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DEBATE PACK

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# Future of the European Medicines Agency

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This Debate Pack has been prepared ahead of the debate on the *Future of the European Medicines Agency* to be held in Westminster Hall on Wednesday 12 October 2016 at 2:30pm – 4pm. The Member in charge of this debate is Daniel Zeichner MP.

This briefing contains recent press and parliamentary material and links to further reading.

## Contents

# 1. Summary

The debate on the Future of the European Medicines Agency will take place on Wednesday 12 October at 2.30pm in Westminster Hall. The member in charge is Daniel Zeichner MP.

The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines developed by pharmaceutical companies for use in the EU.

Founded in 1995, the European Medicines Agency (EMA) works across the European Union (EU) to protect public and animal health by assessing medicines and by providing independent, science-based information on medicines. Its activities include, assessing medicines for marketing authorisations, monitoring the safety of medicines and working to improve access to innovative medical products.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the Department of Health executive agency responsible for licencing and regulating medicines and medical devices in the UK.

## Leaving the EU and the EMA

The EMA is based in London and the vote to leave the EU on 23 June 2016 has led to speculation that it is likely to move when the UK leaves the EU. Following the referendum, it has been reported that a number of other countries have expressed interest as potential new sites for the agency.[1] According to reports in the Guardian and the Financial Times a number of EU states, including Ireland and Spain, have expressed an interest in hosting the EMA.[2]

Following the referendum result, a statement from the EMA explained that its work will continue as normal; as there is no precedent for a Member State leaving the EU, the implications for the location and operation of the EMA are unknown. The EMA also stated that any decision about the location of the agency's headquarters will be decided by common agreement by Member States:

> EMA welcomes the interest expressed by some Member States to host the Agency in future. The decision on the seat of the Agency will however not be taken by EMA, but will be decided by common agreement among the representatives of the Member States. We are confident that the Member States will take the most appropriate decision on EMA's location and arrangements in due course, taking also into account the complex political and legal environment generated by the outcome of the UK referendum.

> The European Regulatory Network as a whole is a very strong and flexible system that is able to adapt to changes without jeopardising the quality and effectiveness of its work. The Agency is in close contact with the EU institutions. As soon as concrete information will become available, EMA will share it with its stakeholders.[3]

In response to a Parliamentary question in September, the Under-Secretary of State for Health, David Mowat, reported that the location of the EMA will be decided once the UK has left the EU, and that it is too early to speculate on this.

According to the Financial Times the EMA outsources up to a third of its work to the MHRA and this work is responsible for a third of the MHRA's income.[4] A report in the British Medical Journal states that this work by the MHRA also makes the UK an attractive location to carry out clinical trials.[5]

The MHRA has responded to the EU referendum result. It has said that it will continue to make a global contribution to improving public health through effective regulation of medicines and medical devices:

> Following the result of the referendum on the UK's membership of the European Union, the focus of the Medicines and Healthcare products Regulatory Agency continues to be on our public health role. We will continue to work to the highest levels of excellence and quality, working with and supporting our customers, partners and stakeholders to protect health and improve lives. [6]

Beyond the future of the EMA and its location, there are wider issues relating to how medicines will be regulated following leaving the EU.

Countries that are members of the EEA, are covered by the EMA, and have access to the centralised marketing authorisation procedure. This may mean that the UK could continue to do so after leaving the EU but this will depend on the negotiations that take place and the resulting position of the UK in the single market. However, EEA countries do not play a role in decision making and the operation of the EMA.

If the UK does not become a member of the EEA, pharmaceutical companies would need to apply for marketing authorisations separately to the Medicines and Healthcare Products Regulatory Agency (MHRA) for a medicine they wished to supply in the UK.

