



House of Commons
Health and Social Care
Committee

**Brexit: medicines,
medical devices and
substances of human
origin**

Fourth Report of Session 2017–19



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*Report, together with formal minutes relating
to the report*

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Health and Social Care Committee

The Health and Social Care Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health.

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Committee reports are published on the Committee's website at www.parliament.uk/hscocom and in print by Order of the House.

Evidence relating to this report is published on the [inquiry publications page](#) of the Committee's website.

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Summary

The United Kingdom's withdrawal from the European Union (EU)—“Brexit”—will affect many aspects of the provision of health, social care and the wider life sciences sector, both in the UK and the EU. In order to minimise harm to their citizens both sides should look to secure the closest possible regulatory alignment as a priority in the next round of negotiations.

We welcome the Government's stated intention to maintain regulatory alignment with the European Medicines Agency (EMA). The UK, with the expertise and capacity of the Medicines and Healthcare products Regulatory Agency (MHRA), has a great deal to offer its European partners. We believe this is in the interests of patients, citizens and governments on both sides of the negotiations. The entire supply chain of pharmaceuticals, from research and development, timely licensing, production, quality control, through to the product being launched and available on a pharmacy shelf, will be adversely affected by regulatory divergence and seriously so in the event of a 'no deal' Brexit.

However, while the European Council has reiterated its wish to have the UK as a close partner in the future, it has also set out that preserving the integrity of the Single Market excludes participation based on a sector-by-sector approach. As negotiations under Article 50 will be conducted as a single package, any provisions which are put in place for continued co-operation between the EU and the UK in the life sciences are dependent on similar agreements being made across the whole of the negotiations. We heard evidence from witnesses that their preferred option was Britain's continued membership of the Single Market and Customs Union or retaining a Norway type EFTA/EEA relationship. We note that the Government has ruled those options out. In the absence of a change in the Government's approach, we believe it is not just prudent, but essential, that scrutiny is undertaken of the Department of Health and Social Care's (DHSC) contingency planning for a 'no deal' situation.

For the benefit of patients, particularly those living with rare conditions, on both sides of the Channel, it is vital that the UK life sciences sector is able to continue to participate in Europe-wide clinical trials. If the UK does not adopt the new clinical trials regulations and is unable to access the infrastructure that has been developed within the EU to underpin them, a variety of difficulties for patients and the life science industry could emerge both in the short and medium to long term.

The UK should seek to continue to be a member of EU Research and Development (R&D) funding and research mechanisms such as Horizon 2020 after leaving the EU, if possible on the same terms as it currently enjoys.

The UK should also seek mutual recognition of pharmacovigilance mechanisms by the MHRA and the EMA as a priority in the next round of negotiations. This should include ensuring that all UK pharmacovigilance organisations continue to be members of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), as the failure to do so could affect patient safety both in the UK and the EU. It is also in the best interests of patients for the UK to continue membership of all of the major EU pharmacovigilance systems and databases, including the European Database on Medical Devices (EUDAMED) and Eudravigilance.

We support the case for free and frictionless trade with the EU. The Government should assess the impact of the loss of parallel imports. We also recommend that the Government undertake further contingency planning on the impact on the supply chain in the event of failure to achieve free and frictionless trade in pharmaceutical products.

We heard a consistent and repeated message during our inquiry that to minimise the risks to all stages of the development and timely supply of medicines and devices, the Government should seek the closest possible regulatory alignment with the EU.

1 Introduction

Our work

1. The UK's withdrawal from the European Union—"Brexit"—will affect many aspects of the provision of health and social care in the United Kingdom. This report is the second phase of our work on Brexit. Given the range and complexity of the questions associated with the impact of Brexit on health and social care, our predecessor Health Committee in the last Parliament focused the first phase of its inquiry on the immediate issues faced by people, including the health and social care workforce as well as citizens who rely on reciprocal healthcare arrangements. Their report, and the Government response to it, can be found on our website.¹

2. This second phase of the work of the Health and Social Care Committee on Brexit focuses on issues relating to medicines, medical devices and substances of human origin. On the basis of the written evidence we received and expert advice provided to us, we identified seven broad areas which have been the focus of our inquiry:

- The influence of the UK both in Europe and internationally
- Regulatory alignment after the UK leaves the EU
- Clinical trials conducted in the UK and the EU
- Trade, customs and supply chains for medicines, devices and substances of human origin
- The future of research and development and clinical trials
- Patient access to medicines and medical devices
- Access to EU pharmacovigilance systems and organisations.

3. Already published on our website is a letter that we have sent to the Secretary of State for Health and Social Care regarding the urgent need for clarification from the UK Government on the details of a transitional period following the UK's official departure from the EU on 29th March 2019.² This letter made the arguments that:

- The life sciences and healthcare sectors need certainty on transitional arrangements as soon as possible
- Businesses and healthcare services must not be forced to transition twice
- Public scrutiny of contingency planning is required to help minimise risks to patient care

1 Health Committee, Eighth Report of Session 2016–17, [Brexit and health and social care - people & process](#), HC640, [Government Response: Brexit and health and social care – people & process](#), December 2017, Cm9469

2 [Chair asks for clarity on Brexit transition period](#), Health and Social Care Committee - UK Parliament, accessed 8 March 2018

4. **We will be evaluating the Government’s response to our letter seeking clarity about the details of a transition period and contingency planning in the event of ‘no deal’, and expect this to be included within the response to this report.**

5. At the outset of this report, we reiterate the conclusion of our predecessors regarding contingency planning:

Giving evidence on the impact of Brexit, Jeremy Hunt MP, the Secretary of State for Health, told us that the Government would not be publishing its own digest of the implications of Brexit because “the publication of what might be called the worst-case scenario could itself have an impact on negotiations.” We do, however, urge the Department of Health to produce a comprehensive list of those issues that will require contingency planning.³

6. Far from undermining the UK’s negotiating position, we consider that clarity about contingency planning is necessary to guarantee patient safety and continued health supplies. There are implications for research and development, safety and supply chains for people and health systems both here and across the EU-27. We believe that it is important that both sides acknowledge this and remain firmly focused on the needs and safety of patients. The European Medicines Agency (EMA) has published its guidance on what is necessary for the UK to maintain continued access to medicines in a ‘no deal’ scenario, and we believe that this one-sided picture may harm public confidence if it is not possible to compare it to the Government’s planned approach.⁴ **We recommend that the Department of Health and Social Care produce a comprehensive list of all the issues relating to the supply of medicines, medical devices and substances of human origin which require contingency planning for the UK leaving the EU. We expect to see evidence that plans are in place to address identified risks to patients.**

Existing models of trade with the EU

7. Although the World Trade Organisation (WTO) sets basic rules around trade, in practice trade agreements between groups of countries go further in eliminating barriers. In particular, although tariffs on pharmaceuticals are largely eliminated at global level, there are widely diverging non-tariff barriers, such as the licensing regimes of different countries.⁵ The EU currently has two key existing models of trade with other countries, which demand different forms of regulatory alignment and jurisdictions:

Norway: the European Economic Area and single market integration

8. The European Economic Area (EEA) is a free trade agreement that extends the Internal Market of the EU to the three participating EFTA States, giving Norway full access to the single market (without a voice in the decision-making of bodies such as the EMA, but with a separate EEA/European Free Trade Agreement (EFTA) court), but which is not inside the customs union, meaning customs processing is still needed. Norway is

3 HC (2015–17) 640, Q 39

4 [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](#)

5 [Licensing regimes - European Commission](#), accessed 4 March 2018

an associated country for a variety of European research programmes including Horizon 2020, meaning it pays a financial contribution, and Norwegian researchers can take part in activities and receive grants.⁶

Canada: a free trade agreement focusing on mutual recognition

9. The free trade agreement with Canada is not focused on the external party adopting the EU's legislation, but rather on mutual recognition of each other's standards where possible. This also means that it does not provide the same degree of market integration as Norway has—though by the standards of trade agreements it is wide-ranging and includes a high degree of alignment.⁷ It includes some provisions that are particularly relevant to this inquiry. For intellectual property, the agreement obliges Canada to put in place additional protections similar to the EU. It also includes mutual recognition of each other's standards and certification bodies; this in principle could mean mutual recognition of authorisations for medical devices, but they are currently excluded, though a priority for future inclusion. It sets a framework for mutual recognition of professional qualifications; which again, in principle could apply to the health professions, though actual recognition depends on specific agreements yet to be negotiated. It also includes mutual recognition of oversight of good manufacturing practice (so manufacturing checks do not have to be duplicated). Canada is not associated to the EU's research programmes.

Options for the UK

10. We heard that from the perspective of the European Commission, the future UK-EU relationship will be one which is grounded in the principles of one of these different relationships.⁸ In 2017 Michel Barnier, the EU's chief negotiator, argued that the UK could choose between the 'Canada' or 'Norway' model, but that any trade relationship with the UK after Brexit would necessarily be one of these two models.⁹ There would be no place for a new relationship to be drawn up, so the UK could choose between one of these existing models, or face no trade deal at all.¹⁰ This was, apparently, reaffirmed by the draft text of the European Council's negotiating position which was published on 7th March, which stated that:

A non-member of the Union, that does not live up to the same obligations as a member, cannot have the same rights and enjoy the same benefits as a member. The European Council recalls that the four freedoms of the Single Market are indivisible and that there can be no “cherry picking” through participation based on a sector-by-sector approach, that would undermine the integrity and proper functioning of the Single Market. The European Council further reiterates that the Union will preserve its autonomy as regards its decision-making, which excludes participation of the United Kingdom as a third-country to EU Institutions, agencies or bodies. The role

6 [Associated Countries - European Commission - Europa EU](#), accessed 2 March 2020

7 [EU-Canada Comprehensive Economic and Trade Agreement \(CETA\)](#), accessed 4 March 2020

8 [Michel Barnier: UK-EU deal will not be a “combination” of Norway model and EU-Canada trade deal](#), Open Europe, accessed 4 March 2018

9 [Michel Barnier: UK-EU deal will not be a “combination” of Norway model and EU-Canada trade deal](#), Open Europe, accessed 4 March 2018

10 [EU-UK Future relationship](#), accessed 5th March 2018

of the Court of Justice of the European Union will also be fully respected. As regards the core of the economic relationship, the European Council confirms its readiness to initiate work towards a free trade agreement (FTA), to be finalised and concluded once the UK is no longer a Member State. Such an agreement cannot offer the same benefits as Membership and cannot amount to participation in the Single Market or parts thereof.¹¹

11. In contrast, the UK Government has been clear that it wants neither Canada nor Norway as a model for a future trade relationship with the EU. The Prime Minister in her Mansion House speech on 2nd March argued:

... The existing models for economic partnership either do not deliver the ambition we need or impose unsustainable constraints on our democracy.

For example, the Norway model, where we would stay in the single market, would mean having to implement new EU legislation automatically and in its entirety - and would also mean continued free movement.

Others have suggested we negotiate a free trade agreement similar to that which Canada has recently negotiated with the EU - or trade on World Trade Organisation terms.

But these options would mean a significant reduction in our access to each other's markets compared to that which we currently enjoy.

