

Freedom of Information Request: Our Reference CTHB_474_18

You asked:

- 1. Please state whether your health board has established a committee or other body with explicit responsibility for planning for Brexit (please state "yes" or "no").**

No, we have not established a Committee or other body for Brexit. However, we have an established a Task and Finish Team as part of our approach led by the Chief Executive.

The Chief Executive Officer receives strategic guidance and direction from the Cabinet Secretary for Health and Social Care who cascades the requirements and situation updates. These are then disseminated to the Executive Directors and the Task and Finish team. In addition the Health Board is either represented on or receives information from a number of bodies, which is then cascaded to the Directorate Managers or departmental managers.

Bodies include:

- Welsh Government
- Public Health Wales
- Welsh NHS Confederation
- Health Emergency Planning Advisor Group (Wales)
- South Wales Local Resilience Forum

- 2. Please list:**
 - a. the dates that this body met between 1st April 2018 and 7th November 2018**

There are no formal meetings set up as yet. Discussions take place as part of daily work. Updates have been provided to a range of staff across the health board.

- b. the members of this body and their job titles**

The Task and Finish Team led by the Chief Executive comprises of the Interim Board Secretary, Interim Head of Corporate Governance and the Civil Contingencies & Business Continuity Manager.

- 3. Please supply:**
 - c. The minutes of all meetings held by this body between 1st April 2018 and 7th November 2018.**

The Task and Finish Team do not produce minutes as discussion are part of their daily work.

d. Any extracts from minutes of board meetings held between 1st April 2018 and 7th November 2018 that relate to Brexit

Please see attachment 1.

4. Please supply any current risk assessment for the health board related to Brexit

Please see attachments 2, 3, 4 and 5

Extracts from Executive Meetings

Informal Executive Meetings

30 July 2019

Brexit No Deal	NHS Confederation leading work – stockpiling of medicines; contingency planning; testing of settled status position. Civil Contingencies and Business Continuity Manager – to raise with emergency planners
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10 September

Business continuity Plans - Brexit	The Deputy Chief Executive Director of Planning and Performance referred to an email received concerning the inclusion of Brexit implications within business continuity planning processes. Agreed to discuss at next meeting Action –Brexit Task and Finish Team to consider concerning any Brexit considerations linked to business continuity planning in preparation for next meeting
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17 September

Business continuity Plans - Brexit	Deputy Head Corporate Services provided an update: <ul style="list-style-type: none">• The potential impact of Brexit on business continuity planning (BCP) had been discussed with the Civil Contingencies Manager who had advised that Brexit would not affect Civil Contingencies planning, however will affect BCP. There are potential financial implications arising from Brexit linked to BCP.• Welsh Government have issued a technical document, however it is ambiguous and does not outline any specific change in practice, just be aware of future Brexit implications• Civil Contingencies and Business Continuity Manager has issued an email to the Executive Team requesting that individual directorates undertake an impact assessment of a No Deal Brexit. The information is required for submission to Welsh Government by 19 October.
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19 November

Brexit	<p>Paper being developed – WAO now asking for information</p> <p>1 The Auditor General is carrying out a programme of work looking at the arrangements that the devolved Welsh public sector is putting in place to manage the implications, risks and opportunities of leaving the European Union (EU). Call for evidence and self-assessment by 30 November 2018. Request attached at end of notes</p>
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Executive Board Meeting

September 2018

Members **NOTED** that Welsh Government had been asked for a list as to what would be looked at by the UK Government, by the Welsh Government and by Health Board's. It was **AGREED** that Brexit would need to be added to the risk register.

October 2018

Exit from the European Union (Brexit)

Members **NOTED** that there were a number of issues concerning Brexit that NHS England/NHS UK were becoming concerned about, including:

- **Stockpiling of Medicines** – There was an intention in the UK to stockpile medicines with a minimum of 6 weeks supply of all drugs that would need to be imported from the EU. This was a contingency measure in the event of a "no deal" Brexit agreement. Consideration was also being given to following the same process for all surgical and medical supplies on a UK basis and an understanding would be required as to access arrangements for supplies.
- **Settled Status Issues for Staff** – It was anticipated that a small number of staff within CTUHB would potentially need to apply for settled status through the EU Settlement Scheme. Members **NOTED** that NHS staff will be taking part in a private pilot of the new application process for the EU Settlement Scheme and that the trial

gateway would be opened for 6 weeks in November for NHS staff. An update on progress and further details concerning the scheme will be sought through workforce directors.

- Other potential issues could include stockpiling of food and energy supplies.

It was understood that clarity on whether there was a deal or no deal Brexit would not be in place until January 2019. The CEO advised that work was underway on a directorate by directorate basis, to identify areas which were identified as being at risk locally or those which were being addressed nationally and across the UK. Business Continuity Plans would need to be amended with plans for implementation for what could last several weeks. Members **NOTED** that consideration may also need to be given to available food storage capacity at the Central Processing Unit (CPU). Members **NOTED** that a list of other matters for consideration would need to be developed over the next 6-8 weeks and that an update report would be presented to the December Executive Board meeting.

