European and External Relations Committee

The EU referendum and its implications for Scotland

Written submission from the Association of the British Pharmaceutical Industry (ABPI) Scotland

1. About the ABPI

1.1. The Association of the British Pharmaceutical Industry (ABPI) Scotland represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in Scotland and across the rest of the UK. Our industry, a major contributor to the economy of Scotland, brings life-saving and life-enhancing medicines to patients. Our members supply 90% of all medicines used by NHS Scotland, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that Scotland remains at the forefront of helping patients prevent and overcome diseases.

2. Introduction

2.1. ABPI Scotland welcomes the opportunity to engage with the European and External Relations Committee inquiry on the implications of Scotland leaving the EU.

2.2. As the Committee are no doubt aware, regulation of pharmaceuticals and for much of the life sciences sector is administered on a UK-wide basis. We draw the Committee’s attention to a submission made by our London colleagues to the House of Commons Science and Technology Committee, which outlines the difficulties surrounding regulation.1

2.3. The pharmaceutical industry in Scotland is the second biggest industrial investor in research and development in Scotland, accounting for 17% of the total. This is ahead of industries such as consumer electronics, extractive industries (including oil and gas), IT and the food and drink sector.2

2.4. To support such high levels of spending, the pharmaceutical sector relies on long-term investment and a stable science and research environment. Developing a new medicine takes on average 12 years from discovery to market authorisation. Creating this stability is important for science and research, attracting global inward investment, and facilitating long-term collaboration between the pharmaceutical industry and Scotland’s world class research base.

2.5. The life sciences represent a key industrial sector for the success of the Scottish economy outside of the EU. Our research based industry depends upon an environment where science and innovation are at the heart of industrial strategy.

2.6. Leaving the EU presents significant challenges for stability of the life sciences sector in Scotland and in the rest of the UK. As for many sectors, EU membership affects all aspects of our research-based industry. What is


2 Economic Impact of the Pharmaceuticals Industry on the Scottish Economy (Oct 2015): Fraser of Allander Institute
particular for our industry is the relative share of EU legislation and jurisprudence that shapes how our research, development, manufacturing and business operations are undertaken. Again we refer the Committee to our previous submission to the House of Commons Science and Technology Committee on pharmaceutical industry regulation.³

2.7 In this submission, we have stuck to areas in which we have expertise. We have tried to answer as many of the Committee’s specific questions as we felt qualified to do.

2.8 We would welcome the opportunity to provide oral evidence to the Committee on as part of your inquiry.

3 Key themes

3.1 Value of pharmaceutical industry to health and wealth of Scotland

3.1.1 The biopharmaceutical industry is a significant contributor to the health and wealth of Scotland today and has the potential to be a strong driver of future success. The industry contributes £824m in direct GVA, over £1.2billion⁴ to the output of the Scottish economy and directly employs 8,000 people in high-value jobs.⁵

3.1.2 Scotland’s universities are world leaders in research and the funding environment ensures research translates to a vibrant SME sector and supports a thriving life sciences ecosystem leading to the development of new medicines.

3.1.3 The industry and its current EU-wide regulatory framework, overseen by the European Medicines Agency (EMA), ensures timely patient access to innovative medicines, including early access through clinical trials, which supports NHSScotland in improving patient outcomes, particularly in cancer.

3.1.4 The UK industry regulator which covers Scotland, the Medicines & Healthcare products Regulatory Agency (MHRA), is a lead influencer in Europe and around the world.

3.2 Innovation – supporting the research, development and commercialisation of new medicines

3.2.1 Scotland’s strong position in life sciences research and commercialisation is predicated on funding and collaboration. We welcome the recent commitment by HM Treasury to underwrite funding for approved Horizon 2020 projects applied for before the UK leaves the European Union⁶.

3.2.2 The Scottish Government should prioritise facilitating access for Scotland to funding streams from both public and private investors

⁴ Economic Impact of the Pharmaceuticals Industry on the Scottish Economy (Oct 2013): Fraser of Allander Institute
⁵ Economic Impact of the Pharmaceuticals Industry on the Scottish Economy (Oct 2015): Fraser of Allander Institute
including research funds and venture capital, including commitments to replacing any funds lost from the EU.

3.2.3 The Scottish Government should ensure that Scottish based researchers can continue to collaborate in and also lead EU-wide research initiatives.

3.3 People – attracting, retaining and developing talent

3.3.1 Ease of movement of people in the EU is central to the collaboration and brain circulation that drives innovation and talent development in the life sciences industry and is viewed as critical for the industry’s ongoing success.

3.3.2 Shaping and growing the domestic talent base will also have a renewed importance for the future of the Scottish life sciences base.