And this would mean customs and regulatory checks at the border that would damage the integrated supply chains that our industries depend on and be inconsistent with the commitments that both we and the EU have made in respect of Northern Ireland.¹²

12. The Prime Minister instead set out the relationship which she will be looking to secure with the EU as one which is "tailored to the needs of our economies":¹³

This follows the approach the EU has taken with its trade agreements in the past - and indeed with its own single market as it has developed. The EU's agreement with Ukraine sees it align with the EU in some areas but not others. The EU's agreement with South Korea contains provisions to recognise each other's approvals for new car models, whereas their agreement with Canada does not. Equally, the EU's agreement with Canada contains provisions to recognise each other's testing on machinery; its agreement with South Korea does not. The EU itself is rightly taking a tailored approach in what it is seeking with the UK. For example, on fisheries, the Commission has been clear that no precedents exist for the sort of access it wants from the UK. The fact is that every Free Trade Agreement has varying market access depending on the respective interests of the countries involved. If this is cherry-picking, then every trade arrangement is cherry-picking. Moreover, with all its neighbours the EU has varying levels of access to the Single

11 [European Council \(Art.50\) \(23 March 2018\) - Draft Guidelines](#)

12 [PM speech on our future economic partnership with the European Union](#)

13 [PM speech on our future economic partnership with the European Union](#)

Market, depending on the obligations those neighbours are willing to undertake. What would be cherry-picking would be if we were to seek a deal where our rights and obligations were not held in balance. And I have been categorically clear that is not what we are going to do.¹⁴

13. While we would be keen to see this relationship materialise between the EU and the UK, we note that it appears to run contrary to certain positions which have previously been outlined by the EU.

14. Initially, while the Government states that ‘cherry picking’ would involve seeking a “deal where our rights and obligations were not held in balance”, the specifics of the obligations which the UK is willing to accept are not clear. The EU and UK do not appear to agree on where this “balance” between rights and obligations lies and subsequent statements suggest ongoing resistance from the EU to sector by sector deals. The Prime Minister noted however, that “The EU itself is rightly taking a tailored approach in what it is seeking with the UK. For example, on fisheries, the Commission has been clear that no precedents exist for the sort of access it wants from the UK.” After the Prime Minister’s speech, some commentators were already reporting a confidential European Commission assessment EU circulated to diplomats from EU states which claimed her Mansion House speech amounted to “double cherry-picking” with “no change in substance” from her government’s previous position.¹⁵

15. Furthermore, the Prime Minister’s speech appears to suggest partial membership of the single market similar to the Swiss model, which involves a complex system of management through joint committees, and the EU unable to enforce its rules in Swiss courts. The EU has already stated that it may reject any more bilateral treaties with Switzerland unless they accept some ECJ rulings.¹⁶

16. In addition, there would appear to be the potential for difficulty for the EU-27 in deciding which economic areas demanded which level of regulatory alignment and continuing UK-EU integration, which could require a long and complex negotiation.

17. We urge the EU to look closely at the proposals for a sectoral approach to regulatory alignment set out by the Prime Minister in March 2018. We also expect both sides to consider first and foremost the implications of ‘no deal’ for individuals, the life sciences and the wider health and social care sector across the whole EU as well as the UK. We note that Article 9 of the Treaty on the Functioning of the European Union obliges the EU, in defining and implementing its activities and policies, to take into account requirements linked to a high level of protection of human health.¹⁷

18. In line with that view, this report makes two key conclusions that are reiterated throughout and apply to almost all aspects of the life science sector and processes within in it. They are:

- i) **The UK should look to secure, as a priority in the next round of negotiations, the closest possible regulatory alignment with the EU.**

14 [PM speech on our future economic partnership with the European Union](#)

15 [EU accuses Theresa May of ‘double cherry-picking’, accessed 8 March 2018](#)

16 [Swiss want arbitration panels to settle disputes with EU, Reuters, accessed 3 March 2018](#)

17 [EUR-Lex - 12012E/TXT - EN - EUR-Lex - Europa EU](#)

Evidence submitted from pharmaceutical companies as well as those involved in the development and supply of medical devices, from academics, healthcare and workforce charities was almost unanimous in the view that regulatory alignment with the EU would be the best post-Brexit option. The continued supply of safe and effective medical devices, medicines and substances of human origin currently on the UK market will be more reliable if we continue alignment with EU regulation. We heard evidence that individuals, the NHS, and business could be adversely affected if this is not achieved. If full regulatory alignment with the EU is not secured, then a distant second-best option for the life science industry and patients in the UK would be alignment with another large market such as the Federal Drugs Agency (FDA). While this form of alignment would raise significant complications, it remains preferable to the worst-case scenario for UK industry and patients, which is the UK endeavouring to create a standalone regulatory system after leaving the EU. There was a consensus that the UK was too small a market to do so and this would see later licensing and release of new medicines and devices than is currently the case.¹⁸

This regulatory alignment should also include, but not be limited to, provisions for an agreement with the EU for Qualified Persons¹⁹ currently working in the UK to continue to have their work recognised in EEA countries, the transposition of Good Manufacturing Practice and Good Distribution Practice into UK law in the EU (Withdrawal) Bill, and the UK adopting the new Clinical Trials Regulations which were approved in the EU in 2014 but have yet to come into effect, along with the incoming Medical Devices Regulations.

- ii) **Industry, patients, and experts need to see evidence of the Government's contingency planning for a situation in which the UK is unable to secure a deal with the European Commission for leaving the European Union.** While the European Council has reiterated its wish to have the United Kingdom as a close partner in the future, they have clearly set out that the four freedoms of the Single Market are indivisible and that there can be no “cherry picking”.²⁰ Any provisions which are put in place for continued co-operation between the EU and the UK in the life sciences are dependent on similar agreements being made across the whole of the negotiations, for every sector of the economy. As such, we believe it is not just prudent, but essential that scrutiny is undertaken of the Government, and the Department of Health and Social Care's contingency planning for a 'no deal' situation. A disorderly UK exit could result in an immediate impact on the supply of essential medicines and medical products, both

18 The UK makes up 3% of the global pharmaceutical market, whereas the EU current accounts for 27%. If the UK were to endeavour to create a stand-alone regulatory system, companies would need to obtain a separate market authorisation here from that for Europe, which takes money and time. As the UK market would be smaller than the EU market, companies may choose to launch in the EU first, or not in the UK at all, which would affect patient access to new treatments. For more information on the size of the UK market, see paragraph 31.

19 Qualified Persons (QPs) are individuals legally responsible for the safe batch release of medicines before they are placed on the market or used in clinical trials. Quality control testing by a QP is performed in one member state and then applies across the EU. For more information on QPs, see paragraph 82.

20 [European Council \(Art. 50\) guidelines for Brexit negotiations](#)

in the UK and the EU-27.²¹ The Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, told us on 23rd January that details of the Government’s contingency planning would not be made public as to do so would undermine the negotiating position of the UK.²² However, we believe clarity about UK contingency planning to guarantee patient safety and continued health supplies will strengthen the UK’s negotiating position by demonstrating that we have a credible fall-back position. In these highly technical areas, with complex supply chains, extensive public scrutiny of any contingency planning will ensure that all relevant aspects are covered to guarantee the health of UK patients regardless of the Brexit outcome. The Health and Social Care Committee and other stakeholders must know the provisions that are being put in place by the UK Government for the possibility of a ‘no deal’ Brexit so that we can hold the Government to account in a meaningful way and ensure that patient safety is not compromised by the Brexit process.

19. Several members of this Committee are firmly of the view that the best outcome for the life sciences sector, the NHS, and for patients would be for Britain not to leave the EU, or at least to remain within both the single market and customs union. This report is written from the perspective of presuming that neither of those scenarios will be taken forward by the Government and therefore that a course of harm reduction should be pursued.

Brexit and the Department for Health and Social Care’s Single Departmental Plan

20. The concerns which we raise—and make recommendations to address—in this report are placed into sharper focus by the almost total lack of reference to Brexit in the Department of Health and Social Care’s Single Departmental Plan for 2018, published during the course of our inquiry.²³ Single Departmental Plans outline the Government’s departmental objectives for the coming year. They were introduced in February 2016 and the second round of the plans was published in January 2018. As was reported by the Institute for Government in December of last year, each Single Departmental Plan outlines several key objectives, which are subsequently broken down into sub-objectives and then the actions which will enable the Government to achieve them.²⁴

21. “Get the best Brexit deal for Britain” is listed as the primary objective for the UK Government as whole, but only four departments explicitly refer to Brexit in their own objectives, and the Department of Health and Social Care is not one of them.²⁵ Despite having the third highest number of Brexit work streams of any department, there are no key objectives, and no sub-objectives, in the Department of Health and Social Care’s

21 [Brexit Health Alliance \(BRX0031\)](#), [Teva UK Limited \(BRX0053\)](#), [Wellcome Trust \(BRX0073\)](#) [and others]

22 Q344

23 [Department of Health and Social Care single departmental plan - Gov.uk](#)

24 [Burying Brexit in the Government’s plans | The Institute for Government](#), accessed 8 March

25 [Burying Brexit in the Government’s plans | The Institute for Government](#), accessed 8 March

Single Departmental Plan which explicitly refer to Brexit.²⁶ In fact, only one action in the entire plan does mention Brexit, stating that to “Lead international engagement on health” the department will:

Assure and co-ordinate EU Exit readiness, working with the Department for Exiting the European Union and the devolved administrations.²⁷

22. Giving evidence on 23rd January, the Secretary of State told us that the Department of Health and Social Care is giving Brexit priority in industry discussions, and stated that “It is incredibly important.”²⁸ We therefore find it surprising that Brexit references appear to make up such an insignificant part of the Department’s Single Departmental Plan for this year. This is particularly worrying when 2018 is a crucial year for achieving readiness throughout the NHS and social care services for Brexit, and for drawing up contingency planning for the possibility of the UK Government failing to secure a deal with the EU before March 2019.

23. When pressed on this issue in oral evidence, the Secretary of State replied that, “I would be surprised if it [Brexit] is not in there [the Department’s SDP] somewhere.”²⁹

24. We note the Secretary of State’s subsequent letter to us, which states:

As the Single Departmental Plan is a high-level summary of Departmental activity, we have included one reference to the central coordination activity for clarity and concision. The specific impacts as a result of EU Exit and the work streams being coordinated across the Department are embedded within existing departmental activity.³⁰

25. Single Departmental Plans are designed to reflect the priorities of each department for the coming year. Brexit must unquestionably be perceived as a priority for the health and social care sector in 2018, for all of the reasons listed in this report. That Brexit was not deemed as warranting either an ‘objective’ or a ‘sub-objective’ but merely an ‘action’ to facilitate these wider objectives in the SDP for the Department of Health and Social Care is deeply concerning.

26. We are concerned about the lack of reference to Brexit in the single Departmental Plan for the Department of Health and Social Care. Brexit poses huge challenges to the life science sector and carries a number of unintended consequences for patients and the NHS. We trust that the Government’s response to the recommendations of this report will reflect that and set out the department’s preparation in greater detail.