Completed By: Andrew Francis Civil Contingencies
and Business Continuity Manager

Date: 23 Nov 2018

CTUHB

To be read in conjunction with Risk assessments from the SSP. Health and the High Level Summary of potential issues for Welsh Health and Social Care Services Post Brexit and other guidance and updates.

[illegible]

Recruitment and Retention	2	1	1	1	2	2	9	Low	Low percentage of staff whos' status as to whether they are from the EU or other country of origin are indicated by the ESR system i.e. approximately 35 staff. Workforce have a plan in place to support EU Nationals with the Government Settlement Scheme.
Recognition of Professional Qualifications	2	1	2	1	2	1	9	Low	
Medicines									
Supply of Radiological/Isotope type medicine	1	1	3	1	3	4	13	Medium	There is concern within the Uk Radiopharmacy Group (NEWSLETTER 2018 Summer Edition) as to the ability to import specialist drugs and isotope based medicines and medical investigated drugs/substances. The Health and Social Services Group Letter: 23 August 2018 Preparations for Leaving the EU, outlines the 6 week stockpile/supply plan and reference to arrangements for air frieghting medicines with short life/special requirements. This issue is to be monitored by the Pharmacy Directorate Manager.
Supply of general medicines and medical consumables	1	1	3	1	3	4	13	Medium	As Above
Regulatory Issues Medicines and Devices	1	1	1	1	1	1	6	Low	Uk will accept EU Legislated Drugs in the interim. Guidance issued to Pharmaceutical companies. This area is out of the control of CTUHB however cascade of any infromation and guidance must be ensured to inform Directorates of the situation. This will be done by the Chief Pharmacist.
Tarrifs on Imported Medicines and Devices	1	1	1	1	1	1	6	Low	Financial Impact analysis is unable to be evaluated until clear additional costs are set. Financial Directorate are aware and will assess when the situation presents usable data. However even if costs increase these will have to be met to enable a servcie to be maintained. The impact may be felt in other areas due to the potential to have to vire budgets from departments/scheme to meet new finacial demands.
Education/Research							0	0	Education and Research:

Clinical Trials									<ul style="list-style-type: none"> As clinical trials are currently managed nationally, UK clinical trial applications will continue to be authorised by the MHRA and ethics committees as they are now. The UK ability to participate in multinational trials will also not change, MHRA will be improving processes to enable closer working with ethics bodies and allowing a single application and a single national decision in the UK. The initial pilot work has started and would continue to be developed post-exit
	1	1	1	1	1	1	6	Low	
Utilities Gas/Electricity	1	1	1	1	1	1	6	Low	Other than possible increased costs the supply network has not been deemed to be at risk due to Brexit

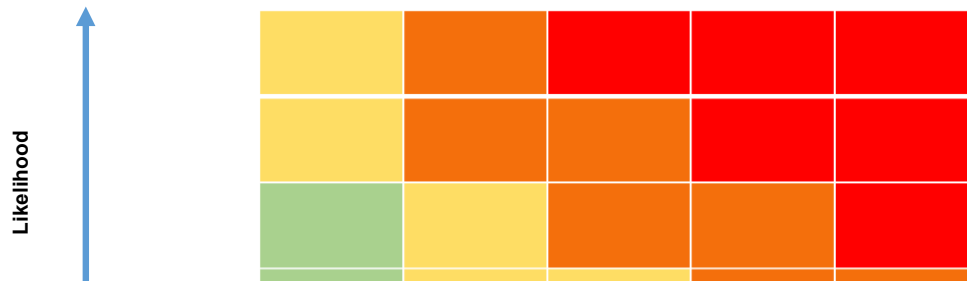
Score:

- | | |
|---|--|
| 1 | 1 - No/little impact |
| 2 | 2 - Minor disruptive impact |
| 3 | 3 - Moderate disruptive impact |
| 4 | 4 - Highly disruptive impact |
| 5 | 5 - Severe and prolonged service failure |

Risk Rating

Score 0-10 = LOW
Score 11-20 = MEDIUM
Score 21 - 30 = HIGH

Risk Matrix





Impact

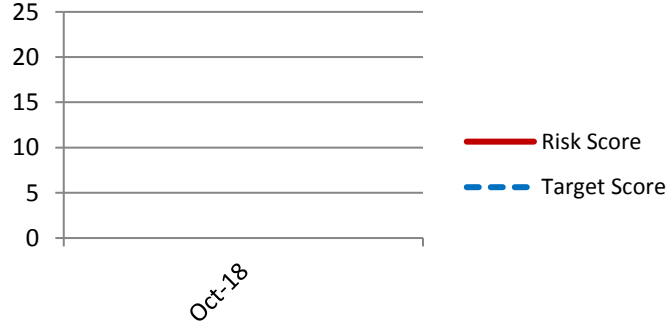
Brexit Risk and Mitigation Summary Table

