

Introduction

1. The Welsh NHS Confederation, which represents the seven Health Boards and three NHS Trusts in Wales, welcomes the opportunity to provide information to the External Affairs and Additional Legislation (EAAL) Committee inquiry into Wales' future relationship with the European Union.
2. On behalf of our members we submitted detailed evidence to the EAAL Committees consultation on the *implications for Wales of Britain exiting the European Union* in November 2016, the Committees inquiry into *Resilience and preparedness: The Welsh Government's administrative and financial response to Brexit* (Appendix 1) on the 10th of October 2017 and provided oral evidence on the 23rd of October 2017. Our position remains the same so the information below provides updated and additional information.
3. The Welsh NHS Confederation, on behalf of our members, is highlighting the possible implications of Brexit on NHS Wales with the Welsh Government, Assembly Members and our stakeholders. In addition, as a member of the Cavendish Coalition and the Brexit Health Alliance, we are ensuring that the impact for Wales is being made clear at a UK level by highlighting the likely effects on Welsh policy and legislation.

Welsh Government

4. As previously highlighted, the exact terms on which the UK will leave the EU are not yet clear, and this presents challenges in terms of forward planning for the Welsh Government. However, over the period since the referendum the Welsh Government has engaged with health and care bodies to identify areas that may be affected by leaving the EU, including NHS Executive Board and Wales NHS Partnership Forum.
5. The Welsh NHS Confederation and our members have been working with Welsh Government officials to consider and assess the scale of impact for Welsh health and social care services post Brexit, including contingency options. Following our evidence session in October 2017, the Welsh NHS Confederation has agreed to be the main contact for coordinating specific Brexit actions across NHS organisations and working with the Welsh Government. This work is intended to support discussions on managing risks effectively within health and social care and will support the development of a shared work programme considering priority areas including; workforce, professional qualifications, reciprocal healthcare, regulatory issues, medicines, research and innovation, procurement and competition law, public health, disease prevention and employment rights. Other relevant areas will also be considered as they arise.

Brexit Health Alliance and Cavendish Coalition

6. As an active member of the [Brexit Health Alliance](#)ⁱ and [Cavendish Coalition](#)ⁱⁱ we have ensured that any briefings produced or any submissions to the UK Government, House of Lords or Westminster Committees reflect the issues impacting on the health and care system in Wales. As you will see from the areas covered below, the Brexit Health Alliance and Cavendish Coalition continue to be active in ensuring that patients, and the healthcare sector that supports them, are in the strongest possible position once the UK leaves the EU.

Workforce

7. The Cavendish Coalition wrote to the [First Minister](#) in March 2017ⁱⁱⁱ to highlight the unique factors which relate to the social care and health workforce. According to the latest figures (November 2017), 1438 individuals directly employed by the NHS in Wales identified themselves as EU nationals (1.6% of the total) on the Electronic staff record.^{iv} This is a significant number of trained, qualified and dedicated staff who could not be replaced in the short term e.g. the percentage of medical and dental professionals working in the Welsh NHS is a higher percentage at 6.4%.

Number of directly employed staff identifying as EU National	September 2016	% of total directly employed workforce	November 2017	% of total directly employed workforce
Add Prof Scientific and Technic	49	1.65%	56	1.8%
Additional Clinical Services	162	0.91%	183	1.0%
Administrative and Clerical	95	0.54%	97	0.5%
Allied Health Professionals	110	1.80%	118	1.9%
Estates and Ancillary	104	1.21%	114	1.3%
Healthcare Scientists	31	1.52%	35	1.7%

Medical and Dental	410	5.84%	460	6.4%
Nursing and Midwifery Registered	352	1.38%	375	1.4%
NHS Wales	1,313	1.50%	1,438	1.6%