Our inquiry

27. We received over 100 written submissions from a wide range of individuals and organisations with an interest in how Brexit will affect UK arrangements for medicines, medical devices and substances of human origin. We took evidence in December 2017

26 [Department of Health and Social Care single departmental plan - Gov.uk](#)

27 [Department of Health and Social Care single departmental plan - Gov.uk](#)

28 Q353

29 Q356

30 Follow up to Health Committee Oral evidence: Brexit – medicines, medical devices and substances of human origin, MHRA, 27 February 2018

and January 2018 from witnesses representing patient and workforce groups, industry, experts and Ministers. We are grateful to all those who gave us evidence. We are also especially grateful to our specialist advisers, Prof Tamara Hervey, Jean Monnet Professor of EU Law at the University of Sheffield, and Nick Fahy, senior researcher at the Nuffield Department of Primary Care Health Sciences and independent health policy consultant, for their assistance throughout this inquiry.³¹

31 Mr Nick Fahy declared the following interests: As part of my academic work, I undertake research and other work related to health policy and systems, which of course includes aspects related to health and Brexit; I am an independent health policy consultant with my own company, Nick Fahy Consulting Ltd (see <http://www.nickfahyconsulting.eu>). In that role, I provide advice on a wide range of health policy issues and how to constructively engage with health policy discussions for a mix of clients, both public (in particular international organizations such as the World Health Organizations) and private (in particular pharmaceuticals companies), including on the health dimension of Brexit; I used to be a member of staff of the European Commission, on long-term special leave (though still of course subject to the normal requirements of the Commission concerning obligations such as confidentiality and avoiding conflicts of interest, in accordance with the EU's Staff Regulations), but resigned in 2017. My ongoing activities (academic and consultancy) require the Commission's authorisation for two years after resignation – both have been approved; During the EU referendum campaign, I was an active campaigner to Remain; I helped to advise the Faculty of Public Health on a proposed amendment to the EU (Withdrawal) Bill which seeks to 'do no harm' to health in the UK post-Brexit; And finally, I am a member of the Labour party, although I have never held any party office, and I have always taken care to avoid any impact on my ability to provide politically neutral and credible advice (as set out in the Civil Service Code, for example)

Professor Tamara Hervey declared the following interests: As part of the Jean Monnet programme, the European Commission paid a contribution of €42805 to The University of Sheffield towards to my salary and to support research activities (principally travel) during the period September 2009 – September 2012. See Ref: 2009–2835 Jean Monnet Ad Personam Chair: Enhancing Teaching, Learning & Research in EU Law. I am currently a co-investigator on two externally funded research projects: PI Fierlback, Dalhousie, Canada, Jean Monnet Network grant EU Health Law and Policy (2017–2020); and PI McHale, Birmingham) ESRC UK in a Changing Europe (Brexit) grant Health Law Outside the EU: Immediate, Intermediate and Long Term Impacts 2017–18. I am a member of the Advisory Board of Healthier In, a 'grassroots campaign that continues to raise the voice of UK health professionals, carers, patients and researchers in the negotiations and policies following the EU referendum. We still believe that full membership of the EU is best for the UK's health care and if 'Brexit means Brexit' then we must fight to work as closely as possible with the EU for effective health policy, data sharing and free movement of health workers and researchers'. See further <http://healthierin.eu/>. I worked pro bono with the Faculty of Public Health on a proposed amendment to the EU (Withdrawal) Bill which seeks to 'do no harm' to health in the UK post-Brexit.

2 Protecting and enhancing the UK's position in Europe and globally

Global life science industry

28. The life science industry is increasingly global. Within the EU, the UK benefits from being part of one of the three major global markets. They are the US, EU and Japan.³² Steve Bates, Chief Executive of the BioIndustry Association, described how developments in other countries, such as China and Brazil, mean the UK would be prudent to adopt a global mindset while seeking to maintain a close relationship with the EU.³³

29. To exemplify this, he explained how the Chinese government has prioritised its country's regulation of medicines and medical products, to kick-start their life science industry, saying:

They have essentially retooled their regulatory route with support from the Gates Foundation in the US, and they have very rapidly adopted some of the best practice around breakthrough designation and other things in an endeavour to kick-start their industry ... I think this is turning the heads of global companies and we should be conscious of it. If you have a very fast new regulator offering fantastic service, with a fantastically large market, at a time when we are removing ourselves from a significant global market, we just need to be on our mettle to make sure that we are making the most of the NHS assets, the NHS data, the genomics stuff, which we have, and be speedy.³⁴

30. We want the UK to remain an attractive place for global life science companies to research, develop, manufacture and launch new medicines, devices and other medical products. A resounding message from the written and oral evidence we received is that continued alignment with the EU and the EMA is by far the best option to achieve that. It is widely accepted that the UK's share of the global life science industry, approximately 3%, means that as a country we are too small to 'go it alone', by creating a standalone regulatory system. Roche, a large pharmaceutical company, told us that the bottom line is that the UK must align with a larger market.³⁵ This assumption is endorsed by the UK Life Science Industrial Strategy, which says:

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.³⁶

32 [Brexit Health Alliance \(BRX0031\)](#) para 2.1

33 Q212

34 Q212

35 [Roche \(BRX0030\)](#) para 2.1

36 [Life Sciences Industrial Strategy - Gov.uk](#) p. 67

International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH)

31. The global nature of the life science industry is exemplified by the International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH). The ICH is a global regulatory body which aims to harmonise the development and registration of pharmaceuticals across the world.³⁷ For example, the ICH's good clinical practice sets standards for the quality of pharmaceuticals globally. These standards are usually adopted into law. The inclusion of ICH standards into the laws of participating members influences the regulatory landscape of countries seeking to export products to these countries. WTO rules covering the resolution of trade disputes refer to the ICH guidelines, thereby giving them further weight internationally. Continued compliance with the ICH is therefore critical for the UK.

32. The EU, as one of the founding members, has significant influence on the ICH's standards. The MHRA, as the UK's representative, currently participates in the ICH as part of the EU's delegation, and sits on many of the ICH's expert working groups, allowing it to influence international standards. Professor Boyd from the Academy of Medical Royal Colleges told us:

It will be very important, once we are outside that, that the UK gets a seat at that table because that is what controls medicines regulation on a global basis. Again, it is something that has not been talked of very much, but it is a very important group and is an example of our international influence.³⁸

33. Dr Beth Thompson from the Wellcome Trust echoed this point, describing the interplay between ICH, EU and domestic legislation, saying:

There is a very interesting interplay between voluntary standards, which may be global and are there to shape the way people trade and to make trade easier, and legislation, both at the UK and EU level. Our regulators in the UK have to keep playing a crucial role across that spectrum of activities. Clearly, direct influence on EU legislation will be harder, and we see that EU legislation is often a gold standard or tends to shape wider international norms for regulation. However, we must make sure that our regulators are well enough resourced so that they can continue to play in that space and be influential. When working on things like the International Council for Harmonisation of clinical trial guidelines, we have to make sure that the MHRA has a key place at that table and can continue its involvement in discussions, because the UK has a very pragmatic, proportionate approach to regulation, and patients everywhere, not just in the UK, would suffer if they lose that important role.³⁹

34. The UK, after Brexit, can apply for Observer status at the ICH and then for full membership, as a Regulatory Member, after two years.⁴⁰ However, once a member, the UK could be its own independent voice at the ICH, as opposed to a member of the EU's

37 [ICH Official web site: ICH, Mission](#), accessed 12 March 2018

38 Q250

39 Q144

40 [Members & Observers: ICH](#), accessed 4 March 2018

delegation. While this brings opportunities for the UK, we heard that we must act now, at the start of a transition period - the earliest we can legally act - if we are to limit the time before full regulatory membership is afforded to us and these opportunities can be sought.

35. The UK should aim to have a seat at the International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) in its own right. We call on the Government to confirm that it will apply for full membership of the ICH at the earliest possible opportunity and to set out its timeline for doing so.

UK's position and influence in Europe

36. The development, manufacture and supply of medicines, medical devices and other medical products is highly integrated across Europe.⁴¹ UK-based researchers, companies and patients participate in, and benefit from, European research collaborations and networks, pan-European clinical trials and pharmacovigilance systems and supply chains in which raw materials and finished products touch several jurisdictions before they are released onto the market.⁴² We support the Government's intention to negotiate the same, or a new, close relationship with the EU and the EMA. We believe this is clearly in the interests of patients, citizens and governments in both the UK and the EU. As Phil Thomson of GSK, one of the UK's leading global pharmaceutical companies told us:

Maybe win-win is the wrong way to describe it because it is just fundamentally important for both sides to get this right. I think you are absolutely right to be thinking about how Europe sees this and the loss of the UK, whether it is pharmacovigilance or that the UK gives more approvals for post-approval studies than any other European country. We have enormous excellence and capacity here in the UK. The UK contributes disproportionately in many regards to what Europe does around health. Therefore, it is in both our interests to prioritise health and the impact particularly on patients in this next round, and what happens with the future arrangement.⁴³

Medicines and Healthcare products Regulatory Agency

37. The UK's expertise and reputation, including that of the MHRA, has enabled the UK to be a maker and a shaper of EU regulations in the life science sector. For example, Dr Beth Thompson from the Wellcome Trust praised the MHRA, saying:

Our very strong regulators—the Medicines and Healthcare products Regulatory Agency—are world leading, and that helps to bring that credibility, for example, in the clinical trials space and in the licensing space. It cannot be underestimated.⁴⁴

38. The loss of the MHRA from Europe was emphasised by Dr Spink from the Genetic Alliance:

... the MHRA's lead on between 20% and 35% of the EMA's licensing and vigilance work—which is higher in the case of advanced therapies—if we

41 [Teva UK Limited \(BRX0053\)](#) p.1

42 [ABHI \(BRX0059\)](#) p.6

43 Q316

44 Q143 [Dr Thompson]

have a gap there in that provision of expertise, you could expect to see a knock-on effect for patients across Europe and also in standards and safety monitoring, and the impact that that might have on exports and imports of innovative products, many of which are manufactured here in the UK.⁴⁵

Influence of the UK Government, national bodies and institutions in European regulations

39. We heard several examples of how the UK has played a prominent role in shaping current and forthcoming EU regulations on medical devices and in-vitro diagnostics, clinical trials, data protection, but also innovative, and often controversial, medical advances. For example, Dr Jane Spink from the Genetic Alliance told us that “The UK has historically provided a lot of influence and thought leadership, particularly with innovative medicines and innovative approaches such as gene therapy, research using human embryos and advanced therapies.”⁴⁶

40. The UK government, national bodies and institutions have been advocates and champions of innovation, whereas some other EU Members States have adopted a more precautionary stance.⁴⁷ Dr Beth Thompson from the Wellcome Trust told us that:

... almost every important piece of legislation that you look at across our sector you see the work of the UK. That is a combination of the UK Government, who do really well at the moment in terms of influencing legislation within Brussels, but also organisations such as the charities—Wellcome, Cancer Research UK and many others—who play a key civil society role in influencing that legislation and bringing often a non-industry or patient voice into those discussions.⁴⁸

41. The UK’s absence from European decision-making could shift the regulatory environment in Europe towards a more precautionary environment.⁴⁹ Such a move could create both opportunities and risks for the UK. However, the worst outcome would be for the UK to become an isolated rule-taker in a more precautionary environment which is less supportive of innovation. We heard worrying signs that the UK’s influence within the EU is beginning to dwindle. Suzanne Halliday, from the British Standards Institution, told us, she had seen:

... the UK already start to lose influence in the European Union... Nothing has changed so far, and in Europe it is already, “You are from the UK. You are leaving. Why would we care what you think?” That is my actual experience now.⁵⁰

45 Q125

46 Q125

47 [Quotient Clinical Limited \(BRX0064\)](#) p.27

48 Q143

49 [Quotient Clinical Limited \(BRX0064\)](#) p.27

50 Q209

42. Echoing this, Hugo Fry from Sanofi, told us:

There are signs that the UK influence, even on sentiment, is waning, so it would be great to have some attention and some political pressure on that to keep it going because we do believe it is important. That is what I would call the “R” bit—the research bit.⁵¹

43. Steve Bates, from the BioIndustry Association, offered a more optimistic observation, saying:

I do not get that sense in my meetings. I get the sense that there is an understanding of the validity of having a science-based, sensible voice with capacity among those people who are on the team or around the table with experts from the UK, and there is a desire to see whether there is the possibility to put something together. They are not quite sure what or how, but I think that there is a pragmatic desire, certainly among some colleagues in the EU 27, and that is because the challenges that we are still going to face—the challenges of new forms of disease and of pharmacovigilance—are going to remain. In a sense, that is why Europe came together in this area, to battle the challenges discovered through the thalidomide scandal and the information flows of that being delayed, which caused problems continuing for a period of time that otherwise need not have. Some people have longer memories, understand the basis for this and have a desire to see that continue. We also have a number of things that work through the Council of Europe and other formats. There are a number of layers of this that you can look at. We have grown together over a generation, over a lifetime, and I do not think everybody is of the view that it is, “Shut the door on your way out.”⁵²

44. We are proud that the UK Government, national bodies and institutions have been champions of innovation inside the European Union, using their expertise and reputation to influence EU decision-making in a way which is innovation-friendly. If a close relationship with the EU and the EMA is not achieved, our view is that the worst position for the UK is that it becomes isolated from, but dependent on, a European Union which, adopts a more precautionary attitude to regulation of the life science industry.

