

Eu exit

22 October 2019

The Department of Health and Social Care (DHSC) is leading the response to EU exit across the health and care sector. NHS England and NHS Improvement are working closely with DHSC to best prepare the NHS.

Professor Keith Willett has been appointed as the Strategic Commander for EU exit for the NHS. The NHS England and NHS Improvement operational response was set out in a <u>letter from Professor Keith Willett</u>. Each NHS organisation has appointed an EU exit senior responsible officer (SRO), who is responsible for ensuring your organisation is prepared for EU exit.

Our role is to ensure the NHS is as prepared as possible for EU exit – including an exit without a deal – so that we can continue to provide world-class healthcare.

This resource is designed to help you develop communications with your workforce and patients. For ease of reference it is laid out with the **background information** for nine areas listed below, followed by key information for NHS organisations and staff on these areas and then key information for patients.

- Medicines
- 2. Medical Devices and Clinical Consumables (MDCC)
- 3. Non clinical consumables, goods and services
- 4. Workforce
- 5. Data
- 6. Reciprocal healthcare and cost recovery
- 7. Vaccines
- 8. Blood and transplant
- 9. Research and clinical network

Please contact your regional EU exit team if you have any queries or comments.

Background

1. Medicines

Over 2.5 million prescription items are dispensed in England every day in primary care alone. Occasionally the NHS experiences temporary shortages of medicines

and has tried-and-tested ways of making sure patients get the medicines they need, even under difficult circumstances.

DHSC has been working closely with the NHS, trade associations, pharmaceutical companies, suppliers of medical devices, and many others to help ensure medicines and medical products continue to be available after the UK leaves the EU.

The government has put in place a multi-layered approach which includes:

- improving trader readiness for new border arrangements
- building up buffer stocks
- procuring extra warehouse space for stockpiled medicines
- securing freight capacity for all medicines, not just those included in the stockpiling. This will be done in two ways:
 - Freight capacity contracts that will help ensure vital medicines continue to enter the UK after Brexit are in place. The firms will operate on routes which have been assessed as less likely to face any potential disruption, if the UK leaves the EU without a deal. Three companies have been awarded contracts for Express Freight Service to deliver medicines and medical products within 24 to 48 hours. This service will help ensure supply of vital medicines and medical products, including radioisotopes.
 - This will mean the NHS will have access to next day delivery on small consignments, including temperature controlled or hazardous products, 48hour delivery for larger loads, and access to specialist services, including hand delivered courier services if needed.

DHSC has been working with suppliers so that they have alternative transport routes in place if disruption occurs:

 So that companies can continue to sell their products in the UK even if we leave without a deal, the Government has made changes to, or clarifications of, certain regulatory requirements. Statutory instruments, covering the regulation of human medicines, medical devices and clinical trials were considered and approved by Parliament.

Key messages for NHS organisations Key messages for patients

2. Medical devices and clinical consumables

The DHSC approach to medical devices and clinical consumables (MDCC) is similar to its approach to medicines in that it includes:

- centralised stock build of products managed by the NHS Supply Chain
- assurance with suppliers so they have contingency measures in place either in the form of buffer stocks or alternative transport plans
- medical devices prioritised on Government contingency freight routes
- procuring freight capacity so medical devices and clinical consumables can be quickly imported if required
- establishing a National Supply Disruption Response (NSDR) unit to to support resolution of supply disruption incidents, should they arise.

Key messages for NHS organisations Key messages for patients

3. Non clinical consumables, goods and services

The non-clinical goods and services workstream looks at the contracts for goods and services used by the NHS that do not relate to supplies of medicines. This includes things like laundry services and food.

Nationally, DHSC has identified categories of national suppliers for non-clinical consumables, goods and services that it is reviewing and managing to plan for any supply disruption. Locally, organisations have been asked to identify goods and services that may be impacted and to ensure that either the providers of these contracts are covered by national measures or, if needed, local mitigation is in place.

Key messages for NHS organisations Key messages for patients

4. Workforce

The government has been clear about the critical role EU nationals play in delivering our health and social care.

Measures have been put in place to ensure EU staff are able to continue living and working in the UK after the UK's departure from the EU. This commitment stands however the UK leaves the EU.