8. In relation to EU nurses, the Nursing and Midwifery Council data obtained by the Health Foundation^v under a FOI suggests that the number of new EU nurses registering to work in the UK dropped from 1,304 in July 2016 to 46 in April 2017. This is a fall of 96%. However, we are seeing some variation across the UK. Notwithstanding, the number of EU registered nurses working in NHS Wales has increased since the EU referendum. In NHS Wales EU nurses and midwives make up approximately 1.4% of the nursing workforce (375 out of 25,905). Since the referendum the number of EU registered nurses and midwives working in NHS Wales has increased from 262 in March 2016 to 375 in November 2017. This increase is likely to be as a result of NHS organisations having undertaken recruitment campaigns, including Train Work Live, within the EU since September 2015.
9. As previously highlighted, our priority in NHS Wales will be to ensure a continuing 'pipeline' of staff for the sector. The immigration system that is in place after the UK leaves the EU will need to ensure that, alongside our domestic workforce strategy, it supports the ability of our sector to provide the best care to our communities and people who use our services.
10. A total exit from the single market, as put forward by the UK Government, will leave the UK completely free to determine its own policies on immigration, with possibly much greater implications for the UK NHS. Under this scenario, it would be crucial to ensure that any future UK immigration rules recognise health and social care as a priority sector for overseas recruitment, from both within and outside the EU.
11. Further information around the priorities for the health and care workforce can be found in the Cavendish Coalition submission to the *House of Lords EU Internal Market Sub-Committee*^{vi} and the Coalition's submission to *British Future*, a cross-party inquiry, which examines the options for guaranteeing the status of EU nationals who are currently living in the UK.^{vii}

Professional qualifications

12. To ensure that EU27 and UK health professionals continue to benefit from mutually beneficial training and education opportunities and automatic recognition of their qualifications, we want continued recognition of professional qualifications of general practice nurses, medical doctors, dentists,

pharmacists and midwives trained in the EU27 and UK before Brexit day and for post-Brexit. In addition, it is important that the EU27 and UK competent authorities continue to use the alert mechanism through the Internal Market Information System to alert each other of health professionals who are prohibited or restricted to practice.

13. As highlighted in our previous evidence, healthcare professions, namely general practice nurses, dentists, doctors, midwives and pharmacists, have a special status under the Recognition of Professional Qualifications Directive 2005/36/EC which makes their mobility easy and safe. The legislation also enables students of those professions to benefit from educational systems other than that of their home country, making the expertise and knowledge in each country available to a much broader public. At the same time, 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.
14. 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.

Research and innovation

15. The UK received €8.8 billion of EU science funding between 2008 and 2013. UK organisations have received €3.2 billion since 2014 through Horizon 2020, €420 million of this coming from the health strand of the programme. The formation of strategic partnerships is vital to the progression of medical research. The UK's access to EU funding programmes is about more than just financial benefit; the collaborative opportunities that are afforded are crucial.
16. For Horizon 2020 and the forthcoming FP9,^{viii} the loss of UK partners in EU backed research projects would impact the expertise available for these projects, and therefore the outcomes. Conversely, even if the UK matches science funding from current EU sources, UK science loses out by having many collaborations made significantly more complex. The UK has one of the strongest science bases of all European countries. A positive cooperation model (e.g., based on mutual investment) should be established, so that the UK remains part of the European Research Area.”^{ix}
17. With this in mind, we welcome the UK government's intention to continue a strong collaboration with European partners in science and innovation, including seeking to agree a far-reaching science and innovation agreement with the EU that establishes a framework for future collaboration. For health

research in particular, this would mean securing that UK patients, the public and organisations can take part in pan-European research, innovation networks and clinical trials and that these can be supported through UK involvement in EU funding programmes such as Horizon 2020 (and its successors) and the EU Health programme. Also, that UK patients can benefit from the UK participation in European Reference Networks for rare and complex diseases post-Brexit.

Regulation of health technologies

18. Securing continuing cooperation and mutual recognition between the EU and UK regarding the authorisation, conformity assessments, testing and surveillance of medicines and medical technologies should be a priority outcome of the negotiations.
19. The UK is currently part of the EU's European Medicines Agency (EMA) network covering more than 500 million people. Divergence from the EU medicines regulatory system may result in the UK becoming a second-tier market after the US, EU and Japan, meaning that patients would gain access to new medicines later.^x
20. 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, but is not limited to, 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.
21. 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.^{xi} 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.^{xii}
22. For further information please see the Brexit Health Alliance response to the Health Select Committee inquiry on *Brexit – medicines, medical devices and substances of human origin*^{xiii} and Brexit Health Alliance written response to *Science and Technology Select Committee Inquiry on Brexit science and innovation summit*.^{xiv} The Alliance recommends that UK should seek to maintain continuity with the EU medicines, medical devices and IVD regulatory systems, including participation in EU regulatory processes and alignment of regulations in order to maintain high standards and to ensure patient safety. This could be achieved by urgently seeking to secure an overarching regulatory

cooperation agreement negotiated with the EU in the context of a broader UK/EU special relationship. We also call for a far-reaching science and innovation agreement with the EU that establishes a framework for future health research collaboration.

