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DEBATE PACK

Number CDP 2017/0229, 17 November 2017

The future of medicines regulation

By Dr Sarah Barber
Nikki Sutherland

This pack has been produced ahead of the debate to be held in Westminster Hall on Tuesday 21 November 2017 from 2.30--4pm on the future of medicines regulation. The debate will be opened by Helen Goodman MP.

Contents

1. News items

Pharmaceutical Journal

Relocation of the EMA: implications for medicines regulation

23 October 2017

http://www.pharmaceutical-journal.com/news-and-analysis/relocation-of-the-ema-implications-for-medicines-regulation/20203731.article

Pharmaceutical Journal

UK may be out of step with Europe on clinical trials regulations after Brexit, minister accepts

16 October 2017

http://www.pharmaceutical-journal.com/news-and-analysis/news/uk-may-be-out-of-step-with-europe-on-clinical-trials-regulations-after-brexit-minister-accepts/20203739.article

Guardian

European Medicines Agency warns of 'permanent damage' from relocation

London-based body must leave UK post-Brexit, but staff survey suggests eight of 19 proposed sites are so unsuitable that move could create 'public health crisis

26 September 2017

https://www.theguardian.com/world/2017/sep/26/european-medicines-agency-relocation-could-cause-permanent-damage

Independent

Europe's drug regulator prepares for Brexit disruption as it plans moving headquarters from London to EU

European Medicines Agency says it will cuts costs on meetings and conferences as it prepares to move away from London

2 August 2017

http://www.independent.co.uk/europe-drug-regualtor-ema-brexit-london-headquarters-eu-move-medicines-agency-city-a7872216.html

The Lancet

What lies in the future of the UK's medicine regulation?

Talha Burki

15 July 2017 DOI: http://dx.doi.org/10.1016/S0140-6736(17)31864-0

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31864-0/fulltext

FT [subscription]

Letter: The UK wants to continue to work with the EU on medicines

From ministers Jeremy Hunt and Greg Clark

5 July 2017

https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b

BBC News Online

Post-Brexit EU drug regulation deal urged by ministers

The UK will continue to co-operate with the European Union on medicine testing after it leaves the bloc, two senior ministers have suggested.

4 July 2017

http://www.bbc.co.uk/news/business-40489359

BMJ

Britain without the EMA

BMJ 2017; 357 doi: https://doi.org/10.1136/bmj.j2168 Cite this as: BMJ 2017;357:j2168

17 May 2017

http://www.bmj.com/content/357/bmj.j2168

New Statesman

What happens when the European Medicines Agency leaves the UK?

EU member states are already bidding for the London-based regulator.

5 April 2017

https://www.newstatesman.com/politics/health/2017/04/what-happens-when-european-medicines-agency-leaves-uk

FT [subscription]

Regulation risk to medicines overplayed

It can be argued that the UK's strengths in pharmaceuticals derive from other factors

6 February 2017

https://www.ft.com/content/967c1d3c-ec69-11e6-930f-061b01e23655

2. Press releases

Nuffield Trust

'No deal' Brexit would harm NHS and its patients, Nuffield Trust warns

7 November 2017

New briefing explores five key areas where the deals the UK government reaches with the EU - or lack of them - will impact upon health and social care.

A 'no deal' Brexit would do serious damage to an already overstretched NHS, the Nuffield Trust warns today. Without deals in place to guarantee the rights of EU staff, secure vital cross border treatment in Northern Ireland and safeguard access to lifesaving drugs, equipment and vital medical products, patients could bear the brunt of a chaotic exit from the European Union.

The warning comes in a new briefing, which looks at the priorities for the NHS as attention turns to a possible trade deal with the EU. The briefing explores five key areas [1] where the deals the UK government reaches with the EU - or lack of them - will impact upon health and social care. It also examines where the NHS might have greater freedoms and flexibility once the UK has left the European Union and what benefits these could bring.

For many things – from medicine regulation to the rights of NHS staff – there is a way through if deals can be secured. But if negotiations collapse entirely or if political red lines get in the way of future co-operation, patient care will suffer.

The report finds that even with an exit deal on money, citizens' rights and Northern Ireland, trade and co-operation deals would be needed so that:

- Delays or charges at the border do not drive up prices of the supplies the NHS relies upon, or risk the loss of vital products with a limited shelf life like radioisotopes;
- British scientists and doctors can keep working as much as possible with European programmes, like Horizon 2020 which has funnelled €420 million into British health research;
- British patients do not face slower access to life saving drugs, and British and European taxpayers do not have to pay more for duplicate regulation in medicines.