45. We support the Government’s intention to negotiate a close relationship with the European Union, including associate membership of the EMA. The UK, with the expertise and capacity of the MHRA, has a great deal to offer its European partners. We believe this is in the interests of citizens and governments on both sides of the negotiations and should be prioritised in the next phase. Failure to achieve an ongoing collaboration would signal the triumph of political ideology over patient care. In the context of continued collaboration with the EMA and maintaining regulatory alignment, it will be in the interests of both sides for the EMA to benefit from the expertise of the MHRA and to continue to allow participation of UK representatives in decision making.

51 Q272

52 Q210

3 Negotiations

EU negotiating position

46. As noted by the Department for Business, Energy, Innovation and Skills, the UK and the EU have outlined a shared objective in the negotiations to protect patient health, and ensure access to medicines.⁵³ The EU’s guidelines for negotiating with the UK indicate that while the European Council reiterates its wish to have the United Kingdom as a close partner in the future, preserving the integrity of the Single Market excludes participation based on a sector-by sector approach, and negotiations under Article 50 will be conducted as a single package in accordance with the principle that nothing is agreed until everything is agreed, which means that individual items cannot be settled separately.⁵⁴

UK negotiating position

47. We welcome the statements from the Prime Minister in her 2nd March speech that outlined the Government’s desire to forge the “broadest and deepest possible partnership”⁵⁵ with the European Union after the UK exits the EU. We are pleased to note in particular the Government’s commitment to a close relationship with the EMA after Brexit through “associate membership”,⁵⁶ and welcome the Government’s “objective of ensuring that these [medicines and medical devices] products only need to undergo one series of approvals, in one country”.⁵⁷ These statements are a positive indication of the relationship the UK is seeking to forge with the EU after Brexit. We go on to discuss these commitments, and the obstacles to their realisation, in further detail in paragraphs 88 to 92 of this report.

48. We also welcome the earlier commitments given in the letter from the Secretaries of State for Health, Rt Hon Jeremy Hunt MP, and Business, Energy and Industrial Strategy, Rt Hon Greg Clark MP, of 5 July 2017 to a continued close working relationship with the European Union after UK Exit day in the interests of public health.⁵⁸ The three principles of the letter were set out as being that

- (i) Patients should not be disadvantaged
- (ii) Innovators should be able to get their products into the UK market quickly
- (iii) The UK must continue to play a leading role promoting public health.

(i) Patients should not be disadvantaged

49. We see this as a positive objective, but one which, in its current form, lacks the clarity required to make it sufficiently measurable, against which the Government can be held to account. We consider that protecting patients should involve, but not be limited to:

53 [Department for Business, Energy and Industrial Strategy \(BRP0018\) para 15](#)

54 [European Council \(Art. 50\) guidelines for Brexit negotiations](#)

55 [PM speech on our future economic partnership with the European Union](#)

56 [PM speech on our future economic partnership with the European Union](#)

57 [PM speech on our future economic partnership with the European Union](#)

58 [The UK wants to continue to work with the EU on medicines, accessed 7 March 2018](#)

- Patient safety being prioritised in the next round of negotiations between the UK and the EU
- UK regulatory alignment with the EU in a transition period and afterwards, following the UK's full departure from the EU, both in the short and the longer term
- The UK focusing on the speed of adoption, meaning the rate at which they are available to patients on the NHS, of new medicines and devices domestically, and measures to galvanise that including the Accelerated Access Review and the Life Sciences Industrial Strategy post-Brexit
- The UK Government publishing strategies for a no-deal situation across all areas of the life science sector, including for supply chains, regulatory alignment, pharmacovigilance and funding. This will be particularly pertinent for cliff-edge issues such as supply chain disruption and medical radioisotopes and safety
- The Government committing to continuing UK involvement with Horizon 2020 and other EU research programmes on terms available to non-EU countries
- Adopting the new EU Clinical Trials regulation into UK law, and clarifying whether it will fall within 'retained EU law' in the EU (Withdrawal) Act, as it will come into force during the proposed 'transition period' to be covered in the Withdrawal Agreement with the EU
- UK maintaining a system of zero tariffs on healthcare goods
- The UK negotiating continued access to EU data sharing networks, pharmacovigilance infrastructure and the new clinical trials infrastructures, in the short and medium term through the Withdrawal Agreement, and in the longer term through a trade agreement or similar with the EU
- Mutual recognition of pharmacovigilance arrangements and Qualified Persons

We comment further on each of those points below.

50. We would also like to see the UK approach the next round of negotiations not just with a focus on issues relating to the health of the UK public, but also with a view to ensuring patients in the EU are not disadvantaged from the UK's withdrawal from the EU. A failure to do so would undermine a commitment to working together in the future for the benefits of patients on both sides of the negotiations.

(ii) Innovators should be able to get their products into the UK market quickly

51. We agree that ensuring innovators are able to get their products into the UK market quickly will be an important measure to ensure businesses continue to see the UK as an attractive market in which to invest and launch their products, and to ensure that patients remain protected both in the UK and the EU. To realise this ambition, the UK Government should look to secure continued regulatory alignment with the EU, to reduce regulatory obstacles for those wishing to invest in the UK both now and in the future, particularly noting the UK Life Science Industrial Strategy's view that 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. We agree with the position of the Life Science Industrial Strategy that any divergence from EU systems will only add value to UK life sciences and patients so long as any such divergences do not jeopardise the UK's ability to participate in European research and regulatory regimes.⁵⁹ At the same time, and to compensate for the effects of Brexit, the UK must continue to implement measures such as the Accelerated Access Review and Life Sciences Industrial Strategy. Adoption of new medicines in the NHS is a national competence and will not be affected directly by Brexit, meaning the UK can continue with existing efforts to speed up the rate of adoption. We endorse the view expressed by Phil Thomson of GSK in oral evidence that

The [Life Sciences] strategy becomes even more important if there is a hard exit from the European Union ... without these points of connectivity, whether it is on regulatory, trade or supply, how the UK then develops itself to be competitive is very important.⁶⁰

(iii) UK must continue to play a leading role promoting public health

52. We welcome the Government's desire to continue the UK's influence in the life sciences sector. This objective will be more challenging after Brexit, but a focus on maintaining the attributes that have made the UK an attractive place to develop and launch new medicines and devices will continue to help it to remain at the forefront of the life sciences industry. This should be undertaken alongside a continued commitment to EU and international regulatory systems such as the ICH, where the UK's influence has been significant so far. We welcome the commitment from both sides of the negotiations that whatever the result of the Brexit talks, the UK's withdrawal should not result in a detriment to patients on either side of the Channel or the Northern Ireland and Republic of Ireland border. That must translate into a commitment from both sides to put the needs of patients above ideology on 'red lines'.

53. We note the EU's guidelines for negotiating with the UK which explain that preserving the integrity of the Single Market excludes participation based on a sector-by-sector approach. Although there may be significant life science sector level mutual interest from the UK and EU on reaching agreement between the two negotiating sides, this is insufficient to ensure a deal is reached, either for the short or medium term in the Withdrawal Agreement or in the longer term in an EU-UK trade or other agreement(s).⁶¹

54. The ongoing UK Exit negotiations have the potential to fall apart if any area of the negotiations fails to agree terms, meaning Government contingency planning for a 'no deal' remains vitally important. The publication of this contingency planning will give much needed security to industry and patients, and allow for planning to be undertaken with a firmer idea of what the UK's fall-back position may be if the negotiations do not reach the desired result. In the highly technical areas around the safety monitoring and regulation of pharmaceutical products with complex supply chains, extensive public scrutiny of any contingency planning will ensure that all relevant aspects are covered to guarantee the health of UK patients regardless of the Brexit outcome.

59 [Life Sciences Industrial Strategy - Gov.uk](#) p. 67

60 Q276

61 [European Council \(Art. 50\) guidelines for Brexit negotiations](#)

55. We welcome the announcement at the Autumn Budget 2017 that HM Treasury is making £3bn of additional funding available over the next two years—£1.5bn in each of 2018/19 and 2019/20—so that departments and the devolved administrations can continue to prepare effectively for Brexit.⁶² An increase in funding to look to minimise the risks and build on the opportunities that Brexit may provide for health and social care (and wider UK sectors) is a positive step. However, without a detailed breakdown of the distribution of this funding by Government department, and then within each department amongst the many areas of policy that Brexit will affect, this figure is too vague to act as significant reassurance to the life science sector and patients that the concerns they have raised in relation to Brexit are being appropriately addressed.

56. We are encouraged that the UK Government has stated that it is seeking to ensure the UK plays a leading role in public health and preventing patients and innovators from being disadvantaged by Brexit. However, we, industry, and patients need tangible measures against which to evaluate these commitments. A detailed breakdown of the funding allocation for the DHSC from the Brexit funding should be published, and this should be accompanied by specific, detailed action points that look to explain how, and on what timeframe, the Government is looking to deliver on its commitments to the life science sector.

57. Following Brexit, the life sciences sector will need a highly supportive domestic agenda. The Government should implement the Life Sciences Industrial Strategy in full and at pace, with a final deadline of 2023. This should be supported with commitment to other domestic measures such as the Accelerated Access Review.

