

Cyfarwyddwr Cyffredinol Iechyd a Gwasanaethau Cymdeithasol/
Prif Weithredwr GIG Cymru
Grŵp Iechyd a Gwasanaethau Cymdeithasol

Director General Health and Social Services/
NHS Wales Chief Executive
Health and Social Services Group



Llywodraeth Cymru
Welsh Government

To: Chief Executives, Health Boards and Trusts

4 April 2019

Dear Colleague

Preparations for Exiting the EU

Subject to any decisions made in Parliament over the next few days, the UK is scheduled to leave the European Union on a 'no-deal' basis, at 11pm (UK time) on 12 April 2019. It is essential that we maintain the intensity of our preparations for managing the health and social care impact of leaving the EU, particularly focussed on ensuring continuity of supply and robust contingency arrangements.

In recent weeks, I have received assurance on the measures that have been put in place within Wales and the wider UK to support EU transition readiness, from the EU leadership group, your EU Exit SROs, and from individual programmes. We collectively reviewed and confirmed the level of assurance at the most recent NHS Wales Executive Board.

The attached annex sets out key work streams, arrangements and actions, which are also summarised below.

This summary has been drafted for a general audience to support onward sharing of these key messages with leaders and managers throughout your own organisation, and to key delivery partners:

- **Medical Devices and Clinical Consumables.** You should report supply issues to your procurement officers in the first instance so that they can seek to resolve these issues through normal supply arrangements. Supplies departments will be able to escalate supply issues to the Welsh Supply Disruption Support Centre who can raise it to the UK National Supply Disruption Response Unit in the event that satisfactory resolution is not possible.
- **Medicines.** You should continue to manage medicines supply issues as per current processes. Any medicines supply issues (regardless of whether or not they are considered to be related to EU Exit) that you are concerned about, or for which you



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require further assistance, should continue to be reported via your Pharmacy Department.

- **Vaccines.** For locally procured vaccines you should follow relevant procedures for Medicines (see above). For vaccines that are ordered through the ImmForm website, you should continue to use existing channels when you need to replenish stock.
- **Clinical Trials.** For clinical trials and clinical investigations supplies, you should seek to resolve the issue through the sponsor of the trial or the organisation running the clinical trial or investigation.
- **Bloods and Organs.** For issues involving blood, blood products or organs, you should continue to use existing channels via the Welsh Blood Service.
- **Tissues and Cells.** For issues involving tissues and/or cells, you should continue to use existing channels via the Human Tissue Authority (HTA) or the Human Fertilisation and Embryology Authority (HFEA) as appropriate. Transplant centres do not need to take any further action.
- **Public Health Security – surveillance and early alerting.** Public Health Wales has identified alternatives to early alerting and response systems currently provided by European Centre for Disease Control (ECDC) in the event of a no deal.
- **Food.** There is no evidence to suggest there will be an overall shortage of food, although there could be a reduction in the choice and availability of certain products imported from the EU such as some types of fresh fruit and vegetables. The NHS is accustomed to handling short term food shortages as a result of seasonal variations and as such we expect that a common sense approach to menu planning will ensure continuous provision of nutritious and balanced meals.
- **Clinical Waste.** No systemic risks to the clinical waste sector have been identified. No further action required.
- **Laundry.** Discussions with suppliers have identified no major risks.
- **Fuel.** The UK Government believes that the fuel industry is well positioned to respond to disruptions to the supply chain whatever the cause. No action is required beyond the National Risk Assumption that essential services should be in a position to run for 10 days without fuel supplies.
- **Data.** Mitigate the potential impact of a no deal by implementing appropriate safeguards set out on the ICO website to any personal data sent from the EU/EEA to the UK.

While there is a good confidence that these measures will provide continued access to medical products and key support services, it is important that we are fully prepared to respond to any disruption or incidents that may arise in order to safeguard our patients. Please continue with work to prepare your organisation for the potential impact of leaving the EU without a deal, and maintain your contingency plans and arrangements. In particular, ensure you have processes in place for the prompt investigation and management of all supply disruption incidents, including escalation through your local

procurement staff to the Welsh Supply Disruption Support Centre.

