

Written Response by the Minister for Health and Social Services to the report of the External Affairs and Additional Legislation Committee entitled: Preparing for Brexit – Report on the Preparedness of the healthcare and medicines sector in Wales.

Overview

Although the UK and EU have signed a Withdrawal Agreement, there remains a high degree of uncertainty about the outcome of the UK's meaningful vote on the agreement. There is still a significant risk of a no deal Brexit. Priority activity is focussed on two aspects which would have an immediate impact in the event of a no deal Brexit on 29 March:

- Operational Readiness – ensuring appropriate and proportional contingency plans are in place to ensure service continuity through the period immediately following 29 March 2019, in the event of a no-deal Brexit; and
- Legislative readiness – ensuring that all necessary legislative changes have been agreed between legislatures and approved through Parliament and National Assembly for Wales.

Welsh Government guidance to health and social care providers has been to prioritise their operational readiness activity towards being prepared for a potential no deal Brexit, and to use existing business continuity and resilience arrangements for preparedness planning, at a regional level, alongside key provider partners.

We are working closely with the UK Department of Health and Social Care and other devolved administrations to ensure robust plans are in place to protect patient safety and healthcare provisions as the UK is due to leave the EU.

I would like to thank members of the External Affairs and Additional Legislation Committee for their continuing work in helping to prepare health and social care organisations in Wales for the potential implications of Brexit. I am pleased to accept all five of the Committee's recommendation and deal with each in greater detail as follows:

Recommendation 1

The Committee recommends that:

The Welsh Government, in its response to this report, provides assurance that communication plans are in place for the run-up to when the UK formally leaves the EU at the end of March 2019. This assurance should include sharing with us:

- **details of the identified risks relating to the Brexit preparedness of the Welsh healthcare sector; and**
 - **details of how the Welsh Government intends to communicate preparedness plans with all levels of the health and social care sectors in Wales.**
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Response: Accept

Leaving the EU is a complex process and will affect health and social care services in many ways. We entirely agree that effective and ongoing communications are required in order to outline the challenges we might face but also to reassure stakeholders that work is being done to safeguard their interests in the run-up to and after the UK is currently due to leave the EU.

Andrew Goodall, Chief Executive of the NHS in Wales and Albert Heaney, Director of Social Services in Wales are both writing to NHS Chief Executives and Directors of Social Services across local authorities as and when required to update on developments in key policy areas and to highlight areas which require consideration, planning and actions to ensure preparedness for exiting the European Union.

Communications have been based on our understanding of the UK Government's position, on the latest assurances given by UK Government Ministers and officials, and on information which has been shared with Welsh Government relating to UK preparedness arrangements.

The situation is fast moving, and so regular correspondence will be supported by a summary Brexit Preparedness Matrix document, which will be managed by Welsh Government and shared as a 'live document' through our regular channels of communication and accountability, including the NHS Wales Executive Board and Directors of Social Services meetings. The matrix highlights the identified risks relating to the Brexit preparedness of the Welsh health and social care sector, the operational actions undertaken, further action planned and the range of key stakeholders involved.

Additionally, we are working closely with the Welsh NHS Confederation, the Association of Directors of Social Services Cymru, the Welsh Local Government Association and a range of stakeholder organisations to help ensure a clear, coordinated communications approach both in the run-up to, and after the UK leaves the EU on 29 March 2019.

We have also established a robust governance structure of key stakeholder groups which allows for regular and formal lines of communications on preparedness measures, and particularly in the event of a 'no deal' Brexit. We will continue to engage widely across the health and care sector in Wales through our four main stakeholder groups:

- A Ministerial Stakeholder Advisory Forum, chaired by myself and attended by the Deputy Minister for Health and Social Services;
 - An EU Transition leadership group chaired by Welsh Government which meets on a monthly basis and is focusing on ensuring operational readiness arrangements are in place for both health and social services in Wales;
 - A Brexit Health and Social Care Civil Contingency Planning Group chaired by Welsh Government is meeting regularly to co-ordinate resilience and business continuity planning; and
 - A four Nations public health group addressing public health associated risks and health security concerns, linked to a joint Welsh Government – Public Health Wales working group considering specific Welsh issues.
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Recommendation 2:

The Committee recommends that

The Welsh Government, in response to this report, outlines details of:

- **its discussions with counterparts in the UK Government on the coordination of its Brexit preparedness in the field of healthcare and medicines; and**
 - **the work underway to ensure that there is sufficient warehouse capacity to meet any potential stockpiling requirements.**
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Response: Accept

Supply of Medicines

Organisations in Wales will be part of a UK-wide approach to ensuring continuity of supply of medicines.