The report argues that an exit deal will be needed to make sure:

- The rights of tens of thousands of EU doctors and nurses are guaranteed, minimising the chances of an exodus making already concerning staff shortages across the NHS worse;
- A hard border does not obstruct Northern Irish people who need to go to the Irish Republic for vital care and vice versa;
- A sudden legal vacuum does not risk supplies of already approved medicines, and human substances like blood plasma;

- Expat pensioners who access healthcare under EU schemes do not feel forced to return, potentially requiring up to £500 million more in annual spending, and 1000 extra hospital beds.

The report also highlights areas where the NHS could have greater flexibility after Brexit. One such area is the opportunity to loosen the restrictions on the hours doctors work under the Working Time Directive, which could free up time for training. However, a return to the long hours of the past would risk driving staff away. Another is in removing elements of competition law currently restricting collaboration between NHS organisations. But the report concludes that the scope for more flexibility here after Brexit may in fact be limited.

Commenting on the report, author Mark Dayan said:

> Many different parts of EU law and EU institutions play an important role in enabling healthcare to be delivered to the standards we see today. Suddenly ending them with no replacement would do serious damage to an already strained NHS.
>
> For many things – from medicine regulation to the rights of NHS staff – there is a way through if deals can be secured. But if negotiations collapse entirely or if political red lines get in the way of future co-operation, patient care will suffer.

European Medicines Agency

EMA's Business Continuity Plan for Brexit published

Plan aims to ensure continuity of Agency's operations

16 October 2017

The European Medicines Agency (EMA) has published today its Brexit Preparedness Business Continuity Plan. The plan aims to safeguard continuity of EMA's operations to protect public health while the Agency prepares for its relocation to a new host city and the departure of the United Kingdom from the European Union (EU). The Business Continuity Plan was presented to the Management Board meeting in October 2017 in line with the principles and methodology that were endorsed by the board at its June 2017 meeting*.

It describes the methodology by which EMA has categorised and prioritised its activities and how it plans to reallocate resources to its core activities if needed. The plan prioritises tasks and activities and classifies them into three categories according to their impact on public health and the Agency's ability to function.

The plan will be continuously reviewed and adapted as necessary.

European Medicines Agency

EMA publishes comments on Member States' hosting bids

Accessibility for delegates and experts and staff retention are key to ensure Agency's ability to function

3 October 2017

The European Medicines Agency (EMA) is today publishing the information it submitted to the European Commission in support of its assessment of the 19 Member States' bids to host the Agency. This decision comes following the recent publication of isolated pieces of information circulating in the press in order to complete the picture and set the record straight.

In view of the Agency's mandate to protect public health in Europe, EMA has undertaken a thorough analysis of the bids against the criteria agreed by the EU27. This is important to inform EMA's efforts to prepare for the move.

To ensure the Agency remains operational and able to deliver on its mission after its relocation, the accessibility of the new seat for delegates and experts and staff retention are key, supported by adequate premises and facilities.

The information provided in the documents published today (annexes) is composed of two different parts and is based on different methodologies.

The first part, referred to recently in the press (A1-A3 below), relates to the technical assessment on the proposed building(s) with indicated layout and facilities and the relocation plan. This assessment was requested by the Commission and was based solely on the information provided in the offers (either available in the public offer or confidential documents/information for which access to EMA was granted).

The second part (B1-B3 below) consists of a review carried out by EMA of the information related to other criteria including accessibility of the location (criterion 2), existence of adequate education facilities (criterion 3), appropriate access to the labour market, social security and medical care (criterion 4) and business continuity (criterion 5).

Based on the Agency's long experience, EMA looked at each of the criteria from various aspects and scored them according to how well they meet EMA's requirements and how they might impact the continuity of EMA's operations. As described in the methodology, EMA's review is not only based on the information provided in the public offers but also on other publicly available information (Annex B3).

Two examples to explain EMA's approach: regarding the accessibility of the location (criterion 2), the close proximity of hotels is an important factor due to the long working sessions at the Agency ending late in the evening. EMA therefore looked at the number of hotels in walking distance of the future premises. Regarding the information provided on airports close to the location, 'close to the location' was not further specified. For the sake of consistency across all Member States' bids,

EMA looked at the availability of flights at all airports identified in the International Air Transport Association (IATA) classification list linked to the candidate host city.