58. **However, we note that because Brexit involves the danger of the UK becoming a less appealing market for life sciences innovations due to the UK's small market share by comparison to the EU and the USA, these domestic measures will be necessary, but not sufficient, to counteract the negative effects of Brexit for patients.**⁶³

62 [Autumn Budget 2017 - GOV.UK](#)

63 How will Brexit affect health and health services in the UK? Evaluating three possible scenarios, [The Lancet](#), accessed 5th March 2018

4 Aligning with the EU on market authorisation and regulation

Regulatory alignment with the EU after Brexit

59. For organisations, businesses and healthcare authorities alike to prepare for business operation both during a transition period and thereafter, they need clarity over the UK's future regulatory alignment with the EMA. Many organisations are looking to make business plans for 2018 and 2019 now.⁶⁴ Johnson and Johnson, in written evidence, described an “urgent need for clarification”⁶⁵ on the level of regulatory alignment that the UK is expecting to reach with the EU by the time of UK Exit day, to ensure there is no disruption of supply of products, and that no unnecessary costs are incurred.⁶⁶

60. The UK's strength in early phase development in the pharmaceutical industry heightens the need for the level of regulatory alignment to be laid out in detail. We heard that the UK's medical technology sector is the third largest in Europe and 98% of the sector is made up of SMEs with less than 250 staff and a turnover of under £5m (82%).⁶⁷ As SMEs frequently have more constricted financial margins than larger pharmaceutical companies, early clarification from the Government on regulatory alignment to allow for detailed business continuity planning is critical.⁶⁸

61. The overriding message from almost all of the evidence received in this inquiry is that the UK should continue to align with the EU regulatory regimes for medicines, medical devices and substances of human origin both during any transition period and afterwards. Evidence submitted from large pharmaceutical companies, SMEs, academics, healthcare and workforce charities was all almost unanimous in the view that regulatory alignment with the EU would be the best post-Brexit option for the NHS, for patients, and for the UK life sciences industry.

62. If the UK diverges from the EU regimes in a manner that adds to the cost and timeliness of existing supply chains, then the UK will become a less attractive market for businesses.⁶⁹ In this scenario, patients in the UK would not only experience delays in access to new treatments, but could also stand to wait longer to access generic drugs coming off patent.⁷⁰ Johnson and Johnson's written evidence summarised the situation:

Given the highly complex and integrated regulatory environment for this sector, we would like to see the UK maintain a regulatory system that is fully aligned with that of the EU. The continued supply of safe and effective medical devices, medicines and healthcare products currently on the UK market will depend on continued alignment with European regulation. J&J is not convinced that a UK-sovereign regulatory model is an improvement

64 Q261 [Emma Greenwood]

65 [Johnson Johnson \(BRX0063\) p.8](#)

66 [Johnson Johnson \(BRX0063\) p.8](#)

67 [Medilink Midlands \(BRX0078\) p.1](#)

68 [Medilink Midlands \(BRX0078\) \[and others\]](#)

69 [Academy of Medical Royal Colleges \(BRX0041\)](#), [Johnson Johnson \(BRX0063\)](#), [The British Generic Manufacturers Association \(BRX0050\) \[and others\]](#)

70 [Academy of Medical Royal Colleges \(BRX0041\)](#), [Johnson Johnson \(BRX0063\)](#), [The British Generic Manufacturers Association \(BRX0050\) \[and others\]](#)

for post-Brexit Britain. It is unlikely whether globally-minded businesses would see it as a viable option to make this investment for a UK-only market authorisation. The UK must avoid introducing barriers to the adoption and diffusion of new medicines and devices. Any standalone approval system could limit the UK's involvement in device development and pre-commercial launch evaluations, as well as access to innovation. Companies would prioritise markets where they can get early access. Taking a different regulatory course at this stage will result in significant disruption for companies and some may choose to withdraw from the UK market, with the result that UK patients no longer have access to the range of products currently available.⁷¹

63. Dr Jayne Spink of Genetic Alliance UK elaborated in oral evidence on the effects on drug development and launch, arguing:

If the UK does not enable that seamless transition to continue collaboration on drug development, the UK will not only not be the first choice of country to launch, but it may be a disincentive to launching in the UK at all.⁷²

64. We heard that regulatory alignment was not just the more desirable option for the life science industry after Brexit, but it could actually be seen as the only *feasible* option. Dr Aisling Burnand of the Association of Medical Research Charities told us:

We have spent the last 40 years putting together frameworks to support research, and clinical trials to benefit patients. We have seen things like General Data Protection Regulation, which is coming into force in May; we have seen the clinical directive. To try to move to creating a new one overnight is just not workable.⁷³

65. Regulatory alignment with the EU was also highlighted as being the favourable option for substances of human origin regulation after Brexit.⁷⁴ EU regulations cover the safety of blood, tissues and organs and have applied since the 2000s following scandals involving blood transfusions across a number of EU countries and ethical considerations involved in the transplantation of organs. The regulations stipulate minimum standards of quality and safety of blood, tissues, cells and organs, from procurement and donation through to the use of these substances in clinical care. In this area and more generally, Professor Jean McHale stressed in oral evidence to this inquiry the importance in the longer term of addressing how policy and law will adapt as these areas develop.⁷⁵

66. As previously outlined, the UK could look to align with EU regulations by adopting EEA membership as countries such as Norway do. However, as Michel Barnier has pointed out, this scenario is likely to be unacceptable to the UK Government as it would breach previously set out 'red lines' including coming under ECJ jurisdiction (to a greater or lesser degree) and accepting freedom of movement.⁷⁶ As such, this inquiry heard limited evidence as to what this would look like for regulatory alignment.

71 [Johnson Johnson \(BRX0063\), para 2.6](#)

72 Q126

73 Q121

74 [Scottish Government \(BRX0033\)](#), [NHS Blood and Transplant NHSBT \(BRX0081\)](#)

75 Q69

76 [PM speech on our future economic partnership with the European Union](#)

67. As a third country, the UK could align with the EU through either a regulatory cooperation agreement or a mutual recognition agreement. However, according to the Medical Research Council, Switzerland gains access to new medicines 157 days later on average than the EU, despite bilateral trade agreements. Similarly, Canada and Australia have mutual recognition agreements with the EMA, but wait on average 6–12 months longer than the EU or US for new drugs to come to market.⁷⁷ Steve Bates of the BIA argued:

If you look at markets that are not within the largest global regulatory environment—not the FDA or the EMA—we see that there is a difference of about 45% of medicines that were not launched in Switzerland, Canada or Australia.⁷⁸

68. The UK could align with another large market after Brexit other than the EU, such as the Federal Drugs Agency (FDA) in the USA, but our evidence was almost unanimous in the view that EU alignment is preferable. Cancer Research UK stated that alignment with the FDA in the USA:

... may seem initially attractive given that drug manufacturers often prioritise the US for launching new drugs, and that the FDA is relatively quick to approve new drugs. However, there would be significant uncertainty in this approach. The US President has suggested deregulating the FDA, which has caused some concern among pharmaceutical companies, since this could pose a risk to patients.

Furthermore, the healthcare system is very different in the US, as is the way that drugs are paid for—with insurance companies playing a significant role rather than a national budget for drugs. Similarly, aligning with the FDA would necessitate a much wider assessment of the UK's approval processes and its wider regulatory framework, such as those governing clinical trials or medical devices, which is far more consistent with that of the EU than the US, due to years of collaboration between the MHRA and EMA. Any significant step away from current practice would necessitate significant resource and would be incredibly risky, especially given the relatively short timelines involved. This would lead to further uncertainty and could jeopardise recent progress made to streamline UK drug approvals.⁷⁹

69. Along with the nature of regulatory alignment after Brexit, evidence to our inquiry also suggested that the duration of this regulatory alignment would be crucial.⁸⁰ Fiona Loud of Kidney Care UK pointed out that, while on 'day one' of the UK leaving the EU the harmonisation of regulations may have been more or less achieved, the question remains over future regulatory divergence.⁸¹ She argued regulatory divergence may be an issue once again in five or ten years' time, and we would like to see provisions put in place to ensure that alignment with the EU on regulations for medicines and medical devices extends beyond simply UK Exit day, with regular and systematic reviews of the level of 'regulatory drift' from EU regulations that the UK undergoes. With this in mind, we welcome the

77 [Medical Research Council \(BRX0074\)](#) para 29

78 Q150 [Steve Bates]

79 [Cancer Research UK's policy statement on drug licensing following the UK's exit from the EU](#), December 2017

80 Q57

81 Q93

confirmation that the Government is seeking a close working relationship with the EMA to replicate the arrangements that we have now, as set out by Prime Minister in her 2nd March speech:

Associate membership of these agencies [including the EMA] is the only way to meet our objective of ensuring that these products only need to undergo one series of approvals, in one country.

But it would also be good for the EU because the UK regulator assesses more new medicines than any other member state. And the EU would continue to access the expertise of the UK's world-leading universities.⁸²

70. We were also encouraged in September to hear Lord O'Shaughnessy assure stakeholders that the EU (Withdrawal) Bill would transpose new EU regulations covering medical devices and in-vitro diagnostics into UK law.⁸³

71. The UK must look to secure, as a priority in the next round of negotiations, the closest possible regulatory alignment with the EU. The continued supply of safe and effective medical devices, medicines and substances of human origin currently on the UK market will depend on continued alignment with European regulations.

72. At the same time, the UK Government should also be open to exploring other potential trade and regulatory agreements with the wider international life sciences community. If full regulatory alignment with the EU is not secured, then a distant second-best option for the life science industry and patients in the UK would be alignment with another large market such as the Federal Drugs Agency in the USA. While this form of alignment would raise significant financial and patient safety issues, it remains preferable to the UK endeavouring to create a standalone regulatory system after leaving the EU.

73. We recommend that the nature and level of UK 'regulatory drift' in the life science sector from the EU be systematically assessed at regular intervals by current and future UK Governments, in order to prevent issues over a lack of harmonisation occurring in the future.

'No deal' risk management

74. We heard that contingency planning is already underway by businesses and organisations for the possibility of a 'no deal' in the Brexit negotiations, a situation which would mean that full regulatory alignment would not be possible. Leslie Galloway of the Ethical Medicines Industry Group stated:

Coming back to the issue of a hard Brexit, on the basis of no information—and, no matter what is said in the media about having reached agreement or whatever, nothing is final until it is final—companies have to be responsible and assume a hard Brexit will happen. As a consequence, marketing authorisations have been moved to mainland Europe, at a very significant

82 [PM speech on our future economic partnership with the European Union](#)

83 [Lord O'Shaughnessy on medical technologies and Brexit, 14 September 2017, Department of Health and Social Care](#)

cost, and they will not come back to the UK. They are making preparations that will protect their businesses and that makes sense, otherwise medicines would not be available to patients.⁸⁴

Phil Thomson of GSK told us:

I can tell you that our latest estimate is somewhere between £60 million and £70 million of cost to be as prepared as we can be in a no-deal, hard Brexit situation. ... We have to move on some of this now because the timeline to implement the laboratories takes 18 months. We cannot and do not want to be in a situation as a company in March 2019 where we have some sort of disruption in supply.⁸⁵

75. This opinion was echoed by Hugo Fry of Sanofi UK, who stated to us that, “There is a lot of work, and I reinforce the point that we have to do this now”,⁸⁶ and Leslie Galloway of EMIG went even further, arguing, “For some companies it is too late ... It is the message we have been delivering for some time.”⁸⁷ Steve Bates also warned us in oral evidence that not all organisations across the life science sector are currently undertaking contingency planning for the possibility that a deal in the Brexit negotiations is not agreed. This lack of preparation poses its own problems, both for businesses and patients, if the UK finds itself exiting the EU without a deal on March 29th 2019:

Some in the industry are prepared to take some risk in the sense of the risk being that hard Brexit is not the outcome that we are heading towards and carry that risk at this point. You can buy certainty by investing against hard Brexit happening in March 2019, which probably means significant disruption with some significant costs, or you can take some risk that perhaps something will come through. That is the uncertainty that companies are operating in at present.⁸⁸