23. In addition, the Alliance has recently published a briefing, *“Brexit and the impact on patient access to medicines and medical technologies”*.^{xv} As part of the briefing the Brexit Health Alliance is calling for:

- No negative impact on patients. Future cooperation on medical devices and medicines to be prioritised in the negotiations, so that patients and the wider public are not negatively impacted from disruptions in the supply of medicines and other health technologies, or from a reduction in standards or safety.
- Patient safety and public health to be guaranteed post Brexit through aligning the UK as much as possible with the EU’s regulation of medicines and medical devices, and by close regulatory cooperation between the EU and UK, as proposed by the UK government.
- Pragmatic solutions allowing patients and the public to benefit from the UK’s participation in EU systems such as data sharing networks, pharmacovigilance and the new clinical trials infrastructures post Brexit.
- An implementation period beyond the two years of Article 50 negotiations (which ends in March 2019). This period should adequately reflect the time needed to ensure relevant customs, trade and regulatory procedures are in place.

Cross-border healthcare

24. The current arrangements work well for the mutual benefit of UK and EU citizens and healthcare systems. Under current EU law, if an EU citizen falls ill or has an accident in another EU/EEA Member State, they can use their European Health Insurance Card (EHIC) to get healthcare on the same basis as the local population. Also, the 1.2 million UK citizens residents in other EU Member States, and around three million EU citizens living in the UK, benefit from getting the same healthcare as the citizens of the country they live in under EU law. Member States reimburse each other subsequently, but the patient doesn’t have to get involved. Special arrangements also apply where patients travel to another Member State for the specific purpose of receiving treatment, for example, because it isn’t available in their home country. The system is also relatively simple for healthcare systems to administer, consequently a significant new administrative burden could emerge for hospitals in the event of the EHIC being discontinued.

25. Every year the UK recoups about £70 million from other EU countries and spends about £150 million on EHIC reimbursements, plus the cost (approximately £500 million a year) of reimbursing other Member States for healthcare provided to British pensioners (bearing in mind there are far more UK pensioners living in EU countries than vice versa). On the other hand, British pensioners living in the EU are using local healthcare systems which are often cheaper than the cost of equivalent care in the UK.
26. For further information around reciprocal healthcare please see the Brexit Health Alliance evidence to the *House of Lords EU Home Affairs Sub-Committee inquiry into Brexit: reciprocal healthcare* in November 2017.^{xvi} As we prepare to leave the EU, the Brexit Health Alliance calls for:
- Straightforward and appropriate access to reciprocal healthcare for both UK and EU patients, preferably by preserving current arrangements;
 - If this is not possible, provisions to be made domestically for the planning and funding of healthcare for UK nationals currently in the EU and vice-versa; and
 - No increased burden for both UK and EU health providers if they are required to handle new, more complex administrative and funding processes, should current arrangements be discontinued.

Public health

27. To ensure that public health for all EU and UK citizens is maintained post-Brexit it is key that there is strong coordination between the EU and UK to deal with pandemics, as well as other health threats, and there is the highest possible level of coordination on health promotion and disease prevention programmes.
28. 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.
29. As diseases know no borders, and as many of Europe's health and demographic challenges are shared, we call for a framework to be put in place between the EU and the UK post-Brexit to ensure that there is knowledge sharing to strengthen public health and to support the response to public health threats.

Conclusion

43. The Welsh NHS Confederation will continue to highlight the possible implications for the Welsh NHS of Britain exiting the European Union with the Welsh Government, Assembly Members and stakeholders but also to the UK Government as part of the Cavendish Coalition and the Brexit Health Alliance.

Appendix 1

Introduction

1. The Welsh NHS Confederation, which represents the seven Health Boards and three NHS Trusts in Wales, welcomes the opportunity to provide information to the External Affairs and Additional Legislation Committee inquiry into resilience and preparedness: The Welsh Government's administrative and financial response to Brexit.
2. The implications of Brexit remain unclear, but it is likely that the impact will be felt across the NHS. More specifically, Brexit could have implications for the commissioning, provision and development of healthcare interventions across the UK given the extent to which EU policy and legislation impact on all aspects of the NHS.
3. The Welsh NHS Confederation, on behalf of our members, is highlighting the possible implications of Brexit on NHS Wales with the Welsh Government, Assembly Members and our stakeholders. In addition, as a member of the Cavendish Coalition and the Brexit Health Alliance, we are ensuring that the impact for Wales is made clear at a UK level by highlighting the likely effects on Welsh policy and legislation.