EMA expects that the publication of this information will be useful for Member States when deciding on a suitable new host city and thereby ensuring that the Agency will be fully operational during and after its relocation.

The two annexes include the following documents:

A1: Summary of EMA technical comments (on the building)

A2: EMA technical comments – detailed grid (on the building)

A3: EMA technical comments – applied methodology (on the building)

B1: Summary of EMA contributions (on other criteria)

B2: Other criteria – detailed grid

B3: EMA comments on other criteria – applied methodology

The Association of the British Pharmaceutical Industry (ABPI)

Pharmaceutical industry respond to joint letter from Jeremy Hunt and Greg Clark in the Financial Times

4 July 2017

A joint letter from Jeremy Hunt, Secretary of State for Health, and Greg Clark, Secretary of State for Business, published today by the Financial Times, has outlined the UK Government's plans for the regulation of medicines as the UK leaves the European Union (EU).

In response to the letter Mike Thompson, ABPI Chief Executive, said:

> This letter is a welcome recognition that the future of medicines regulation is a key priority for the Government as we negotiate a new relationship with the EU.
>
> It also signals a readiness to take a pragmatic approach to Brexit negotiations that puts people's health first. This is a great first step and we look forward to seeing more detail in the coming weeks and months.
>
> If patients in Europe are to continue to get safe and effective medicines in a timely fashion, the focus must be on agreeing regulatory partnership between the UK and the EU.
>
> The timeframes we need to meet to ensure no disruption or delay mean that confirmation of a reciprocal approach from the EU would provide welcome certainty to more than 500 million patients.

The Association of the British Pharmaceutical Industry (ABPI) are at the heart of a health sector-wide effort, post-Referendum, to establish consensus on key Brexit issues such as a regulation, trade, immigration and UK science. This has been to ensure that patients and public health are central to Brexit negotiations, and that UK Life Sciences is in as

strong a position as possible as the UK establishes a new relationship with Europe.

This work is ongoing, and continues to involve more than 200 global experts from leading pharmaceutical and biotech companies; leading academic groups and research charities (such as the Wellcome Trust); the UK's Medicines and Healthcare products Regulatory Agency (MHRA); the NHS and Public Health England; and a vast range of UK Government departments.

About the ABPI

The ABPI represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. We represent companies who supply more than 80 per cent of all branded medicines used by the NHS and who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome disease.

Globally our industry is researching and developing more than 7,000 new medicines.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

House of Commons Health Select Committee

Brexit – medicines, medical devices and substances of human origin inquiry

21 September 2017

The Health Committee launches inquiry into regulatory arrangements needed to guarantee safe and effective supply of medicines, medical devices and products post-Brexit.

- Inquiry: Brexit – medicines, medical devices and substances of human origin
- Health Committee

Regulatory arrangements

The UK’s withdrawal from the European Union (EU) and the European Atomic Energy Community (Euratom) means new regulatory arrangements must be put in place from 29 March 2019 to guarantee the safe and effective supply of medicines, medical devices, medical products and substances of human origin in the UK.

Patients, the NHS and the UK's life science industry need certainty about what the UK's regulatory arrangements will be after Brexit and a smooth transition towards them. There are also major implications for the future of medical research and development.

Terms of Reference

The Health Committee would like to receive written submissions on the following questions:

- What are the key considerations that arise for companies, healthcare services and regulatory bodies in the UK as a result of the UK's withdrawal from the EU? Focussing on patients and the public, what needs to be done to ensure that any adverse impact is minimised or eliminated, and that opportunities to enhance services are maximised?
- Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced? What are the respective opportunities, risks and trade-offs involved?
- How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?
- How will withdrawal from the European Union affect the UK's ability to influence international standards in life sciences?
- What arrangements are needed to ensure the safe, effective and timely supply of medical radioisotopes over the short, medium and long-term?
- What are the implications for medical research and development, including for the timely patient access to new medicines, technologies and other relevant medical innovations developed within or outside the UK? How can any adverse consequences be avoided or mitigated and any potential opportunities be enhanced?

