Preparing for Brexit -

Report on the preparedness of the healthcare and medicines sector in Wales

November 2018

Introduction

With less than five months until the UK leaves the European Union, it is an apposite time to explore in more detail the preparedness of various sectors in Wales. This second report, in a series of three, looks at the implications of Brexit for healthcare and medicines in Wales and should be read as a companion to our previous work how.the.welsh.Government is preparing for Brexit, which was published in January 2018.

- 1. In our January 2018 report, we made a total of seven recommendations, of which recommendations one, three and four were relevant to the healthcare sector in Wales. During the course of 2018, a clearer picture has emerged in terms of the eventual outcome of negotiations and the potential shape of a final Brexit deal. Whilst some uncertainty remains, the UK Government has made a number of commitments and proposals in terms of how it would like to see EU-UK relations operate after Brexit. They have included:
 - publication of a negotiated text on a final Withdrawal Agreement between the UK and the EU:
 - publication of the UK Government's White Paper on the future relationship between the United Kingdom and the European Union;



- publication of the UK Government's "no deal" notices.
- 2. On 14 November 2018, the final negotiated text of a draft Withdrawal Agreement between the UK and the EU was published. This agreement deals with the so-called "divorce issues" arising from the UK's exit from the European Union. Our report is being published to the backdrop of ongoing political developments relating to the Withdrawal Agreement. However, we note that it faces a number of political hurdles before various preparedness issues, particularly a "no deal" scenario, can be ruled out entirely. The timescales for these political hurdles are likely to extend well into 2019, we therefore consider scrutiny of the Welsh Government's preparedness work to be important in the meantime.
- **3.** In summer 2018, we decided to write to stakeholders for a progress update in relation to:
 - the preparedness of the healthcare and medicines sector in Wales for the UK's departure from the EU;
 - how the Welsh Government is leading efforts to prepare the Welsh healthcare and medicines sector for the UK's departure from EU, including contingency planning for a "no deal"; and
 - any other issues stakeholder might wish to bring to the attention of the External Affairs Committee.
- **4.** We received responses from:
 - the Association of the British Pharmaceutical Industry (ABPI);
 - the Royal College of Nursing Wales (RCN Wales);
 - the Welsh NHS Confederation (the NHS Confederation); and
 - the British Medical Association Cymru Wales (BMA Cymru).
- **5.** To explore some of the themes from the written responses in more detail, we held oral evidence sessions on the <u>8 October 2018</u> with Dr Richard Greville, of the Association of the British Pharmaceutical Industry; Dr Stephen Monaghan of BMA Cymru Wales; Lisa Turnbull, of the Royal College of Nursing Wales; and Vanessa Young, of the Welsh NHS Confederation.
- **6.** We wrote to Carwyn Jones AM, First Minister of Wales, to request an update in relation to the recommendations of our report "How is the Welsh Government

preparing for Brexit?" and received a response on 10 September 2018 and a further response on 2 November 2018.

- **7.** We questioned the First Minister in more detail during an oral evidence session on **5 November 2018**.
- **8.** This report summarises some of the key themes of the evidence received and sets out our view and recommendations.

1. Preparedness of the healthcare and medicines sector - key themes and findings

1. 1. Background

9. In our January 2018 report, we outlined a number of issues relating to the potential impact of Brexit on the healthcare and medicines sector in Wales which included the need for a stronger steer from the Welsh Government about how they should be preparing.¹

1. 2. General planning and communication

10. A central theme to the written evidence received was that of continuing uncertainty and the fact that there are still a number of "unknowns" about the UK's exit from the European Union.² The Royal College of Nursing Wales (RCN Wales) told us that:

"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."