In April 2018, the UK Government (UKG) performed a risk assessment across all UK medicines to find volumes of those with an EU touchpoint and therefore, a potential supply chain delay.

UK Government has agreed with medicines manufacturers and suppliers that they will maintain a 6-12 month period of delayed imports (i.e. a six-week buffer, rather than a six-week stockpile, over and above their usual reserves, to ensure continued supply in the event of any border delays).

The companies will follow their usual procedures for dealing with NHS Wales orders for supplies, on a UK basis. Given the distributed nature of medicines supply, and the

industry-led approach, these arrangements will operate on a whole of UK basis. The Department of Health and Social Care has been assured by most manufacturers and suppliers that they can meet this requirement.

The Department of Health and Social Care has tendered for potential additional warehousing and storage facilities and has started to award contracts to suppliers. It is working with HMRC to develop a method for prioritising supplies ordered by the NHS. Part of the support to manufacturers will include funding to offset the costs of additional capacity needed for the storage of medicines. In order to attempt to secure the continued supply of medicines and other prioritised goods, the Department of Transport has awarded contracts to increase the number of voyages by roll-on roll-off lorry ferries (between Portsmouth/Le Havre, Plymouth/Roscoff and Poole/Cherbourg). Routes from Immingham and Felixstowe are also planned. The aim is to avoid any bottlenecks at Dover and Folkestone.

The UK Government has drafted regulations which would permit pharmacists to dispense a smaller amount of a medicine than noted in the prescription in the event of a shortage, such as the recent shortage of Epi-Pen adrenalin injectors. The regulations will apply automatically in Wales if and when approved by Parliament.

WG officials have fortnightly discussions with The Department of Health and Social Care and the lead agencies to review progress and assess the adequacy of arrangements. Our current guidance to health boards and trusts in Wales, and to other providers of health and care services, is that they do not need to individually stockpile medicines in readiness for a potential no-deal Brexit. Local stockpiling by health and social care providers is unnecessary and could cause shortages in other areas, which would put patient care at risk.

Medical Devices and Clinical Consumables

Welsh Government and NHS Wales Shared Services are working closely with UK Government on contingency plans to ensure supply continuity of medical devices and clinical consumables (MDCC).

MDCC suppliers have been asked to build additional stocks within the UK, however the supply chain is much wider and there are many small providers, so there is not a sector wide assurance as there is for medicines.

The Department of Health and Social Care has made extensive use of external consultancy (Deloitte) to carry out a full supply chain analysis of all products used by the NHS, and some supplies through wholesalers to primary care and social care settings, in England. Welsh Government have engaged Deloitte to undertake a similar detailed analysis for NHS Wales and the social care sector in Wales. The output of this work is a contingency plan specific to Wales but strongly informed by the England approach, with options to determine whether and how Wales should use the five UK contingency measures led by NHS England.

At the time of writing, Deloitte were due to report on their recommendations and options are expected to include additional or complementary 'Localised Build' stocks in Wales, and recommendations on the relationship between Wales and England with regard to warehousing capacity, inventory build and management, and particularly the National Supply Disruption Service. The outcomes of this work, alongside continued engagement at official level with devolved administrations and The Department of Health and Social Care, will inform a Wales supply continuity plan to be initiated in the event of a no-deal.

Based on the analysis already completed, there is currently no need for Welsh health and social care providers to stockpile additional medical devices and clinical consumables beyond their full business as usual stock levels.

Recommendation 3:

The Committee recommends that

The Welsh Government outlines, in its response to this report, details of how it is pressing the UK Government for continued regulatory cooperation between the UK and the EU in terms of access to medicines and clinical research after Brexit.