Summary

4. The Brexit negotiations have only recently started so it is difficult to be specific on the measures which should be put in place to mitigate risks and to take advantage of opportunities. That said, the implications of a UK withdrawal from the EU are anticipated to affect all parts of the health care system.
 - a. Many aspects of UK health and social care services have been influenced by European Union policies and legislation. Depending on the settlement, the UK's exit from the EU could have a profound impact on the UK economy and the delivery of public services.
 - b. From a NHS perspective, possible implications on workforce, research and innovation, and health technology regulation are priority issues which must be considered carefully during the withdrawal negotiations. Another key area is infrastructure, including the road network, because this can impact on ambulance response times and the transportation of vital medicines across borders.
 - c. On workforce, while the UK Government has now given some reassurance that EU nationals can remain in the UK post-Brexit, our priority will be to

ensure a continuing 'pipeline' of staff for the sector, including recognising health and social care as a priority sector for overseas recruitment. We continue to ask the UK Government to provide clarification that EU professionals who are already working for the NHS across the UK, or who will be recruited during the leave negotiations, will be allowed to remain after Brexit.

- d. On research and innovation, our aim is that NHS organisations across the UK will be able to continue to participate in EU collaborative programmes and lead and contribute positively to European Reference Networks post-Brexit.
- e. On health technology regulation, our priority is that NHS patients will continue to benefit from early access to the wide range of innovative health technologies available on the EU market and ensure that they do not miss out on the opportunities offered by participation in EU clinical trials.
- f. Alongside these priorities, we have identified public health, employment law and cross-border healthcare as other areas in which risks or opportunities emerging from Brexit should also be considered.

Welsh Government

- 5. With negotiations ongoing, we appreciate the difficulties that the Welsh Government faces. Across devolved areas that the Welsh Government has legislative competence, the Brexit negotiations could have a significant impact on thousands of policies, regulations, directives and legislation, including areas relating to health and care. The NHS in Wales continues to liaise with the Welsh Government to raise awareness and provide feedback on the key areas highlighted below.
- 6. In relation to structured engagement with the NHS, there is a standing verbal item on the Welsh Partnership Forum^{xvii} relating to Brexit. This is a quarterly opportunity for colleagues to share information and raise issues relating to Brexit.

Budget

- 7. The annual funding of the NHS depends on the performance of the economy. It is a concern therefore that 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.^{xviii} 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 to join the

European Economic Area. If this is not the case, the shortfall will potentially be as high as £28 billion – which is £540 million a week. The repercussions will be felt by NHS Wales.

Workforce

8. Across the UK, the NHS is heavily reliant on EU workers. While the UK Government has given some reassurance that EU nationals can remain in the UK, we believe the priority must be to ensure that the UK can continue to recruit and retain much needed health and social care staff from the EU and beyond, whilst increasing the domestic supply.
9. In July 2017, 1,388 individuals directly employed by the NHS in Wales identified themselves as EU Nationals (1.55% of the total) on the Electronic staff record. As the table below shows there has been a 6% increase in the number of employees identifying as EU nationals since July 2016, but it is not it is too soon to tell if this represents an identifiable trend. It is also important to note that around 35,000 staff have not recorded any nationality on the staff record.

Number of directly employed staff identifying as EU National	September 2016	% of total directly employed workforce	July 2017	% of total directly employed workforce
Add Prof Scientific and Technic	49	1.65%	54	1.77%
Additional Clinical Services	162	0.91%	189	1.04%
Administrative and Clerical	95	0.54%	95	0.51%
Allied Health Professionals	110	1.80%	120	1.96%
Estates and Ancillary	104	1.21%	112	1.30%
Healthcare Scientists	31	1.52%	30	1.47%
Medical and Dental	410	5.84%	435	5.99%
Nursing and Midwifery Registered	352	1.38%	353	1.38%
NHS Wales	1,313	1.50%	1,388	1.55%

