



BRIEFING PAPER

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Brexit and medicines regulation

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Summary

Since the referendum result in June 2016, there has been much focus on what Brexit might mean to different areas of policy and legislation. How and when we get access to medicines and how their safety is ensured is one area where the UK process is currently significantly interwoven with the work of the other EU Member States.

Currently, the European Medicines Agency (EMA) (based in London) provides and coordinates licensing, expertise and support for medicines and medical devices throughout the EU. Pharmaceutical companies may choose to licence a medicine only in one EU country, but it is likely that they will opt for the centralised, or mutual recognition procedure, that allows them to sell a product throughout the EU.

The Medicines and Healthcare Product Regulatory Agency (MHRA) is the body responsible for licensing and regulating medicines and medical devices in the UK. It currently works with the EMA both as part of a regulatory network, and as a rapporteur doing a significant amount of work on behalf of the European Agency.

The future for medicines regulation, and the location of the European Medicines Agency, following Brexit has been the subject of attention from the Government, pharmaceutical industry and medical organisations since June 2016. There have been calls for the Government to ensure that links with the EMA remain and concerns that leaving the EMA will result in a delay in access to innovative medicines, and a loss of investment from the life sciences sector in the UK. In contrast, it has also been suggested that leaving the EU could mean positive changes to the regulatory approach in the UK.

In a letter to the *Financial Times* in July 2017, the Secretary of State for Health, Jeremy Hunt, and the Secretary of State for Business, Greg Clark sought to provide reassurance on Government plans with regards to medicines regulation following Brexit. It stated that the "UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety." If the desired relationship with the EU was not achieved, the letter said that any new regulatory system would protect the interests of patients and support the UK life sciences industry.

A Government policy paper, published in September 2017 as part of the Brexit negotiations, on Collaboration on Science and Innovation, stated that the UK will look to continue working closely with the EMA, and that existing agreements between the EMA and third countries such as Switzerland, USA and Canada provide a precedent which the UK could build on.

In September 2017, the Commons Health Select Committee launched an inquiry on Brexit – medicines, medical devices and substances of human origin. The deadline for submissions of written evidence has recently closed and oral evidence sessions are expected in November and December.

On 20 November 2017, the EU Council announced that Amsterdam will be the new location for the EMA.

This briefing paper provides an overview of current medicines regulation in the UK and the relationship with the EMA and regulatory agencies in EU Member States. It will consider what the options may be in this area following Brexit, and present comment on these from stakeholders. The paper is narrowly focused on medicines regulation and does not discuss potential changes to research funding and clinical trials regulation following Brexit.

1. Current medicines regulation

This section provides an overview of the current medicine regulatory bodies and processes in the UK and throughout the European Union (EU) and the European Economic Area (EEA).

For a more detailed description of the regulation of medical products in the EU, a 2015 European Parliament Research Service briefing, [Medicinal products in the European Union: The legal framework for medicines for human use](#) may be useful.

1.1 The regulatory bodies

There are currently two regulatory bodies through which UK medicines can be licensed, medical devices are regulated and a medicine's safety is monitored. The European Medicines Agency performs all these roles on an EU and EEA (European Economic Area) country wide basis. The Medicines and Healthcare Products Regulatory Agency is the UK-based regulator. These two bodies currently work closely together.

The European Medicines Agency

The [European Medicines Agency \(EMA\)](#) is an agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines.

The EMA works across the European Union (EU), performing a number of functions, including:

- Assessing both human and animal medicines for marketing authorisations;
- Providing independent evidence based information on medicines;
- Monitoring the safety of medicines post authorisation; and
- Assessing and regulating medical devices.

[Over 50 national medicines authorities](#) from EU Member States and EEA countries and others collaborate with the EMA. The EMA describes this as a "*unique regulatory framework*" that offers the following benefits to EU citizens:

- Enables Member States to pool resources and coordinate work to regulate medicines efficiently and effectively;
- Creates certainty for patients, healthcare professionals, industry and governments by ensuring consistent standards and use of best available expertise;
- Reduces the administrative burden through the centralised authorisation procedure, helping medicines to reach patients faster;
- Accelerates the exchange of information on important issues, such as the safety of medicines.¹

The majority (about 89%) of the EMA budget comes from fees and charges. These include fees for processing marketing authorisation

¹ EMA, [European medicines regulatory network](#) [accessed 7 September 2017]

applications, and for scientific advice. In 2017, the total budget of the EMA was €322 million:

- €285.1 million came from fees and charges levied for regulatory services;
- €16.5 million came from the EU (€16.125 million) and EEA contributions (€0.398 million); and
- €20.4 million came from other sources including corrections to budgetary imbalances in the previous year²

More detailed information on the work of the EMA can be found in a recent European Parliament Research service briefing, [European Medicines Agency: A look at its activities and the way ahead](#).

The Medicines and Healthcare Products Regulatory Agency

The [Medicines and Healthcare products Regulatory Agency](#) (MHRA) is the Department of Health executive agency responsible for licensing and regulating medicines and medical devices in the UK.

Its responsibilities include:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- supporting innovation and research and development that's beneficial to public health
- influencing UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health.³

The budget of the MHRA for the 2016/17 period was £157.2m. As with the EMA, most of this (£128.7m) comes from trading activities such as income from fees.⁴

² EMA, [Funding](#), [accessed 2 October 2017]

³ MHRA, [About us](#) [accessed 7 September 2017]

⁴ MHRA, [Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2016/17](#), July 2017

Box 1: The International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

The International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is an influential organisation that works to harmonise medicines registration globally, and brings together the regulators and pharmaceutical industry on this issue.⁵ The ICH comprises of the regulatory bodies of the UK, EU the US and Japan. The Council sets guidelines regarding the requirements for medicines registration that whilst not legally binding, are required for any company wishing to import medicines into the EU, Japan or the US.

Currently, the UK participates in the ICH as part of the EU delegation, and also plays a role in several ICH expert working groups.

1.2 Regulatory procedures

Before a medicine can be sold or prescribed in the UK it must usually receive a marketing authorisation (see box 2) either from the European Medicines Agency or from the UK Medicines and Healthcare products Regulatory Agency (MHRA).

A marketing authorisation will only be issued if [clinical trials](#) have proved that the medicine:

- successfully treats the condition it was developed for;
- has acceptable side effects; and
- meets high safety and quality standards.

