



Law Society
of Scotland

Written Evidence

Health and Sport Committee

Impact of leaving the European Union on health and
social care in Scotland



January 2018

Introduction

The Law Society of Scotland is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

Our Health and Medical Law Sub-committee welcomes the opportunity to consider and respond to the Scottish Parliament's Health and Sport Committee call for written evidence on the Impact of leaving the European Union on health and social care in Scotland

General comments

In April 2017, the UK Parliament's Select Committee on Health published its report on the potential impact of the UK withdrawal. In September 2017 we submitted an analysis paper to the Scottish Parliament's Health and Sport Committee. The submitted paper¹ provides a brief reflection on the impact that leaving the European Union may have on healthcare and public health in the United Kingdom with particular focus on Scotland. We are aware that some decisions have recently been taken, notably the relocation of the European Medicines Agency.²

We are also actively engaging with the UK and Scottish Parliament in their consideration of the European Union Withdrawal Bill 2017 - 2019³. In April 2017, the UK Parliament's Select Committee on Health published its report on the potential impact of the UK withdrawal from the EU⁴ and we responded to the UK Parliament's EU Home Affairs Sub Committee call for written evidence on Brexit and reciprocal healthcare.⁵

¹ The UK withdrawal from the EU and the potential impact on health related matters – Law Society of Scotland Analysis Paper

² European Medicines Agency(2017 Press Release. *EMA to relocate to Amsterdam, the Netherlands* Available from:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/11/news_detail_002857.jsp&mid=WC0b01ac058004d5c1
[Accessed Jan 22 2018]

³ <https://www.lawscot.org.uk/research-and-policy/influencing-the-law-and-policy/our-input-to-parliamentary-bills/bills-201718/european-union-withdrawal-bill-2017-19/>

⁴ Select Committee on Health Report <https://publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm> [Accessed 26 Jan 2018]

⁵ <https://www.lawscot.org.uk/media/359207/hea-brexit-call-for-evidence-reciprocal-healthcare-response-to-the-eu-home-affairs-committee.pdf>

Specific comments

1) How could the potential risks of Brexit for health and social care in Scotland be mitigated?

We believe there should be continuous monitoring to help ensure that UK negotiators appreciate a clear understanding of the Scottish arrangements regarding health and the implications of withdrawal. Many current initiatives and alliances of shared interests will unsurprisingly take a broad UK perspective and it is suggested that Scotland should be viewed as distinctive. We recommend that the relevant stakeholders in Scotland should promote a clear understanding and promotion of how its organisations are currently structured, their existing strengths and the future priorities.

The regulation of health by the EU can be understood within a thematic approach to policy making. We recommend that scrutiny be given to ascertain the overall costs and benefits of existing EU regulation. Consideration should be given as to how individual states, both within and outwith the EU, have implemented or incorporated EU health regulation with a view to developing workable post Brexit options for the UK.

The licensing of medical products

Medical licensing remains a major concern and the UK has to decide on how it will licence medicines in the UK once it leaves the European Medicines Agency. We recommend an evaluation of the existing contributions and alignments from major organisations such as the Medicines and Healthcare products Regulatory Agency (MHRA) as well as a review of the role of other organisations which have, to date, not played a part. For example, the Scottish Medicines Consortium (SMC) which advises boards on the clinical and cost-effectiveness of newly licensed medicines. The SMC does not however currently licence medicines in Scotland.

A possible solution post March 2019, would be the EMA maintaining a partnership with the UK domestic regulatory agency, the MRHA, allowing for mutual recognition of medicine approvals. It

currently makes a major contribution to the EMA, taking the lead in approving 20% of all medicines in the EU⁶ and has been described as having a ‘symbiotic’⁷ working relationship with the EMA. This would not resolve the concerns that a separate application from pharmaceutical companies to the MHRA would be time consuming and a ‘less efficient regulatory process’.⁸ The MHRA’s business plan for 2017-18 makes it clear that they are aware of the challenges in progressing their post-date Brexit strategy and a top priority is to:

‘[D]evelop consensus around a proposed model for future regulation of medicines and medical devices in the UK, post Brexit which protects public health, facilitates innovation and minimises burden on industry in order to influence and support HMG negotiations and make the UK an attractive global regulator.’⁹

Another possible option for the UK is not to adopt an independent system for authorising and licensing medicines and medical devices but one of cooperation in the enhancement of public health through the sharing of information. Switzerland has a confidentiality agreement with the EMA and the European Commission’s Directorate general for Health and Food safety, the Swiss Agency for Therapeutic Products (Swissmedic) and the Swiss Federal Department. for Home Affairs. It covers the sharing of non-public information in order to enhance public health protection. This has been in place since July 2015 and is valid for five years.¹⁰ It complements a mutual recognition agreement between the EU and Switzerland which regulates the areas of quality and manufacturing. Swiss regulation therefore follows EU regulation in many areas. However, there is no automatic recognition of marketing authorisations granted by the EU. Marketing authorisations are granted by Swissmedic and includes the supervision of clinical trials. Account is taken of other comparable marketing authorisation systems, including, for example, the EU or USA.

It therefore remains to be seen whether the role of the Scottish Medicines Consortium could be adapted to become a licensing authority in its own right or support an enhanced role for the MHRA.

⁶ Reuters Business news (April 2017) With Brexit underway , EU drugs agency prepares to leave London. Available from: <http://www.reuters.com/article/us-britain-eu-pharmaceuticals-idUSKBN1771XM> [Accessed June 15 2017]. Some commentators place this even higher .