We will stand up the H&SSG (Health) Desk from 8 April as part of the Welsh Government Emergency Co-ordination Centre Wales (ECCW) arrangements. NHS contingency planners will be aware of these arrangements, which are intended to support co-ordination and communications across the health and social services sector through the Brexit period.

I would like to cover two further key areas:

- **Reciprocal healthcare arrangements.** The UK Government issued a statement on 19 March 2019 clarifying the situation for UK citizens who require healthcare in EU / European Free Trade Association (EFTA) countries, and EU/EFTA citizens requiring healthcare in the UK after the UK leaves the EU. Please [read the statement in full \[via this embedded link\]](#), which contains detailed guidance covering a range of scenarios. The UK Government has confirmed that, in a no deal scenario, they will protect the healthcare rights of citizens from EU Member States and EFTA States, who are living lawfully in the UK. This means that they will retain their entitlement to access NHS-funded health care on the same basis as now.
- **The rights of EU health and social care staff and the Settled Status Scheme.** Ministers wrote to all members of staff last week (copy attached) covering arrangements for settled status and ongoing recognition of professional qualifications. For healthcare and social care staff, this means that EU nationals who are currently practising in the UK can continue to do so and that professionals qualified in the EU can continue to be registered after exit day even if we leave without a deal. I ask you to encourage all EU citizens working in the sector and living in Wales to apply for the Settled Status Scheme which opened on 30 March 2019.

I am very grateful for your support over the last few months, and for the work of your staff and key partners. As a result, we are as prepared as we can reasonably be for what remains even at this late stage an extremely uncertain outcome with unpredictable impact.

I will update you as soon as I have further information. In the meantime, please cascade this message as appropriate to your staff and partners.

Any queries regarding this letter should be directed to HSSBrexit@gov.wales. I also recommend [subscribing](#) to the weekly Brexit e-newsletter produced by the Welsh NHS Confederation as a very helpful resource of current developments and publications from across the UK.

Yours sincerely



Dr Andrew Goodall CBE

cc: EU Transition Leadership Group
EU Transition SROs
Directors of Social Services
Welsh NHS Confederation
Association of Directors of Social Services (Cymru)

Annex 1: Contingency Planning Arrangements for a No Deal Brexit

Annex 2: Ministerial letter to health and social services staff

Contingency Planning Arrangements for a No Deal Brexit (as at 3 April 2019)

Health and Social Care Services in Wales

Medical Devices and Clinical Consumables

Advice to local health bodies has been to monitor stock levels of medical devices and clinical consumables; avoid stockpiling while considering some adjustments to the timings of deliveries; and to order goods earlier and not at the last minute. Should the UK leave the EU without a deal and disruption to the supply of medical devices and clinical consumables be anticipated, there is a range of measures that will be activated to enable the continuation of safe services.

It is important that any anticipated supply issues are considered fully at the local level using normal business processes. Local clinicians will need to work closely with frontline procurement and regional supply chain staff who will have access to up to date information on the likely availability and delivery these products. Therefore, it is essential that clinicians locally are fully engaged in this important aspect of patient care, particularly if a shortage means that an alternative item needs to be secured. In these circumstances, where business as usual processes have been exhausted, your local procurement team will have access to:

- contingency supplies of medical devices and clinical consumables that have been stocked in a dedicated warehouse in SE Wales
- a Supply Disruption Support Centre that has been established to support local teams to address any issues in the supply of medical devices and clinical consumables. The operational hours of the centre is 8:00 to 18:00 – Monday to Friday – and the contact number is 0300 1234 727. To assist in the resolution of any supply issues, the centre will be supported by the National Clinical Leads.