Box 2: Types of marketing authorisations

Marketing authorisations are the European licensing system for medicines. There are several routes that applicants can take to obtain a marketing authorisation, at the EU and national level:

- **Centralised procedure:** This is set out in [Regulation \(EC\) No 726/2004](#) and allows applicants to apply for a marketing authorisation to the EMA which will then apply across the EU and EEA countries. This approach is compulsory for certain medicines such as orphan medicine products and biotechnology products.
- **Mutual recognition procedure:** This is set out in EU [Directive 2001/83/EC](#) and applies to most medicines that do not have to be licenced through the centralised procedure. This process means that if a medicine has been assessed and licensed in one EU Member State (the 'Reference Member State'), this can then be recognised throughout the EU and in EEA countries under the EMA.
- **Decentralised procedure:** This is set out in [Directive 2004/27/EC](#) which amends Directive 2001/83/EC. The procedure can be used for most conventional medicines. An application for a marketing authorisation application is submitted to several Member States at one time. One of these Member States is allocated to be the 'Reference Member State' and will undertake the assessment. When the licence is granted it will apply in the Reference and other concerned Member States.
- **National procedure:** An application for a marketing authorisation may be made to one national authority, to apply only in that Member State (eg. the MHRA in the UK)

There are special licensing procedures for certain medicines - for example, biosimilars and herbal medicines.

For more information on licencing procedures, the following sources may be useful:

⁵ [ICH website](#)

- MHRA, [Guidance: Apply for a licence to market a medicine in the UK](#)
- European Commission, [Authorisation procedures for medicinal products](#)
- Taylor Wessing, [Types of marketing authorisation](#)

Initial marketing authorisations are valid for five years and then may be renewed on the basis of a re-evaluation.

Pharmacovigilance

The EMA plays a major role in monitoring the ongoing safety of drugs in the EU. Following the granting of a marketing authorisation, and wide use of that medicine, certain adverse effects might be noted that were previously unknown. Post authorisation monitoring is an important feature of medicines safety.⁶

The [Pharmacovigilance Risk Assessment Committee](#) (PRAC) is the committee responsible for monitoring safety issues for medicines, and undertaking assessments. The Committee is made up of representatives from regulatory bodies across the EU, including the MHRA.⁷

PRAC also coordinates an EU wide system for reporting suspected adverse effects in medicines, [Eudravigilance](#). It can be used by Member States, the EMA and the pharmaceutical industry.

The MHRA conducts safety monitoring of medicines on a UK-wide basis. This includes undertaking inspections of UK-based marketing authorisation holders to ensure that they have an effective system for monitoring medicines, maintain documentation on this, and have sufficient staff to undertake this work.⁸ The MHRA also runs the [Yellow Card Scheme](#), which is used to collect evidence on medicines safety issues. Reports on side effects, defective products and adverse incidents on medicines, device and vaccine can be made through this scheme.

⁶ EMA, [Pharmacovigilance \[accessed 7 September 2017\]](#)

⁷ EMA, [Pharmacovigilance Risk Assessment Committee \(PRAC\) \[accessed 7 September 2017\]](#)

⁸ MHRA, [Guidance: Good pharmacovigilance practice \(GPvP\)](#), July 2016

2. Medical devices

A medical device is any instrument (other than a medicine) that is used to diagnose or manage a medical condition. The definition covers a wide range of products including syringes, dressings, surgical tools, scanners and some medical apps.⁹

The regulatory procedures for medical devices is currently set out in the [Medical Devices Regulations 2002](#) (as amended) which implement the following three EU Directives:

- Medical Devices Directive (93/42/EEC);
- Active Implantable Medical Devices Directive (90/385/EEC); and
- In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Medical devices that are certified under the regulations as conforming to the Directives are CE marked¹⁰ and can be marketed and sold anywhere in the EU.

Devices are classified according to [guidance set out by the European Commission](#) and the certification process is different for each class of device. These processes are set out in detail in [MHRA guidance on the gov.uk website](#).

For most devices, audits of the production process and conformity assessments must be carried out and these are done by a notified body. A [notified body](#) is an organisation that has been designated by an EU Member State (the designating authority in the UK is the MHRA) to assess whether manufacturers and their medical devices meet the requirements set out in legislation. There are currently around 50 notified bodies in the EU - five of these are in the UK.¹¹

Manufacturers can apply to any notified body in the EU and once they have the necessary certification, their products can be sold anywhere in the EU.

New EU regulations for medical devices

In April 2017, two [new EU regulations](#) were adopted by the European Parliament and the Council. ¹² [Regulation \(EU\) 2017/745](#) will regulate general medical devices and will apply after a 3 year transition period, and [Regulation \(EU\) 2017/746](#) will regulate in vitro diagnostic medical devices and will apply after 5 years.

⁹ More detail on the definition of medical devices is provided in MHRA, [Guidance on legislation: Borderlines between medical devices and medicinal products](#), May 2016

¹⁰ The CE marking is required for many products. It:

- shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements
- is an indicator of a product's compliance with EU legislation
- allows the free movement of products within the European market

¹¹ MHRA, [Guidance: Notified bodies for medical devices](#), December 2014

¹² European Commission, [Revisions of Medical Device Directives \[accessed 7 September 2017\]](#)

The European Commission website provides information about the changes introduced by the new Regulations:

The new Regulations contain a series of extremely important improvements to modernise the current system. Among them are:

- stricter ex-ante control for high-risk devices *via* a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level;
- the reinforcement of the criteria for designation and processes for oversight of Notified Bodies;
- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations;
- the introduction of a new risk classification system for *in vitro* diagnostic medical devices in line with international guidance;
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification;
- the introduction of an “implant card” containing information about implanted medical devices for a patient;
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- the strengthening of post-market surveillance requirements for manufacturers;
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.¹³

¹³ Ibid.

3. EMA relocation following Brexit

The European Medicines Agency (EMA) is currently based in London and employs over 800 people from around Europe. It is widely reported that the location of the Agency has led to significant UK investment from the life sciences sector.¹⁴ Following the result of the referendum on leaving the EU on 23 June 2016, the EU has been planning for the EMA to relocate.

In June 2017, the European Council agreed the procedures for the decision making process on the future location of the EMA and the European Banking Authority.¹⁵ A July 2017 European Parliament Research Service briefing, [European Medicines Agency: A look at its activities and the way ahead](#), provides more information on the agreed procedure:

As outlined in the European Council document, the resulting procedure consists of a call for offers from the EU-27, based on 'specified objective criteria'. Member States have until 31 July 2017 to submit their bids for hosting the EMA. The Commission will then examine the offers on the basis of the 'stipulated unweighted criteria' and convey its assessment to the Secretary-General of the Council of the EU by 30 September 2017. This assessment will inform political discussions in the autumn. The decision on the relocation will be taken by the EU-27 leaders by vote, following a specific process. The vote is expected to be held on the margins of the General Affairs Council (Article 50) meeting of 15 November 2017.

19 cities applied to host the EMA prior to the deadline on 31 July.¹⁶

On 20 November, the EU Council announced that Amsterdam will be the new location for the EMA.¹⁷ More information about Amsterdam's bid for the EMA, can be found on the [website for the bid](#) and the document, [The Dutch bid for the European Medicines Agency](#).

In August 2017, the EMA published a business continuity plan in order to deal with the "*uncertainty and workload implications*" linked to the UK leaving the EU and the EMA relocation.¹⁸ The plan categorises and prioritises tasks. It reports that in order to free up staff to prepare for Brexit, a number of EMA activities have been temporarily suspended, for example, the development of a new EMA web portal providing information on medicines.

