

31 August 2018

David Rees AM
Chair of the External Affairs and Additional Legislation Committee
Ty Hywel
National Assembly for Wales
Cardiff Bay
CF99 1NA

Dear David

RE: Follow-up inquiry into how the Welsh Government is preparing for Brexit – health and medicines

Thank you for your letter and invitation to respond to your Committee's follow-up inquiry into how the Welsh Government is preparing for Brexit. This is a vitally important issue and we are very pleased that the Committee is looking at it in detail. We outline our response to the specific areas of interest to you below.

The preparedness of the healthcare and medicines sector in Wales for the UK's departure from the EU

On 10th July the Royal College of Nursing Wales held a seminar to discuss the implications of Brexit on the health and social care sectors. This was attended by a number of professional bodies and other trade unions and provided an excellent opportunity to discuss in detail the issues and concerns for the sector. As such, whilst as the Royal College of Nursing we do not represent the entire healthcare and medicines sector and cannot speak for it, we are able to provide an overview of the discussions which we have had with colleagues from across the sector. We are also attaching the follow-up report which we produced following the event on 10th July and this can be found attached.

A central theme to all areas of concern is uncertainty, and the fact that the full implications and risks posed by Brexit are, to a certain extent, an unknown quantity. This makes it difficult to predict or plan for the future. Until the full implications of Britain leaving the European Union are fully understood, there will be uncertainty around

issues such as workforce supply, workers' rights terms and conditions, research funding and collaboration and reciprocal healthcare arrangements. It is essential therefore that the Welsh Government commissions research and engages with experts in order to help mitigate this uncertainty, and enabling an informed assessment of possible risks.

Furthermore, throughout this period of uncertainty it is vital that quality of care is maintained and that nurses and health care workers from the EU who are working across the UK continue to feel valued. We know that there has been a decline across the UK in the number of nurses from the European Economic Area (EEA) joining the UK workforce, whilst at the same time there has also been a significant number of staff from the EEA who have left the Nursing & Midwifery Council (NMC) Register in order to return to their home country.

How the Welsh Government is leading efforts to prepare the Welsh healthcare and medicines sector for the UK's departure from the EU, including contingency planning for a 'no deal'

The Royal College of Nursing Wales have held a number of meetings with Welsh Government officials regarding Brexit which have provided opportunities to be updated on the efforts of Welsh Government in preparing for Brexit. We are reassured that work is being undertaken in many of the key areas of health and social care, and that a certain amount of contingency planning for a possible 'no deal' scenario is being conducted. We remain concerned however that this work is relatively early on in its development and that sufficient time to work through all of the detail may be running out.

The UK Government has recently published a number of technical papers setting out information to help prepare for the event of a 'no deal', a number of which are related to health and medicine. We hope the Welsh Government is working closely with the UK Government on the detail of this guidance notes, particularly in relation to vital areas such as the supply of medicines.

With only a matter of weeks left before the UK Government is expected to have a deal on the table, there are a number of significant unknowns and areas of uncertainty which must be clarified. For instance, there were a number of questions which were raised during discussions at our event in July and included in our final report, and these are directed at both Welsh Government and UK Government. These questions are:

1. What plans does the UK Government have to update the EU/EEA agreement to ensure that nurses from the EEA looking to revalidate post-Brexit are able to do so?

Currently all nurses who are on the Nursing and Midwifery Council register have to re-register every three years through a process known as revalidation. Post Brexit if there is no clear EU/EEA agreement in place then potentially those nurses who are currently on the register and looking to revalidate may not be able to do so under the Nursing and Midwifery Order 2001.

2. Is the Welsh Government planning new guidance for the NHS on data sharing and access to the relevant international electronic systems in relation to public health protection?

Central to the control of infectious diseases is data protection and data sharing. Without rules underpinning the EU system of data sharing, it is unclear how necessary data will be shared and accessed. It is thought that this could even lead to reintroducing a system of quarantine in order to control the spread of disease. The centre for disease control is based in Stockholm but, under data protection legislation, they would not be able to share their data legally with the UK once is outside of the EU. The UK must retain the ability to contribute to, and compare, surveillance data to ensure health systems can deal with cross-border health threats e.g. infectious diseases and the threat of antimicrobial resistance and have robust protection arrangements.

3. Has the Welsh Government completed an assessment of risk to the continued and uninterrupted supply of medicines, medical radioisotopes, vaccines, equipment, devices and other supplies?