Scrutiny

The Health Committee is responsible for scrutinising the work of the Department of Health and its associated public bodies. Submissions should therefore address matters for which the Secretary of State for Health is responsible. However, comments are welcome on matters where the Secretary of State for Health may not have lead responsibility, but where the withdrawal negotiations have important implications for the safe and effective supply of medicines, medical devices, medical products and substances of human origin in the UK.

The submission

Respondents need not provide responses to all questions. Equally, if there are any crucial issues not captured under the questions we pose, please highlight what they are and explain their salience.

Written submissions should not exceed 3000 words and should be submitted by *Thursday 26 October 2017*. Public hearings are expected to be held in November and December 2017.

Medicines and Healthcare products Regulatory Agency

MHRA and making a success of Brexit

27 June 2016 Last updated:11 August 2017

The Agency's response to the outcome of the EU referendum.

Following the outcome of the EU referendum, the Medicines and Healthcare products Regulatory Agency (MHRA) is working closely with the Government to analyse the best options and opportunities available for the safe and effective regulation of medicines and medical devices in the UK.

While negotiations continue, the UK remains a full and active member of the EU, with all the rights and obligations of EU membership firmly in place. Working with our partners, stakeholders and customers, our focus remains: protecting health and improving lives.

Medicines regulation

Playing a full, active role in European regulatory procedures for medicines remains a priority. We contribute significantly in both the centralised and decentralised regulatory procedures, including new rapporteur and reference member state (RMS) appointments, and maintain our programmes for implementing EU legislation as required by our obligations as a Member State. We are also fully engaged in European and national scientific advice services and in delivering our EU inspection-related duties.

Devices regulation

Our role in regulating medical devices and in vitro diagnostic (IVD) devices remains integral. We oversee the essential work of the five UK Notified Bodies; together they are responsible for assessing the majority of devices currently placed on the EU market. Our preparations to implement proposed new Regulations for Medical Devices and IVDs continue.

Vigilance and market surveillance

We maintain our role in vigilance, market surveillance and taking direct action, where needed, to protect patients and public health, and we continue to co-ordinate with other Competent Authorities, across Europe and internationally, in these and other areas.

Statements are also available from the British Pharmacopoeia and the National Institute for Biological Standards and Controls (NIBSC)

Future regulatory partnership

On 4 July the UK Government gave a clear, public statement of its desire to retain a close working partnership in respect of medicines regulation after the UK leaves the EU, in the interests of public health and safety. The statement, published in the Financial Times, by the Secretary of State for Health and Secretary of State for Business, Energy and Industrial Strategy laid out the three principles which will underpin the development of a post-Brexit regulatory system for medicines and devices: patients should not be disadvantaged; innovators should be able to access the UK market as quickly and simply as possible; and we will continue to play a leading role in both Europe and the world in promoting public health.

These principles and the government's position were developed further in a speech by the Parliamentary Under Secretary of State at the Department of Health, Lord O'Shaughnessy, at the BIA/MHRA conference in London on 14 July.

EMA/EU & CMDh notices to Marketing Authorisation Holders

We are aware of the recent notices to Marketing Authorisation Holders issued by the EMA/EU-27 and CMDh advising of preparations MA holders may want to consider ahead of the UK's exit from the EU.

Until the exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. We therefore continue to play a full role in the network and to undertake our work as a Reference Member State (RMS) in the decentralised procedure, and as (co-) rapporteur in the centralised procedure. If, however you do want to consider preparation for any potential changes to marketing authorisation or RMS, please see the information provided by the EMA and the HMA.

Whatever the outcome of the negotiation we will continue to collaborate with all involved to deliver the current speed of authorisations, access to new and innovative medicines and devices and to continue to ensure the quality, safety and efficacy of all medicines and devices, to safeguard an uninterrupted level of public health protection.

Association of the British Pharmaceutical Industry (ABPI)

ABPI react to news of delay to decision on future location of the European Medicines Agency (EMA)

23 June 2017

Following news that an announcement regarding the future location of the European Medicines Agency (EMA) will be delayed until the European Commission's General Affairs Council in November 2017, the

Association of the British Pharmaceutical Industry (ABPI) have issued the following statement.

Dr Virginia Acha, Executive Director, Research, Medicine & Innovation said:

> We acknowledge the extensive range of issues that must be addressed during the Brexit negotiations, but the timeframes we need to meet to ensure no disruption or delay to medicines supply will require securing swift agreement on both sides with regards to future medicines regulation. This is even more important given the fact that this crucial issue affects directly the health and wellbeing of citizens in both Europe and the UK.
>
> For patients and public health it is imperative to secure a future working partnership between UK and EU regulatory regimes in order to maintain capacity, processes and timeframes for the introduction of new medicines for patients. It will be critical to avoid divergence and duplication of regulatory regimes, so that patient safety is not put at risk.