11. Vanessa Young, Director of the Welsh NHS Confederation echoed this during oral evidence describing "a very uncertain environment". Ms Young told us:

"It's just really important, I think, that we have really regular and consistent communication across the whole sector. One of the things the Welsh NHS Confederation has agreed to do with all of the people

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¹ National Assembly for Wales, External Affairs and Additional Legislation Committee, "<u>How is the Welsh Covernment preparing for Brexit?</u>" – January 2018

² Written evidence, Royal College of Nursing Wales; Welsh NHS Confederation; BMA Cymru Wales

³ Written evidence, RCN Wales

who were present at our round table, who were representing all parts of the sector, is to pull together a frequently asked questions briefing and we've gone out to everybody and said, 'What are the things that are concerning you? What are the questions that you want answering?', and then we're going to work with Welsh Government colleagues to try and answer those questions consistently and in one place. But, necessarily, over the next few months, we'll continue to see uncertainty around Brexit. We'll have to keep updating that and recognise that it's a dynamic process and the way in which we communicate will continue to need to be dynamic."⁴

- 12. In written evidence the NHS Confederation told us that in 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 the NHS Executive Board and Wales NHS Partnership". The NHS Confederation also stated it has agreed to be "the main point of contact for coordinating specific Brexit actions across NHS organisations".
- **13.** RCN Wales emphasised the need for greater communication from the Welsh Government to inform planning.⁷ Lisa Turnbull told us:

"What we would say is that we would welcome much stronger communication. For example, we know that there is a portal for businesses to look at and provide them with guidance and support. There is a useful discussion hub on Public Health Wales, but that seems to relate specifically, as you'd expect, to public health questions and policy questions, whereas what we would be looking for, perhaps, is a more central depository, whether that's on HOWIS or on the Welsh Government site, actually providing that clear planning guidance."

14. Lisa Turnbull of RCN Wales added that:

"I think strategic planning has begun, which we welcome very much, but I think that needs to be communicated further and faster, and people need to communicate, as I say, at all levels, including, now, they

⁴ Record of Proceedings, <u>paragraph 239</u> - 8 October 2018

⁵ Written evidence, Welsh NHS Confederation

⁶ Ibid.

⁷ Record of Proceedings, <u>paragraph 223</u> - 8 October 2018

⁸ Record of Proceedings, paragraph 224 - 8 October 2018

need to think about communicating to the wider workforce and, indeed, to the general public that this work is ongoing."9

- **15.** The need for greater communication was also emphasised by Dr Richard Greville of ABPI during oral evidence.¹⁰
- **16.** Vanessa Young, Director of the Welsh NHS Confederation told us that there was recognition "across the sector" about the need for an "effective communication strategy" and that this work was being taken forward by the EU Transition Leadership Group, chaired by the Welsh Government."
- 17. In correspondence, the First Minister stated that the Welsh Government has set up groups in order to engage with stakeholders, including the creation in September this year, of the "Health and Social Care Brexit Ministerial Stakeholder Advisory Forum" made up of "senior leaders from across the health and social services sector" and is led by the Cabinet Secretary for Health and Social Services.¹²

1. 3. Our view

We heard that whilst communication with the sector has improved since our first report in January 2018, gaps remain in terms of information filtering through to all levels. We expect a redoubling of communication efforts in the coming months as the final outcome of the Brexit negotiations becomes apparent. Planning for this should already be in place and we would welcome assurance from the Welsh Government that this is the case.

Recommendation 1. We recommend that the Welsh Government, in its response to this report, provides assurance that communication plans are in place for the run-up to when the UK formally leaves the EU at the end of March 2019. This assurance should include sharing with us:

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

⁹ Record of Proceedings, paragraph 226 - 8 October 2018

¹⁰ Record of Proceedings, paragraph 233 - 8 October 2018

¹¹ Record of Proceedings, <u>paragraph 231</u> - 8 October 2018

¹² Correspondence from the First Minister on preparedness - 2 November 2018

1. 4. Scenario planning and "no deal"

- **18.** RCN Wales noted in its submission that they are reassured that work is underway 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 also being undertaken.¹³ However, the RCN also noted concerns 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".¹⁴
- **19.** BMA Cymru Wales told us that at its annual representative meeting in June 2018, the organisation voted to change its policy "to opposition to Brexit and to support the public having a final say on the Brexit deal". They added that the BMA "continues to work with other organisations to highlight the dangers of a 'no deal' Brexit and engage and raise concerns with the Welsh Government".
- **20.** During oral evidence, the First Minister, Carwyn Jones AM, repeated his concerns about the implications of a "no deal" likening the UK Government's technical notes to "preparations for war". The First Minister went on to tell us that the Welsh Government would not be publishing separate Wales-specific notices but look to supplement the UK Government's notices where necessary. The First Minister told us:

"I'd argue that more important than producing notes is the dialogue we are having with different groups as part of the work on Brexit. For example, there's the environment and rural affairs round-table stakeholder group that was convened soon after the referendum itself. There's a health Brexit group as well. Rather than saying, 'Look, here's a set of notes that are different to the UK Government's', or identical, what we're saying is, 'Let's sit around the table on a regular basis and then work through the issues so that you're aware of what might happen and what problems might result.'."