¹⁴ The Times, [More than 800 jobs put at risk if medicine watchdog is forced out](#), 2 July 2016

¹⁵ European Council, [Decision on the procedure for relocation of EU agencies currently located in the UK, 22/06/2017](#), June 2017

¹⁶ European Commission, [Relocation of the UK-based EU agencies](#), 1 August 2017

¹⁷ EU Council, [European Medicines Agency to be relocated to Amsterdam, the Netherlands](#), 20 November 2017

¹⁸ EMA, [EMA prepares for Brexit](#), 1 August 2017

3.1 Impacts of the relocation

The EMA have highlighted risks in relation to the relocation of the agency, these include staff retention and recruitment, and a loss of UK expertise.

Externally, concerns have also been raised that an EMA move could result in job losses and a reduction in investment in the life sciences sector in the UK which currently benefits from being located close to the regulator.¹⁹

Staffing concerns

In January 2017, the Executive Director of the EMA, Guido Rasi, expressed concerns that the agency had lost a significant number of senior staff since the referendum, and more resignations could be expected due to uncertainty about location following Brexit.²⁰

The results of an EMA retention staff survey published in September 2017 showed that, for some of the potential host cities for the agency, staff retention rates could be less than 30%:

The [results of the survey](#) emphasize the importance of the upcoming decision on the EMA's future seat as the retention of skilled and experienced staff is crucial for the Agency's continuity of operations.

The outcome that was shared with staff earlier this month revealed that for certain locations staff retention rates could be significantly less than 30%. This would mean that the Agency is no longer able to function and, as there is no backup, this would have important consequences for public health in the EU. In a best case scenario, EMA could keep up to 81% of its workforce.

In accordance with the current business continuity planning, four clusters of candidate cities have emerged. The first cluster includes those cities where 65% or more of EMA staff indicated that they are likely to move. In the second cluster are cities where staff retention would range between 50 and 64%. The third cluster includes those to which between 30 and 49% of staff are likely to relocate. In the last cluster are those cities where less than 30% of EMA staff said they would follow.²¹

The EMA went on to state that some staff losses can be absorbed *“but beyond a critical threshold the Agency will no longer be able to fulfil its mandate to protect the health of European citizens.”*²²

The results of the survey were anonymised but the *Financial Times* reported that it later emerged that Amsterdam was the site with the best case scenario for staff retention – keeping up to 81% of the workforce.²³

¹⁹ The Times, [More than 800 jobs put at risk if medicine watchdog is forced out](#), 2 July 2016

²⁰ Financial Times, [London-based regulator for EU drugs fears staff exodus](#), January 2017

²¹ EMA, [Update on EMA relocation preparedness](#), 26 September 2017

²² Ibid.

²³ [European Medicines Agency moves to plug staffing gap after Brexit](#), Financial Times, 6 October 2017

MHRA work on behalf of the EMA

The Medicines and Healthcare products Regulatory Agency (MHRA) is one of the larger national medicines authorities in Europe. Its size and location near the EMA means that it conducts a significant amount of work on behalf of the European agency - working as an appointed rapporteur. In January 2017, the Secretary of State for Health, Jeremy Hunt reported in evidence to the Health Select Committee that the MHRA does around 40% of the testing for the EMA, and often the most complex cases.²⁴

In its 2017 Work Programme, the EMA reported that currently, UK experts constitute 15% of its expert base and conduct around 20% of the scientific work. It reports that losing this workforce will increase workload for EU experts and action is required to ensure output is not affected.²⁵

[The Financial Times](#) has reported that the work outsourced to the MHRA from the EMA is responsible for a third of the MHRA's income.²⁶ It is also thought that this work on behalf of the EMA contributes to making the UK an attractive location to carry out clinical trials.²⁷

Cost of the relocation

Another issue raised is the cost associated with an EMA relocation. This includes the lease for the building in Canary Wharf where the EMA is currently located, which has over 20 years remaining. The Financial Times has reported that under the terms of the lease, the EU will owe the landlord €16million a year plus taxes until 2039, totaling €400million.²⁸

A June 2017 European Commission position statement on the financial settlement, stated that the UK should cover the costs relating to the withdrawal process, including the relocation of agencies or other Union bodies.²⁹ The UK Government has not commented on the issue of relocation costs, and a financial settlement is a current issue in Brexit negotiations. A Commons library briefing paper, [Brexit: the exit bill](#), provides further information on the negotiations on the financial settlement.

In August 2017, the online newspaper *EU Observer* reported that a presentation made to the European Parliament estimated the total cost of EMA relocation to be €582.5 million.³⁰ These costs included the rental obligations for the property in Canary Wharf, staff relocation, costs for the agency move and preparation for the new site.

²⁴ Health Committee, [Oral evidence: Brexit and health and social care](#), HC 640, 24 January 2017

²⁵ EMA, [Work programme 2017](#), January 2017

²⁶ Financial Times, [Brexit Briefing: Bitter medicine](#), 4 August 2016

²⁷ BMJ, [How "Brexit" might affect the pharmaceutical industry](#), 10 May 2016

²⁸ Financial Times, [EU agency faces €400m London rent bill after post-Brexit move](#), 27 April 2017

²⁹ European Commission, [Position paper transmitted to the UK: essential principles on the financial settlement](#), 12 June 2017

³⁰ EUObserver, [Cost of moving EU drug agency could top €580mn](#), 31 August 2017

Beyond the future of the EMA and its location, there are wider issues relating to how medicines will be regulated following leaving the EU (discussed in section 4).

4. Medicines regulation after Brexit

Summary

All EU Member States are part of the EMA. EEA countries are also part of the EMA, and have access to the centralised marketing authorisation procedures. However, these countries do not play a role in decision making and the operation of the EMA. For other countries, such as Switzerland, Australia and Canada the EMA has mutual recognition agreements, which in each case outline what element of manufacturing/ distribution practice will be recognised.

In January 2017, the Secretary of State for Health said that, whilst he did not want to prejudge the negotiations between the EU and the UK, he did not expect the UK to stay in the EMA. He said he hoped that there could be a mutual recognition agreement between the EMA and the UK. In a joint letter with the Secretary of State for Business, Energy and Industrial Strategy to the *Financial Times* in July 2017, Jeremy Hunt said that the UK is fully committed to a close working relationship with the EU, and that the aim is to maintain access to innovative medicines and a strong regulatory framework. The letter stated that the “*UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety.*” If the desired relationship with the EU was not achieved, the letter said that any new regulatory system would protect the interests of patients and support the UK life sciences industry.

A Government policy paper, published in September 2017 as part of the Brexit negotiations, on Collaboration on Science and Innovation, stated that the UK will look to continue working closely with the EMA, and that existing agreements between the EMA and third countries such as Switzerland, USA and Canada provide a precedent which the UK could build on.