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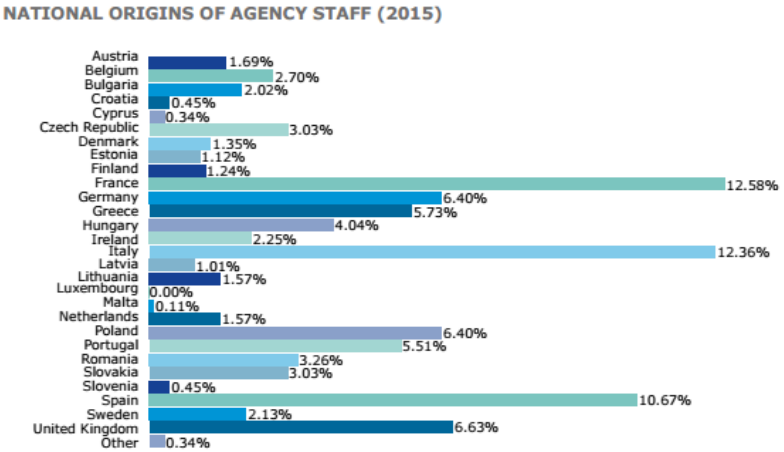
3 EMA, Statement on the outcome of the UK referendum, 6 July 2016
4 Financial Times, Brexit Briefing: Bitter medicine, 4 August 2016
5 BMJ, How "Brexit" might affect the pharmaceutical industry, 10 May 2016
6 MHRA, Medicines and Healthcare products Regulatory Agency statement on the outcome of the EU referendum, updated 11 August 2016

# 2. Pharmaceutical industry in the UK

The following data summarises employment in the EMA and provides some economic background to the pharmaceutical industry in the UK.[7]

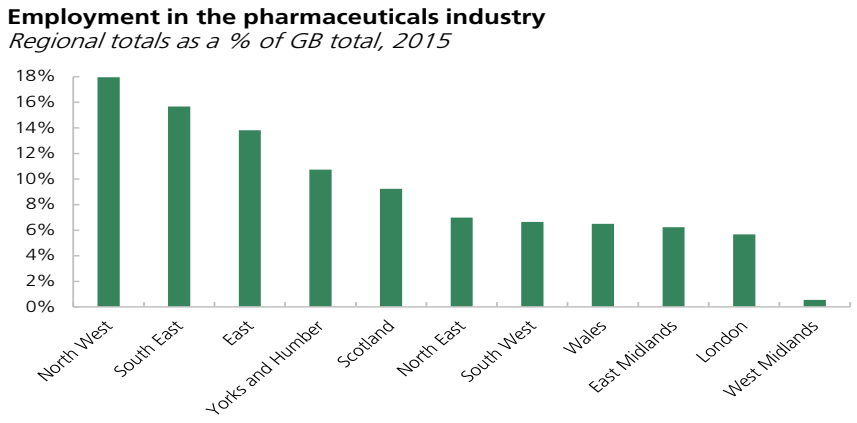
### Employment the EMA

The EMA employs 890 people as of December 2015. All EMA staff are based in the Agency's London office at Canary Wharf. From the Agency's Annual Report for 2015, staff are 70% female. As the chart below shows only 7% of EMA staff are of UK national origin.[8]




### Employment in the pharmaceuticals industry

There were 34,000 employees in the whole of the UK pharmaceutical industry in 2015, roughly the same number as in 2009, but down 7,000 since 2011.The chart below shows that the North West of England is the UK region or country with the most pharmaceutical employees (6,000 or 18% of the total). 16% or 5,000 are based in the South East and a further 14% in the East of England




7 The pharmaceutical industry is defined as the manufacture of basic pharmaceutical products and pharmaceutical preparations (SIC code 21). Economic output is in terms of Gross Value Added (GVA) a measure similar to GDP.

8 EMA, *Annual Report 2015*, 2016, p90

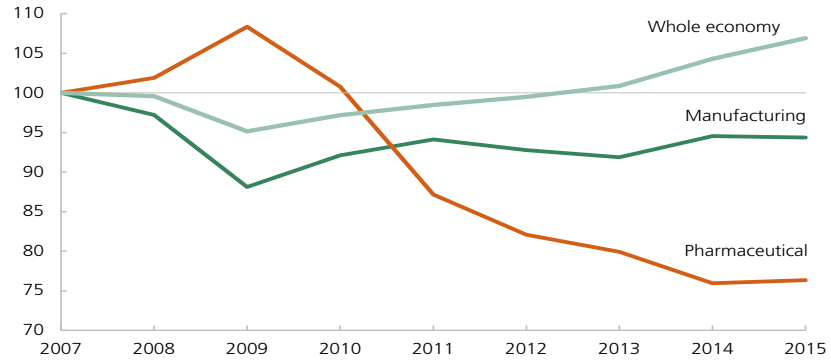
## Economic output

The pharmaceutical industry in the UK was worth £12.7 billion in 2015. This was 1% of total UK output, and 8% of the manufacturing sector's output.