The Welsh Government has been working closely with UK Government and other devolved administrations to ensure continuity of supply for medical devices and clinical consumables in the event of a no-deal Brexit. The approach includes participation in the UK National Supply Disruption Response (NSDR) system, consisting of a centralised stock build based in the North of England; a dedicated shipping channel to move urgently needed products not stocked in the UK via alternative sea routes and airfreight; and supplier preparedness work to maximise the robustness of their contingency plans. The NSDR system will also enable the escalation and resolution (including clinical assessment of the use of alternative products or treatments) of any issues should they arise

Medicines and Vaccines

At the UK level, the primary objective has been to create a stockpile of an additional UK-located rolling six weeks stockholding of all medicines, including non-centrally procured vaccines, used in the UK which have a touch-point (e.g. they are themselves or any of their constituents are manufactured solely or partly) in the EU or wider European Economic Area (EEA).

Stockpiling has been largely successful. UK Government wrote to marketing authorisation holders (MAHs) in August last year asking that they stockpile. Of the over 12,300 medicines identified as requiring stockpiling; the vast majority met the stockpiling requirements by 29 March. Fewer than <2% require alternative arrangements such as manufacturers of equivalent products increasing stockholding or identification of other mitigation approaches (such as alternative routes or therapeutic alternatives).

It is important to recognise there are well established mechanisms for managing shortages led by the very experienced medicines supply team based at DHSC and these are being strengthened in preparation for EU exit. Wales will, as now, continue to participate in and draw on the expertise of the DHSC Medicines Supply team in responding to shortages. Most notably through the Chief Pharmaceutical Officer's (CPhO) membership of the newly formed UK Medicines Shortages Response Group which is part of wider EU exit contingency planning. This, and other links established, will aim to ensure any UK response is cognisant of the context in Wales (and the other devolved nations).

We have also established the Medicines Shortage Advisory Group (Wales) chaired by the CPhO. The group will provide advice to the CMO on the Wales response to shortages, ensuring appropriate Wales-specific intelligence and advice is fed into the MSRG and its recommended actions are applied appropriately in Wales.

Further detailed advice on responding to potential medicines shortages will be provided to Health Boards, Community Pharmacy Wales and GPC Wales shortly.

Radioisotope

The supply continuity position is considered robust in terms of the two main suppliers' preparations and additional work underway with the remainder regarding preparation for air freighting. The main two suppliers, responsible for 85% of supply, will air freight into East Midlands Airport for up to six months and are working directly with NHS customers on delivery arrangements. However, there are likely to be delays on the day of delivery due to the timing of flights and transit through the airport that may impact scheduled appointments.

In the event of a no deal, suppliers of radioisotope will have to make a customs declaration with the recognised commodity code, electronically and in advance, which will need to match the physical paperwork on presentation at the border. If this is in order the supplier goes through a 'route 6' process – which is no further checks. This is an additional step over what is currently in place as the UK will be outside the customs union but is the streamlined process that applies to non-EU imports. The infrastructure is in place to deliver this process and suppliers are being notified of these arrangements.

The UK Government does not believe that suppliers are required to get advance consent to ship radioisotope but the importer will have to continue to provide advance notice of its intent to import and use a radioactive substance in line with UK requirements to the competent authority (e.g. the relevant environment agency body). The import cannot continue unless this notice is given and acknowledged according to the Shipment of Radioactive Substances Regulations, which has passed through Parliament in recent weeks. This advance notice can cover multiple shipments and last up to three years. This continues a similar process that is in place under Euratom.

In the event of a no deal, the UK will no longer be a party to the European Observatory on the Supply of Medical Radioisotope.

The Royal College of Radiologists, British Nuclear Medicine Society and UK Radiopharmaceuticals Group have published guidance for radiopharmaceutical and nuclear medicine teams. NHS bodies in Wales are encouraged to give this document due consideration. The guidance can be found at:

https://www.rcr.ac.uk/sites/default/files/no_deal_brexit_planning_guidance_for_nuclear_medicine_teams_march_2019.pdf

Clinical Trials

The UK Government is working with organisations running clinical trials and has encouraged these organisations to consider their supply chains for clinical trials ahead of 12 April, and ensure appropriate contingency arrangements are in place for their supplies, including of trial drugs and other medical products.

A comprehensive assessment of clinical trials has been undertaken across the UK to identify those trials which use supplies that come from or via the EU/EEA.