10. While the number EU citizens within the whole Welsh NHS workforce are relatively small, there are some key points to note:
- a. The highest concentration of EU staff appears to be in medical and dental workforce accounting for around 6%;
 - b. There is a differential distribution of staff across Wales with higher concentration of EU nationals working in health boards with the greatest recruitment challenges (i.e. Hywel Dda University Health Board and Betsi Cadwaladr University Health Board);
 - c. The current uncertainty around the EU negotiations may lead to staff looking for opportunities outside the UK and for potential applicants to be deterred from applying;
 - d. Incidents of harassment of foreign workers and cases of EU nationals feeling that they are no longer welcome in the UK may have an impact on EU/EEA workers' willingness to remain in the UK, even if permanent freedom to remain is granted. One of the present impacts of the EU Referendum has been the sharp rise in cases of 'hate incidents' and intolerance towards foreign citizens, some of which have been directed against NHS employees. A number of Health Boards in Wales have expressed their views publicly about supporting their workforce and that hate crime will not be tolerated.
11. While we welcome the recent announcement that more healthcare professionals will be trained domestically, workforce planning is not an exact science and it is extremely difficult to predict accurately the number of professionals that will be needed in the future to ensure the smooth and safe operation of the health and care system. Shortages in specific areas can take 2-3 years to develop, but may need 10-15 years for the trained workforce to adapt, by which time other solutions have usually been found and different workforce shortages may have emerged. In addition, many healthcare systems across the world compete for healthcare specialists and the UK is not immune from home grown professionals leaving the NHS to work overseas. It is to be expected, therefore, that our sector will need to continue to recruit overseas trained professionals, including from within the European single market, to operate smoothly and to offer safe and high-quality services to patients in the future.
12. We are disappointed that the UK Government has stated that it is their position to leave the EU single market and custom union without setting out future immigration rules. The freedom of movement provisions of the EU single market makes it possible for healthcare professionals qualified in other parts of the EEA to access the UK employment market without having to obtain visas and work permits, unlike citizens from non-EU countries. This makes it quicker and easier for the NHS to recruit staff from the EU, especially into shortage areas and specialties. The UK benefits enormously from the single market in

this respect, as we are a net importer of healthcare professionals qualified in other parts of the EU.

13. In addition, the EU legislation on mutual recognition of qualifications means that currently many EU healthcare professionals are “fast-tracked” for registration with the General Medical Council, the Nursing Midwifery Council or other relevant regulatory bodies. EU rules mean that the process for professional registration and the right to practise legally in the UK is different to non-EEA trained practitioners; for example, it does not systematically require pre-registration competency and language testing by the regulator. These arrangements are reciprocal so that UK-qualified practitioners can also practise relatively easily elsewhere in the EU, although the outbound flow is less.
14. Our priority in NHS Wales will be to ensure a continuing ‘pipeline’ of staff for the sector. The immigration system that is in place after the UK leaves the EU will need to ensure that, alongside our domestic workforce strategy, it supports the ability of our sector to provide the best care to our communities and people who use our services.
15. A total exit from the single market, as put forward by the UK Government, will leave the UK completely free to determine its own policies on immigration, with possibly much greater implications for the UK NHS. Under this scenario, it would be crucial to ensure that any future UK immigration rules recognise health and social care as a priority sector for overseas recruitment, from both within and outside the EU.

Employment law

16. A substantial proportion of UK employment law originates from the EU and provides important protections for nurses, social care and health staff; in particular, rules on health and safety at work, information and consultation on collective redundancies and safeguarding employment rights in the event of transfers of undertakings (TUPE).
17. The UK Government has already stated its intention to protect workers’ rights after Brexit and, as the largest employer in the country, we very much welcome this. 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.^{xixxx}

Research and innovation

18. Clinical research and innovation are key components of NHS activity across the UK and the NHS has a long tradition of EU collaborative research. Subsequent EU Research and Innovation funding programmes have acted as catalysts for this collaborative work, filling gaps in the research pipeline, and allowing researchers across Europe to gather forces to find responses to common challenges, both at clinical and operational levels, that confront health systems in Europe.
19. European programmes have, for example, supported research into health economics and the resilience of healthcare systems, for the public good. At the bottom line, the NHS across the UK wants to access research which brings affordable innovation and, most importantly, benefits to NHS patients. This is not possible, at least to the same extent, through participation in collaborative research with other regions of the world, such as the USA, where commercial interests are often the key driver of research.
20. EU research grants have also been crucial for the Welsh NHS' ability to attract and retain some of the most renowned clinicians in the world, who often decide to work for the NHS due to its excellent reputation in leading EU collaborative medical research initiatives, including through the EU research programme Horizon 2020.
21. Collaboration at EU level has helped the NHS across the UK to develop new treatments, adopt innovation more quickly, and improve the quality of healthcare it provides. We would like to ensure that the NHS can continue to participate in EU collaborative research programmes post-Brexit. It is important that Brexit does not impact on cross-European partnerships, exchange of good practice and mutual training opportunities, for example staff or student exchange, sharing and learning from best practices and successful policies.