In May 2017 the EMA and the European Commission published a notice to the license holders of medicinal products with a centrally authorised marketing authorisation. This set out that, following the UK submission of notification of withdrawal from the EU, from 30 March 2019, the UK will become a ‘third country’ and that this will have legal consequences for UK based pharmaceutical companies.

4.1 What could be the outcome for future UK medicine regulation?

There is existing EU legislation on medicines that is likely to remain after the UK leaves the EU. However, EU regulations on medical devices have come into force but will not apply prior to Brexit day. It appears, these will not be automatically converted into UK law under the *European Union (Withdrawal) Bill*.

Clause 3 of the *European Union (Withdrawal) Bill 2017* intends to convert existing EU law that applies in the UK into domestic law. Clause 3 (1) states that it converts all EU law that is ‘operative’ prior to exit day. Clause 3(3) defines ‘operative’ as any provision which, if it is stated to come into force at a particular time and then apply from a later date, actually applies immediately before Brexit day.

The [Explanatory Notes to the European Union \(Withdrawal\) Bill](#) state that “where the date of application falls after exit day, the provision is not converted.”

Marketing authorisations

As discussed in Section 1, marketing authorisations in the EU are generally governed by two pieces of legislation – Regulation 726/2004 (which applies directly in the UK), and Directive 2001/83 which is implemented in the UK through the [Human Medicines Regulations 2012](#).

In the case of the legislative requirements for marketing authorisations, it seems that these will apply in the UK following Brexit under the terms of the *EU (Withdrawal) Bill*. However, the ability to participate in EU-wide marketing authorisation procedures requires more than the implementation of EU law in this area, it will require some form of cooperation and mutual recognition between the UK and EMA.³¹ There will be no continued automatic access to the EMA unless this is negotiated.

The new EU medical device regulations

The new EU Regulations on medical devices ([Regulation \(EU\) 2017/745](#) and [Regulation \(EU\) 2017/746](#)) will only apply in Member States after the day that the UK will exit the EU. The general medical devices will apply after a 3 year transition period (2020), and the in vitro diagnostic medical devices regulations will come into force after 5 years (2022). This has led to concerns about what this will mean for the application of the legislation in the UK.³²

It appears, from clause 3 of the *EU (withdrawal) Bill*, that the new EU regulations on medical devices would not be converted into UK law on Brexit day because, although they will be in force (all EU regulations become immediately enforceable in all Member States simultaneously), they will not apply and so will not be 'operative' within the meaning of Clause 3. However, the MHRA has reported that its preparations to implement the Regulations continue.³³

More information on Clause 3 and the *European Union (Withdrawal) Bill* in general can be found in the library briefing paper, [European Union \(Withdrawal\) Bill](#).

The options for future regulation

There has already been some discussion about what medicines regulation may look like in the UK following Brexit.

The Chairman of the MHRA, Professor Sir Michael Rawlins, in evidence to the Lords Science and Technology Select Committee in January 2017, stated that there are two broad options – one where the UK remains within the system and another where the MHRA becomes a sovereign regulator:

There are two broad options. One is that we can remain within the system and contribute to the scientific discussions. We might even be able to remain within the system not only operationally but have some influence over new regulations and directives. The

³¹ Taylor Wessing, [Brexit and medicines regulation \(June 2017 update\)](#), June 2017

³² Field Fisher, [It's all a question of timing: Medical Devices, In Vitro Diagnostic Devices, EU Regulations, and Brexit](#), 19 July 2017

³³ MHRA, [MHRA and making a success of Brexit](#), updated August 2017

alternative option is related to whether or not we are a sovereign regulator and do it ourselves. Even as a sovereign regulator we would still need to have some mutual recognition arrangements with the EU. For example, we would want to have mutual recognition arrangements over inspections. We contribute to the EU's inspectorate going around India, China, wherever, looking at manufacturing sites, but we cannot do it all on our own; we need to share out the burden. It has to be two-way traffic.

He went on to highlight medical device regulation as being of particular importance for mutual recognition. He said that the MHRA wanted an arrangement where they can still appoint notified bodies in the UK, and that these be recognised across Europe.³⁴

Box 3: What is a mutual recognition agreement?

There has been some discussion of a mutual recognition agreement (MRA) between the UK and the EU following Brexit.

MRAs are bilateral agreements that are primarily used in trade negotiations to promote trade and facilitate market access in goods between the EU and third countries. They set out where regulators will accept the test results/licencing processes of another country and vice versa.

The EMA has a number of mutual recognition agreements with countries outside of the EEA. This includes Switzerland, Turkey and Canada.

A potential MRA between the UK and the EMA could involve recognition of:

- Good Manufacturing Practice (GMP) - a code of standards for the manufacture, packaging and supply of a medicine;³⁵
- Good Distribution Practice (GDP) - standards for the quality of the medicine to be maintained throughout the supply chain from manufacturer to wholesaler, to pharmacist to patient;³⁶
- Medical devices – for the UK to continue its role in appointing notified bodies and participating in assessing medical devices.

There has been some recent discussion about the extent to which a mutual recognition arrangement could mean that the UK will be able to work with the EMA. Some commentators have said that this could mean that a single process could be retained that would cross two legal jurisdictions, for example the Nuffield Trust report that:

The most ambitious option suggested for the period after we leave the EU is that we would retain a single process which would now cross two legal jurisdictions, British and European. Under this approach, the suggestion appears to be that pharmaceutical companies could approach either the British regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), or the European regulatory system with a new product. The regulator would then carry out an assessment resulting in a recommendation made to both the European Commission and the British Government.

There would be an agreement that both decision-making bodies would tend to abide by the recommendations of either regulatory system. Decisions of the MHRA would be open to judicial review before UK courts, but would remain outside the jurisdiction of the

³⁴ House of Lords Select Committee on Science and Technology, [Corrected oral evidence: Brexit: regulation and standards \(Question 4\)](#), 10 January 2017

³⁵ EMA, [Good-manufacturing-practice and good-distribution-practice compliance \[accessed 30 June 2017\]](#)

³⁶ *ibid*

European Court of Justice, even though the Commission taking decisions based on its evidence would be within its jurisdiction.³⁷

4.2 Government approach

The Secretary of State for Health, Jeremy Hunt, in evidence to the Commons' Health Select Committee in January 2017, said that he did not expect the UK to stay within the EMA. However, he said he was hopeful that the UK would continue working closely with the EMA:

I do not expect us to remain within the European Medicines Agency, but I am very hopeful that we will continue to work very closely with the EMA. This country has a closer relationship with the EMA than any other member state of the EU. The MHRA, which is our national regulator, does around 40% of the testing for the EMA, and it is not just the easy 40%; it is often the most complex and difficult cases. We have the foundations for a sensible, strong partnership, which means that, potentially, we could have mutual recognition between the EMA and the MHRA going forward. I will be open to having the closest possible relationship on those things, but I cannot prejudge the negotiations.³⁸

Mr Hunt said that whilst he was hoping for the closest possible relationship he did not think that the Government would agree to anything that made the UK subject to the jurisdiction of the European Court of Justice.³⁹

In a letter to the *Financial Times* in July 2017, Jeremy Hunt, and the Secretary of State for Business, Energy and Industrial Strategy, Greg Clark said that the UK is fully committed to a close working relationship with the EU, and that the aim is to maintain access to innovative medicines and a strong regulatory framework.⁴⁰

They said three principles would assist the development of a regulatory system post-Brexit:

We have three principles which will help us rise to the challenge of developing a new regulatory system post Brexit: patients should not be disadvantaged; innovators should be able to get their products into the UK market as quickly and simply as possible; and we continue to play a leading role promoting public health.