We note that a degree of uncertainty remains in terms of reciprocal healthcare arrangements after Brexit, particularly in the event of a "no deal". However, we also note that the UK Government has recently introduced the Healthcare (International Arrangements) Bill, which aims to address these issues.

We note the concerns of stakeholders regarding the continuing uncertainty in relation to the future of UK access to medical radioisotopes and believe that this situation needs to be clarified as a matter of urgency.

Response: Accept

Falsified Medicines Directive

The Delegated Regulation to the Falsified Medicines Directive (FMD) will come into force in February 2019. The new regulation will require manufacturers to place safety features on all medicines and contribute financially to the establishment of an IT verification system that will allow the assessment of the authenticity of a medicine at the time of supply to the patient.

Falsified medicines include those medicines with little or no active ingredients, the wrong active ingredients, fake or tampered packaging, and those where products and/or packaging have been stolen for re-use or re-sale.

If the UK exits the EU on the basis of the Prime Minister's Deal then the Withdrawal Act is due to convert existing EU law into UK law and preserve the laws made in the UK to implement our EU obligations. This means that the duties of the FMD would continue to apply, unless specifically revoked.

Clinical Research

The UK Government is committed to a competitive service for clinical trial assessments after EU Exit, regardless of the outcome of negotiations. UK Government has issued guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a 'no deal' scenario.

The Department of Health and Social Care continue to engage with the life sciences industry regarding contract research trials of IMPs. However, some organisations may be involved in running investigator initiated trials, other industry collaborative clinical trials, or non-commercially funded trials of IMPs; or clinical trials or clinical investigations using medical devices. All organisations running these clinical trials or clinical investigations in Wales have been advised to liaise with trial and study sponsors to understand their arrangements for ensuring continuity of supply chains for clinical trial of IMPs and medical devices which come from, or via, the EU or EEA are guaranteed in the event of border delays.

Welsh Government officials are in regular contact with The Department of Health and Social Care and Medicines & Healthcare products Regulatory Agency officials to receive updates and contribute to planning activity.

The UK Government and Medicines & Healthcare products Regulatory Agency are preparing the Statutory Instrument on the Clinical Trials Regulations. This is applicable UK wide.

Reciprocal Healthcare

There have been concerns in relation to the legislative fixes for reciprocal healthcare in a No Deal scenario, including the UK Government Healthcare (International Arrangements) Bill.

The Bill makes arrangements to provide for elements of reciprocal healthcare to continue following exit from the EU and into the future. It is likely that this would be with specific EU countries the UK Government has made reciprocal arrangements with. However the legislation could also be used to give effect to healthcare arrangements with other third countries. The Bill makes provision for matters which are within the Assembly's legislative competence.

However it is recognised that this is a complex area, and as UK Government will be entering into reciprocal arrangements on behalf of the whole of the UK there is a case for this being legislated for on a UK basis. Welsh Government has raised concerns that the Bill does not include provision to seek the consent of Welsh Ministers to the

making of regulations which will implement the detail of new healthcare agreements, even though these would place obligations on the Welsh NHS; and that the Bill includes a general provision enabling regulations to be made which could amend, repeal or revoke a Measure or Act of the National Assembly for Wales.

The Minister for Health and Social Services has raised concerns with the Parliamentary Under Secretary of State for Health, Lord James O'Shaughnessy, and made clear that the Bill as drafted was highly unlikely to receive consent from the Assembly. A legislative consent memorandum was laid on 15 November which stated that a decision on whether consent is recommended will be informed by the outcome of ongoing discussions with UK Government. These discussions have been progressing and at time of writing amendments are expected to be laid to the Bill. An update to the Assembly will be provided in due course on its progress.

Although this Bill provides the legal basis for individual reciprocal arrangements to be made, there is additional uncertainty as to the status of EU citizens moving to the UK and their right to access services, including healthcare. Arrangements in Wales will be informed by policy in England and as such discussions are continuing with UK Government.