Regulation of health technologies

22. The integrated nature of supply chains for medicines across Europe and the shared regulatory framework, mean that Brexit may have a negative impact on the supply, regulation and safety monitoring of medicines for patients in all EU 27 countries. Continued co-operation and alignment between the EU and the UK on the regulation of medicines is the best outcome for patients across Europe.
23. The EU has competence to regulate health technologies, such as pharmaceuticals and medical devices, but also products of human origin such

as blood, tissues and cells. This is because these products circulate in the EU single market and therefore a set of common standards and rules are needed to ensure their safety and quality.

24. The pharmaceutical industry is one of the EU's most important and fastest-growing industries, investing an estimated €35 billion in Research and Development (R&D) in Europe and directly employing around 745,000 people^{xxi}. The UK is a key player in European pharmaceuticals, constituting 10% of the EU's total production and contributing approximately 20% of the EU's total R&D. Between January and October 2016, €11 billion of EU pharmaceutical imports originated from the UK providing medicines to patients across Europe while EU pharmaceutical exports to the UK totalled €17 billion. In Wales, the life sciences sector employs around 11,000 people^{xxii} based at more than 350 companies and has a turnover of circa £2 billion per year. These include companies in the ground-breaking fields of medical technology – biopharmaceuticals, regenerative medicine, diagnostics, e-health and biotechnology. Recognising this inherent strength and potential, the Welsh Government has established initiatives such as the Life Sciences Hub^{xxiii} and Life Sciences Research Network Wales^{xxiv} to ensure ongoing development of the sector in Wales, which is expected to deliver significant (over £1 billion) economic impact by 2022.
25. Having a single EU regulatory framework has allowed new health technologies to be brought more quickly to the market for the benefit of patients. For example, pharmaceutical companies can make new medicines available everywhere in the EU through the single centralised marketing authorisation procedure provided by the European Medicine Agency, instead of having to apply for authorisation in each individual member state. Maintaining access to this centralised authorisation procedure is the main priority for the UK pharmaceutical/life sciences industry.
26. A single EU system has also allowed a higher level of patient safety and public health protection to be achieved through a close-knit network of competent authorities in member states and the European Medicines Agency, collaborating, exchanging information, and bringing their expertise to the table in a way that adds value, whilst avoiding duplication of effort.
27. The EU regulatory framework spans the full process needed to bring new health technologies to the market, starting from the clinical research phase. It is for this reason that the authorisation and conduct of clinical trials are also regulated by the EU. This is particularly relevant from an NHS perspective, given the vast number of clinical studies conducted by the NHS.
28. The EU and the UK should agree to focus on solving the issues around medicines as early as possible during the negotiations. Appropriate transitional arrangements need to be put in place to ensure that European patients can continue to access their medicines without disruption. In the event that the UK continues to have full access to the single market, the EU medical

regulatory framework will continue to apply and any change would be minimal. At the other extreme, an exit from the single market would leave the UK free to determine its own medical regulation, with possibly much greater implications for the NHS. Under such a 'hard Brexit' scenario, it will be essential to ensure that our patients continue to benefit from early access to the wide range of innovative health technologies which are available on the EU market.

Cross-border healthcare

29. As the right to receive healthcare in another EU country is regulated by the EU, leaving the EU may have consequences for NHS patients in terms of their ability to access cross-border healthcare. This could mean that, in the future, British citizens on holiday in Europe might no longer be able to use the European Health Insurance Card, which allows them to receive emergency or immediately necessary healthcare on the same terms as the residents of that country.
30. EU law also allows Britons who are abroad for a longer period of time – such as pensioners living abroad, or UK citizens who work in another EU country – to be entitled to receive healthcare in the country where they live on the same basis as the local population. It should be stressed that these rules are reciprocal and therefore uncertainty also exists on whether EU citizens will be entitled to receive healthcare in the UK following Brexit.
31. If the UK were to leave the EU single market, these systems would in principle no longer apply, unless bilateral agreements were negotiated. Consideration should be given by negotiators to possible implications for patients and how to ensure that a fair alternative system is put in place, either with the EU as a whole, or with those EU countries, such as Spain, which have high numbers of UK nationals living there.

Public health

32. A significant proportion of the domestic legislation in public health and consumer protection originates from the EU, as the EU has legislative competence in these areas. If EU rules were no longer enforceable in the UK after we leave the EU, we would recommend ensuring the same, or higher, level of safety is guaranteed through domestic standards and regulations thereafter.
33. 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 sale and marketing of tobacco products.