Clinical trial and clinical investigation supplies will be prioritised on alternative routes to ensure that the flow of all these products can continue unimpeded.

Operational guidance to NHS organisations and primary care practitioners states that their participation and recruitment into clinical research, including trials, should continue as normal unless specific instructions from an individual sponsor or formal communications are received.

While the UK Government is working very closely across all Devolved Nations to limit any impact of the UK leaving the EU without a deal on clinical trials/investigations, early intelligence of any potential or developing issues would help the Department of Health and Social Care (DHSC) consider any action at the earliest opportunity, ideally before disruption has occurred.

The Clinical Trials Disruption Response Group in DHSC (which is responding to issues UK wide) would welcome sponsors, or other entities running clinical trials and clinical investigations supplies, getting in contact as soon as they are aware of an issue with supply by emailing - ctcontingencyplanning@dhsc.gov.uk

Blood and Blood Products

There is a well-established, cooperative joint working relationship between the four UK countries, the effect of which is to provide assurance around quality, safety and accessibility of blood products across the whole UK.

In terms of the governance arrangements, there is a UK Blood Forum which represents all of the blood service CEOs, alongside a Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. There is currently a UK-wide approach to the Advisory Committee on the Safety of Blood Tissues and Organs (DHSC secretariat) and the UK Quality Managers Forum is also in place, which has a regulatory focus with regard to the UK Blood Safety and Quality Regulations 2005.

The Welsh Blood Service (WBS) has confirmed that there are positive inter-operability arrangements between the Devolved Administrations and UK Government. These are reinforced by Memorandums of Understanding (MOUs) and Contractual agreements. All four services support each other based on these agreements and long established and constructive working relationships are in place.

In terms of wider risk management and mitigation, the UK Government website (www.gov.uk) states the following:

- If there's no deal, the current blood safety and quality standards for blood and blood components would not change. The Blood Safety and Quality Regulations 2005 would be retained in UK law under the EU (Withdrawal) Act powers. The new regulation would maintain the current standard of blood quality and safety on exit day and enable updates to be made to the blood safety and quality standards to respond to emerging threats and changing safety, quality standards and technological advances.
- The UK Government are engaging with blood establishments (NHSBT are leading on this and linking through the UK Quality Forum and UK Business Continuity group), the MHRA and devolved administrations to ensure that there is day one operability for blood safety and quality. The UK Government are currently, consulting with the devolved administrations to ensure that there is flexibility to update the safety and quality standards to respond to emerging threats and changing safety, quality standards and technological advances.

Confidence levels in Wales for consumable items critical to the blood supply chain are positive at present and orders have been raised to maximise the inventory for Wales. The WBS is planning to hold and maintain around 12 weeks of critical stock for blood supply chain critical items, compared to about a month's supply of products under normal circumstances.

Organs, Tissues and Cells (including reproductive cells)

Statutory instruments were laid in November 2018 in case of a no deal EU exit:

- The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019
- The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019
- The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

Leaving the EU without a deal would result in the failure of the existing domestic legislation to work as intended. The changes made by these statutory instruments ensure that the requirements in relation to quality and safety of organs, tissues and cells (including reproductive cells) will remain broadly the same once the UK leaves the EU. These regulations have been prepared as part of wider contingency planning for a no deal scenario and could be revoked or amended as required. They also make necessary changes to reflect that the UK and EU countries will consider each other as third countries if there is no deal. This means that licensed establishments will need to make administrative changes to continue to import organs, tissues and cells from EU countries.

In event of a no deal, the UK will become a third country for the purposes of the EU Tissues and Cells Directive and the EU Organ Donation Directive.

UK establishments responsible for the import of tissues and cells from EU member states will require an import licence that covers this activity as the UK be become a third country on exiting the EU. If establishments already have an import license, they can apply to vary this to include individual EU member states. A requirement of import licences is that establishments have written agreements in place with third country suppliers, as set out in Directions 002/2018.

UK establishments that send tissues and cells to any EU member states will require an export licence that covers this activity.