3.4 Regulation – enabling patient access to safe, innovative medical technologies

3.4.1 Effective regulatory frameworks for clinical trial, licensing and pharmacovigilance regulations are essential both for patient safety and for Scotland to remain competitive. For the benefit of medicines discovery, development and access, in a world where disease does not recognise borders or boundaries, continued Scottish participation in EU regulatory frameworks and ongoing regulatory alignment, including future collaboration between the EMA and MHRA, would be one route to achieve this.

3.4.2 Failure to maintain intellectual property (IP) protections would make Scotland a less attractive market in which to launch innovative products.

3.4.3 There are also a number of additional regulations affecting the research environment that will need to be reviewed to ensure there is no unintended negative impact for the life sciences sector, through duplicative processes and additional costly bureaucracy, on leaving the EU.

3.5 Trade and Fiscal – ensuring continuity of supply of new medicines for Scottish patients and the framework for export success

3.5.1 Maintaining access to the EU customs union (to facilitate free movement of goods), as well as the Free Trade Agreements (FTAs) the EU has negotiated with third countries is important for supply of medicines to patients in Scotland and to Scotland’s exports.

3.5.2 Import / export requirements could impact patient access to medicines and should be avoided, for example through a mutual recognition agreement.

---

4. Opportunity

4.1 Scotland has a successful biopharmaceutical industry but there is a chance to further enhance the domestic environment and ensure greater success in the future. This could be delivered through domestic policy action to support opportunities such as translational medicine, making NHS Scotland a unique location for clinical trials through the ongoing Montgomery Review, and fiscal or other incentives where possible.

The Committee's questions

The alternatives to EU membership?

- ABPI Scotland has no comment to make.

The implications of these alternatives for Scotland?

- ABPI Scotland has no comment to make.

How the withdrawal process might be managed at the EU and UK level?

- At this critical time, it is vital that we send a strong message that Scotland and the rest of the UK is open for business. We would like Scotland's and the UK's political leaders to ensure that the roadmap for the UK leaving the EU secures the future of our country's pharmaceutical industry.
- For example by minimising business uncertainty and ensuring that the pharmaceutical industry is a partner in any and all discussions that will affect our sector. The UK Government has set-up a government industry taskforce, and ABPI Scotland are in dialogue with the Scottish Government on this issue.

What steps would be involved in this process and how individual policy fields might be dealt with?

- As above, we believe the best way to deal with the myriad of issues around pharmaceuticals is for the ABPI Scotland as representatives of the industry, and the Scottish Government to work closely in partnership.

The amount of time that might be required to deal with the negotiations?

- It is impossible to put a figure on, but ABPI Scotland would urge all parties to begin looking at the issues around pharmaceuticals as quickly as possible, to minimise business uncertainty and to ensure patients continue to get their medicines.

How the interests of Scotland and the other constituent parts of the United Kingdom can be represented in those negotiations?

- The ABPI is the trade body that represents the pharmaceuticals industry across the UK. ABPI Scotland, based in Edinburgh will continue to work with the Scottish Government, as our colleagues based in Belfast, Cardiff and London will do with their respective governments.
What role the Scottish Government should have in those negotiations?

- It is not for ABPI Scotland to decide who is or is not included in what negotiations. We do believe that the best way to meet this significant challenge is for all stakeholders to work closely in partnership.

The positions likely to be taken by other Member States in the negotiations?

- ABPI Scotland has no comment to make.

The implications for the devolution settlement of withdrawal from the EU?

- ABPI Scotland has no comment to make.

The implications for UK and Scots law of a withdrawal from the EU, particularly the need to repeal legislation and prepare new legislation to fill the gaps left by EU legislation?

- We would refer again to our submission made by our London colleagues to the House of Commons Science and Technology Committee which deals with the issues of regulation\(^8\).

The scale of the task and the implications for the Scottish Government and Scottish Parliament?

- The scale of the task around pharmaceuticals is considerable, however we cannot comment on the implications for the Scottish Government or Scottish Parliament.

The impact on Scotland’s economy of termination of ESIF support and access to the Horizon 2020 programme?

- ABPI Scotland have no comment to make on ESIF funds.
- With regards Horizon 2020 funding, we welcome the recent commitment by HM Treasury to underwrite funding for approved Horizon 2020 projects applied for before the UK leaves the European Union.

The implications for Scotland’s funding settlement of withdrawal from the EU?

- ABPI Scotland has no comment to make.

The position of EU citizens in Scotland in the event of withdrawal from the EU?

- ABPI Scotland has no comment to make.

The extent to which EU citizens in Scotland have acquired rights?

- ABPI Scotland has no comment to make.

The contribution that EU citizens make to Scotland’s economy and society?

- Ease of movement of people in the EU is central to the collaboration and brain circulation that drives innovation and talent development in the life sciences industry and is viewed as critical for the industry’s on-going success.