NHS Confederation

Patients at risk in Brexit negotiations, Brexit Health Alliance warns

1 August 2017

An alliance of leading healthcare organisations has called on the government to protect the interests of patients in the Brexit negotiations with the EU.

The Brexit Health Alliance, which brings together the NHS, medical research, industry, patients and public health organisations, has warned that patients will suffer unless negotiators make sure that issues such as healthcare research and access to new medicines are given the attention they deserve.

> There are great opportunities but also great dangers in these negotiations," Niall Dickson, co-chair of the Alliance, said. "Patients stand to lose out if we cannot go on collaborating in major medical research studies; if we cannot access new treatments and medical devices as we do now; and if UK nationals in the EU are no longer able to benefit from access to healthcare abroad, and vice versa. It is also vital that there is a firm commitment on all sides to joint co-ordination in response to public health threats.

The Alliance is also calling for EU citizens' right to receive healthcare in the UK to be preserved.

The Alliance has set five priorities for the negotiators

1. Maximum levels of research and innovation collaboration

2. Regulatory alignment for the benefit of patients and population health

3. Preservation of reciprocal healthcare arrangements

4. Robust coordination mechanisms on public health and wellbeing

5. A strong funding commitment to the health and public health sectors

The Alliance argues it is in both Europe's and the UK's interests to maintain co-operation on all these areas.

Mr Dickson said:

> We hope that the publication of these five priority areas will help support the government to achieve the best result for patients and for healthcare across the UK.
>
> There is a huge amount of expertise within the Alliance and we urge the Government to make good use of this to make sure that these vital issues affecting the health and wellbeing of everyone in the UK are not forgotten alongside all the other issues in the negotiations.

Read the priorities in full.

The Brexit Health Alliance is co-chaired by Niall Dickson, chief executive of the NHS Confederation, and Sir Hugh Taylor, former Permanent Secretary at the Department of Health and current chairman of Guys and St Thomas's NHS Foundation Trust.

Bringing together the leading organisations representing patients, public health, the NHS, research, and industry, members of the Alliance include:

Academy of Medical Royal Colleges,

Association of Medical Research Charities,

Association of British Healthcare Industries,

Association of British Pharmaceutical Industries,

Association of UK University Hospitals,

Bio Industry Association,

Faculty of Public Health,

Medical Schools Council,

National Voices,

NHS Confederation (including Mental Health Network, NHS Clinical Commissioners, NHS Employers, NHS Partners Network),

NHS Providers,

Northern Ireland Confederation for Health and Social Care,

Richmond Group of Charities,

Scottish NHS Chief Executive Group,

Welsh NHS Confederation

3. Parliamentary Questions

European Medicines Agency: Location

Asked by: Whitford, Dr Philippa

To ask the Secretary of State for Health, what assessment he has made of the potential effect of the relocation of the European Medicines Agency on clinical trials and access to medicine in the UK.

Answering member: Steve Brine | Department: Department of Health

As part of the European Union exit negotiations, the Government will discuss with the EU and Member States how best to continue cooperation in the field of access to medicines and clinical trials.

The United Kingdom is committed to collaborating with the European Medicines Agency following the UK's departure from the EU.

While we cannot pre-judge the outcome of the negotiations, our aim is to ensure that patients in the UK and across the EU will continue to be able to access the best and most innovative medicines and be assured that their safety is protected through the strongest regulatory framework and sharing of data.

The UK is also committed to offering a competitive service for clinical trial assessment. This covers regulatory approval from the Medicines and Healthcare products Regulatory Agency as well as services from the Health Research Authority, and related ethics service, National Institute for Health Research, and the National Health Service. The UK is working towards implementation of the new European Clinical Trials Regulation, whose application date will be set by the European Commission. The current regulatory approval legislation will stay in place until such time as any changes are needed so there will be no interruption in UK clinical trials approval.

HC Deb 31 October 2017 | PQ 109850

European Medicines Agency

Asked by: Creagh, Mary

To ask the Secretary of State for Health, what preparations his Department has made to replicate the relevant functions of the European Medicines Agency after the UK leaves the EU.