34. The issue of smoking may also be affected, as the EU has a significant role in ensuring a cross-border approach to anti-smoking measures. The Tobacco Products Directive, having survived a number of High Court challenges, is now in the process of implementation.
35. Furthermore, the EU has several mechanisms to respond to and combat major cross-border health threats, including communicable disease outbreaks. This has allowed considerable improvement in the degree of information sharing and response co-ordination on an EU level in cases such as Ebola and swine flu pandemics. Continued access to these EU coordination mechanisms and networks, such as the European Centre for Disease Prevention and Control (ECDC), should be sought during the negotiations, as it would be more difficult for the UK to tackle in isolation what are inherently transnational threats.

Food Regulation

36. While not directly linked to the NHS, 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.
37. With the EU likely to continue to be an important export market for the UK after Brexit is complete, exporting companies will look to continue to maintain their manufacturing standards at the EU approved level. Food manufactured for the UK market and food products coming into the UK market might not have to abide by the rigours EU standards though, if the regulation is not carried across into UK law. Consumers could therefore start to see a decline in the standard of their weekly food shop.
38. Finally, 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 and not going far enough to help consumers make healthy choices.

Cavendish Coalition and Brexit Health Alliance

39. The Welsh NHS Confederation has been highlighting the possible implications for the Welsh NHS of Britain exiting the EU with the Welsh Government, but also to the UK Government through being a proactive member of the Cavendish Coalition and the Brexit Health Alliance.

40. The Cavendish Coalition is made up of 36 health and social care organisations^{xxv} united in their commitment to provide the best care to their communities, patients and residents. The coalition recognises that the talented and diverse group of people we all employ and represent are central to the success of that commitment, and that these individuals from the UK, Europe and across the world make a vital contribution to delivering care to the UK's population. We are committed to working together to ensure a continued domestic and international pipeline of high calibre professionals and trainees in health and social care in the future.

41. The Brexit Health Alliance^{xxvi} brings together the NHS, medical research, industry, patients and public health organisations. The Alliance seeks to make sure that issues such as healthcare research, access to technologies and treatment of patients are given the prominence and attention they deserve during the Brexit negotiations, and will argue that it is in both Europe and the UK's interests to maintain co-operation in research and in handling public health issues. It calls on the UK government to make sure there is a commitment to medical research and providing alternative funding, and that UK citizens' right to receive healthcare in EU countries is preserved. The areas that the Alliance focuses on includes:

- Supporting maximum levels of research and innovation collaboration;
- Ensuring regulatory alignment for the benefit of patients and the public's health;
- Preserving reciprocal healthcare arrangements;
- Ensuring robust coordination mechanisms on public health and well-being; and
- Securing a strong funding commitment to the health sector and the public's health.

How to mitigate risks and take advantage of opportunities

42. At this stage of the negotiation process, we have the following main recommendations:

- a. If the UK were no longer to be part of the EU Customs Union and could therefore embark in the negotiation of trade deals with different economic regions across the globe, particular care would need to be paid to respective public health policies and standards applied, as other trade blocks will be pushing for mutual recognition of their standards, which could be set at a lower level of safety compared to the EU's. International free trade deals are very complex and take time to negotiate. While we recognise the UK Government may wish to agree deals quickly, for each trade pact it will also be crucial to ensure a high level of public health protection by conducting an in-depth analysis of the standards applicable to each individual economic sector and ensuring that, whenever deemed necessary, reservations are agreed with our counterpart.
- b. Given the complexity of negotiations and the variety of policy areas that will be covered, we strongly recommend that organisations with specific expertise and knowledge in these respective areas are consulted by the UK Government and Welsh Government when drawing up the detailed approach to particular issues. This will allow a well-informed negotiating position to be shaped and avoid the risk that some of the implications could be overlooked.
- c. To reduce uncertainty in the run up and during the negotiations, whenever possible clarification should be provided by the UK Government. For example, the clarification given by the Treasury Office on EU funding programmes has been extremely helpful in reassuring our EU funding partners that it is safe to involve UK organisations in new funding bids. Similar clarification in other areas will be very welcome.

Conclusion

44. The Welsh NHS Confederation will continue to highlight the possible implications for the Welsh NHS of Britain exiting the European Union with the Welsh Government and Assembly Members but also to the UK Government as part of the Cavendish Coalition and the Brexit Health Alliance.