The letter highlighted a need to place patient safety first, continue supporting medical research and scientific collaborations across Europe, and for the UK to continue to lead in medical innovation. It also stated that the "*UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety.*" If the desired relationship with the EU was not achieved, the letter said that any new regulatory system would protect the interests of patients and support the UK life sciences industry.

³⁷ Nuffield Trust, [How will our future relationship with the EU shape the NHS?](#), 7 November 2017

³⁸ Health Committee, [Oral evidence: Brexit and health and social care](#), HC 640, 24 January 2017

³⁹ Ibid.

⁴⁰ [The UK wants to continue to work with the EU on medicines](#), Financial Times, 5 July 2017

This letter was welcomed by representatives of the pharmaceutical industry. For example, the ABPI said that the letter recognised the importance of future medicines regulation in Brexit negotiations, and signalled “*a readiness to take a pragmatic approach to Brexit negotiations that puts people’s health first.*”⁴¹

Following the publication of the letter in the *Financial Times*, representatives of UK and European pharmaceutical and life sciences industry wrote to the Minister for Exiting the EU, David Davis, and European Commission Chief Negotiator, Michel Barnier, calling for a smooth transition into any new framework to ensure no disruption to patient access to medicines.⁴²

It stated that the Secretaries of States’ letter had signalled a possibility to maintain close ties, and that securing an agreement would be in the best interest of public health and patient safety:

We would like to explore this possibility to maintain close regulatory ties between the EU and the UK and to begin these discussions immediately. The maintenance of previously granted European marketing authorisations both in the UK and the EU, and the continued cooperation between national competent authorities as facilitated by the EMA and European Commission, will be important in achieving this. Similarly, any changes to the EU-UK trading relationship should not adversely affect the research, development, manufacture and supply of medicines across Europe, including for clinical trials. Securing such a cooperation agreement would be in the best interest of public health and patient safety. The UK’s MHRA currently makes a significant contribution to the work of the European regulatory network (EMA, HMA, CHMP, CMDh), and its withdrawal would mean a loss of capacity and expertise for the network for the review of medicines as well as the capacity across Europe for the surveillance and safety supervision of products.⁴³

The letter went on to say that an unorderly withdrawal could result in a disruption to the supply of life-saving medicines in the UK.⁴⁴

A Government policy paper on Collaboration on Science and Innovation, published in September 2017 stated that the UK will look to continue working closely with the EMA, and that existing agreements between the EMA and third countries such as Switzerland, USA and Canada provided a precedent which the UK could build on:

The **European Medicines Agency (EMA)** is an agency of the EU, which protects human and animal health in the EU and across the European Economic Area (EEA) by ensuring that all medicines available on the EU market are safe, effective and of high quality. The UK Government’s 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 by the strongest regulatory framework and sharing of data. In this context, the UK is fully committed to continuing the close working relationship with our European partners, in the interests of public

⁴¹ ABPI, [Pharmaceutical industry respond to joint letter from Jeremy Hunt and Greg Clark in the Financial Times](#), 4 July 2017

⁴² [Letter to Michel Barnier and David Davies](#), 13 July 2017

⁴³ *ibid*

⁴⁴ *ibid*

health and safety. Drug development and clinical trials are a global business, and the UK believes a deep and special relationship with the EU remains the best way to promote improved patient and animal health outcomes, both in Europe and globally.

The UK will therefore look to continue to work closely with the EMA and other international partners. In areas such as inspections, safety of medicines and exchange of information, the EMA cooperates with regulatory bodies around the world and the EU has specific agreements in place with the USA, Canada, Japan, Switzerland, Australia, New Zealand and Israel that enable this. These provide precedents which the UK and the EU could seek to build on.⁴⁵

4.3 Response from the regulators

EMA Notice

The EMA has provided information about its ongoing work and the preparations for Brexit:

The EMA is essential to the functioning of the single market for medicines in the EU. The Agency's work is vital to providing EU citizens with effective, safe and high-quality medicines and to maintain a regulatory environment that fosters innovation and the development of new medicines.

The Agency continues its operations, in accordance with the timelines set by its rules and regulations.

However, EMA needs to prepare in a timely manner to ensure that it can continue to deliver on its mission and protect public and animal health beyond March 2019.

EMA is working on the assumption that the UK will become a third country as of 30 March 2019. This is without prejudice to the outcome of the withdrawal negotiations.

The UK fully participates in the activities of EMA. It continues to participate in all formal meetings and retains its speaking and voting rights.⁴⁶

In May 2017, the European Commission and the EMA published a Notice to all licence holders of those medicines with a centrally authorised medicines marketing authorisation. This stated that from 30 March 2019 the UK will become a 'third country' and that this would have legal consequences for medicines with a centrally authorised marketing authorisation:

In this regard, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of certain legal repercussions, which need to be considered:

- EU law requires that marketing authorisation holders are established in the EU (or EEA);

⁴⁵ Department for Exiting the European Union, [Collaboration on science and innovation: a future partnership paper](#), 6 September 2017

⁴⁶ EMA, [United Kingdom's withdrawal from the European Union \[accessed 30 June 2017\]](#)

- Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, batch release etc.

Preparing for the withdrawal is therefore not just a matter for European and national administrations, but also for private parties. Marketing authorisation holders may be required to adapt processes and to consider changes to the terms of the marketing authorisation in order to ensure its continuous validity and exploitation, once the United Kingdom has left the Union.⁴⁷

A Q&A document prepared alongside this notice provides guidance on what licence holders may have to do prior to the UK leaving the EU to ensure that the sale of their medicines would not be affected. This included that the marketing authorisation holder will need to be established in the EU, and would therefore need to ensure its licence holder will be located within the EEA; and that from the date of withdrawal products coming from the UK into the EU Member States would be considered as imported products.⁴⁸

In June 2017, the Telegraph reported that, Dr Virginia Acha, executive director of research, medical and innovation at ABPI estimated that the restructuring costs associated with EMA guidance for pharmaceutical companies would run to hundreds of millions of pounds.⁴⁹ However, she also cautioned that the document only set out one scenario – “*the hardest of hard Brexits*”.