After Brexit the UK may find it more difficult to access medicines and medical devices if we choose to create new frameworks which are different from EU regulations. This may cause delays in new drugs being made available for patients, with the potential to cause significant harm. Ensuring timely access to medicine is critical for all patients in the UK. The UK Government should also agree mutual recognition of the CE mark between the UK and the EU. The CE mark indicates compliance with EU health and safety standards and allows for free movement of products.

Similarly, there are serious concerns within the health arena in relation to radioisotopes and their movement (currently governed by Euratom). Radioisotopes are highly valuable in medicine, and are widely used in the diagnosis and treatment of disease. Not surprisingly, there are tight regulations surrounding the transportation and importation of radioactive materials. Radioisotopes also have a very short half-life and rapid decay meaning there cannot be any delays in the products reaching patients if they are to be effective. Plans need to be put in place now to ensure that the supply of these resources is not interrupted.

4. What are the arrangements for implementing the Falsified Medicines Directive and what will happen after March 2019?

the Falsified Medicines Directive which is due to be rolled out across EU member states from 9 February 2019. The Directive aims to address the significant problems and threats caused by fake medicines. Under the Directive, all new packs of prescription medicines put on the market from February 2019 will need to be booked onto a European Medicines Verification System (EMVS) and will have to have two safety features: a unique identifier and an anti-tampering device. Health

professionals will be required to scan medicines prior to administering them and that would then record them as decommissioned from EMVS. IT systems will have to register with SecureMed which is setting up 13 national hubs, and the equipment to scan medicines will need to be available in all GP practices, pharmacies and hospitals.

There are clearly significant logistical and financial implications for complying with this Directive, and there is a complete lack of clarity over what work is currently underway to prepare for being compliant, or what alternative measures will be put in place after Brexit to ensure the UK is still safeguarded against false medicines.

5. What scenario-planning is the Welsh Government doing in case of a 'no deal'?

Although this is a question which is being posed to stakeholders as part of your Committee's inquiry, this is an area which we would also value more information, and we would be grateful for any detail the Committee is able to gather and share with stakeholders in this area. Through our meetings with Welsh Government officials we know that some work is being undertaken by Welsh Government in relation to a 'no deal' and this is certainly very welcome. However, what this work entails, or the Welsh Government's official line in terms of what a 'no deal' would mean for Wales is not clear. Considering the increasing amount of consensus that a 'no deal' is a distinct possibility, more information should be in the public domain about what scenario-planning the Welsh Government is conducting.

In addition to the above questions, our report also makes a number of recommendations for the Welsh and UK Governments:

1. The Welsh Government needs to prepare a strategy for international and EU recruitment. The needs of the health and social care sector in Wales need to be a factor in any future UK immigration framework.
2. Health and Social Care professions in Wales value highly the ability of the Welsh Government to make and implement policy and legislation for Wales to be responsive to the country's needs. Our hope is that the Welsh Government and the UK Government will work together over the repatriation of legal powers from the EU in a manner that robustly protects the devolution settlement for Wales.
3. The Welsh Government must engage as widely as possible with relevant experts and agencies within the health sectors in order to inform future policies or legislative changes.
4. The Welsh and UK Government should work closely to ensure that statutory employee protections continue.
5. The Welsh Government needs to prepare a strategy around continued access and promotion of participation in international and EU research collaboration specifically considering its impact on improving patient care and workforce retention. The UK Government also need to consider this matter at UK level.

6. The Welsh and UK Governments should ensure a regulatory system is in place, without break of continuity, to ensure the continued mutual recognition of professional qualifications
7. The Welsh and UK Government should ensure that clear arrangements are in place protect the healthcare rights of Welsh citizens living in Europe and EU citizens living in Wales. Furthermore these arrangements need to be clearly communicated to the communities concerned and to health and social care service providers.
8. The Welsh and UK Government should ensure that arrangements for the continued surveillance of infectious diseases, sharing of relevant data and cross-border health control are in place. Moreover these arrangements need to be communicated clearly to the relevant health and social care organisations and other public bodies both accountable and responsible for action

As with the other areas of uncertainty, the Royal College of Nursing and other organisations across the profession would welcome any work that the Committee is able to carry out which might encourage or support the Welsh Government in progressing these recommendations and in engaging with stakeholders.

We would be very happy to provide further information or to discuss with you in more detail if that would be helpful.

Kind regards

Yours sincerely

A handwritten signature in black ink, appearing to read 'Tina Donnelly', written in a cursive style.

**TINA DONNELLY, CBE, TD, DL, FRCN, CCMi
DIRECTOR, RCN WALES**