Cross-Party Group on Life Sciences
Tuesday 5th of February 2019, Committee Room 1
Brexit and impact on Life Sciences
Minutes

MSPs Present:
Kenneth Gibson MSP- Convener
Ivan McKee MSP
Tom Mason MSP

Apologies:
Graham Simpson MSP
Miles Briggs MSP

1. Opening, Welcome and Introductions.

The Convener, Kenneth Gibson MSP, welcomed everyone to the fifth meeting of the Cross-Party Group (CPG) and outlined the discussion points for the session.

2. Minutes of the previous meeting (30th October 2018)

The minutes of the previous meeting were accepted by the group and seconded by Alison Culpan.

3. Ivan McKee, Minister for Trade Investment and Innovation

Mr McKee committed to attending the group on a regular basis, which he believes, reflects the importance of the sector to the Scottish Government (SG). The Minister also outlined what has happened since the CPG last met:

- Promising new turnover numbers were revealed which showed the industry was worth £5.2bn in Scotland, up from around £4bn the year before.
- Mr McKee, commented that the sector was well on its way to meeting targets set by the Scottish Government Life Sciences Industry Leadership Group.
- The Minister attended the sector conference and was pleased at both the attendance and the discussion points.
- He also highlighted the BERD (Business Enterprise Research and Development) figures which confirmed that the sector is a key driver in increases in Scottish R&D spending.
- There was also a Scottish Government debate on life sciences in January which showcased the strengths of the sector and the challenges going forward.
- In relation to Brexit he identified three key talking points:
    - He outlined the SG position which is for either a postponement of Article 50, a "people's vote" or customs union membership.
    - Understood that the Life Sciences sector will be effected in a number of ways, including: uncertainty, future access to talent, potential disruption of cross-border supply chains and the status of the future regulatory environment.
    - The SG is doing its best to prepare and the Minister highlighted work recently undertaken with Ernst and Young whilst also sign-posting the Scottish Enterprise Brexit Toolkit.

Key points from the Q and A with Mr McKee.

- The Minister revealed that he had been on near monthly outreach events to Europe to both advocate for the Scottish Government's position and to stress that Scotland welcomes and values the contribution of EU migrants.
- In response to questions on student visas, Mr. McKee made it clear that this was a reserved matter but that Scotland's separate 4-year degree programme must be considered in any future immigration system. He also emphasised that free university education had been guaranteed to EU students for at least the next year.
- When asked on the continuation of the Horizon 2020 project and whether applications could still be made, he stated that this was as yet unclear with funding only confirmed until the end of the current period.
- Mr. McKee stated that the Government was aware of industry preparations, but despite this knowledge there were outlying factors like border control and port capacity that are almost impossible to prepare for.
- When asked about whether Scottish ports could provide additional capacity he stated that this was a possibility, but it would depend on the situation at southern ports as there would be an additional expense incurred by importers/exporters when using Scotland.
- He implored businesses with specific issues to come to the SG and they would endeavour to help.

Mr Gibson added:

- That the UK has until the end of the month to signal they will contest EU parliamentary elections, if not, these 81 seats will be reallocated to the rest of Europe;
- That his wife, Patricia Gibson MP, had asked the Prime Minister for clarity on Horizon 2020 funding before the Christmas recess, but was still not any further forward.

4. Professor Andrew Tobin- Impact of Brexit to research

Professor Andrew Tobin presented on his dementia and malaria research at the University of Glasgow's Tobin Laboratory.

Dementia Research:

- His team have identified the protein receptor in the brain responsible for memory and learning and are using drugs to mimic the function of this receptor.
- Mice are injected with prion disease (BSE) and experiments around memory are used to determine their success in preventing memory loss.
- The initial results have been successful, and the team is taking the findings to the USA.
- Brexit impacts this research in several different ways:
    - The majority of the team (post doc students) are from EU member states;
    - The mice are from France;
    - The experimental equipment is from Italy;
    - The drugs are from USA/Australia.

Malaria Research:

- 1.2 million die every year as a result of Malaria and 36% of the global population are at risk of infection.
- Professor Tobin explained how the parasite develops and uses the body's red blood cells to multiply.
- The project his team are working on is to prevent the parasite from binding and entering these cells. So far, results have been successful.