<p><u>Workforce:</u></p> <p>Risk:</p> <ul style="list-style-type: none"> • EU Staff may return to their home countries due to insecurity of situation. • Exact number of EU staff unknown at present as recording has not been required for Employment reporting to date. Hence target group and full impact difficult to evaluate. • There is a very low risk of immediate impact to the NHS. <p>Mitigations:</p> <p>The Workforce team have a clear understanding of the impact and the actions to be taken including future recording of data. They are fully briefed on the EU Settlement Scheme.</p> <p>They have a plan that they will activate when advised by the National Workforce forums. The Government will maintain a status quo and the implementation of a Settlement scheme is intended to make working within the UK and in particular the NHS as easy as possible for Current and future EU National.</p>	<p><u>Medicines/Medical Devices:</u></p> <p>Risk:</p> <ul style="list-style-type: none"> • Potential for delays in medicine and medical device supply chain leading to shortages. • Potential shortages of other related products such as Blood products and in particular other Time and Temperature critical items such as radio-isotopes. • Risk is reduced to low HOWEVER the planning assumptions are based on a 6 week period of disruption. This needs to be monitored for change. • Potential for specialist equipment such as X-Ray, MRI scanners and other such equipment used by Radiology may experience delays in service and repair. <p>Mitigations:</p> <p>Medicines:</p> <p>The UK and Welsh Government have initiated plans to stock pile additional medicines (6Weeks) and have informed HB's and Pharmacies that no local stock piling is necessary.</p> <p>In addition UK Gov and WG have gained assurance from over 75% of medicine suppliers that there will be suitable contingencies in place.</p> <p>The UK Government have stated "To ensure such medicines will continue to be authorised for use in the UK, all CAP MAs will automatically be converted into UK MAs on 29 March 2019. MHRA will write to all CAP Marketing Authorisation Holders (MAHs) prior to 29 March 2019 to inform them of the conversion process (known as "grandfathering") and to provide them with the opportunity to opt out of receiving a UK MA".</p> <p>CTUHB Pharmacy are evaluating any potential issues with direct suppliers who may not be part of the UK Gov/WG planning assumptions. Contact is being made with these suppliers to gain assurances of their contingency plans.</p>
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	<p>Medical devices:</p> <p>Radiology will evaluate their equipment service contracts that may not form part of the UK/WG Brexit “No Deal” planning for Health.</p> <p>These suppliers are in the process of being contacted to gain assurances of their contingency plans.</p> <p>The UK will recognise medical devices approved for the EU market and CE-marked. The UK will comply with key elements of the Medical Devices Regulation and Invitro Diagnostic Regulation which will be in place until 2022.</p>
<p><u>Estates and Facilities Management:</u></p> <p>Risk:</p> <ul style="list-style-type: none"> • There is potential for service and repair contracts to be affected by the delay and or shortage of specialist parts and materials supplied from the EU or distributed from the country of origin i.e. Japan via an EU State. E.g. Lift maintenance components supplied from Spain, Major equipment components such as scanners supplied by EU states. • Capital projects may have building materials or equipment supplied from the EU delayed. <p>Mitigations:</p> <p>The Estates team consider the impact on Capital projects to be minimal with some risk being contractually borne by the main contractors.</p> <p>In relation to other service maintenance contracts the Head of Estate is contacting essential suppliers to seek confirmation of their business continuity plans and assurances of continued service contract delivery.</p>	<p><u>Other:</u></p> <p>Education and Research:</p> <ul style="list-style-type: none"> • As clinical trials are currently managed nationally, UK clinical trial applications will continue to be authorised by the MHRA and ethics committees as they are now. The UK ability to participate in multinational trials will also not change. • MHRA will be improving processes to enable closer working with ethics bodies and allowing a single application and a single national decision in the UK. The initial pilot work has started and would continue to be developed post-exit.

Risk Register Category – Service / Business Interruption (1)

Strategic Objective	Risk Reference	Description of risk identified	Initial Score	Current Score	Trend	Controls	Last Reviewed	Scrutiny Committee
Business Continuity Brexit	043 (NEW)	Risk of interruption to service sustainability, provision and destabilising the Board's financial position as a result of Brexit.	16	16			New Risk	Executive Board

