. Other transfers can continue to take place on the basis of established international agreements.

- In some ad-hoc data sharing instances, which happen as a one off, for example for emergency care, transfers may take place in line with the derogations listed under Article 49, Chapter V, GDPR; for example transfers necessary for important reasons of public interest, or to protect the vital interests of the data subject or of other persons.

Research and clinical trials

EU research and innovation funding schemes

- The UKG 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.

- 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 Exit day. 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.
- No action is required at this stage. Further information will be communicated to the HSC and professional bodies in due course.

Clinical trials and clinical investigations

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

- DHSC continues to engage with the life sciences industry regarding contract research clinical trials of IMPs and medical devices. The Department is working closely with DHSC and the other devolved administrations to assess the potential impact of 'no deal' exit on clinical trials and investigations and to gain a greater understanding of those which might be affected by supply issues. This includes examining Investigational Medicinal Products, medical devices, in vitro diagnostic devices, advanced therapy medicinal products, radioisotopes and other clinical consumables which originate from, or travel through, the EU and EEA. 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 the plans for supply chains for IMPs and medical devices as soon as possible.

- The UKG 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, unless they receive information to the contrary from a trial sponsor, organisation managing the trial or clinical investigation, or from formal communications.

Clinical Trial Regulation

- The new EU Clinical Trials Regulation (CTR) 536/2014 will not be in force in the EU by 31 October and so will not be incorporated into UK law on exit day. The UKG has previously advised that during the proposed implementation period, there is a clear commitment to align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals. In the event of no-deal exit from the EU, the UKG has committed to re-align with the parts of the EU's CTR legislation that are within the UK's control.

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

ANNEX A – Action Cards

Card	Audience
1	All HSC providers: • HSC Trusts • Independent providers of health and social care services • GP practices • Health service dentists • Community pharmacies • Opticians
2	Health and Social Care Board and Public Health Agency

Card 1 – Action Card for all HSC Providers

Role

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

All organisations should continue with their business continuity planning, taking into account this guidance, incorporating local risk assessments, and escalating any points of concern on specific issues through normal departmental channels.

In line with normal procedures, if you are an independent sector or third sector organisation providing services under contract from an HSC Trust or any other HSC organisation, please contact the relevant HSC organisation regarding any queries or issues which significantly impact on service continuity.

Actions required

Local EU Exit readiness preparations

Risk assessment and business continuity planning

- Undertake an internal assessment of risks associated with ‘no deal’ EU Exit, covering, but not be limited to:
    - The key areas identified nationally and detailed below.
    - Potential increases in demand associated with wider impacts of a ‘no deal’ EU Exit.
    - Locally specific risks resulting from ‘no deal’ EU Exit.

- Continue normal business continuity planning taking into account the instructions in this guidance and working with wider system partners to ensure plans across the health and social care system are robust.

- Where possible, test existing business continuity and incident management plans against ‘no deal’ EU Exit risk assessment scenarios to ensure these are fit for purpose.

Communications and escalation

All organisations to:

- Ensure your Board or management is sighted on EU Exit preparation and take steps to raise awareness amongst staff.
- Review capacity and activity plans, as well as annual leave, on call and command and control arrangements around Exit day, but at this point there is no ask to reduce capacity or activity around this time.

Reporting, assurance and information

HSC Trusts to:

- Be aware that if additional reporting is required, DoH will provide further guidance on requirements.

- For queries relating to specific areas in this guidance, please contact the relevant departmental officials. Any immediate risks or concerns about provision of HSC service continuity should be escalated to the HSCB in the first instance via normal channels.

Family Health Practitioners:

- Any immediate risks or concerns about provision of HSC service continuity should be escalated to the HSCB in the first instance.

Independent Health Care / Third Sector Organisations:

- Any immediate risks or concerns about provision of HSC service continuity should be escalated to the organisation with whom you hold the contract, in most cases, this will be the appropriate HSC Trust.