Recommendation 4

The Committee recommends that the Welsh Government calls on the UK Government, to guarantee continuing access to medical radioisotopes after Brexit and ask that the Welsh Government outlines the actions it has taken to fulfil this recommendation in its response to our report.

Response: Accept

Radioisotopes are imported for diagnostic and therapeutic use by the NHS, primarily for cancer care. Due to the half-life of the isotopes, it is not possible to stockpile supplies. Radioisotope is usually imported overnight from continental Europe via Dover and distributed by road. This relies on frictionless customs arrangements and unimpeded transit between continental Europe and the UK.

In terms of the UK Government's withdrawal agreement being approved or the UK exiting the EU without a deal, the UK's subsequent withdrawal from Euratom will in itself not impose tariffs on the import of radioisotope. The principle risk to the supply of radioisotope is thought to lie with any disruption to the flow of goods at ports in the event of a 'no deal' Brexit. There are potential regulatory concerns if the UK leaves on a 'no deal' basis and chooses to leave Euratom.

UK Government is confident it has identified all the relevant suppliers of radioisotope as part of its Medicines Supply Programme. All those companies captured have been encouraged to develop contingency arrangements. With regard to radioisotope, this is primarily airfreighting the products, which is likely to have a cost implication for the NHS. Prioritisation of road freighted radioisotope has been discounted due to the absence of reciprocal arrangements in the event of a 'no deal' scenario.

Welsh Government officials have been liaising with UK Government to determine if withdrawing from the European Atomic Energy Community under the terms of the withdrawal agreement or in a no deal scenario will have implication for intelligence sharing regarding supply of radioisotope, the regulation and customs processes for the cross border transportation of radioisotope, and the licensing of suppliers. These discussions are ongoing.

Recommendation 5

The Committee recommends that the Welsh Government, in its response to this report, outlines:

- **the exact timescales for completion of its research on the implications of Brexit for the social care sector;**
- **details of how it intends to ensure that the social care sector can take account of its findings, including communicating those findings to practitioners; and**
- **details of its preparations in terms of updating plans for recruitment and retention of health and social care staff after Brexit.**

Response: Accept

The Welsh Government has commissioned Ipsos MORI to undertake research on the composition of the social care and child care workforce to understand the contribution of non UK EU workers and identify any vulnerabilities which might exist if recruitment and retention of EU workers is negatively by the UK Government's migration policy on leaving the EU. This research is being undertaken in two parts:

- the primary part: quantitative analysis focussing on assessing the number of workers from the UK, EU and rest of the world, working in the range of different provider settings and roles within social care and childcare across Wales; and
- the secondary part: qualitative research exploring the of non UK EU workers considering any issues around staff recruitment, retention, skills, staff costs and how these have been affected since the referendum to leave the EU.

The quantitative analysis will be presented to stakeholders on 6 February, with the full report following in March. On 14 February the WLGA, NHS Confed and ADSSC are hosting a stakeholder workshop focussing on Brexit preparations which will examine the workforce research findings in depth and consider implications for the provision of care services. The research will also be published on the Welsh Government website and shared with all those who have contributed to it.

As noted in our “Brexit and Fair Movement of People” policy document, the potential impact of Brexit on EU nationals working in the health and social care sector not only affects doctors and nurses. Other health professions, including allied health professionals, midwives, pharmacists, paramedics, healthcare assistants and support workers such as cleaning staff, are also likely to be affected. Indeed, the effects of Brexit migration changes may be most keenly felt in roles requiring less skilled workers in both the NHS and Social care sectors. Brexit is likely to lead to a tighter health and social care labour market across the UK, and across all professions and types of staff, which will require us to work even harder to compete for staff, promoting Wales as a desirable location to train work and live.

Social Care Wales is leading the development of a recruitment and retention campaign which will launch in the New Year. Alongside this, Social Care Wales is working with Health Education Improvement in Wales to develop a workforce strategy for health and social care setting out how current and future workforce needs will be met. The findings of the research will be fed into the development of the campaign and workforce strategy.

For health, the All-Wales Directors of Workforce & Organisational Development are leading on the workforce implications of Brexit and ensuring the workforce strategy addresses the consequences of Brexit.