Objective: Service / Business Interruption (2) (New)		Director Lead: Chief Executive Officer Assuring Committee: Executive Board		
Risk: Risk of interruption to service sustainability, provision and destabilising the Board's financial position as a result of Brexit.		Date last reviewed: n/a		
Risk Rating (consequence x likelihood): Initial: 4 x 4 = 16 Current: 4 x 4 = 16 Target: 3 x 3 = 9		Rationale for current score: Whilst Brexit negotiations continue the Health Board must prepare for every eventuality based on a thorough risk assessment on the impact of Brexit on the Health Board. Rationale for target score: Whilst Brexit negotiations continue the Health Board must prepare for every eventuality based on a thorough risk assessment on the impact of Brexit on the Health Board.		
Level of Control = 50%				
Date added to the risk register November 2018				
Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)		
<ul style="list-style-type: none"> Carry out gap analysis/risk assessment on Brexit Complete the Wales Audit Office (WAO) call for evidence self-assessment Respond to WG as requested to inform of plans Directorate Business Continuity plans being updated – particularly in Medicines Management; Facilities (food); ICT; Workforce; Estates; R&D Regular dialogue with Welsh Government and working with the Welsh NHS Confederation Emergency Planning, Preparedness & Response (EPPR) for the sites transferring to CTUHB from ABMU managed by the Governance work stream of the project. Small number of staff within CTUHB potentially need to apply for settled status through the EU Settlement Scheme. Establish internal Brexit group 		Action	Lead	Deadline
		Work nationally with Welsh Government, Local Resilience Forums and other HBs and Trusts to share business continuity plans.	Board Sec CCM	March 2019
		Continue with strong controls in place to ensure “business as usual” through robust business continuity plans	Board Sec CCM	Ongoing
		Working with other HBs and Welsh NHS Confederation learn lessons from other organisations and provide information on SharePoint to allow opportunities for staff across the HB to identify and areas of concern	Board Sec CCM	April 2019
Assurances (How do we know if the things we are doing are having an impact?)		Gaps in assurance (What additional assurances should we seek?)		
The Health Board is providing services “business as usual” with no interruption to service sustainability and provision of patient care.		Undertake a business continuity exercise to test existing business continuity plans to identify any gaps in resilience.		
Current Risk Rating		Additional Comments		Ref No.
Current Risk Rating: 4x4 =16		Whilst Brexit negotiations continue the Health Board will work with other organisations to identify risk		New 043

High Level Summary of potential issues for Welsh Health and Social care services post-Brexit
Document Status: V0.1 – 15 Jan 2018 - early draft for discussion with Welsh NHS Confederation and Social Care Wales

This is a working document, intended to support discussions on managing risks effectively within health and social care in Wales. It will support the development of a shared work programme.

Brexit theme	Risk/problem description	Potential impact	Inherent risk score	Actions/activities/Risk reduction measure	Risk owner	Residual risk score
Workforce recruitment and retention	Brexit appears to be having an impact already, especially on the recruitment and retention of EU nationals in some parts of the workforce which is contributing to shortages of key staff.	Most likely outcome A suitable deal is struck, including on movement of people. Some limited impact on recruitment and retention of EU staff in health and social care organisation		The announcement that EU citizens currently living in the UK will be able to remain is helpful. We hope it will persuade as many of them as possible to stay and continue to make a valuable contribution to the health and care workforce. Is there more we can do on the back of this in relation to communication messages with staff currently working in the health and care system in Wales?	Director of Workforce and Organisational Development NHS. To be Confirmed	
	(notably, since the referendum the number of EU registered nurses working in NHS Wales has increased.) Nurses are included on the UK Shortage Occupation List but other allied professions are not and this may have a bearing.			Continue our efforts to increase the domestic NHS workforce, although it will take time for many of these policies to result in extra staff on the front line e.g. 5 – 10 years.		
	[DN – add current actual data here – new data due at end January]]			Ensure our <i>Train Work Live</i> campaign will continue to target nurses in EU countries if new immigration rules allow post 31 st March 2019.		
	A worst case scenario could see loss of current staff, or failure to recruit new, health and care staff from other EU countries.	Worst case we leave with no deal. Movement of Residents of EU countries into UK is restricted. EU nationals working in health and care organisations leave their jobs in Wales (either for better paid ones elsewhere due to increased demand, or to leave the UK). The health and care system will find it difficult to recruit EU citizens.		Action: need data further broken by categories/specialties, including NHS and social care to identify whether there are any specific risk areas, e.g. transplant surgeons. <ul style="list-style-type: none">- Welsh NHS Confed commissioning further analysis through working with NWSPP- Work with Social Care Wales and other relevant organisations (WLGAs etc) to receive workforce data		
	A likely scenario may still see restrictions on migration numbers that may have an impact on the availability of staff, particularly for those groups not on the United Kingdom Shortage Occupation List			Consider how both the NHS and social care can continue to recruit lower-skilled workers from the EU and elsewhere, who are less likely to arrive under migration systems focused on encouraging higher-skilled individuals.		
	The effect may be most keenly felt in roles requiring less skilled workers in both NHS and Social care. It will also impact NHS and social care if skilled people leave the UK because it may take years to train UK citizens to fulfil these roles e.g. medical, dental, radiographers etc			Consider further actions, e.g. paying the fees for any nationalisation process.		
				Welsh NHS Confederation/ NHS Wales Employers are part of the Cavendish Coalition specifically campaigning around workforce issues so will keep the Welsh Government updated of any developments.		