More information on the future plans for the EMA in relation to the UK are provided on its [United Kingdom's withdrawal from the European Union webpage](#), including discussions on how work on evaluation and monitoring of medicines will be distributed between Member States following Brexit.⁵⁰

MHRA

The MHRA [responded to the referendum](#) result in June 2016 (updated in July 2017). It stated that playing a full and active role in European regulatory arrangements remained a priority for the regulator. It highlighted areas such as medicines and medical device regulation, where it currently plays a significant contributory role.⁵¹

The 2016-17 MHRA Annual report identifies Brexit is a potential risk to the agency's ability to undertake its public health protection role.⁵² It reported that a cross-Agency task force has undertaken work looking at different potential scenarios following leaving the EU, and the implications for the MHRA.

⁴⁷ EMA and European Commission, [Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use](#), 2 May 2017

⁴⁸ EMA and European Commission, [Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure](#), 31 May 2017

⁴⁹ [UK pharma sector faces 'crisis' without early Brexit deal](#), The Telegraph, June 2017

⁵⁰ EMA, [United Kingdom's withdrawal from the European Union](#)

⁵¹ MHRA, [News story: MHRA and making a success of Brexit](#), August 2016

⁵² MHRA, [Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2016/17](#), 19 July 2017

4.4 Impacts of a change to medicines regulation in the UK

Concerns have been raised about potential delays for patients accessing medicines in the UK outside of the EMA, and the need for more staff and infrastructure to take over the work done by the EMA and the other regulatory agencies in the network. The possible wider impact on the pharmaceutical industry and the economic cost to the UK has also been the subject of attention.

However, some commentators have said that leaving the EU may mean that the regulatory process in the UK could be changed. An example of this is that there could be greater parallel working between the MHRA and NICE (see box 4) to get medicines licensed and funded more quickly.

Access to medicines

Professor Sir Michael Rawlins, Chairman of the MHRA, has said that a concern he has about Brexit is that the UK could be at the “back of the queue” when it comes to access to new medicines:

One of the biggest worries I have about Brexit and standing alone as a regulator is that we are only 3% of the world market for new drugs and if we are not careful we are going to be at the back of the queue. Japan, America and Europe will be at the front of the queue and we will be at the back. This is why I emphasised in replying to Lord Ridley how important it is to put ourselves in a position where we can be at the front of the queue, not the back, like doing health regulatory assessments and health technology assessments in parallel and not in series.⁵³

These concerns have been echoed by a former head of the MHRA, Sir Alasdair Breckenridge. In an interview with the Today programme on 9 February 2016, he said that the UK market is small compared with the EU market - this may mean that drugs manufacturers would not perceive getting a licence to sell in the UK as a priority.⁵⁴ It has been reported that in Switzerland (a country that is not within the EMA, but has a number of bilateral mutual recognition agreements with the agency) regulatory processes mean that marketing approvals are agreed on average 157 days after EMA approval.⁵⁵

The UK EU Life Sciences Steering Committee was established by the Government in 2016 to look at issues relating to the life sciences following the decision to leave the EU. It is chaired by the Chief Executives of GlaxoSmithKline and AstraZeneca and its members include the Association of the British Pharmaceutical Industry, the BioIndustry Association and the Wellcome Trust.⁵⁶ The group's September 2016 report, *Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU*, emphasised that not only does

⁵³ House of Lords Select Committee on Science and Technology, [Corrected oral evidence: Brexit: regulation and standards](#), 10 January 2017

⁵⁴ BBC News, [Cancer drugs may be delayed after Brexit, say experts](#), 10 February 2017

⁵⁵ Charles River Associates, [Assessing the impact of a change in the UK relationship with the EU on the life sciences industry](#), May 2016

⁵⁶ HL Written Question 3656, [UK EU Life Sciences Transition Programme Steering Group](#), 12 December 2017

the UK benefit from the current common regulatory framework; but that the EMA also benefits from the UK expertise in this area. The Committee argued that these benefits would be lost by a move to a standalone UK regulator – this would be costly and could cause delays in access to medicines:

No longer being within the European regulatory system could result in:

- Delayed or no regulatory submission to the UK for new medicines, due to the UK effectively becoming a “second priority” launch market, resulting in delayed (relative to European patients) or no access to new products, for UK patients
- Disruption to the supply of life saving medical technologies as a result of border inspections for products going to or from Europe
- Falsified medicines reaching UK patients if the UK is not part of EU-wide monitoring systems.⁵⁷

A [February 2017 joint statement](#) from the APPG on Medical Research, the APPG for Rare, Genetic and Undiagnosed Conditions, the APPG on Muscular Dystrophy, and life science industry partners, such as the Academy of Medical Sciences, Medical Research Council, and Cancer Research UK, also urges the Government to maintain close ties with the EMA. It warns that national systems of medicines regulation can lead to delays in access to medicines.⁵⁸

Potential changes to the licensing processes

In response to questions from the Lord’s Science and Technology Select Committee in January 2017, the Chairman of the MHRA, Sir Michael Rawlins, said that there are things that could be done to put the UK “in a position where we can be at the front of the queue” for medicines. For example, the drug licensing process could be done in parallel with the assessment by NICE and that this could speed up patient access to medicines.⁵⁹

Box 4: What does NICE do?

The National Institute for Health and Care Excellence (NICE) provides evidence-based information for the NHS on the effectiveness and cost-effectiveness of healthcare interventions. It publishes mandatory technology appraisal guidance (stipulating clinical interventions – mainly medicines – which must be funded by NHS commissioners) as well as advisory clinical guidelines and public health guidance.

The technology appraisal process involves looking at:

- evidence from clinical trials and peer reviewed research showing how well a medicine or treatment works, including its likely impact on mortality and quality of life (such as pain or disability);

⁵⁷ [Maintaining and growing the UK’s world leading Life Sciences sector in the context of leaving the EU](#), UK EU Life Sciences Transition Programme Report, for the UK EU Life Sciences Steering Committee, 6th September 2016

⁵⁸ APPG on Medical Research, the APPG for Rare, Genetic and Undiagnosed Conditions, the APPG on Muscular Dystrophy, and life science industry partners. Joint Statement: [How to secure the best for life sciences after Brexit: five key areas](#), February 2017

⁵⁹ House of Lords Select Committee on Science and Technology, [Corrected oral evidence: Brexit: regulation and standards](#), 10 January 2017

- economic evidence on how much it costs the NHS; and
- the views of clinicians, patients and other stakeholders.