Establishments which import or export reproductive cells from/to the EU will need to have appropriate authorisation from the Human Fertilisation and Embryology Authority (HFEA). The draft regulations provide for a six-month transitional period. This will allow establishments time to comply with any requirements that result from the UK becoming a third country.

Further guidance on timelines for applying for, or varying, a licence will be issued in due course.

After the UK leaves the EU, there will no longer be a requirement to use the Single European Code (SEC), unless establishments wish to do so. However, establishments must still ensure the traceability of tissues and cells (including reproductive cells) e.g. the traceability systems that were in place before the introduction of the SEC.

Transplant Centers do not need to take any further action. NHS Blood and Transplant (NHSBT) is working with UK regulator, the Human Tissue Authority (HTA), to ensure that agreements are in place with EU organisations.

Non- Clinical Goods and Services

Non-clinical goods and services include categories of goods/ services such as IT (service agreements/ infrastructure), waste management, facilities management, service maintenance contracts, laundry services and food / catering.

We wish to update you on some specific categories:

Food

In developing our contingency plans on food supplies for a no deal Brexit, Welsh Government has been engaging with the UK Government, wholesalers, distributors and retail food suppliers. The message from these sources is consistent that thorough preparations are being made and there is no evidence to suggest there will be an overall shortage of food. It is therefore essential that food is not stockpiled as this may cause disruptions to supply.

However, there could be a reduction in the choice and availability of certain products imported from the EU, such as some types of fresh fruit and vegetables. As part of your business planning for a no deal Brexit, we recommend that you consider ways in which meals could be adapted if the availability of some ingredients is limited. UK dietary advice,

as depicted by the Eatwell Guide <https://beta.gov.wales/eatwell-guide> is based on a wide range of foods. In the case of reduced availability of a food item, substitution with alternative foods within each food group can be made. Welsh Government is developing advice on food for public sector settings to support EU exit contingency planning. This will be published on the Welsh Government website in due course and we will notify you once this is made available.

Clinical Waste

The DHSC has engaged with a number of organisations and stakeholders in the clinical waste sector, to understand the nature of risks associated with EU Exit.

This activity has not identified any systemic risks to the clinical waste sector. We therefore, can advise no further action is required.

Laundry

The DHSC has engaged with a range of laundry suppliers both internally and externally to the health and care system. The engagements have covered linen stocks, detergents, workforce, machinery spares, packaging and logistics. The discussions with suppliers have identified no major risks. For those suppliers engaged with, potential risks relating to the supply of detergents were mitigated by supply chain assurances of a significant stock build.

Nevertheless, we encourage all health and social care organisations in Wales to continue discussions with their suppliers locally, including maintenance suppliers.

Fuel

The UK Government believes that the fuel industry is well positioned to respond to disruptions to the supply chain whatever cause.

The Welsh Government will continue to work with the fuel industry to ensure that no risks from leaving the European Union impact fuel supplies. We encourage all health and social care organisations in Wales to talk to their local resilience forum regarding contingency arrangements.

Data Protection

At present, the UK benefits from the free flow of personal data with the European Economic Area (EEA) and adequate third countries. If the UK leaves the EU without a deal, the UK will transitionally recognise all EEA states, EU and EEA institutions, adequate third countries and Gibraltar, as though they have been subject to an affirmative adequacy decision by the UK. This means that, for example, personal data will continue to flow freely from the UK to the EU/EEA. However, at the point of exit, EU/EEA law 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.

Health and social care organisations in Wales can take steps to mitigate the potential impact of no deal by implementing appropriate safeguards to send personal data from the EU/EEA to the UK. Guidance has been published by the NHS Confederation and includes links to further information published by the Information Commissioners Office (ICO),

Department for Digital, Culture, Media and Sport (DCMS) and European Data Protection Board information note.

Rare Diseases

We have been working with the UK Government and other UK countries in relation to rare disease. European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. There are 24 ERNs and in November 2018, the six European Reference Networks (ERNS) with a UK lead had transferred their coordinator to an EU counterpart.