- EU Settlement Scheme: The scheme allows all EU citizens who already live in the UK to secure their long-term right to live and work here. Anyone who has been resident in the UK for five years will qualify for 'settled status', and those who have been resident for less than five years will qualify for 'pre-settled status', which can be converted into 'settled status' once they have been resident in the UK for five years. 'More information relating to the EU settlement scheme can be found here.
- Recognition of professional qualifications: The government has put in place legislation that will require UK health and social care regulators to continue to accept the EEA and Swiss qualifications they accept automatically. EEA and Swiss qualifications that are not accepted automatically will continue to be

assessed against the standard of UK qualifications, as is currently the case. . This means EU health and care professionals currently practising in the UK will continue to be able to do so following the UK's departure from the EU. Professionals qualified in the EEA and Switzerland will continue to be able to apply for registration in the UK after exit day, regardless of whether a deal is reached between the UK and the EU.

Key messages for NHS organisations Key messages for patients

5. Data

Each NHS organisation is a data controller and therefore has its own legal obligation to meet the terms of the General Data Protection Regulations (GDPR). If the UK leaves the EU without a deal, data within the UK will still be managed in the same way under GDPR.

Once the UK leaves the EU, it will be possible to continue sending data from the UK to EEA countries, and from the EEA to the UK if appropriate mitigations are in place. The NHS data workstream, with DHSC, the Department for Digital, Culture, Media and Sport (DCMS), and the Information Commissioner's Office (ICO), has identified relevant appropriate safeguards for the risks that arise in relation to transfers of data depending on the nature of the UK's departure from the EU, and has shared these with NHS organisations.

Key messages for NHS organisations Key messages for patients

6. Reciprocal healthcare and cost recovery

If the UK leaves the EU with a deal, the current reciprocal healthcare arrangements should continue as now until the end of 2020.

If the UK leaves the EU without a deal, EEA and Swiss nationals who visit the UK may not be covered for NHS healthcare in the way they are now. Likewise, the situation for UK nationals accessing healthcare when visiting an EU country is likely to change. The government is actively seeking reciprocal bilateral arrangements with Member States and will publish up to date information on the latest position with each Member State on gov.uk.

- UK nationals travelling to the EU and EU citizens visiting the UK, who may previously have relied on EHIC cards, should obtain appropriate travel insurance.
- People already living in the EU who have their healthcare funded by the UK, including pensioners and students, will have their healthcare costs covered for six months in the event of a no deal Brexit.
- EU citizens living in the UK on exit day will continue to be entitled to NHS care. If they are temporary visitors in the UK before exit day they are entitled to care

as long as their temporary stay continues. However, visitors arriving after exit day may no longer be entitled to NHS care.

Key messages for NHS organisations Key messages for patients

7. Research and clinical networks

The government has guaranteed that it will underwrite, funding for all successful competitive UK bids submitted to Horizon 2020 until the end of 2020. Both the guarantee and the extension will apply for the lifetime of projects. UK clinical trial applications will continue to be authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) and ethics committees, and the UK's ability to take part in multinational trials will not change.

If the UK were to leave the EU without a deal, UK clinicians may be required to leave European Reference Networks (ERNs). The UK will continue to be a leader in rare diseases diagnosis and treatment in Europe. In any EU Exit scenario patients will continue to have the same access to UK expertise as they do now.

DHSC has communicated with sponsors of trials to emphasise their responsibility for ensuring the continuity of Investigative Medicinal Products (IMPs) supplies for their trials. DHSC and NHS England have established a Clinical Trials Shortage Disruption Group to help ensure leaving the EU does not have adverse consequence on or clinical trials in England.

Key messages for NHS organisations Key messages for patients

8. Vaccines

Public Health England (PHE) manages stockpiles of vaccines for the national immunisation programme, as part of its business as usual (BAU) planning. It is working closely with vaccine suppliers to help to ensure existing stockpiles are maintained if UK supply is disrupted.

DHSC is also working to help ensure sufficient stockpiles of vaccines that are not centrally procured, such as those for the adult influenza vaccination programme and for other NHS and non-NHS uses outside the national vaccination programmes, such as travel and occupational health, in its medicines contingency programme, as set out under 1. Medicines.