Recognition of Professional Qualifications	MRPQ – mutual recognition of professional qualifications. Agreeing way forward will be key to simplifying movement of professionals. Directive 2005/36/EC, amended by Directive 2013/55/EC creates a system of recognition of professional experience and promotes automatic recognition of professional experience across the EU. In practice, the recognition of professional qualifications laid down in Directive 2005/36/EC enables the free movement of professionals such as doctors or architects within the EU. Other professions, such as lawyers or sailors, fall under the scope of different legislation.	Likely Outcome: To be defined following deep dive workshop		MRPQ is one of the next 'Deep dives' in early February as the impact is far wider than just health. Anticipate more detail on likely outcome, UK preferred position and contingency options after that. One of the key areas that Brexit Health Alliance (BHA) is working on. The Welsh NHS Confederation are part of the Alliance and keep the Welsh Government updated of any developments.	WG: Head of Professional Education and Regulation NHS Wales: To be confirmed	
	As a result of Directive 2005/36/EC patients and consumers are adequately protected by an alert mechanism established by the Directive. This allows the competent authorities of all Member States to quickly warn each other if health professionals have been prohibited or restricted from practicing the profession in one country or have used falsified diplomas for their application for the recognition of their qualification. This framework allows a high degree of professional mobility without jeopardising patient safety and quality of care. Patients and professionals benefit from this transfer of knowledge and specialised expertise which contributes to continuously improving the quality of healthcare in Europe. GMC has said that Brexit strengthens the case for reforming professional regulation, as it provides an opportunity to make progress in two distinct areas: improving the checks we can put in place to ensure all doctors practising in the UK meet the same standards – whether they qualified in the UK, Europe or elsewhere – and improving training for doctors by creating greater flexibility in postgraduate training.					
Reciprocal healthcare	Under current EU law, EU citizens benefit from rights to reciprocal healthcare when they are in any of the European Union's 28 Member States. These rights apply whether they are travelling temporarily between EU Member States, for example, on holiday or studying abroad, residing permanently or long term in another EU country, or when travelling to another EU Member State specifically to receive pre-arranged medical treatment. There are about 53 million visits made to the EU from	Likely Scenario: an ongoing arrangement 'akin to the EHIC scheme'. Worst Case: Without EHIC, costs would transfer to the individual – people travelling abroad in the EU would need to take out voluntary private travel		UK government has confirmed that EU nationals currently living in the UK and UK nationals currently living in the EU will be able to continue to reside abroad and will have the same access to health care as they do now. Future arrangements, including those relating to EHICs or the rights of UK and EU nationals to access health care when moving abroad in the future, have not yet been discussed. However, the UK has said that it intends to seek an ongoing arrangement 'akin to the EHIC scheme' as part of negotiations on future arrangements with the EU.	WG: Director of Mental Health, NHS Governance and Corporate Services NHS: to be confirmed	

	<p>the UK each year, and 25 million visits from the EU to the UK. Only around 1 per cent of these visits results in an EHIC claim, but EU countries receive about £150 million per year from the UK to compensate for EHIC use by UK citizens. Consequently, a significant new administrative burden could emerge for hospitals in the event of the EHIC being discontinued.</p> <p>Once the UK leaves the European Union, these reciprocal rights will come to an end, unless both the UK and the EU agree to continue or replace them.</p> <p>See Brexit Health Alliance (BHA) paper for deeper analysis - http://www.nhsconfed.org/resources/2017/10/maintaining-reciprocal-healthcare-for-patients-after-brexite</p> <p>Reciprocal healthcare also covers the Mutual Recognition of Prescriptions.</p>	<p>insurance in the same way as they would when travelling outside the EU.</p>	<p>This is subject to a deep dive in February. Anticipate more detail on likely UK preferred position and contingency options after that.</p> <p>BHA will continue to lead UK campaign - Welsh NHS Confederation are a member and will share information with WG and WG share relevant information with the Welsh NHS Confederation to ensure Welsh issues are highlighted</p> <p>What data is available on how much is reclaimed by NHS Wales (c/f how much could be?)</p>		
Cross border healthcare provision	<p>EU reciprocal healthcare also covers situations where it is not the patient travelling, but instead it is the clinical services which cross the border. This is the case in telemedicine, when a healthcare professional in another EU country performs the medical consult or procedure for a patient.</p> <p>The provision of cross-border e-Health/telemedicine services is rather limited today, due to a range of barriers that continue to exist, such as legal uncertainty on issues such as liability, data privacy, and reimbursement of costs. Nevertheless, there are increasing efforts at EU level to address these challenges, including in the context of operational arrangements for the newly established European Reference Networks - the most advanced and innovative form of cross-border co-operation between healthcare providers across the EU.</p> <p>This is a very important development which has the potential to revolutionise the delivery of EU cross-border healthcare for the benefit of patients, clinicians and healthcare providers alike. Risk is that post-Brexit, Welsh residents and professions will not be able to</p>				