Sir Michael also said that the UK may be able to make part of the licensing process quicker:

Other approaches to making ourselves more attractive so we are not at the back of the queue are what I have been putting my mind to. We could be swifter than the EU. Right at the very end it is not the European Medicines Agency that gives marketing authorisation; it is the Commission en collège, and it takes 67 days on average. Someone I know very well in the pharmaceutical industry told me that each day of delay for a pharmaceutical marketing authorisation costs the company about \$1 million. That is \$67 million gone waiting for the Commission to decide to meet en collège. That is one part of it, but there are other aspects. Without impeding the quality or the standards we would want to speed up the process.⁶⁰

Another suggestion for future regulation is that the MHRA could also use the approvals of other medicines regulators, such as the Food and Drug Administration (FDA) in the United States. The Nuffield Trust, in a November 2017 report, suggested that this may allow for UK cooperation with countries like Australia and Japan to create a new significant regulatory bloc. However, it warns that this would take time and is uncertain. It may result in short term delays in access to medicines.⁶¹

[The independent 2017 Industrial Life Sciences Strategy](#) for the Office of Life Sciences, provides recommendations to Government. It warns that whilst there may be an opportunity for the MHRA to develop a new regulatory approach to innovative medicines following Brexit, it should not jeopardise its participation in EU systems and processes. It states that:

...relatively speaking, the UK market is too small even with the fastest and most innovative regulatory system in the world, to stand alone from a larger decision-making bloc.⁶²

Role in the ICH

Upon leaving the EU, the MHRA may lose a role in the ICH contributing to the development of internationally accepted guidelines on medicines registration.

An October 2017 briefing paper, ['Brexit and Pharmaceuticals' Regulation: Optimising the UK's post-Brexit influence in global standards-setting](#) (part of an ESRC funded project on Health law outside the EU) sets out what action the UK may take to regain a role in the

⁶⁰ Health Committee, [Oral evidence: Brexit and health and social care](#), HC 640, 24 January 2017

⁶¹ The Nuffield Trust, [How will our future relationship with the EU shape the NHS?](#), 7 November 2017

⁶² Office for Life Sciences, [Independent report: Life sciences: industrial strategy](#), August 2017

ICH. This would require the UK to apply to be an observer at the ICH, and then apply to be a member two years later.⁶³

Financial impact

Both the EMA and the MHRA are mostly funded through fees and charges for their work on medicines and medical devices. The EMA also receives some financial contribution from the EU budget, and the MHRA receives a contribution from the Department of Health. One of the impacts of moving away from the regulatory network of the EMA could be that the MHRA's workload will increase significantly. Responding to this could mean that increased investment and staff will be required, at a cost to the UK regulator. It is not known whether this will require further financial investment from the Government, or if trading activity will continue to support the majority of the work of the agency.

The impact on parallel trade

Parallel importing of a medicines refers to the practice where a medicine produced, licenced and sold in another country is imported for sale in the UK. Due to the difference in pricing across the EU, this results in savings for UK buyers. In order to conduct this business in the UK, there are requirements set out by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Parallel imports are allowed in the EU, through a common trademark system. This system, and the legal principle of 'exhaustion' are summarised in a blogpost from the law firm Hogan Lovells:

In a nutshell, once a product labeled with a trademark has been sold by the trademark owners or sold with their consent, the trademark right is said to be "exhausted" and can no longer be enforced by the owner. However, the effect of exhaustion of trademark rights is limited to such goods that were first distributed to the market within the EU. According to the Agreement on the EEA, distribution to Iceland, Liechtenstein or Norway would also lead to trademark exhaustion for the complete EU as well as these three mentioned countries. Given that restriction, it is clear that parallel imports is a business model that is strictly limited to trades within the EU and Iceland, Liechtenstein and Norway. Any imports from outside the EEA that happen without the consent of the pharmaceutical company, who holds the relevant trademark rights to the drugs involved, immediately constitutes a trademark infringement.

Concerns have been expressed that this will mean that UK companies outside the EU would no longer be able to parallel import medicines. The Healthcare Distribution Association (the organisation that represents medicines and medical devices suppliers in the UK (HDA)) has said that this could result in an increased risk in medicine shortages, and an increase in the cost of medicines.⁶⁴ It reports that parallel trade has led to direct savings for the NHS - €986.2 million between 2004 and 2009. In its response to the Health Committee's Inquiry on Brexit – medicines,

⁶³ Mark Flear, [Brexit and Pharmaceuticals' Regulation: Optimising the UK's post-Brexit influence in global standards-setting](#), October 2017

⁶⁴ HDA, [HDA Opinion on Brexit](#).

medical devices and substances of human origin inquiry, the HDA state that:

..parallel imports of medicines into the UK provide both certainty of supply, when there is not enough UK stock (because of a sudden spike in demand), and incentivised purchasing competition which saves the NHS over £100m per annum, on current estimates.⁶⁵

4.5 Health Committee Inquiry

In September 2017, the Commons Health Select Committee launched an inquiry on Brexit – medicines, medical devices and substances of human origin.⁶⁶ The deadline for submissions of written evidence has recently closed and oral evidence sessions are expected in November and December.

In an Opposition day debate on sectoral impact assessments on exiting the EU, the Chair of the Health committee, Sarah Wollaston provided more detail on the Committees inquiry:

The Health Committee will shortly begin an inquiry entitled “Brexit—medicines, medical devices and substances of human origin”. We will be considering, among other issues, how we can guarantee safe, effective and timely access to medicines and substances of human origin; the future of medical research and development; how we will co-operate and collaborate across Europe after we leave the European Union; and access to the appropriate workforce. The stakes could not be higher. The Committee does not want to damage the national interest; we want to do our job on behalf of patients, this House and the public.⁶⁷

She also said that she had requested sectoral assessment papers on life sciences, pharmaceuticals and medical services from the Secretary of State, and that the Committee would be able to do a better job with access to these.⁶⁸

⁶⁵ HDA, [HDA Submission to the Health Select Committee's inquiry on Brexit](#)

⁶⁶ Health Committee, [Brexit – medicines, medical devices and substances of human origin inquiry](#), 21 September 2017

⁶⁷ [HC Deb 1 November 2017 c 925](#)

⁶⁸ *Ibid.*

5. Pharmaceutical industry in the UK: statistics

This section sets out key statistics on the pharmaceutical industry in the UK and the EMA.

5.1 Importance of the industry to the economy

Overall figures

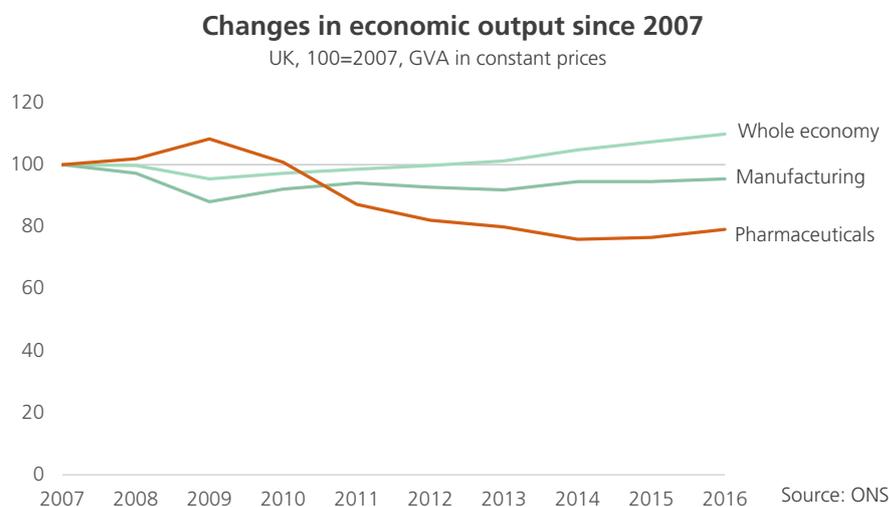
The pharmaceutical industry in the UK is significant – it had output worth **£12.8 billion in 2016**.⁶⁹

This was 1% of total UK output, and 7% of the manufacturing sector's output.