To ask the Secretary of State for Health, what assessment his Department has made of the number of staff required to replicate the relevant functions of the European Medicines Agency after the UK leaves the EU.

To ask the Secretary of State for Health, what assessment his Department has made of the cost to the public purse of replicating the

relevant functions of the European Medicines Agency after the UK leaves the EU.

Answering member: Steve Brine | Department: Department of Health

Our overall aim in the negotiations is to ensure that patients in the United Kingdom and across the European Union continue to be able to access the best and most innovative medicines while being assured that their safety is protected. We are committed to continue a close working relationship with the European Medicines Agency (EMA), and the exact nature of this relationship will be determined through our negotiations.

The UK already has substantial capacity and expertise to regulate and evaluate the safety of our medicines. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) directly assesses the vast majority of medicines used by patients within the UK. The MHRA is globally recognised for its expertise and they typically undertake between 20 – 35% of the EMA's licensing and vigilance work, including a significant proportion of pharmacovigilance work and safety referrals.

HC Deb 16 October 2017 | PQ 106105; PQ 106104; PQ 106103

NHS: *European Medicines Agency*

Asked by: Onwurah, Chi

To ask the Secretary of State for Health, what assessment the Government has made of the potential effect on the NHS budget of the UK withdrawing from the European Medicines Agency.

Answering member: Steve Brine | Department: Department of Health

As part of the exit negotiations the Government will discuss with the European Union and Member States how best to continue cooperation in the field of medicines regulation in the best interests of both the United Kingdom and the EU. While it would not be appropriate to pre-judge the outcome of the negotiations, the Government's position was clarified in an open letter to The Financial Times, dated 5 July 2017. In that letter we made clear that our aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines and be assured that their safety is protected through the strongest regulatory framework and sharing of data.

HC Deb 21 July 2017 | PQ 5306

European Medicines Agency

Asked by: Brake, Tom

To ask the Secretary of State for Exiting the European Union, what assessment the Government has made of the effect on access to newly developed drugs and treatments of the UK ceasing to be a member of the European Medicines Agency.

Answering member: Mr Robin Walker | Department: Department for Exiting the European Union

We recognise the importance of a close cooperative relationship between the UK and EU in the field of medicines regulation and science and research collaboration.

As part of the negotiations the Government will discuss with the EU and Member States how best to continue cooperation in the field of medicines regulation in the best interests of business, citizens and patients in the UK and the EU.

HC Deb 20 Jul 2017 | PQ 5526

European Medicines Agency

Asked by: Lord Lester of Herne Hill

Her Majesty's Government what is their assessment of the benefits and costs to the UK of membership of the European Medicines Agency.

Answering member: Lord O'Shaughnessy | Department: Department of Health

We recognise the important role that the European Medicines Agency plays in the protection of human and animal health.

In the negotiations, the Government will discuss with the European Union and Member States how best to continue cooperation in the field of medicines regulation in the best interests of both the United Kingdom and the EU. As my Rt. hon. Friends the Secretaries of State for Health and Business said in their 4 July letter in the Financial Times, the UK is fully committed to continuing the close working relationship with our European partners. Our aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines and be assured that their safety is protected through the strongest regulatory framework and sharing of data.

I underlined this message, in particular the value the UK places on ongoing co-operation, at the BioIndustry Association and Medicines and Healthcare products Regulatory Agency conference on 14 July.

HL Deb 18 July 2017 | PQ HL625

Brexit: EU Institution Relocations

Asked by: Lord Anderson of Swansea

My Lords, how are we best to construe the fact that two Cabinet Ministers felt the need to write their joint letter to the Financial Times? That is probably unprecedented. Does it not mean that there is a certain concern among the more moderate members about the harsh line of the more extreme members? For example, regarding the licensing suggestion with the European pharmaceutical authorities, does it not mean that we have not given up altogether our hope that the European Medicines Agency will remain at Canary Wharf?

Answered by: Baroness Anelay of St Johns

On removal, the European Commission has made it clear that it intends to move the two agencies. That is a decision for the EU to make. Regarding the letter written by my right honourable friends, who could not but welcome the fact that they refer to the importance of placing patient safety at the heart of regulation, providing certainty and long-term stability to the market and building on the UK's legacy as a leader in medical innovation? There is entire Cabinet agreement on that.