⁷ Hansard (12 October 2016) House of Commons Debate on European Medicines Agency. Available from: <https://hansard.parliament.uk/commons/2016-10-12/debates/C1A87D11-1F3E-4BAF-8DC0-2023B96AD963/EuropeanMedicinesAgency> [Accessed 16 June 2015] at p. 2

⁸ Hansard (12 October 2016) House of Commons Debate on European Medicines Agency. Available from: <https://hansard.parliament.uk/commons/2016-10-12/debates/C1A87D11-1F3E-4BAF-8DC0-2023B96AD963/EuropeanMedicinesAgency> [Accessed 16 June 2015]

⁹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/637000/Agency_Business_Plan_2017-18_v1.2_-_final_.pdf

¹⁰ European Medicines Agency- Switzerland (2017) Available from : http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/document_listing/document_listing_000262.jsp&mid=WC0b01ac058009b148 [Accessed July 17 2017]

Health care coverage is a highly visible priority for UK citizens. Whilst it has been agreed that the existing reciprocal arrangements will continue in relation to the European Health Insurance Card (EHIC) for those resident in EU states prior to the Brexit date, for UK or EU citizens who wish to travel and avail themselves of this arrangement post Brexit, the position is currently less clear. We recommend that negotiations are given priority in this area and reciprocal and mutually beneficial arrangements for health care coverage and maintaining cross border healthcare are progressed.

Health research is another area which succeeds on the basis of strong networks producing excellence and innovation within the health related disciplines. These networks are already fracturing. We recommend that the UK and EU seek ways to preserve the major contribution that the UK currently makes to research within the EU. We believe that given the willingness of those who work in this area, current negotiations may provide an opportunity to foster new relationships and stronger collaboration in the future.

Nuclear medicine, diagnostic and treatment

The UK Government has announced its intention to leave the European Atomic Energy Community (Euratom) as part of the Brexit process. This was first announced within the explanatory notes¹¹ which accompanied the European Union (Notification of Withdrawal) Bill 2016-17.

Nuclear technology is used for the diagnosis and treatment of cancer. British nuclear reactors cannot produce radioisotopes, which form the core material for nuclear treatment. Hinkley Point C will have the ability to produce medical radioisotopes, however this will not come on line until around 2027. Currently radioisotopes, which have a very short lifespan, are sourced and provided by the Euratom Supply Agency (ESA) which facilitates easy access and transfer of nuclear diagnostic and medicinal nuclear material speedily across the EU. Withdrawal from the Euratom raises major concerns of the supply and availability of this life saving material.

There is a serious concern that the early diagnosis and treatment of cancer will be greatly affected by leaving the Euratom. Representatives of the medical profession gave evidence to the House

¹¹ <https://publications.parliament.uk/pa/bills/cbill/2016-2017/0132/en/17132en.pdf>

of Lords on the potential implications of Brexit for the supply of radioisotopes on 22 November 2017. Representatives of the British Medical Association, the British Nuclear Medicine Society and the Royal College of Radiologists urged the Government to provide more detail on the exact procedures that will apply to transports of such products after Brexit. They expressed particular concerns about the possibility of new customs controls on transports from the EU. The delays resulting from such controls could necessitate a new approach to importation given that any delays could render the isotopes useless and hoped that the UK would have as close a relationship as possible with Euratom post Brexit.¹²

Workforce

The concern over the future of recruitment and retention of the workforce which contributes to the provision of health and social care in Scotland has been well documented.¹³ We believe that engaging with representative organisations that are in a position to provide evidence on workforce and the impact of any future immigration policy should be adopted.

2) How could the potential benefits of Brexit for health and social care in Scotland be realised?

We suggest that the risks and benefits are in essence linked, therefore please refer to our response to question 1 above.

3) In what ways could future trade agreements impact on health and social care in Scotland?

We are not in a position to answer this question, beyond our awareness that this issue was raised in relation to the Transatlantic Trade and Investment Partnership (TTIP). Ultimately the impact on the NHS, as on any other public service, would depend (as with a commercial contract or any international treaty) on the terms of the agreement.

We have recently, and more generally, responded to the Department for International Trade consultation; Preparing for our future UK trade policy.¹⁴ In addition we provided oral evidence before the UK Parliament's Public Bill Committee on 23 January 2018¹⁵ on the Trade Bill 2017-19.

¹² UK Parliamentary papers 10 Jan 2018. Available from <https://publications.parliament.uk/pa/cm201719/cmselect/cmeuleg/301-viii/30107.htm>. [Accessed 17 Jan 2018]

¹³ Institute for Public Policy Research (2016) becoming one of us reforming the uk's citizenship system for a competitive, post-brexit world. Available from: https://www.ippr.org/files/publications/pdf/becoming-one-of-us_August2016.pdf [Accessed Jan 17 2018]

¹⁴ https://www.lawscot.org.uk/media/359078/lss-response-to-dit_preparing-for-future-uk-trade-policy_november-2017.pdf

¹⁵ Hansard report Column 52 [https://hansard.parliament.uk/commons/2018-01-23/debates/60ff06a4-8b0c-4d46-852c-56fb43d58623/TradeBill\(SecondSitting\)#](https://hansard.parliament.uk/commons/2018-01-23/debates/60ff06a4-8b0c-4d46-852c-56fb43d58623/TradeBill(SecondSitting)#) [Accessed 25 Jan 2018]

4) The Joint Ministerial Committee (EU Negotiations) has agreed a definition and principles to shape discussions within the UK on common frameworks including enabling the functioning of the UK internal market. What implications might this have for health and social care in Scotland and what are your views on how these common frameworks are agreed and governed?

We are not in a position to answer this question.

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