Supply of medicines and vaccines

All health and social care providers to:

- Follow the Chief Pharmaceutical Officer's advice not to stockpile medicines. No clinician should write longer prescriptions for patients.

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

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

- Note that incidences involving the over-ordering or stockpiling of medicines will be investigated and followed up with the relevant HSC Trust or organisation.

- 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 communication channels.

Heads of Pharmacy HSC Trusts

- Participate in meetings of the EU Exit Medical Supplies Group, chaired by the Chief Pharmaceutical Officer.

- Put in place arrangements, including a dedicated resource, to support the implementation of contingencies to assure continuity of treatments to patients.

Supply of medical devices and clinical consumables

- Note that there is no need for health and 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, provide further guidance. Send queries about medical devices and clinical consumables provided by BSO PaLS 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 contingency planning is kept under review, and the Department will communicate further guidance as and when necessary.

Supply of non-clinical consumables, goods and services

HSC Trusts and other bodies to:

- Be aware that 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.

- Send queries about non clinical consumables and goods and services provided by BSO PaLS to your usual contact.

All organisations to:

- 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 keep local business continuity plans updated to ensure continuity of supply in a 'no deal' scenario.

- The Department will communicate further guidance as required.

Workforce

- Develop your local business continuity plans taking account of the potential risks that EU nationals may leave Northern Ireland, or frontier workers may experience some form of disruption in getting to work (although this is not considered to be a reasonable worst case scenario at this stage).

- Assess whether your organisation has seen 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 nationals. The scheme will remain open until at least the end of 2020, so there will be plenty of time for EU staff to register. Further information can be viewed online.

- 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. Consider the implications of further staff shortages caused by EU Exit across the health and social care system, such as in 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.

- Notify the HSC Board at the earliest opportunity if there is a risk to the delivery of your contracted services.

- Escalate concerns through existing reporting mechanisms.

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

Professional regulation (recognition of professional qualifications)

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

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

- Await further information from the UK Government on the future arrangements for health and social 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 Exit day.

Reciprocal healthcare

All organisations to:

- Note that the current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until Exit day.

- 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 Exit day.

HSC Trusts to:

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

- Ensure there is capacity available for dealing with any changes to reciprocal healthcare arrangements. This will include Payment Officers reading revised guidance, attending briefing meetings and working to revise trust processes and familiarise staff with any new arrangements.

- Note that the Department will provide updates and further information in due course. This information will cover cost recovery charging after Exit day to enable trusts to amend processes and familiarise staff if reciprocal healthcare arrangements change.

GP practices to:

- Continue to complete the standard form for patients registering with the practice and return to BSO as normal. Read and apply any additional guidance issued by the BSO or Department on patient registration.

Research and clinical trials

EU research and innovation funding schemes

- Note that the UK 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 online and all queries should be sent to EUGrantsFunding@ukri.org.

- Contact DoH officials with information regarding any Third Health Programme grant, and any queries that you have, as soon as possible.

Clinical trials and clinical investigations

- Follow the UK 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 (IVDs), 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 clinical investigations in the UK.

- Liaise with trial and study Sponsors to understand their arrangements to ensure clinical trials and clinical 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 coordinate with the lead site or Chief Investigator in the UK, or organisation managing the clinical trial/investigation, e.g. Clinical Research Organisation for a single approach to the Sponsor.

- Continue participating in and/or recruiting patients to clinical trials and clinical investigations up to and Exit day. 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.

- Escalate concerns through existing reporting mechanisms.

Data Transfer Risks

- Undertake regular reviews of activity that may lead to potential 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.

- Undertake regular reviews of data transfer mitigations to ensure partner organisations remain confident in ability to share health and care information.

- 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 DCMS 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 mitigation actions such as standard contractual clauses.

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. Trusts should discuss these costs with their regional HSCB teams.

Queries

- Medicine shortage queries should be raised through business as usual routes.

- Medical devices and clinical consumables queries to routine BSO PaLS contact.