Key messages for NHS organisations Key messages for patients

9. Blood and transplant

NHS Blood and Transplant (NHSBT) is leading on the preparation for EU exit for blood and organs. This work is integrated into DHSC and NHS planning arrangements. All imported blood or products of human origin will be covered by government contingency planning. Blood: NHSBT collects blood from donors in

England and does not export or import outside the United Kingdom for the majority of routine demand for red blood cells, platelets and plasma. We import and export very small numbers of rare red blood units for specific patients. We import from the EU around 6.5% of the plasma units issued in the UK, for patients born after 1996 as a precautionary safety measure against exposure to the risk of variant Creutzfeldt-Jakob disease.

Organs: The majority of the UK's organ transplants are carried out with organs from UK donors. Only a small number of transplanted organs from deceased donors, around 0.5% a year, come from European countries.

Key messages for NHS organisations Key messages for patients

Information for NHS organisations and staff

1. Medicines

- Prescribe and dispense as normal: Doctors and pharmacists should explain to patients that they should continue to order their prescriptions as normal. Prescriptions covering longer durations than normally prescribed should be avoided. Prescription durations will be monitored and investigated where necessary.
- Provide patients with information: NHS leaders and clinicians should keep patients and health professionals informed about plans for continuity of supply.
- Don't stockpile locally: It is not helpful or appropriate for anyone to stockpile medicines locally – organisations stockpiling risks pressure on availability of medicines. Hospital stock levels will be monitored and over-ordering of medicines will be investigated.
- Report shortages through usual routes: Any shortages should be reported through usual routes. A national Medicines Shortage Response Group (MSRG) will provide clear governance, communication and decision-making to improve the management of medicine shortages.
- Ensure your organisation is familiar with the latest information on supply disruption: This includes making sure your organisation is able to share the information in supply disruption emails, Central Alerting System alerts and other system communications with clinicians. Medicines shortages will be managed at a national level in line with usual practice.

There is also information for patients on NHS.uk/Brexit-medicine

2. Medical devices and clinical consumables

- Measures are in place to help ensure that even if there are transport delays, stocks will continue to be available.
- Do not stockpile products. Organisations should maintain BAU stock levels.
- Delivery times of goods may change. Ensure all staff are aware of these changes in practice and that business continuity plans are in place.

3. Non clinical consumables, goods and services

- National and local measures are in place to help ensure that the non-clinical goods and services the NHS needs to function continue to be available.
- If you have a concern about a consumable or service your organisation relies on, speak with your organisation's SRO.

4. Workforce

- The government and the NHS support EU staff, who make an important contribution to health and social care services across the UK. Your contribution to the NHS is vital and everything possible is being done to ensure you are able to continue your work providing world-class care with the NHS after the UK's departure from the EU.
- If you are an EU citizen legally resident in the UK at exit day, then your employment contract will not change and you will have no problem carrying on working as you do now. If you have not already done so, you are encouraged to apply to the EU Settlement Scheme.
- The EU Settlement Scheme is open to all EU citizens, including NHS staff, and can allow you to gain 'settled' or 'pre-settled status'.
- Legislation has been put into place that continues to to recognise EEA and Swiss qualifications. If you are registered with the General Medical Council, Nursing and Midwifery Council, General Pharmaceutical Council, General Dental Council, or Health and/or Care Professions Council, your registration will continue after the UK leaves the EU, regardless of whether a deal is agreed.
- There will be no need for any change to existing employment contracts if the UK leaves the EU without a deal and therefore no question of EU staff needing to reapply for their own jobs because of EU Exit.
- For any professional registration queries, please contact your relevant professional regulator.

5. Data

- NHS organisations and staff should continue to handle data in the same way they currently do (which is covered by GDPR).
- Your organisation's data protection officer should have put in place safeguards to ensure that data flows to and from the UK and the EEA will continue uninterrupted after exit day.

6. Reciprocal healthcare and cost recovery

This information will apply if the UK leaves the EU without a deal.