76. Businesses are faced with a choice between two options: investing substantial resources in preparations for a ‘no deal’ that may never come to fruition, with consequential costs which the NHS will eventually bear in purchasing their products, or declining to prepare for a ‘no deal’ at all and running the risk of being unprepared should this situation emerge on March 29th 2019. On being asked whether the sooner businesses have certainty over the UK’s desired relationship with the EMA the better, Phil Thomson of GSK responded, “Absolutely, yes.”⁸⁹ When pressed on this at the final evidence session of this inquiry, Lord O’Shaughnessy stated that:

... we want to be in a position where we can defer or even dismiss those kinds of spending commitments because of guarantees we can give about the future relationship, but we are not there yet.⁹⁰

77. We reiterate the point made in our letter to the Secretary of State regarding Brexit transitional arrangements (15 February 2018), that rather than undermining the UK’s

84 Q175 [Leslie Galloway]

85 Q285

86 Q293

87 Q215 and Q216

88 Q214 [Steve Bates]

89 Q290

90 Q344

negotiating position, clarity about contingency planning to guarantee patient safety and continued health supplies will strengthen the UK's negotiating position by demonstrating that we have a credible fall-back position.⁹¹ This contingency planning should be published as soon as possible to alleviate the concerns of businesses and patients. The European Medicines Agency has published its guidance on what is necessary for the UK to maintain continued access to medicines in a 'no deal' scenario, and we believe that this one-sided picture may harm confidence if it is not possible to compare it to the Government's planned approach.⁹² Contingency planning is already taking away money that could otherwise be invested into pharmaceutical research or patient care, and calming the fears of life science companies to prevent them from investing in a 'no deal' scenario should be considered a priority in the next round of negotiations with the EU.

Batch testing, QPs and Good Manufacturing and Distribution Practices

78. In line with the consistent calls for regulatory alignment with the EU after Brexit, evidence submitted to this inquiry also argued that the UK should avoid any duplication of the requirements covering batch testing, Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).⁹³ The GMP and GDP are international standards converted into EU law and then applied to practice across Member States relating to production processes and supply chains.⁹⁴ Steve Bates of the BIA told us:

In the UK, we have the second highest number of all good manufacturing practice sites [in the EU]. The impact for manufacturers will be increased cost of doing additional batch testing, if we end up with a hard Brexit.⁹⁵

79. As regulatory divergence over GMP and GDP will place unnecessary financial burdens on UK businesses and make the UK less desirable as a market as outline below, we believe that the UK should look to transpose these regulations into UK law in the EU (Withdrawal) Bill.⁹⁶

80. Throughout this report, we have used textboxes and diagrams to illustrate case studies of the arguments we are conveying. The first of these can be seen below:

91 [Letter to the Secretary of State regarding Brexit transitional arrangements, 15 February 2018](#)

92 [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](#)

93 [Brexit Health Alliance \(BRX0031\) p. 4, Teva UK Limited \(BRX0053\) p.1](#)

94 [Good manufacturing practice and good distribution practice - Gov.uk](#)

95 Q185

96 Q185

Box 1: Case Study: Availability of medicines for prostate cancer patients

Prostate cancer treatment utilises a product which is manufactured only in the UK and is marketed in over 80 countries. State of the art, sterile, manufacturing facilities have been built and investment continues to support both the manufacture of this highly complex product and the testing laboratories, equipment and skilled staff required to assure product quality. The low turnover, long-service workforce has developed and retained the technical capability required to ensure the on-time release of this treatment to meet the needs of patients in over 80 markets. Total manufacture lead time is 12 months from active pharmaceutical ingredient (API) production to finished pack release.

Impact on patients:

- Faced by the possibility of a ‘no deal’ Brexit scenario, the manufacturer has begun planning the duplication of quality testing in an EU27 location.
- However, the calculated time for the manufacture and quality control testing is at least 42 months. This would affect the supply of this cancer treatment to patients, including up to 120, 000 in Europe each year.
- Due to the technical complexity of the analytical methodology and specific equipment required, it will be extremely challenging to transfer such knowledge from the UK to testing laboratory within the EU27 by April 2019.

A continued agreement and mutual recognition on testing between the UK and EU, or a suitable transition period and a future relationship between the UK and EU that maintains alignment on medicines regulation and trade would reduce the risk of complete supply disruption.

Source: Brexit and the impact on patient access to medicines and medical technologies - Brexit Health Alliance, January 2018

81. Qualified Persons (QPs) are individuals legally responsible for the safe batch release of medicines before they are placed on the market or used in clinical trials. Quality control testing by a QP is performed in one member state and then applies across the EU. If QPs in the UK are no longer recognised in other EEA countries, then there will be a requirement for any medicines or devices exported from Britain to have a QP based in each customer’s country.⁹⁷ The fear expressed by many organisations in written evidence was that this will increase the cost of doing business and thus dissuade companies from investing in British trials, as well as leading to those QPs currently residing in the UK moving to other EEA states.⁹⁸ The severity of this issue was underlined by Thermo Fisher in written evidence, who stated that:

Brexit jeopardises the entire clinical trials industry as pharmaceutical companies feel they cannot now commission new trials in the UK as the drugs would not be easily exportable to the European Economic Area.⁹⁹

97 [Thermo Fisher Scientific \(BRX0012\)](#) para 2.5

98 Q225 [Professor Boyd]

99 [Thermo Fisher Scientific \(BRX0012\)](#) para 2.1

82. Thermo Fisher went on to call on the Government to provide some form of reassurance around the future of QPs in the UK:

We have not received an assurance or recognition of QP status as a lynchpin in the life sciences ecosystem. Without this [we] cannot continue to function in the long-term. The likely result—which we have already seen through a steep drop off in our inward investment—will be businesses moving their manufacturing sites out of the UK.¹⁰⁰

83. These business decisions relating to investment in contingency planning for a ‘no deal’ Brexit will, we heard, ultimately have implications for patient care and the NHS. Steve Bates of the BIA argued that:

There could be a cost implication for the NHS, which would then have a knock-on effect [on patients] because this stuff does not come for free. Then there is delay, and once you are in a second-division market or regulatory environment, global companies will see this as a place where they may choose not to come.¹⁰¹

84. While we are pleased to note the Government’s position that arrangements must be put in place to protect patients, we are concerned that the contingency planning has not been made public to ensure it has received the appropriate scrutiny to guarantee its effectiveness. Additionally, while Lord O’Shaughnessy was correct to point out in oral evidence that “The MHRA does about a fifth of the EMA’s pharmacovigilance work, so, from a domestic capacity point of view, we do have domestic capacity”,¹⁰² this conclusion appeared to have been reached without consideration that many UK QPs are relocating or making plans to relocate to the EU already over fears that mutual recognition agreements may not put in place. This is likely to significantly affect the QP capacity the UK retains domestically after Brexit.

85. To allay fears within the life science sector, and to prevent the relocation of Qualified Persons (QPs) from the UK to the EU-27, the Government must seek agreement with the EU for those QPs currently working in the UK to continue to have their work recognised in EEA countries, ideally in the Withdrawal Agreement for the short to medium term and in regulatory cooperation or a mutual recognition agreement for the longer term.

86. At the same time, as any Brexit deal, and the agreements proposed within it, could collapse, we recommend that the Government publish its contingency planning as soon as possible for a situation in which no mutual recognition of QPs in the UK and EU is agreed. This should include proposals to prevent the exodus of UK QPs, and contingency planning around the training and recruitment of new QPs to fill any vacancies.

87. Furthermore, as regulatory divergence over Good Manufacturing Practice and Good Distribution Practice will place financial burdens on UK businesses and make the UK less desirable as a market, we recommend that the UK should transpose these regulations into UK law in the EU (Withdrawal) Bill.

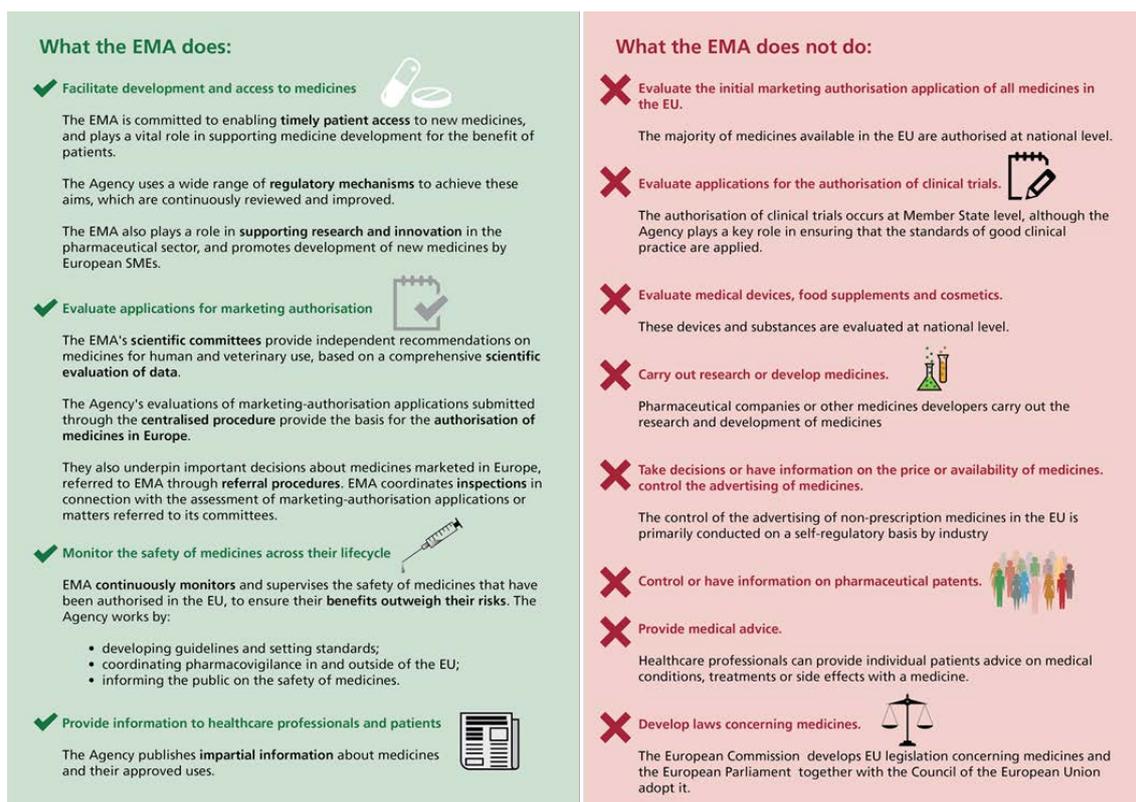
100 [Thermo Fisher Scientific \(BRX0012\)](#) para 2.6

101 Q186

102 Q393

The UK's relationship with the EMA

88. 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, but 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 outline what element of manufacturing or distribution practice will be recognised. The EMA has wide ranging responsibilities, but, as the diagram below shows, these only make up part of the total life cycle for products in the life science sector:¹⁰³



89. After a protracted period of delay, we welcome the clarity provided by the Prime Minister in her speech of 2nd March regarding the UK's planning for its future relationship with the EMA, with the preferred position being that of 'associate membership'. She explained how:

We would, of course, accept that this would mean abiding by the rules of those agencies and making an appropriate financial contribution.