The chart below shows how the pharmaceutical industry has performed since before the financial crisis, compared with the whole manufacturing sector and the whole UK economy.

**Economic output since 2006**

*UK, 2006=100, Gross value added, constant prices*




Following the financial crash in 2008, output from the whole manufacturing sector fell by 9% in 2009 compared with 2008. The impact of the crash was felt later in the pharmaceutical industry (output grew by 6% in 2009), but in the years since then output from the pharmaceutical industry has fallen sharply.

Between 2009 (when output peaked) and 2014, output from the pharmaceutical industry fell by 30% in real terms. It is now below the level last seen in 2001. It has been argued that the growth of generic medicines and the 'patent cliff' in pharmaceuticals is behind this fall in output.[9]

[9] Financial Times, *Pharma tries to avoid falling off 'patent cliff'*, 6 May 2012; Deloitte, *2015 life sciences output: UK*, 2014

# 3. Press articles

The Daily Telegraph
September 19, 2016
British life science industry seeks to remain in the EU's medicines agency
Julia Bradshaw

The Observer
September 17, 2016
EU countries in scramble to 'steal' UK-based research centres; European commission under pressure to move flagship projects to rival cities, says ex-president
Daniel Boffey

The Times
5 September 2016
Brexit to cost jobs if UK loses pharma watchdog
Tom Whipple,
[Subscription required]

The Financial Times
August 4, 2016
Brexit Briefing: Bitter medicine
Andrew Jack
[Subscription required]

The Guardian
27 July 2016
GSK says Britain is still an attractive place to invest
Julia Kollewe and Angela Monaghan

Financial Times
July 22, 2016
Roche chief warns of Brexit impact on UK drug research
[Subscription required]

Financial Times
July 1, 2016
Madrid begins land-grab for London-based EU agencies
Tobias Buck and Jim Brunsden
[Subscription required]

The Daily Telegraph
June 30, 2016
Big pharma ready to swallow the Brexit pill; the industry stands ready to embrace changes in inward investment and regulation
Julia Bradshaw

The Telegraph
29 June 2016
Big Pharma might have shrugged off Brexit, but Britain's life sciences industry faces an uncertain future
Julia Bradshaw

FT.com
May 8, 2016
UK would lose two pharma bodies in event of Brexit, lawyers warn
Andrew Ward
[Subscription required]

**Journals**

The Pharmaceutical Journal
28 June 2016
Brexit could cause 'significant' delays in getting new drugs to patients, industry warns
Elizabeth Sukkar

British Medical Journal
10 May 2016
How "Brexit" might affect the pharmaceutical industry
Anne Gulland

# 4. Press releases

**European Medicines Agency (EMA)**
6 July 2016
Statement on the outcome of the UK referendum: EMA's procedures and work streams continue as usual

The European Medicines Agency (EMA) acknowledges the outcome of the referendum of 23 June 2016. A majority voted against United Kingdom's (UK) continued membership of the European Union (EU) and it is now up to the UK government to decide how to act upon the outcome of the referendum.

EMA would like to underline that its procedures and work streams are not affected by the outcome of the referendum. The Agency will continue its operations as usual, in accordance with the timelines set by its rules and regulations.

No Member State has ever decided to leave the EU, so there is no precedent for this situation. The implications for the seat and operations of EMA depend on the future relationship between the UK and the EU. This is unknown at present and therefore we will not engage in any speculations.

EMA welcomes the interest expressed by some Member States to host the Agency in future. The decision on the seat of the Agency will however not be taken by EMA, but will be decided by common agreement among the representatives of the Member States. We are confident that the Member States will take the most appropriate decision on EMA's location and arrangements in due course, taking also into account the complex political and legal environment generated by the outcome of the UK referendum.