- Staff should be aware of the advice to provide to patients.
- Healthcare cover may change for EU citizens who visit the UK after exit day and whose country does not have a reciprocal healthcare agreement with the UK. Those visitors will be charged for accessing NHS healthcare, unless it is a

7 | EU exit: October 2019

- service that would be free of charge for everyone, or they are exempt from charging.
- In a scenario without a deal, amended charging regulations will come into force from exit day. Guidance on these amended regulations is on the DHSC website
- DHSC, NHS England and NHS Improvement will provide updates and further information as the position on post-EU exit reciprocal arrangements develops.

7. Research and clinical networks

- The NHS and the government are working with organisations running clinical trials to help ensure that research continues as normal in the coming months. They have encouraged these organisations to consider their supply chains for clinical trials and ensure appropriate supplies of trial drugs and medical products are in place.
- Continue participating in and/or recruiting patients to clinical trials and investigations. Only stop recruitment to trials where you are requested to do so by a trial sponsor, the organisation managing the trial or clinical investigation, or through formal communications from the MHRA.

8. Vaccines

- Don't stockpile vaccines beyond BAU levels. Over-ordering will be investigated.
- All organisations should reassure patients that arrangements are in place to ensure that the vaccines they may need will be available after we leave the EU.

9. Blood and transplant

- Hospitals should expect NHSBT to behave as it does now, including arrangements for reference services.
- Organisations should not stockpile products from NHSBT.
- Continue to order/request tissue products and stem cells as normal. Hospitals should not stockpile tissues.

If you have any questions, direct these through your local NHSBT hospital customer services manager.

Information for patients

There is information for patients on NHS.uk/brexit-medicine

1. Medicines

You don't need to take any special action to keep getting your medicines and medical products after Brexit.

The NHS, the Department of Health and Social Care and medical companies are prepared for Brexit. Plans are in place to help ensure you keep getting your medicines and medical products. What you should do:

Your medicines and prescriptions

- If you or someone you care for regularly take medication you should keep ordering your prescriptions in the usual way and take your medicines as normal.
- If you are concerned about treatment, please speak to your pharmacist, GP or specialist.

Clinical trials

- Clinical trials are expected to continue as normal in the coming months.
- If you are concerned about a clinical trial you or a family member are taking part in, please speak with the NHS organisation that is hosting the trial.

What we're doing:

The plans developed by the NHS and Department of Health and Social Care cover all medicines and medical products. This includes:

- all prescribed medicines
- over the counter medicines (medicines you can buy without a prescription)
- medical devices eg surgical instruments, gloves and gowns
- nutritional products
- bloods, blood and transplant products (there are some medicines that are derived from blood plasma such as immunoglobulin, albumin, and clotting factors)
- vaccines

These plans cover the entire United Kingdom, Isle of Man & The Channel Islands.

We've asked GPs and pharmacists to continue to prescribe medicines and medical products as usual and avoid issuing longer than normal prescriptions.

Extra supplies already in the UK

Companies supplying the UK with medicines and medical products already have additional stocks in the UK in preparation for Brexit.

The Department of Health and Social Care has secured more warehouse space to keep the extra medicines in.

Transport to keep medical deliveries coming into the UK

The government now has contracts with transport services to keep the flow of medicines and medical products coming in to the UK.

This includes aeroplane courier services to get medicines into the UK within 24 hours if needed, as well as priority space on other routes such as ferries.

Other information related to healthcare and Brexit

If you are a healthcare professional, see NHS England's guidance for healthcare professionals - Frequently asked questions about patients' access to medicines after Brexit

2. Medical devices and clinical consumables (MDCC)

- The information on MDCC set out in the background and information for NHS organisations and staff, can also be shared with patients.
- It is important that patients only order their medical devices as normal and continue to use them as normal.
- If you are concerned, please speak to your doctor or pharmacist.

3. Non clinical consumables, goods and services

 National and local measures are in place to help ensure that the non-clinical goods and services, including food for hospitals, that the NHS needs to function continue to be available.

4. Workforce

- Measures have been put in place to help the NHS to maintain staff levels following EU Exit.
- Under UK legislation, the qualifications of EU staff will continue to be recognised in the UK.

 The EU Settlement Scheme is open to all EU nationals currently resident in the UK. Irish citizens are not required to apply to the scheme, although in some circumstances they may wish to. Non-Irish family members of Irish citizens will need to apply. The process to register is simple and free to all.