	access this.				
Regulatory issues: Medicines & devices	<p>Medicines and medical devices</p> <p>EU legislation provides a harmonised approach to medicines regulation across the EU member states. The UK is currently part of the centralised authorisation system operated by the European Medicines Agency (EMA) which will be moving from London to Amsterdam.</p> <p>Some concern has been expressed that if the UK leaves the EMA arrangements and develops its own drug approval system, the UK may lose its 'tier 1' status and end up at the back of the queue for new medicines (Rawlings 2017). For example, in Switzerland and Canada, which have separate approval systems, medicines typically reach the market six months later than in the EU</p> <p>On medicines, over 2,600 final products have some stage of manufacture based in the UK and 45 million patient packs are supplied from the UK to other EU-27/EEA countries each month and over 37 million patient packs are supplied from the EU-27/EEA to the UK each month. This demonstrates the importance of maintaining frictionless trade to meet patient needs for medicines across Europe.</p> <p>The UK has the highest number across the EU of phase I clinical trials, those testing a new drug or treatment for the first time, and the second highest number of phase II and phase III clinical trials. It has also the highest number of trials across the EU for both rare and childhood diseases. There are over 1500 clinical trials being conducted in multiple EU member states that have a UK-based sponsor and over half of these trials are scheduled to continue beyond March 2019.</p> <p>Clinical trials for new drugs are currently carried out on a national level but subject to EU regulations, including for registration of trials. The revised EU clinical trials directive, due to take effect in 2018, will harmonise arrangements across the EU with the aim of creating a single-entry point for companies that wish to carry out trials of new drugs on participants in different countries.</p> <p>Some in the pharmaceutical industry have expressed concern that leaving the EU could result in the UK losing out on some trials that might otherwise benefit</p>	<p>Likely Scenario: A comparable approach is agreed, ensuring continued access to medicines and trials</p> <p>Worst Case: No mutual agreement is reached. Availability of some current medicines is compromised. Access to new medicines is delayed.</p> <p>Office of Health Economics (November 2017 report) analysed that the implications could be: Reduced availability of medicines in the UK; delays of two to three months or more for marketing authorisation applications to be submitted in the UK; delays of up to five months in signal detection and management for pharmacovigilance in the UK and the EU27/EEA; delays in the management of crises and public health threats in the UK and the EU27/EEA, and shortages of medicines in both jurisdictions. If FTAs are not in place by March 2019, companies will face tariff measures and non-tariff measures (including delays) which could lead to medicines shortages in the UK and the EU27/EEA.</p> <p>EU nationals working in the pharmaceutical industry in Wales could leave. Could impact on investment by pharmaceutical companies in the UK in the future.</p>	<p>Link with the BHA campaign and material they produce through the Welsh NHS Confederation and other stakeholders. The campaign aims to secure a cooperation agreement between the UK and the EU on regulation of medicines and medical devices.</p> <p>UK analysis is underway to identify and quantify any issues in the UK medicines supply chain post Brexit.</p> <p>Do we need to commission more analysis?</p> <p>ABPI have done a lot of work on this area e.g. (xxx Information redacted under Section 40(2)(xxx) attending a lot of meetings in Brussels on post Brexit issues http://www.abpi.org.uk/insight-analysis so include them as well to get an industry view.</p> <p>The European Medicines Agency and the European Commission have issued guidance to help pharmaceutical companies prepare for Brexit, so that supply of medicines will not be disrupted as the UK leaves the EU.</p> <p>Press UK Government to ensure transitional arrangements address continued patient access to medicines, ensuring there is minimal disruption to patients receiving medicines after the UK leaves the EU.</p>	<p>W/G: Chief Pharmaceutical Officer / Head of NISCHR</p> <p>NHS: To be confirmed</p>	

	<p>patients, as the UK would no longer be part of the harmonised procedure. These trials are particularly important for rare diseases and personalised medicine, as multi-country trials provide researchers with access to the large populations required.</p> <p>Disrupted arrangements or divergent approaches could lead to availability and supply chain problems for medicines used by UK patients</p> <p>The UK also participates in the EudraVigilance system for pharmacovigilance, operated and monitored by the EMA, which reports on and captures medicines safety, and Eudamed, the EU-wide database for medical devices and in vitro medical devices. The loss of the UK's engagement in these systems would significantly reduce their effectiveness, at a time when there are more medicines and devices coming on the market than ever.</p> <p>Furthermore, the implications of a divergence in regulatory frameworks given the newly adopted In Vitro Diagnostic Medical Devices (IVDs) and Medical Devices (MDs) Regulations, are of great concern to the medical technology sector. The EU-wide IVDs and MDs legislations have played a key role in delivering high-quality care to patients for over 25 years, allowing them timely access to safe and effective medical technologies. In the event that there are two divergent regulatory systems as a result of Brexit, patient access to medical technologies risks being hindered. As a consequence, both parties need to ensure the full availability of medical technologies for patients once the negotiations have come to an end.</p> <p>The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) is a significant contributor to EU systems and processes, both for medicines and medical technologies. This includes scientific and clinical assessments, surveillance and supervision of products, and reporting adverse events. A continued regulatory alignment between the EU and UK will ensure that European patients have timely access to innovative new medicines, generic and biosimilar medicines, and medical technologies</p>					
Research and trials	<p>Welsh research organisations benefit substantially from involvement in international collaborative research funded through European Research programmes such as Horizon2020 and the 3rd Health</p>	<p>Likely scenario: Continued access to international collaborative programmes is</p>		<p>It is important that we continue to benefit from the collaboration of researchers and scientists across the EU, and that the immigration system supports its position as a global leader in life sciences.</p>	<p>WG: Head of NISCHR NHS: To be confirmed</p>	