- All other queries should be directed to EU.Exit@health-ni.gov.uk

Card 2 – Action Card for HSCB and PHA

Role

In addition to current responsibilities, HSCB and PHA should ensure that their contracted health and care services are ready to manage the risks arising in a ‘no deal’ exit.

HSCB and PHA 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 the potential implications of ‘no deal’ on health and care services should be discussed at HSCB/PHA board level on a regular basis to ensure sufficient oversight.

Actions for HSCB and PHA

In addition to actions required of all organisations, HSCB and PHA should consider the following local EU Exit readiness preparations.

Risk assessment and business continuity planning

- Undertake an internal assessment of risks associated with EU Exit, covering, but not be limited to:
    - The 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 ‘no deal’ EU Exit.

- Continue normal business continuity planning taking into account the instructions in this guidance and working with wider system partners to ensure plans across the health and care system are robust.

- Where possible, test existing business continuity and incident management plans against EU Exit risk assessment scenarios to ensure these are fit for purpose.

Emergency Preparedness

- Begin preparation for running of HSC Silver Command as and when required.

Supply of medicines, vaccines, medical devices and clinical consumables for primary care

- Support implementation of the Chief Pharmaceutical Officer's advice for services not to stockpile medicines, noting clinicians should not write longer prescriptions for patients.

- Advise providers that there is no need to contact suppliers of medicines, medical devices and clinical consumables directly.

- Inform providers that staff should be encouraged to reassure patients that they should not store additional medicines, devices or consumables at home as the UK Government is working with industry to ensure a continued supply of medicines, medical devices and clinical consumables from the moment we leave the EU.

- Inform providers that incidences involving the over-ordering or stockpiling of medicines, medical devices or clinical consumables will be investigated and followed up by the relevant HSC Trust or HSC Board.

- Share letters from the Department aimed at an HSC and wider health and care provider audience as needed. (NB RQIA will share communication with the independent sector).

- Continue to report current shortage issues and escalate queries for medicines, medical devices and clinical consumables supply issues unrelated to current shortages through existing communication channels.

- PHA should ensure that contingencies are in place for the continuity of clinical trials in liaison with national plans.

- The HSC Board should put in place arrangements, including a dedicated resource, to support the implementation of contingencies to assure continuity of treatments to patients using primary care services.

Workforce

- Encourage healthcare providers that deliver your commissioned services to publicise the EU Settlement Scheme to their staff who are EU nationals, and support them to apply for the scheme. The scheme will remain open until at least the end of 2020, so there will be plenty of time for EU staff to register.

- Monitor the workforce impacts of EU Exit in your primary care providers' and highlight risks to the Department via normal channels.

Reciprocal healthcare

- Note that the current arrangements for reciprocal healthcare and for overseas visitors and migrant cost recovery will continue to operate until Exit day.

- Continue to process applications to register for care in a timely fashion, applying the latest guidance from the Department. Relevant staff to meet as needed with the Department to discuss and familiarise themselves with revised guidance.

- Proactively identify any issues to the Department at an early stage.

- Note that the Department will provide updates and further information in due course. This information will include use of the Cross Border Healthcare Directive and S2 route.

Research and clinical trials

- Note that the UKG 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 online, as soon as possible. Further guidance can be found online 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.

Clinical trials and clinical investigations

- Support your providers to respond to the DHSC's comprehensive assessment of the expected impact of '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 clinical 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, for a single approach to the Sponsor.

- Support your providers to participate in and/or recruit to clinical trials and clinical investigations up to Exit day. This should occur unless providers 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.

- Note Clinical trials that rely on transfers of personal data from the EU/EEA to the UK may be impacted by revised data sharing arrangements in the event of a “no deal” scenario.

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

Queries

- Medicine shortage queries should be raised by business as usual routes.
- Medical devices and clinical consumables should be raised through routine BSO PaLS contacts.

All other queries should be directed to EU.Exit@health-ni.gov.uk