I want to explain what I believe the benefits of this approach could be, both for us and the EU.

First, associate membership of these agencies is the only way to meet our objective of ensuring that these products only need to undergo one series of approvals, in one country.

Second, these agencies have a critical role in setting and enforcing relevant rules. And if we were able to negotiate associate membership we would be able to ensure that we could continue to provide our technical expertise.

Third, associate membership could permit UK firms to resolve certain challenges related to the agencies through UK courts rather than the ECJ.

Fourth it would bring other benefits too. For example, membership of the European Medicines Agency would mean investment in new innovative medicines continuing in the UK, and it would mean these medicines getting to patients faster as firms prioritise larger markets when they start the lengthy process of seeking authorisations.

But it would also be good for the EU because the UK regulator assesses more new medicines than any other member state. And the EU would continue to access the expertise of the UK's world-leading universities.

And, of course, Parliament would remain ultimately sovereign. It could decide not to accept these rules, but with consequences for our membership of the relevant agency and linked market access rights.¹⁰⁴

90. We are encouraged that the Government has clearly articulated its desired future relationship with agencies such as the EMA, and we believe that associate membership is a desirable model for the UK. However, we note the draft text of the EU negotiating position which states that:

The European Council further reiterates that the Union will preserve its autonomy as regards its decision-making, which excludes participation of the United Kingdom as a third-country to EU Institutions, agencies or bodies. The role of the Court of Justice of the European Union will also be fully respected.¹⁰⁵

91. There appears a fundamental disjunction between the ambitions of the EU and the UK with regards to UK EMA membership, and we fail to see a clear solution that could be reached during the negotiation process. While there may be significant sector level advantages for the EU and the UK in allowing UK associate membership of the EMA, this does not guarantee that such a relationship will be ensured after the UK exits the EU. UK Exit negotiations are being conducted as a 'single package', meaning they have the potential to fall apart if any area of the negotiations fails to agree terms. The Government must therefore engage in contingency planning for how, if associate membership of the EMA is not achieved, they will be looking to fulfil their objectives of ensuring products only need to undergo one series of approvals, in one country and contributing to the setting and enforcing of relevant rules. The publication of this contingency planning will give much needed security to industry and patients, and in the highly technical areas around the safety monitoring and regulation of pharmaceutical products with complex supply chains, extensive public scrutiny of any contingency planning will ensure that all relevant aspects are covered to guarantee the health of UK patients regardless of the Brexit outcome.

104 [PM speech on our future economic partnership with the European Union](#)

105 [European Council \(Art.50\) \(23 March 2018\) - Draft Guidelines](#)

92. We welcome the Government's announcement that it will seek associate membership of the European Medicines Agency (EMA). We call on negotiators from both sides to put the needs of patients first and foremost as negotiations on this matter progress. However, the EU's draft negotiating position appears to suggest that continued UK EMA membership may be rejected. We therefore recommend that the Government publish any contingency planning it has undertaken for a situation in which associate membership of the EMA is not achieved.

5 Continued collaboration in other areas of the life science sector

Research and development and clinical trials

Current participants in clinical trials

93. The first stage in the life science product cycle involves research and development and clinical trials. We heard that almost a quarter of all clinical trials in the EU are multinational; and that international recruitment of patients will be an increasingly important aspect of clinical trials, as the move towards personalised medicines—involving targeted treatments - means that many trials will involve patient cohorts with more specific requirements.¹⁰⁶ We received evidence that raised the issue of those patients in the UK and EU who are currently engaged in clinical trials which involved some form of cross-EU collaboration. As Aisling Burnand of the Association of Medical Research Charities noted in oral evidence:

Currently, there are over 1,500 clinical trials taking place that have a UK sponsor and 50% of those are going to continue post 2019. There will need to be clarity on what happens to patients involved in those trials and what the legal status is of some of those things.¹⁰⁷

94. Clinical trials are regulated by the EU Clinical Trials Directive, which was transposed into UK law in 2004.¹⁰⁸ The harmonisation of clinical trials regulations facilitates the conduct of trials across all EU Member States, as there is only one set of standards to comply with, reducing the financial and collaboration burdens on organisations and researchers.¹⁰⁹ The EU in 2014 approved the new EU Clinical Trials Regulation (CTR), which will streamline the operation of multi-country EU trials through greater harmonisation, with a single portal for all applications.¹¹⁰ As the implementation of the CTR has been delayed, the CTR is not covered by the EU (Withdrawal) Bill that is before Parliament, and so will not automatically become part of UK law on Exit day. Emma Greenwood of Cancer Research UK told us:

From a clinical trials perspective, a new regulation will be coming in. What we do in the UK has to be sufficient for them [the EU] to agree that we can continue to co-operate. The way the regulation is currently drafted you have to be a member state. Although there is willingness to get to the right end point, we have not yet seen what it would take for the other member states in the EU to endorse that approach.¹¹¹

95. There was a strong consensus in the evidence provided to this inquiry that the UK should adopt the new CTR into UK law.¹¹² However, adopting these regulations into law

106 [Academy of Medical Sciences \(BRX0071\)](#) para 6

107 Q127 [Aisling Burnand]

108 Parliamentary Office of Science and Technology, *Regulating Clinical Trials*, October 2017

109 Parliamentary Office of Science and Technology, *Regulating Clinical Trials*, October 2017

110 [Quintiles IMS \(BRX0018\)](#) p.3, [Wellcome Trust \(BRX0073\)](#) p.2

111 Q229 [Emma Greenwood]

112 [Quintiles IMS \(BRX0018\)](#) p.3, [Wellcome Trust \(BRX0073\)](#) p.2 [and others]

will not guarantee that the UK can benefit from the new regulations, as simple statutory alignment does not guarantee continued collaboration, which also demands mutual agreement to continued co-operative working. We were told that if the UK is unable to secure continued harmonisation on clinical trials after exiting the EU this could create a variety of issues, the most urgent of these being the status of those UK based patients who are currently engaged in multinational EU Clinical Trials. Emma Greenwood of Cancer Research UK told us:

My understanding is that the MHRA is currently working under the assumption that we will essentially be aligned [on clinical trials], but this is only possible if there is agreement that the EU will endorse that approach. Until there is more detail, it is impossible for the EU to say whether that [allowing the UK to participate in the CTR] would prove to be acceptable to them for an arrangement. If you are a business making decisions in the next six months, it is not enough certainty.¹¹³

Continued participation in clinical trials

96. In addition to the short-term considerations around current participants in clinical trials, we heard evidence that for the UK life science industry, the NHS and UK patients, it is critical that the UK achieves long-term continued participation in EU clinical trials. If the UK does not adopt the CTR and is unable to access the infrastructure that has been developed within the EU to underpin them, a variety of issues for patients and the life science industry could emerge both in the short and medium to long term:

- Added burdens would be placed on researchers and clinical trial sponsors, as they would have to apply different rules in the UK and the EU. This is particularly important as over half of UK trials currently in operation have sites in the EU.¹¹⁴
- Problems could arise in recruiting sufficient cohorts of patients for clinical trials, particularly in the case of paediatric medicine and rare diseases. The UK has a much smaller population (66 million) than the EU (512 million) and the US (323 million). If isolated, the UK could be a less attractive destination for cutting-edge research, thereby restricting UK patients from being able to participate. For example, patients are increasingly being stratified based on the genetic profile of the cancer, which further reduces the number of eligible patients an individual country. On paediatric medicine, the number of children involved in clinical trials increased by 6000% following the EU Paediatric Regulations.¹¹⁵
- A negative impact on the UK's position as a market leader in clinical trials. Sanofi told us that it invests around £44.5 million in research and development trials in the UK, which form part of multi-site, multi-country trials. This has been made possible by the UK's participation in the EU's harmonised regulatory processes, and they gave the stark warning that such investment would either be limited or non-existent if the UK could not access EU clinical trials.¹¹⁶

113 Q261

114 [Wellcome Trust \(BRX0073\)](#) p.2

115 [Brexit Health Alliance \(BRX0031\)](#) p.3

116 [Sanofi UK \(BRX0029\)](#) p.2

- Patient participation in clinical trials and access to treatments could become more difficult. If diagnosed with a relevant condition, 89% of patients would be willing to participate in a clinical trial.¹¹⁷ The Association of Medical Research Charities told us that alignment with EU clinical trials regulations is important to ensure that UK patients can participate in trials.¹¹⁸ For example, according to the Genetic Alliance, clinical trials are a key means by which patients can gain accelerated access to new and innovative treatments, which risks seriously affecting those with a rare disease.¹¹⁹ Dr Jayne Spink stated in oral evidence that:

In terms of rare disease research, it is completely impractical to imagine a clinical trial within one state just because there are too few numbers. There has been about €900 million of funding since FP7 into 160 projects that are researching orphan medicinal products in the context of rare diseases. The ability to participate as part of those funding collaborations and clinical trials collaborations is fundamental to patients in the UK.¹²⁰

97. The Medical Technology Group similarly argued in written evidence that:

The UK's success at R&D in the pharmaceutical sector is driven by the unique potential of the NHS in hosting clinical trials, the recognition of UK clinical trials across the rest of the EU, and our ability to develop and attract talent. The UK's departure from the EU threatens this base and it is thus essential that steps are taken to mitigate these risks, through harmonisation with the EU Clinical Trials Directive. Establishing a regulatory regime for clinical trials that diverges from EU standards would increase the burden on UK researchers. This would make the UK a less appealing destination to conduct trials.¹²¹

117 [Academy of Medical Royal Colleges \(BRX0041\) para 6](#)

118 [Association of Medical Research Charities \(BRX0052\) p.1](#)

119 [Genetic Alliance UK \(BRX0067\) p.1–2](#)

120 Q115

121 [Medical Technology Group \(BRX0039\) p.2](#)

Box 2 Potential delays in access to new medicines for rare disease patients

Duchenne muscular dystrophy is a severe type of muscular dystrophy for which there is no cure and limited treatment options available. At any one time, there are estimated to be 26,000 patients in the EU, and 2,500 people affected by Duchenne muscular dystrophy in the UK.

There are several promising treatments progressing through the clinical trials process and a number of these are awaiting authorisation by the EMA. One particular drug could be assessed by the EMA in the next few years. If successful, these medicines could effectively slow down the progression of the condition and result in significant benefits to those affected.

Without a UK link to the EMA's medicines approvals process, and considering the small population size and market opportunity for pharmaceutical industries, individuals with Duchenne muscular dystrophy in the UK could face lengthy delays in accessing the medicine compared with patients with the same condition living in EU countries.