	<p>Programme, and funds such as ESIF to establish and support research infrastructure.</p> <p>Without access to EU funding and collaborative projects, the Welsh science excellence risks falling behind.</p> <p>EU also provides research networks, infrastructure, legal frameworks, research standards and policies that underpin scientific research, and replacements will be needed if continued access is not available after Brexit.</p> <p>Organisations, including NHS, will become less attractive for professionals wanting to undertake research.</p>	<p>agreed, although access conditions may differ from current arrangements, e.g. UK partners may not be able to lead projects.</p> <p>ESIF programme will cease in Wales. This may be replaced by new UK- programmes.</p> <p>Worst case scenario: Wales would not be able to participate in EU trials, particularly rarer conditions</p>		<p>In the short term, the government has committed to honor funding agreements for ESIF projects that were signed before the Autumn Statement 2016, even where these continue after the UK has left the EU. Funding for projects signed after the Autumn Statement will be funded if they provide strong value for money and are in line with domestic strategic priorities. For Horizon 2020 projects, the government will underwrite the funding for all successful bids that are submitted before the UK leaves the EU, December 2017 announcements suggest this may extend to the end of 2020, ie the current H2020 programme. This would be beneficial as there are calls in 2019/20 that could be of interest to Welsh bodies.</p> <p>The UK government has stated that it wishes to 'establish an ambitious agreement on science and innovation that ensures the valuable research links between us continue to grow'. While it may be possible to continue to participate in some research programmes after the UK leaves the EU (non-EU countries are able to participate in Horizon 2020 as associates or third countries, for example), it is possible that projects in the UK would be eligible to receive EU funding and the UK would have limited influence over work programmes.</p> <p>If this evolves into a UK funding programme, how do we construct this in a devolved context?</p> <p>Consider commissioning/consolidating analysis of recent and projected EU research income, as well as assessment of impact on reputation and capability of programmes such as SEREN</p> <p>Highlight other international research schemes that we can continue to access, or consider negotiating access to.</p>		
Innovation	<p>Having a single EU medical regulation system has enabled new health technologies to be brought to market sooner for the benefit of patients.</p> <p>A separate testing and approval system may delay access to innovations and attractiveness of Wales to undertake trials/demonstrations.</p>	<p>Likely scenario Still have access to medial regulation system to develop new health technologies.</p> <p>Worst case scenario: Wales is not seen as an attractive place to work in practice to test and develop health technologies.</p>		<p>Push for close coupling at UK level.</p> <p>Is there space for Devolved divergence? Don't think so.</p> <p>Strengthen HTAW links to international counterparts.</p> <p>Accelerate Digital Health Ecosystem international links</p>	<p>WG: Deputy Director, Technology and Innovation NHS: To be confirmed</p>	
Procurement and competition law	<p>Relevant EU procurement directives have already been incorporated into UK law, so the UK government would need to repeal or amend the law if it wished to substantially alter or reverse current arrangements. Although a combination of the Competition Act and</p>	<p>Likely Scenario: Largely unchanged regulatory environment.</p>		<p>Consider commissioning analysis of procurement spend in NHS which is contracted and supplied from another EU member state, including analysis on what proportion could have a positive impact on Welsh economy if shifted.</p>	<p>WG: NHS: To be confirmed or NHSWSSP</p>	