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¹³ Written evidence, Royal College of Nursing Wales

¹⁴ Ibid.

¹⁵ Written evidence, <u>BMA Cymru Wales</u>

¹⁶ Ibid.

¹⁷ Record of Proceedings, paragraph 91 - 8 October 2018

¹⁸ Record of Proceedings, <u>paragraph 100</u> - 8 October 2018

¹⁹ Record of Proceedings, paragraph 101 - 8 October 2018

1. 5. Our view

We note the concerns expressed by stakeholders about the implications of "no deal" and the lack of sufficient time to prepare for such an outcome. More specific concerns raised with us about the implications of Brexit for the continued supply of medicines (including in the event of a "no deal") are addressed in the following section.

1. 6. The supply of medicines

- 21. The supply of medicines to patients after Brexit was raised as a concern in the evidence received.²⁰ ABPI stated in its evidence that 45 million patient packs of medicine move from the UK to the EU27 every month, with 37 million packs moving in the other direction.²¹ ABPI told us that it had therefore been underlining the importance of evaluating individual supply lines for individual products, particularly those with complex supply lines and those with temperature control requirements.²²
- 22. Dr Richard Greville of ABPI expanded upon this during oral evidence stating that "the continuity of supply" was at the "forefront of people's minds".²³ Dr Greville told us that industry was currently being asked to evaluate supply lines and regulatory requirements and that the "number one ask is for a deal with regulatory co-operation and frictionless trade and movement across borders".²⁴ Dr Greville added that ABPI members were currently working on medicine supply contingency planning:

"Basically that's a request from the UK Government for manufacturers to increase their stock within pre-wholesaler of up to and including six weeks' additional stock of medicines. So, 'pre-wholesaler' means that the stockpiling is done at the cost of the manufacturer within warehousing that the manufacturer maintains and pays for. So, that, I think, is the difference between the stockpiling. I think Nessa was talking about stockpiling within the NHS, and the ask on

²⁰ Written evidence, Royal College of Nursing Wales

²¹ Written evidence, **ABPI**

²² Ibid.

²³ Record of Proceedings, <u>paragraph 210</u> - 8 October 2018

²⁴ Record of Proceedings, paragraph 211 - 8 October 2018

manufacturers is for us to stockpile an additional six weeks within prewholesaler facilities within the UK."²⁵

23. Dr Greville also told us about some of the considerations that need to be made by the industry in terms of stockpiling:

"There are certain issues with regard to the costs of bringing additional stock to the UK. There are also issues about the costs of the additional warehousing needed and, obviously, if the warehousing isn't an option that's possible for whatever reason, the costs of air freight are also a consideration. And for all of the above, you also need to consider the capacity availability in the UK. Medicines are slightly different from a lot of other goods in that they are very heavily regulated. So, it isn't a case of creating a warehouse without any appropriate regulatory sign-off and certification. So, all of that will inevitably take time, but close collaboration and engagement between the Welsh Government and the UK Government on this topic might be very useful."²⁶

24. Vanessa Young told us that "in terms of supply of medicines, the UK Government is taking the lead for the pharmaceutical industry in preparing to have sufficient stockpile of medicines".²⁷ In terms of the role of the Welsh Government, Ms Young told us:

"what the Welsh Government is asking individual organisations to do is to review and rehearse promptly existing business continuity and resilience arrangements within organisations and to do that with their local and regional partnerships and through local resilience forums. And then, they have provided a checklist to give us areas of particular things to focus on in terms of those actions, starting with resilience and continuity. So, confirming that existing arrangements are up to date, they're working with partners to pay particular consideration to Brexit and that plans are in place for a rehearsal for January next year.