- Once again Brexit affects their research in a number of ways:
    - This is an international project with a multi-cultural team, including researchers from Europe and Africa;
    - The drugs are from Spain;
    - The blood serum used in experiments is from Sweden.
- Therefore, complications because of Brexit could impact the future success of this project which is aimed at delivering anti-malarials for the Bill and Melinda Gates foundation.

Q and A with Professor Tobin

- Professor Tobin explained that the greatest stress for non-EU researchers is obtaining and maintaining their Tier 4 visa status. He doesn't want EU researchers to be caught by what is he feels is an overly-bureaucratic and expensive system.
- Barriers to accessing talent could significantly impact the ability of universities across the UK to attract and maintain talent, especially if the pathway to future employment is muddied.
- Professor Tobin explained that after Brexit he wrote to his post-docs to explain that they were wanted and welcome in Glasgow. He believes that more work is required to convince current and prospective students that the UK wants and values their skills.
- Professor Tobin was asked about the destination of previous researchers, and he confirmed that a substantial proportion stay within the UK Life Sciences sector. It was noted that a future shortage of EU researchers in academia would eventually filter down and result in a skills shortage for the wider life sciences sector.
- Further concerns were raised about the effective operation of a "points based" system and Professor Tobin agreed that more needs to be done to attract students post-Brexit and to sustain the morale of existing researchers.

5. Professor Stuart Ralston - Impact of Brexit on access to and Licensing of Medicines

Professor Ralston presented on the role and function of the Commission for Human Medicines, the MHRA, the relationship between the MHRA and EMA with particular reference to and the possible consequences of Brexit on access to medicine and the "marketing authorisation" process for new medicines. He emphasised that the views expressed were his own, rather than those of the MHRA.

- The Medicines and Healthcare Regulatory Authority is a trading agency of the Department of Health and plays a key role in the licensing of new medicines. It employs over 1200 people.
- Most new medicines are licensed in EU member states by the European Medicines Agency (EMA) through the centralised process. Other, mostly generic, medicines can be licensed by individual Member States through other processes depending on their needs.
- The EMA process is popular with companies as it allows one central port of entry for licensing to 28 Member States.
- Professor Ralston explained the process, the various reporting stages, and detailed that it takes some a minimum of 277 days from initial submission to approval of a new medicine.
    - Following an initial application, questions are asked after 90 and 180 days by rapporteurs (effectively referees from Member States). The UK has traditionally played a key role in this process and in previous years has acted as rapporteur or co-rapporteur more frequently than any other EU28 country. As a consequence, the MHRA had developed considerable expertise in this area. The UK also plays a leading role in the mutual recognition and de-centralised processes. For licensing of medicines
- Professor Ralston also touched upon the "Norwegian model". He explained that while Norway is not a member of the EU it has regulatory alignment with the EMA. While Norway

can act as a rapporteur, it has no vote in licensing decisions and has no influence on EMA policy.

- Professor Ralston explained that a "no deal" Brexit would result in the UK being entirely outside the auspices of the EMA. The MHRA would therefore be solely responsible for licensing new medicines in the UK. This would inevitably represent a substantial increase in workload as compared with the current situation.
- He explained that a "Withdrawal Agreement" scenario, under Mrs. May's current deal, would result in acceptance of EMA decisions until 2021 but with the UK playing a relatively passive role in the process.
- Why would a "no-deal" scenario matter? Under the current situation the EU (through the EMA) is typically second after the USA (through the FDA) in licensing new medicines which results in patients receiving cutting edge treatments faster.
- Under a "no deal" Brexit there is a potential concern that the pharmaceutical industry would focus efforts on gaining marketing authorisation first in the USA, EU and Japan and only after that submit applications for marketing authorisation in other countries such as the UK, Switzerland and Canada.
- In order to mitigate this threat, the MHRA has put procedures in place to encourage companies to submit early to the UK by conducting a targeted assessment process with the aim of making medicines available to UK patients in a timely manner.
- Nonetheless, this would require companies to submit both to the EU and (separately) to the UK which would result in the duplication of effort and cost for the pharmaceutical industry.
- Post-Brexit opportunities were briefly touched upon. Michael Gove's had previously asserted that with Brexit, it may be possible to leaving the European Clinical Trials Directive. However, it was pointed out that this would be unlikely since few companies would want to conduct clinical trials on medication under conditions that could not be accepted in Europe and elsewhere.