The European Regulatory Network as a whole is a very strong and flexible system that is able to adapt to changes without jeopardising the quality and effectiveness of its work. The Agency is in close contact with the EU institutions. As soon as concrete information will become available, EMA will share it with its stakeholders.

For the time being, the Agency, its 890 employees and all the European experts contributing to EMA's work will continue to focus on EMA's mission to protect human and animal health and ensure access to medicines that are safe, effective and of good quality.

**Medicines & Healthcare products Regulatory Agency (MHRA)**
27 June 2016
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.

MHRA will be engaging widely with our stakeholders to fully understand and maximise the opportunities of Brexit.

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

Customers, partners and stakeholders approaching MHRA continue to have access to our internationally recognised expertise and we maintain the highest quality services. For further information, please get in touch with your usual contact points in the Agency.

**Association of the British Pharmaceutical Industry (ABPI)**
24 June 2016
UK must send strong signal it is open for business

Following the result of the United Kingdom's referendum on membership of the European Union, Mike Thompson, CEO of the Association of the British Pharmaceutical Industry (ABPI) has said:

"The voice of the British people has been heard. This creates immediate challenges for future investment, research and jobs in our industry in the UK. With that being the case, we are committed to working closely with the government to agree what steps need to be taken to send a strong signal that the UK is open for business."

# 5. Parliamentary Questions

European Medicines Agency

**Asked by: Gwynne, Andrew**
To ask the Secretary of State for Health, whether his Department expects the European Medicines Agency London headquarters to be relocated.

**Answering member: David Mowat | Department of Health**
The future arrangements which apply in relation to European Union (EU) institutions based in the United Kingdom should be determined once the United Kingdom has left the EU. It is too early to speculate on the future location of the European Medicines Agency.

**15 Sep 2016 | Written questions | House of Commons | 46075**

Medical Treatments

**Asked by: Baroness Thomas of Winchester**
To ask Her Majesty's Government, in the light of the result of the referendum on the UK's membership of the EU, what plans they have for ensuring that the conditional approval of the European Medicines Agency for new treatments continues to have validity in the UK.

**Answering member: Lord Prior of Brampton | Department of Health**
The previous Prime Minister was clear that the negotiation for Britain's future relationship with Europe needed to begin under the new Prime Minister, and we now have got to look at all the detailed arrangements.

The Department has launched a ministerial industry strategy group to prepare for the renegotiation on the new European Union/United Kingdom relationship, which includes looking at the relationship between the UK and the EU medicines regulatory framework.

**20 Jul 2016 | Written questions | House of Lords | HL1088**

Department of Health: EU Law

**Asked by: Redwood, John |**
To ask the Secretary of State for Health, what EU directives related to his Department's responsibilities are awaiting transposition into UK law.

**Answering member: Jane Ellison | Department of Health**
With regards to transposition, the Department is currently finalising the following:

- European Qualifications (Health and Social Care Professions) Regulations 2016, which will transpose the relevant sections of the revised Mutual Recognition of Professional Qualifications Directive into the healthcare regulators' governing legislation;
- Commission Implementing Decision (EU) 2016/787 and certain aspects of the Tobacco Products Directive 2014/40/EU;

- Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells;
- Commission Directive (EU) 2015/566 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells; and
- Elements of the Falsified Medicines Directive 2011/62/EU (safety feature elements).

With regards to negotiations, the Department is currently leading on:

- Regulations on Medical Devices and In Vitro Diagnostics; and
- Amendments to Regulation No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

**04 Jul 2016 | Written questions | House of Commons | 40888**

Department of Health: EU Action

**Asked by: Redwood, John**
To ask the Secretary of State for Health, which EU (a) legislative and (b) other proposals his Department is leading negotiations on for the Government in the Council of the EU.

**Answering member: Jane Ellison | Department of Health**
With regards to transposition, the Department is currently finalising the following:

- European Qualifications (Health and Social Care Professions) Regulations 2016, which will transpose the relevant sections of the revised Mutual Recognition of Professional Qualifications Directive into the healthcare regulators' governing legislation;
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**04 Jul 2016 | Written questions | House of Commons | 40908**

# 6. Useful links

### The Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.

### European Medicines Agency

The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU), located in London. It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.

### Association of the British Pharmaceutical Industry (ABPI)

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

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