5. Data

- General Data Protection Regulations (GDPR) will still apply after the UK leaves the EU.
- NHS organisations are putting in place steps to ensure that any transfers of patient data are able to continue uninterrupted.
- If you would like more information on how your data is handled and processed by particular NHS organisations, you should contact their data protection team.

6. Reciprocal healthcare and cost recovery

This information will apply if the UK leaves the EU without a deal.

UK nationals travelling to the EU

- If you are a UK national travelling to the EEA or Switzerland, you should prepare for possible changes to how you access healthcare, if the UK leaves the EU without a deal.
- If you have an EHIC, this will be valid until the exit day but may not be accepted after this, if the UK leaves the EU without a deal.
- The latest information for UK nationals travelling to the EEA is available on nhs.uk
- The government always advises UK citizens to take out comprehensive travel insurance when going overseas, to both EU and non-EU destinations. Make sure your insurance has the necessary healthcare cover to ensure you can get any treatment you might need, for example if you have any pre-existing conditions.

EEA and Swiss residents living/visiting/moving to UK

Living in the UK

- Citizens from these countries living lawfully in the UK on or before exit day will still be eligible for free NHS care after the UK leaves the EU, as long as they remain ordinarily resident.
- Their families will also be eligible for free NHS care, as long as they meet the ordinarily resident test, even if they arrive after the UK leaves the EU.

Moving to the UK after exit day

To be eligible for free NHS care, citizens who move to the UK after exit day must:

- meet the ordinarily resident test
- comply with relevant immigration requirements, once freedom of movement ends

 Irish citizens will only need to meet the ordinarily resident test to be eligible for free NHS care.

Visiting or studying in the UK

- Visitors from EEA and Switzerland will be chargeable unless either of the following applies:
- a healthcare agreement is in place with the country of residence
- an exemption within the charging regulations applies (for example if they are accessing an exempt service).

Visitors from the EEA countries and Switzerland whose visit to the UK starts before exit day will not be charged for treatment in England for as long as their temporary stay continues. For tourists, this will be until the end of their holiday. For students, this will be for the duration of their course, as long as they stay on it.

UK nationals living in the EU/EEA

- If you have an S1 certificate, it may not be valid, depending on how the UK leaves the EU and on decisions by and arrangements with your host state.
- The government encourages citizens to register for access to healthcare in the EU/EEA country they live in, as some residents may need to be a long-term resident or pay social security contributions to access free or discounted healthcare. Make sure you have all the right documentation and it is up to date.
- People already living in the EU who have their healthcare funded by the UK, including pensioners and students, will have their healthcare costs covered for six months in the event of a no deal Brexit.
- If you are living in the EU but the UK government currently pays for your healthcare, you may use NHS services in England without charge when visiting the UK.
- More information for UK pensioners, students and workers living in the EU/EEA can be found on gov.uk

7. Research and clinical networks

- The NHS has a long tradition of supporting cutting-edge research to ensure our patients have early to access the newest treatments available.
- The NHS and the government are working with organisations running clinical trials to help ensure that research continues as normal in the coming months. They have advised these organisations to consider their supply chains for clinical trials, and to ensure they have appropriate arrangements in place to assure the continuity of supplies for clinical trials and investigations
- Those responsible for recruiting patients for clinical trials and investigations should continue to do so. Only stop recruitment to trials where you are requested to do so by a trial sponsor, the organisation managing the trial or

clinical investigation, or through formal communications, such as from Government.

8. Vaccines

- The government, NHS and Public Health England have been working closely together to ensure vaccines will continue to be available as needed after the UK leaves the EU.
- Where vaccines need to be brought in from the EU they are covered by the government's contingency plans, which means the products can be quickly imported at short notice if necessary. This will include air freight for products which have a short shelf life and cannot be stockpiled.

9. Blood and transplant

- Blood and transplant products will continue to be available. The UK is largely self-sufficient for these products. However, where they need to be brought in from the EU, these products are covered by the government's contingency plans, which means the products can be quickly imported should they be required. This will include air freight for products which have a short shelf life and cannot be stockpiled.
- Blood donors should continue to donate blood as normal.