In a no deal scenario, clinicians would be required to leave European Reference Networks (ERNs). 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.

Vaughan Gething AC/AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

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Y Dirprwy Weinidog Iechyd a Gwasanaethau Cymdeithasol
Deputy Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf / Our ref: MA-P/VG/1300/19

29 March 2019

Dear Colleague,

We are writing jointly to all members of staff working in health and social care services in Wales to update you on the ongoing preparations for the possible UK exit from the European Union.

As you will no doubt have heard, the European Council has agreed to extend Article 50. If the UK Parliament is unable to agree a deal, we will leave the EU without a deal on 12 April. If Parliament agrees a deal before 12 April, the European Council has agreed to extend our leave date until 22 May to get the necessary legislation passed. You'll be aware that the UK Parliament is discussing other ways forward.

We have been clear from the outset that a no deal Brexit would be catastrophic for health and social care services in Wales. Whilst leaving the EU with a deal remains the stated priority of the UK Government, the prospect of a disorderly 'no deal' Brexit is still a very real and worrying possibility. So we at the Welsh Government continue to plan for every eventuality, and particularly to ensure we protect and safeguard the quality of our public services in the event of a no deal scenario.

Contingency planning

Firstly we would like to say that we wholeheartedly appreciate the effort which is taking place within your organisations and across Wales to prepare for a possible no deal situation.

We are confident there are clear and strong plans in place to make sure services are protected, as far as possible, from any disruption. This work has included detailed preparations for any disruption to medicines, medical devices and clinical consumables, non-clinical goods and services, vaccines, blood and organs, clinical trials, tissues and cells, food, laundry, and fuel.

These are uncertain times, but our message to you is please continue as you are and operate in your usual way. There may need to be some alternative planning or working arrangements in the next few months, but there are well tested contingency plans for this.

We know that your focus is on maintaining safe, high-quality health and social care for the people you care for. We urge you and your colleagues to remain vigilant in your advice to

them particularly with regards over-ordering or over-prescribing medicines. Local stockpiling is unnecessary and could cause shortages which would put those that need medicines at risk. We appreciate your continued support with reassuring those you care for about this.

The rights of EU health and social care staff and the Settled Status Scheme

We recognise and value the significant contributions that EU nationals provide in delivering health and social care services. If you are an EU national, we want you to stay and you will always be welcome to live and work in Wales. We will continue to work closely with the Home Office to ensure you are aware of your rights.

We would strongly encourage all EU citizens working in the sector and living in Wales to apply for the Settled Status Scheme which opens on 30 March 2019. This is available either on a 'settled status' basis for those who have been in the UK for five years, or on a 'pre-settled status' basis for those who have lived in the UK for fewer than five years.

We want to ensure that every EU citizen has the information and support they need to apply to the Scheme. You can access direct information via these Home Office quick links below:

- [EU Settlement Scheme guidance](#)
- [Access assisted digital support](#)
- [ID document scanner locations](#)
- [Sign up to receive EU Citizen Email Alerts from the Home Office](#)
- [Sign up to receive the Community Bulletin](#)
- [European Temporary Leave to Remain Guidance](#)

Recognition of professional qualifications

We recognise the importance of maintaining mutual recognition of professional qualifications (MRPQ) for the health and social care workforce. This will continue to support the movement of health and social care professionals across Europe.

The UK Government and Welsh Government have put in place legislation that means European qualifications will continue to be recognised by all professional regulators covering the health and social care sectors. This includes the General Medical Council, Nursing and Midwifery Council, General Pharmaceutical Council, General Dental Council, Health and Care Professions Council and Social Care Wales.

For healthcare and social care staff, this means that EU nationals who are currently practising in the UK can continue to do so and that professionals qualified in the EU can continue to be registered after exit day even if we leave without a deal. Further details are available from your relevant professional body.

Whatever your nationality, we want to thank all of you for your continued contribution to the safe and high quality delivery of health and social care services in your communities.

Yours sincerely,

Vaughan Gething AC/AM

Y Gweinidog Iechyd a Gwasanaethau
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