[...]The second area is in terms of continuation of supply and the focus there is on the extent to which organisations are confident of their inventory management arrangements. So, how confident are we that we have up-to-date, accurate, real-time inventory data for our

²⁵ Record of Proceedings, paragraph 211 - 8 October 2018

²⁶ Record of Proceedings, paragraph 214 - 8 October 2018

²⁷ Record of Proceedings, paragraph 194 – 8 October 2018

medicines and consumables? Then, the final point is around critical machinery and equipment."²⁸

25. In its written submission, the Welsh NHS Confederation also told us that, in August 2018 the Deputy Chief Executive of NHS Wales, Simon Dean, sent a letter to all NHS Chief Executives in Wales advising "that they do not need to take any steps to stockpile additional medicines beyond their current stock levels and there is no need for clinicians to write longer NHS prescriptions".²⁹

1. 7. Our view

We heard from stakeholders that continuity of supply of medicines in the context of a "no deal" Brexit is a key concern for the health service in Wales. We understand from the evidence received that preparations are underway to ensure continuity of supply and agree that coordination between the UK Government and the Welsh Government will be needed in terms of contingency planning.

Recommendation 2. We recommend that the Welsh Government, in response to this report, outlines details of:

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

1. 8. Mutual recognition of standards and reciprocal arrangements

26. In written evidence, the Welsh NHS Confederation outlined the findings of its Policy Forum, which has been endorsed by 20 organisations in Wales.³⁰ The findings include calling for the preservation of current reciprocal healthcare arrangements after Brexit; continued mutual recognition of professional

²⁸ Record of Proceedings, paragraphs 196 and 197 - 8 October 2018

²⁹ Written evidence, Welsh NHS Confederation

³⁰ Welsh NHS Confederation, <u>The key issues for health and social care organisations as the UK prepares to leave the European Union</u>

qualifications; and regulatory alignment "for the benefit of patients and the public's health".³¹

27. During oral evidence, Vanessa Young expanded upon preparations in this area telling us that:

"The point to make on the technical notices, actually, is that there are a number of areas where they're still silent. We haven't had technical notices on issues like reciprocal healthcare, on much of the public health protection issues and on mutual recognition of qualifications, for example. So, there are a number of areas where we're still waiting to understand that UK position. But they are issues on which we're aware the UK is leading, but in discussion with devolved administrations." 32

28. RCN Wales told us that:

"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." 33

29. On 26 October 2018, the UK Government introduced the Healthcare (International Arrangements) Bill, which contains provisions to give the government legal powers to fund and implement any international agreements – including, but not limited to, agreements with the EU — in relation to healthcare after Brexit.³⁴

³¹ Written evidence, Welsh NHS Confederation

³² Record of Proceedings, paragraph 255 - 8 October 2018

³³ Written evidence, Royal College of Nursing Wales

³⁴ UK Government, "<u>New law proposed to safeguard UK citizens' healthcare abroad after Brexit</u>"– 26 October 2018

30. Dr Stephen Monaghan of BMA Cymru Wales and RCN Wales expressed concerns about continued access to medical radioisotopes after Brexit.³⁵ Dr Monaghan said:

"On supplies, specifically, and communication about them, it would only be fair to say that certainly one area where the communications are not adequate, because the position has not been clarified enough, including in the technical notices, is on radioisotopes. So, because we are, as things stand, leaving Euratom—which the BMA regrets—we will not be able to legally obtain radioisotopes from EU member states. They won't be able to export them to us—any European company. So, what we haven't seen is clarity as to where the radioisotopes are, therefore, going to come from should there be no deal. So, we've seen some detail, obviously, about consumables, about medicines and medical devices, but radioisotopes is a specific area and very heavily regulated—even more heavily regulated than pharmaceuticals, arguably."36

31. Lisa Turnbull of RCN Wales told us that:

"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."³⁷

1. 9. Our view

We heard that continued regulatory cooperation is necessary to ensure continued access to new medicines and clinical trials. This echoes what we heard during our previous work on "Wales' future relationship with Europe", We note that the <u>UK Government's Future Relationship White Paper</u> proposes

³⁵ Written evidence, <u>Royal College of Nursing Wales</u>; Record of Proceedings, <u>paragraph 189</u> - 8 October

³⁶ Record of Proceedings, paragraph 249 - 8 October 2018

³⁷ Written evidence, Royal College of Nursing Wales

continued participation in the European Medicines Agency and also proposes maintaining integrated supply chains, to avoid customs and regulatory delays at the border (which is relevant to the supply of medicines and other healthcare products).