Trends

The industry performed better than the manufacturing sector and the whole economy immediately following the financial crisis and recession of 2008.

However, since then the pharmaceutical sector has performed considerably worse. In 2016, pharmaceutical industry output was 21% lower than its 2007 level.⁷⁰



Employment

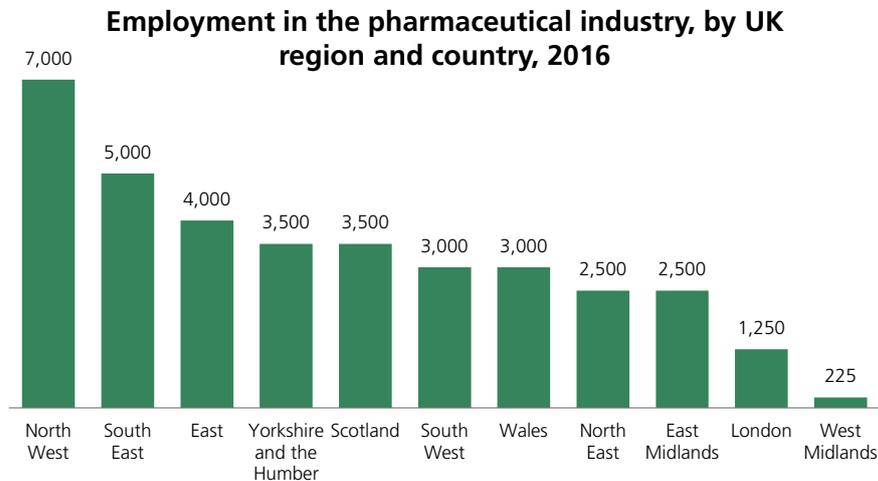
There were **36,000 employees** in the whole of the Great Britain pharmaceutical industry in 2016.

⁶⁹ 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.

ONS, [UK GDP\(O\) low level aggregates](#), 25 October 2017 – current prices

⁷⁰ ONS, [UK GDP\(O\) low level aggregates](#), 25 October 2017, Series KLA8, KL8V, KL5X – constant prices

The North West of England is the UK region or country with the most pharmaceutical employees (7,000 or 19% of the total). 14% or 5,000 are based in the South East.⁷¹



Trade

There is considerable trade in pharmaceuticals – **medicine and pharmaceutical products represent about 8% of goods exports** from the UK and about **5% of goods imports** to the UK.⁷²

UK imports of medicine and pharmaceutical products were worth £24.8 billion in 2016, and mostly came from the EU.

UK exports of these products were worth £24.9 billion – of these around half went to EU countries.

UK trade in medicinal and pharmaceuticals products, 2016 (£ billions)

	Exports	Imports	Balance
EU	11.9	18.2	-6.3
Non-EU	13.0	6.6	6.4
Total	24.9	24.8	0.1

Source: HMRC, UK Trade Info

As a % of total trade in goods

	Exports	Imports
EU	8.3%	7.7%
Non-EU	8.1%	2.8%
Total	8.2%	5.3%

Source: HMRC, UK Trade Info

5.2 The EMA

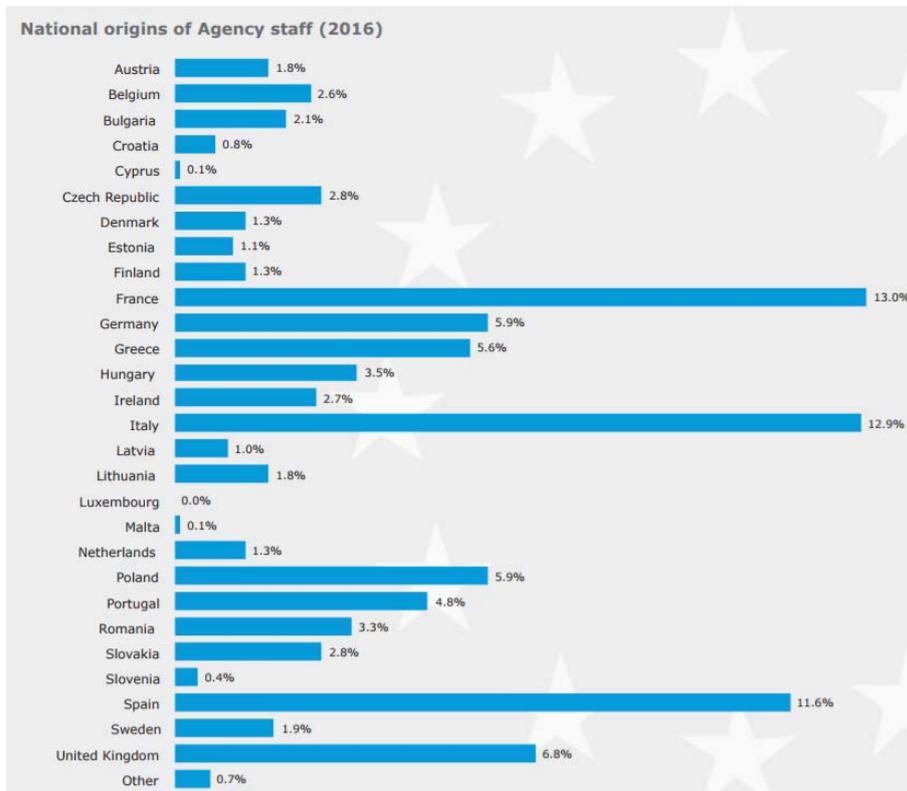
The EMA employs 897 people as of December 2016.

All EMA staff are based in the Agency's London office at Canary Wharf.

⁷¹ ONS, *Business Register and Employment Survey*, SIC code 21 (Manufacture of basic pharmaceutical products and pharmaceutical preparations)

⁷² HMRC, *UK Trade Info*, Trade Tariff Chapter 30 (Pharmaceutical products)

Female staff made up 70% of the EMA workforce. As the chart below shows, only 7% of the EMA's staff are of UK national origin.⁷³



See Section 1 for information on the budget of the EMA.

⁷³ EMA, [Annual Report 2016](#), May 2017, p84

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