ⁱ <http://www.nhsconfed.org/BrexitHealthAlliance>

ⁱⁱ <http://www.nhsemployers.org/your-workforce/need-to-know/brexit-and-the-nhs-eu-workforce/the-cavendish-coalition>

ⁱⁱⁱ <http://www.nhsemployers.org/-/media/Employers/Documents/Cavendish-Coalition/Cavendish-Coalition-letter-to-First-Minister-of-Wales-29-03-17.pdf?la=en&hash=75A1F2A509CAE30F9F61B5DB740CE3F04F9B9C52>

^{iv} This is the number recorded on the Electronic Staff Record as at November 2017. 34,795 individuals nationality are unknown/ blank therefore the number could be higher.

^v <http://www.health.org.uk/news/new-data-show-96-drop-nurses-eu-july-last-year>

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- vi <http://www.nhsemployers.org/-/media/Employers/Documents/Cavendish-Coalition/House-of-Lords-Inquiry---EU-Internal-Market-Sub-Committee-FINAL-091116.pdf?la=en&hash=9043EFEEF7C91D1326D95C450EA6EF324FD22C6>
- vii <http://www.nhsemployers.org/-/media/Employers/Documents/Cavendish-Coalition/British-Future--submission-September-2016.pdf?la=en&hash=10094FE09DB13B35D9891828CEF3B3722BD2FFC1>
- viii Horizon 2020 is the current EU Programme for Research and Innovation which runs till 2020. Framework Programme 9 will be the successor programme to Horizon 2020
- ix <http://ec.europa.eu/research/conferences/2017/shaping-our-future/index.cfm?pg=home>
- x http://www.amchameu.eu/system/files/position_papers/amcham_eu_position_paper_-_brexit_and_the_future_eu-uk_relationship.pdf
- xi Technopolis, [The impact of collaboration: the value of UK medical research to EU science and health](#)
- xii [Brexit EFPIA survey results:](#)
- xiii <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/brexit-the-regulation-of-medicines-medical-devices-and-substances-of-human-origin/written/72019.html>
- xiv <https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2017/brexit-and-science-summit-17-19/>
- xv <http://www.nhsconfed.org/resources/2018/01/brexit-impact-patient-medecines-medical-technologies>
- xvi <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/eu-home-affairs-subcommittee/brexit-reciprocal-healthcare/written/74299.html>
- xvii The WPF is a tripartite forum with representatives from the Welsh Government, NHS Employers and Trade Unions.
- xviii Health Foundation, July 2016, NHS Finances Outside the EU
- xix Health and Safety Executive (2002) Second Evaluation of the Manual Handling Regulations (1992) and Guidance. HSE Books: Sudbury
- xx Health and Safety Executive (2003) Evaluation of the implementation of the use of work equipment directive and the amending directive to the use of work equipment in the UK. HSE Books: Sudbury
- xxi European Federation of Pharmaceutical Industries and Associations (2017), 'The Pharmaceutical Industry in Figures', p.4.
- xxii <http://gov.wales/topics/businessandeconomy/sectors/life-sciences-sector/?lang=en>
- xxiii <https://www.lifescienceshubwales.com/>
- xxiv <http://www.lsrnw.ac.uk/>
- xxv Members of the Cavendish Coalition: Association of Dental Groups, Association of Directors of Adult Social Services, Association of Independent Healthcare Organisations, Academy of Medical Royal Colleges, Association for Real Change, Association of UK University Hospitals, British Dental Association, British Medical Association, Care England, Care Forum Wales, Care and Support Alliance, Chartered Society of Physiotherapy, Council of Deans of Health, Mental Health Network, National Association of Primary Care, National Care Association, National Care Forum, Vic Rayner, New NHS Alliance, NHS Clinical Commissioners, NHS Confederation, NHS Employers, NHS European Office, NHS Partners Network, NHS Providers, Northern Ireland Confederation for Health and Social Care, Registered Nursing Home Association, Royal College of Nursing, Shelford Group, Skills for Care, Skills for Health, The Company's Chemists' Association, The Royal College of Midwives, The Welsh NHS Confederation, Vanessa Young, Director, UNISON, United Kingdom Homecare Association and Voluntary Organisations Disability Group.
- xxvi Brexit Health Alliance founding members: Academy of Medical Royal Colleges, Association of Medical Research Charities, Association of British Healthcare Industries, The Association of the British Pharmaceutical Industry, Association of UK University Hospitals, Bio Industry Association, Faculty of Public Health, Medical Schools Council, National Voices, NHS Confederation (including Mental Health Network, NHS Clinical Commissioners, NHS Employers, NHS Partners Network), NHS Providers, Northern Ireland Confederation, Richmond Group of Charities, Scottish NHS Chief Executive Group and Welsh NHS Confederation