	<p>Competition Regulations continues to prohibit anti-competitive behaviour, leaving the EU would allow policy-makers to modify these arrangements and other relevant legislation.</p> <p>In recent years, public services in Wales have been exploring more collaborative approaches to delivering services exemplified by the new models of care currently being developed in many areas. Leaving the EU could provide an opportunity to align the law with this approach, providing greater clarity and certainty to local areas as they implement new care models. This particularly relevant in the context of the Parliamentary Review recommendations</p>	<p>Worst case scenario:</p> <p>If no trade deal is agreed, the UK will fall back on World Trade Organization rules, which could see specific tariffs being be imposed on some goods and services. In addition to any wider economic implications, this could increase the cost of many goods and services for the NHS and social care sector, and could also impact on supply, including of drugs and treatments.</p>		<p>Showcase how novel and innovative procurement can already take place within the regulations, delivering social benefit and innovation (e.g. SBRI in BCUHB)</p>		
Public health	<p>EU legislation covers everything from food labelling to disease control. EU legislation surrounding emission controls have been successful in reducing pollution levels across both road traffic and industry, while the Commission has also shown a willingness to enforce directives in many areas including water quality and the safe and marketing of tobacco products. The EU has a significant role in ensuring a crossborder approach to anti-smoking measures. The Tobacco Products Directive, having survived a number of High Court challenges, is now in the process of implementation.</p> <p>Food regulation can impact on public health initiatives surrounding food hygiene, obesity and healthy eating. With EU regulation, such as EU General Food Laws which seek to protect human health and consumers' interest in relation to food, the future of the UK's own food standards measures is currently unknown. The UK Government is yet to have come forward with its plan for a replacement to this regulation. The Government could simply copy EU regulations in this area, resulting in no change to current rules. On the other hand, the UK Government could use this opportunity to amend the regulation, possibly lowering the standards to open up our market to new trade partners. The withdrawing from the EU legal framework on food could potentially offer opportunities. EU law in this area has been considered, on some occasions, to be too conservative</p>	<p>Likely scenario: Continued coordination between the EU and the UK to deal with pandemics and health promotion.</p> <p>Worst case scenario: Delays in crisis management and action if there are outbreaks.</p>		<p>The European Medicines Agency and the European Commission have issued guidance to help pharmaceutical companies prepare for Brexit, so that supply of medicines will not be disrupted as the UK leaves the EU.</p> <p>Once the UK leaves the EU, it will be up to the government to decide whether it wants to go further and faster than the EU in matters of public health or implement less stringent public health standards.</p> <p>However, in some areas of public health, particularly those relating to health security and air quality, it makes sense to continue current arrangements as closely as possible.</p>	<p>WG: Deputy Director, Deputy Director, Public Health</p> <p>Public Health Wales</p>	

Comment [ML1]: More information required here from Public Health Wales.

	<p>and not going far enough to help consumers make healthy choices.</p> <p>Effective communications mechanisms are in place to manage public health crises/outbreaks. Across Europe and internationally.</p> <p>European patients benefit from the UK's engagement in systems designed to protect public health across Europe. For example, the UK is substantially involved in the surveillance activities of the European Centre for Disease Control, which provides EU countries with protection from the 52 notifiable communicable diseases, outbreaks and public health risks, through a single database.</p> <p>Delays in communication around crisis management or divergence in standards and procedures between Europe and the UK post Brexit could lead to delays in action.</p> <p>Arrangements to be established/maintained to ensure ongoing links re e.g. outbreaks</p>					
	<p>Leaving the EU may present some opportunities, in particular the chance to go further and faster on public health regulation, for example, MUAP and Tobacco</p> <p>Food standards are also covered in this section, both maintaining standards and any consideration of deviations</p> <p>BHA campaigning to ensure that public health for all EU and UK citizens is maintained post-Brexit through; Strong coordination between the EU and UK to deal with pandemics, as well as other health threats; and Highest possible level of coordination between the EU and UK on health promotion and disease prevention programmes.</p>					
Employment rights	<p>Working time directive</p> <p>While no changes are proposed immediately post-Brexit, any decision in the future to amend the working time directive would need very careful consideration.</p> <p>Employment rights provides important protections for nurses, social care and health staff; in particular, rules on health and safety at work, information and</p>	<p>Likely Scenario: A comparable approach is agreed.</p> <p>Worst case scenario:</p>			<p>WG: Director of Workforce and Organisational Development</p> <p>NHS: To be confirmed</p>	

	consultation on collective redundancies and safeguarding employment rights in the event of transfers of undertakings (TUPE).				
	While amendments would be welcomed by those who argue that the current limit reduces flexibility for providers and restricts training opportunities in some specialties (see, for example, Independent Working Time Regulations Taskforce 2014), it would remove an important legal protection for workers and could result in health and social care staff working longer hours, exacerbating the pressures they are under, could lead to increase sickness and potentially posing risks to patient safety.				
	The EU's key health and safety related directives provide a legal framework for employers to reduce the risks of stress, violence, musculoskeletal disorders (MSDs), biological hazards, stress and violence to health and social care staff. MSDs and stress are particularly prevalent in the nursing workforce and the main cause of sickness absence in the sector and, arguably, without the directives the situation would be worse. The implementation of hoists and other lifting equipment, as required by the Manual Handling Directive, has been proven to significantly reduce the risks for social care and health staff and the people they care for				
	Furthermore, any changes would have implications for NHS employment contract terms and conditions.				
		Likely scenario:			
		Worst case scenario: The annual funding of the NHS depends on the performance of the economy. Leading economists have suggested that Brexit could lead to an economic downturn. The Health Foundation has previously estimated that the NHS budget in England could be £2.8 billion lower than currently planned by 2019-20. In the longer term, the analysis concludes that the NHS funding shortfall could be at least £19 billion by 2030-31 – equivalent to £365 million a week – assuming the UK is able			
Funding & Finance overall	Health and social care take the largest proportion of the Welsh Government budget. If the performance of the wider UK economy deteriorates, this will bring further pressure on Minister's funding options.				

Comment [N12]: Difficult to risk manage this because what actions can we do to impact on the economy.