Recommendation 3. We recommend that the Welsh Government outlines, in its response to this report, details of how it is pressing the UK Government for continued regulatory cooperation between the UK and the EU in terms of access to medicines and clinical research after Brexit.

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

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

Recommendation 4. We recommend that the Welsh Government, calls on the UK Government, to guarantee continuing access to medical radioisotopes after Brexit and ask that the Welsh Government outlines the actions it has taken to fulfil this recommendation in its response to our report.

1. 10. Potential implications for the health and social care workforce

- **32.** The Welsh NHS Confederation's written evidence highlighted that (as of April 2018) 1,462 individuals directly employed by the NHS in Wales identified themselves as EU nationals (around 1.6 per cent of the total workforce).³⁸ According to BMA Cymru approximately 6.4 per cent of doctors currently working in the medical workforce in Wales are EEA graduates.³⁹
- **33.** Lisa Turnbull of RCN Wales raised concerns about the lack of reliable data in terms of the social care workforce:

"Our concern, which we've identified, is that, although there are a number of EU-registered nurses working in NHS Wales—our concern is what we don't know. So, our concern is how many are working in the independent sector, and also, specifically, around the unregistered

³⁸ Written evidence, Welsh NHS Confederation

³⁹ Written evidence, **BMA Cymru Wales**

workforce, so people such as care workers—what proportion are EU? The care home sector is fragile; it is very dependent on them for keeping that provision open. And of course, it has a huge impact then on what the NHS's operation is, in terms of the whole-systems approach. So, we are concerned specifically around that area, and we would welcome more—certainly the outcome of this research, and more information about this research that is currently under way, because it is an area of concern for us. [...] As I said, one of the areas is not just your highly skilled, highly specialised roles, but also, equally important, is the very important skills that the care workforce has, and the work that they do in the independent sector in care homes."40

34. BMA Cymru told us that migration from the EEA and elsewhere provides a range of benefits to the UK beyond staffing:

> "Medicine and medical research thrives on the interchange of experience, knowledge and training across countries and backgrounds. Allowing doctors and medical researchers to work, train, teach, conduct research and practice in different countries contributes to widening the understanding of healthcare and advances new breakthroughs in medicine."41

35. BMA Cymru also stated that:

"Any reduction in the number of doctors migrating to the UK, or an increase in the number leaving the UK because of Brexit, will have a destabilising effect on the medical workforce, and the staffing of health and social care services across the UK. This will impact on already over stretched staffing levels on hospital wards, in GP practices and in community settings across the UK, putting at risk the quality of patient care and patient safety."42

36. During oral evidence, Lisa Turnbull of RCN Wales told us that issues around the sustainability of the workforce and mutual recognition of qualifications also needed to be addressed:

> "One aspect of that is the impact on a sustainable workforce, and there are a number of other issues with a sustainable workforce that we are concerned about—what any future immigration system might look like

⁴⁰ Record of Proceedings, paragraph 290 - 8 October 2018

⁴¹ Written evidence, **BMA Cymru Wales**

⁴² Ibid

and its impact, particularly around not just registered professionals, such as nurses, but also around healthcare support workers, particularly in the independent sector, so not just within the NHS. There are other issues affecting that, such as the recognition of professional qualifications, which need to be very clear."43

37. In written correspondence, the First Minister told us that £200,000 had been allocated under the EU Transition Fund for research on the likely implications of Brexit for the social care workforce.⁴⁴

1. 11. Our view

As highlighted in our previous work on the implication for Wales of leaving the EU, Brexit preparedness, and in our work on Wales' future relationship with Europe, concerns remain among stakeholders about the implications of Brexit for the health and social care workforce. We heard that a lack of robust data, particularly in terms of the make-up of the social care workforce, are hampering the ability of health service in Wales to prepare for Brexit, although we also note that Welsh Government commissioned research is underway in this area.

Recommendation 5. We recommend that the Welsh Government, in its response to this report, outlines:

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

⁴³ Record of Proceedings, paragraph 183 - 8 October 2018

⁴⁴ Correspondence from the First Minister on preparedness - 2 November 2018