HL Deb 06 July 2017 | Vol 783 c975

Brexit: EU Institution Relocations

Asked by: Lord Harrison

My Lords, according to the briefing paper from the House of Commons, the hard Brexit expulsion of the European Medicines Agency and the European Banking Authority will cost us jobs, tax revenues and personnel with deep knowledge of banking and medicines, and will incur the costs of this relocation to another country. Could the Minister detail the bright, sunlit uplands for opportunity foreseen by Brexiteers for this dark and wilful act of self-harm?

Answered by: Baroness Anelay of St Johns

My Lords, as this country goes into the light of being able to decide its own future and laws, we will continue to press hard for the stability and the economy we have had heretofore. That also means we will press hard to continue the safety of products in the medical and life sciences world. The locations of agencies in themselves do not determine the future health of our economy or the safety of our products. What will determine that is achieving that deep and special relationship with the European Union. That is what we shall do.

HL Deb 06 July 2017 | Vol 783 c973

NHS: Drugs

Asked by: Day, Martyn

To ask the Secretary of State for Health, what assessment he has made of the effect on obtaining authorisations for new drugs of the UK withdrawing from the European Medicines Agency.

Answering member: Steve Brine | Department: Department of Health

The extent to which European Medicines Agency procedures will apply in the United Kingdom after we have exited the European Union will be subject to negotiations. Whatever the outcome of negotiations, the Government will ensure that we have a regulatory system that protects the best interests of patients – without regulatory delay in the approval of new medicines - and encourages innovation.

HC Deb 05 July 2017 | PQ 1340

European Medicines Agency

Asked by: Day, Martyn

To ask the Secretary of State for Exiting the European Union, what estimate he has made of the annual value to the economy from the European Medicines Agency having been located in London in each of the last five years.

Answering member: Mr Steve Baker | Department: Department for Exiting the European Union

We recognise the important role that the European Medicines Agency (EMA) plays in the protection of human and animal health.

In the negotiations the Government will discuss with the EU and Member States how best to continue cooperation in the field of medicines regulation in the best interests of both the UK and the EU.

We have a world class research base and world beating universities and businesses that mean the UK life sciences will continue to thrive. As shown by the recent investment decisions by GSK, Alnylam and Novo Nordisk, the UK remains open for business. It is in the interests of the UK and EU to secure a mutually beneficial agreement for business and citizens across Europe.

HC Deb 04 July 2017 | PQ 1089

Drugs: Marketing

Asked by: Baroness Hayter of Kentish Town

Her Majesty's Government whether they plan to convert EU Regulation 658/2014 into UK law; and, if so, which UK body will assume the role of the European Medicines Agency for the setting and charging of fees to UK-based marketing authorisation holders.

Answering member: Lord O'Shaughnessy | Department: Department of Health

The Medicines and Healthcare products Regulatory Agency sets and charges fees for marketing authorisations in the United Kingdom which are granted nationally and not approved centrally by the European Medicines Agency. The extent to which European Medicines Agency procedures will apply in the UK after we have exited the European Union will be subject to negotiations. The Government will ensure that the UK's full approval regime is ready and operational as soon as the UK has formally departed the EU.

HL Deb 29 June 2017 | PQ HL74

4. Useful links and further reading

Medicines and Healthcare products Regulatory Agency *Speech given by Lord O'Shaughnessy on Brexit and medicines regulation* Delivered on14 July 2017 (Transcript of the speech, exactly as it was delivered)

https://www.gov.uk/government/speeches/speech-given-by-lord-oshaughnessy-on-brexit-and-medicines-regulation

UK EU Life Sciences Steering Group *Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU* September 2016

https://www.bioindustry.org/uploads/assets/uploaded/9a93e20b-1a6a-4f08-b965a6dd3a982884.pdf

BMA briefing: *medicine and medical device regulation* 17 October 2017

https://www.bma.org.uk/collective-voice/influence/europe/brexit/bma-brexit-briefings/medicines-and-medical-devices-regulation

Department for Exiting the European Union *Collaboration on science and innovation - a future partnership paper* 6 September 2017

This paper outlines the UK's objectives for an ambitious science and innovation agreement with the EU. It sets out examples of where the UK sees potential mutual benefit in a close working relationship, exploring precedents for each. The paper invites discussion with the EU on how best to shape our future partnership in this area.

https://www.gov.uk/government/publications/collaboration-on-science-and-innovation-a-future-partnership-paper

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