Q and A with Professor Ralston

- When asked about whether the UK could accept FDA decisions as part of a rubber-stamping process, Professor Ralston cautioned that this hadn't been explored in detail at the present time.
- He was also asked about MHRA "rubber stamping" EMA decisions. In response to this he pointed out that the UK plays a central role in shaping EMA decisions through its role in the assessment process and that it would be unsatisfactory for the MHRA to accept decisions made by others without any input.
- He also pointed out that, reflecting this fact, most developed countries such as Australia and New Zealand, Canada and Switzerland have their own regulatory authorities.
- Professor Ralston was also asked about a potential future role for the SMC in offering market authorization. He pointed out that while the SMC did a valuable job, their focus was on the assessment of products that already have marketing authorisation and that they would not have the expertise to conduct the in-depth assessment that was necessary for marketing authorisation.

6. George Davidson, GlaxoSmithKline - Industry preparations for Brexit

- Explained that GSK is relatively well-prepared for Brexit given the information available to plan to date but clearly anything could happen given the uncertainty remaining. GSK is dependent on an integrated European supply chain and the use of external partners who may be less well equipped to deal with the complex planning given the size of their organisations

- Mr. Davidson stressed that patient wellbeing and maintaining continuity of supply is GSK's sole focus.
- GSK employs 14,000 people in the UK of which 10% are non-UK EU citizens. In Europe, GSK, employs a further 30,000 at 17 plants, which demonstrates the integrated nature of their supply chain.
- Mr. Davidson explained that there are five main workstreams GSK has focused on to tackle Brexit challenges: Manufacturing and supply, Regulatory, Trade and Tax, People, and R & D.
- Preparations to date have included some 13,000 pack changes to comply with European rules.
- GSK estimate having spent around £70m preparing for Brexit. Mr. Davidson felt such significant investment was needed to try and ensure continuity of supply but could potentially have been spent more productively in other areas of their business.
- There was also further focus on the desire for continued collaboration with EU partners around R&D and people and the extension of Horizon 2020 after Brexit.
- GSK hopes to see mutual recognition agreements in place, and any future system must be seamless to avoid delays at borders which could ultimately impact supply.
- Mr. Davidson also explained that GSK hopes fluid working between its many manufacturing plants and other parts of their business would still be possible after Brexit as a regular supply of medicines depends on working collaboratively both internally and externally.
- There was also additional focus on the Falsified Medicines Directive – which has just launched. It's important that this is incorporated into UK law as it will save patient lives and has also been a significant workload alongside Brexit preparations.

Q and A with George Davidson

- When pressed on how long supplies would last Mr. Davidson, and Alison Culpan from ABPI, stated that despite the hard work of innovative companies a lot would depend on the 83% of medication that comes from generic producers.
- Several members asked about "good news" given the lack of certainty with Brexit and Mr. Davidson added that whilst there were still many unknowns for everyone, he felt GSK, and presumably other large companies, had taken all the steps they could to try and ensure continuity of supply and were in as good a position as possible given the current uncertainty

Alison Culpan added

- That it was unclear what could be done to incentivise pharma after Brexit, especially considering money and funding from the Life Sciences strategy was still underspent.

Linda McGlynn (Diabetes Scotland) added

- That there were concerns within the diabetes community about access to insulin and it was important to remember that patients will suffer most from any disruption. She also called on the Government to reassure patients and provide additional information in order to prevent patients stockpiling.

7. Closing Remarks

The convener thanked all four contributors and reminded members of the date for the next meeting (28th May 5:45pm CR5).

He also encouraged members to put forward suggestions, to his office and the secretariat, to cover at the next meeting.

Mr Gibson also made it clear that members should approach their individual MSPs if they have any specific questions that they would like Government to answer.

Non-MSP attendees:

Damian Crombie (Astra Zeneca), Alison Culpan (ABPI), Kerry Douglas, Kirsty Gelsthorpe (ABPI), Claire Headspeath (ABPI), Graeme Rose (ABPI), Sally Hughes, Philip Jones, David Littlejohn (University of Strathclyde), Mairi Claire Macpherson, Linda McGlynn (Diabetes UK), Sarah Nimmo (Ettrickburn), Duncan Rory (Heriot Watt University), Paul Ryan, Alison Strath (Scottish Government), Zieda Taylor (Chiesi), Sarah Tobin, David Eadie (Novonordisk), Mike Barret (SULSA).