Source: Brexit and the impact on patient access to medicines and medical technologies - Brexit Health Alliance, January 2018

98. A point made across evidence submitted to this inquiry was that simply aligning with EU rules on clinical trials will not be enough to ensure the same level of collaboration with the EU as the UK currently enjoys. As Dr Beth Thompson said in oral evidence:

There will need to be some legislative fix to manage clinical trials, but it is not as simple, if that is simple at all, as fixing the legislation itself. We also need to negotiate alignment because it is a partnership. We cannot just unilaterally say we will take part.¹²²

99. The regulation of clinical trials across the EU in the future will also require common access to supporting IT infrastructure such as the Clinical Trials Portal which is currently under development.¹²³ The Association of Medical Research Charities argued that the UK's participation in EU systems such as the Clinical Trials Portal would be essential to ensuring patients have access to health innovations after Brexit.¹²⁴

100. Sir Hugh Taylor, Chair of the Brexit Health Alliance, also made the point that clinical trial participation and the holding of these trials in the UK benefits clinicians and the treatment they are able to provide. He noted:

By participating in clinical studies, from the clinician's point of view, they get to experience the use of medicines under development, so that when those medicines are approved they know some of the advantages and disadvantages of those medicines. Of course, if they do not partake in those, they are going to miss out and will only know about those medicines when they are approved.¹²⁵

101. Clarity is therefore needed on the future of UK clinical trials. In oral evidence, Dr Ian Hudson of the MHRA told us that after Brexit:

122 Q127

123 [Association of Medical Research Charities \(BRX0052\) para 16](#)

124 [Association of Medical Research Charities \(BRX0052\) para 16](#)

125 Q220

The ability to run a multinational trial including the UK does not change ... You will still be able to have the same protocol that is submitted for approval in the UK and the clinical trial run in the UK, and that data combined with data from the study done anywhere else.¹²⁶

102. However, while Dr Hudson is technically correct that the UK will not be physically unable to run clinical trials after exiting the EU, this does not adequately take into account the relative desirability of conducting trials in the UK as opposed to conducting them elsewhere for businesses. If the UK has no access to the new Clinical Trials Portal, and has a divergent regulatory system from the remainder of the EU, it may be that we are *able* to conduct clinical trials here, but that the increased regulatory and financial burdens make it sufficiently *undesirable* to dissuade businesses from doing so. Dr Hudson stated that: “The UK is a great place to do clinical research. None of that changes, whatever the outcome of Brexit.”¹²⁷ We believe this is an understatement of the risks that Brexit poses for UK clinical research.

103. For the benefit of the UK life science industry, the NHS and UK and EU patients, UK participation in cross-EU clinical trials is important. If the UK does not adopt the CTR and is unable to access the infrastructure that has been developed within the EU to underpin them, a variety of issues for patients and the life science industry could emerge both in the short and medium to long term.

104. The Government should recognise that while a commitment to transferring the Clinical Trials Regulation into UK law is a positive starting point for patient safety in the UK, this is insufficient to guarantee continued UK access to EU clinical trials. This will demand co-operation and willingness from other stakeholders in the EU. The Government should make public its contingency planning for the possibility that the UK is unable to secure continued participation in these trials, both for current participants in trials and for the future of UK clinical trials.

105. We welcome the Government’s aim to play a full part in new clinical trials regulations and medical devices regulations.¹²⁸ We would like to see much more detail of what this will entail in practice, and we expect to see that detail in the Government’s response to this report.

106. We urge the Government to commit to adopting the new Clinical Trials Regulation into UK law following Brexit and to secure a joint statement with the EU committing to continued collaboration on clinical trials following the UK’s exit from the EU.

107. We recommend that the Government provide urgent confirmation of the status of UK citizens currently engaged in ongoing clinical trials. It is critical that this is covered in the Withdrawal Agreement that the UK strikes with the EU, ideally in the provisions on citizens’ rights.

Regulatory alignment over EU rules for data protection

108. We heard that data sharing across the EU is essential for public health, and that UK compliance with EU rules on data protection will secure patient access to products,

126 Q358

127 Q359

128 [Lord O’Shaughnessy on medical technologies and Brexit](#)

minimising the potential for adverse impacts of the UK's withdrawal from the EU and maximising opportunities to enhance services.¹²⁹ As highlighted by the Wellcome Trust, the UK is currently a world leader in genomics and research using health data, both of which rely on international collaboration and sharing data across borders. In order to ensure this collaboration continues, a straightforward exchange of personal data with the EU and other countries after Brexit will be important.¹³⁰ The UK Government and wider life sciences sector have been instrumental in shaping the direction of the General Data Protection Regulation (GDPR), and the outcome is a system agreed by stakeholders to be beneficial for UK health research.¹³¹ We heard that the Data Protection Bill currently before Parliament must therefore maintain the provisions of the GDPR, and the UK must harmonise legislation on data sharing with the EU.¹³²

109. We were encouraged by the statement made by the Prime Minister on 2nd March which argued that:

... The free flow of data is also critical for both sides in any modern trading relationship too. The UK has exceptionally high standards of data protection. And we want to secure an agreement with the EU that provides the stability and confidence for EU and UK business and individuals to achieve our aims in maintaining and developing the UK's strong trading and economic links with the EU.

That is why we will be seeking more than just an adequacy arrangement and want to see an appropriate ongoing role for the UK's Information Commissioner's Office. This will ensure UK businesses are effectively represented under the EU's new 'one stop shop' mechanism for resolving data protection disputes.¹³³

110. The European Commission has the power to offer an 'adequacy statement' under Article 45 of Regulation (EU) 2016/679, which determines whether a country outside the EU offers an adequate level of data protection, whether by its domestic legislation or by virtue of the international commitments it has entered into. The effect of such a decision is that personal data can flow from the EU (and Norway, Liechtenstein and Iceland) to that third country without any further safeguard being necessary, meaning transfers to the country in question will be assimilated to intra-EU transmissions of data.¹³⁴ The draft text of the European Union's negotiating position states that:

In the light of the importance of data flows in several components of the future relationship, personal data protection should be governed by Union rules on adequacy with a view to ensuring a level of protection essentially equivalent to that of the Union.¹³⁵

While we understand that this statement reflects an initial negotiating position rather than an unchangeable position, and therefore over-scrutiny of the fine print may ultimately lead

129 [Wellcome Trust \(BRX0073\) p.3](#)

130 [Wellcome Trust \(BRX0073\) p.3](#)

131 [Wellcome Trust \(BRX0073\) p.3](#)

132 [Wellcome Trust \(BRX0073\) p.3](#)

133 [PM speech on our future economic partnership with the European Union](#)

134 [Adequacy of the protection of personal data in non-EU countries](#)

135 [European Council \(Art.50\) \(23 March 2018\) - Draft Guidelines](#)

to misguided conclusions, this text from the European Council suggests that an adequacy agreement alone will be all that is on offer to the UK regarding data flows in the upcoming negotiations.

111. We strongly support the UK Government’s desire to seek ‘more than just an adequacy agreement’ under Article 45 of the General Data Protection Regulation with the EU so as to secure lawful data flow, including of personal data for health research, between the EU and the UK. We look forward to seeing further detail of the arrangements which the Government is seeking to achieve. We note the Council’s preparedness to reconsider its offer should the UK position evolve.¹³⁶ We urge the Government to be ready to be flexible, should detailed proposals of arrangements for lawful data flow require such flexibility. The Government should clarify whether it will look to secure these arrangements with the EU from UK ‘Exit Day’ or at the end of any transitional period.

Research and collaboration networks

112. We heard that scientific research in the life science sector is international and intrinsically collaborative.¹³⁷ Easy movement of researchers, innovators and specialist technicians has given the UK a competitive advantage over non-EEA nations, by opening up access to skills and international networks.¹³⁸ International movement is a feature of researchers’ careers—72% of UK-based researchers spent time at non-UK institutions between 1996 and 2012. 27.7% of academic staff at universities are from outside the UK—31,600 from other EU nations and 23,000 non-EU internationals.¹³⁹ We were told that across the life science sector, NHS healthcare scientists lead on a variety of European Commission funded research grants, with research and development projects often benefitting from multicentre collaborations from a larger pool of viable participants and specialist researchers than exists at national level. The Royal Pharmaceutical Society elaborated on this in their written evidence submission, stating:

Over recent years the rapidly increasing cost and complexity of research has meant that collaboration with colleagues both within and beyond the EU has become more important.¹⁴⁰

113. Sir Hugh Taylor of the Brexit Health Alliance noted in oral evidence that UK access to EU funding programmes has greater than purely financial benefits:

We are a net beneficiary at the moment from the European funding on research. There is the potential for the Government to match EU funding. But it is not just a question of funding, but of using that funding to access trials and collaboration networks.¹⁴¹

114. UK access to EU research funding means that a number of UK medical research charities are listed as participants across Horizon 2020 and Innovative Medicines Initiative

136 [European Council \(Art.50\) \(23 March 2018\) - Draft Guidelines](#) para 13

137 [Brexit Health Alliance \(BRX0031\)](#) para 8.1

138 [Brexit Health Alliance \(BRX0031\)](#) para 8.1

139 [Brexit Health Alliance \(BRX0031\)](#) para 8.1

140 [The Royal Pharmaceutical Society \(BRX0026\)](#) para 13

141 Q222

projects.¹⁴² Horizon 2020, for example, provides an established platform for collaborating with European partners for six of the UK's top ten research partners, allowing access to a multi-national financial resource that promotes collaboration and the sharing of expertise, which ultimately improves clinical outcomes. We heard that a loss of UK partners in EU backed research projects would affect the expertise available in these projects, and therefore the clinical outcomes both in the UK and the EU.¹⁴³ Conversely, even if the UK matches science funding from current EU sources, UK science is likely to lose out by having many collaborations made significantly more complex.¹⁴⁴

115. Research carried out in isolation would potentially limit the UK's ability to translate research into products in the market due to the financial and logistical requirements, and, as the UK currently has the largest pipeline of therapeutic treatments in Europe, while 25% of the world's top prescription medicines were discovered in the UK, the risk this could pose to the UK life sciences would be considerable.¹⁴⁵

116. The UK should continue to be a member of EU research and development funding and research mechanisms such as Horizon 2020 and the Innovative Medicines Initiative after leaving the EU, if possible on the same terms as they currently enjoy. If the same relationship is not possible, we still advocate membership of these funding and research systems in order for UK R&D to enjoy the collaborative opportunities they provide.

Free movement of researchers

117. We also heard evidence that the ability of the UK to continue to attract researchers from the EU and around the world would be integral to the future of R&D in the UK. John Maingay of the British Heart Foundation told us in oral evidence that the key to minimising the potential negative effects of Brexit on UK R&D would be to develop:

... a simpler and fairer immigration system post Brexit that will apply to all these researchers across the world that helps us retain and attract the highest-quality researchers. It really does come down to what sort of immigration system is going to apply to future researchers wherever they are from.¹⁴⁶

118. In response to this, we welcome the statements from the Government that the (Withdrawal) agreement should also facilitate bilateral and multilateral research relationships, which will be important for maintaining strong links with individual Member States once the UK has left the EU. In particular, the UK and the EU must ensure that their research communities can continue to access the high-level skills that support innovation in science and technology. The Government has made clear that, although freedom of movement will cease to apply in the UK, the UK will continue to welcome the brightest and best.¹⁴⁷

142 [Brexit Health Alliance \(BRX0031\)](#) p.6

143 [Brexit Health Alliance \(BRX0031\)](#) para 8.6

144 [High Level Group on maximising impact of EU Research and Innovation Programmes](#)

145 [British Medical Association \(BRX0036\)](#) para 5.2

146 Q245

147 [Brexit and health and social care - people & process](#), Health Committee, HC640, Para 62, [Government response to the House of Commons Health Committee report Brexit and health and social care – people & process](#) December 2017, Cm9469 p.9

119. We welcome the Government’s statements of their desire to have a future immigration policy that recognises the value that life science researchers bring to the UK, but would like to see further details about what this policy would look like. The failure to achieve an immigration policy post-Brexit that helps the UK to retain and attract the highest-quality researchers could have a significant adverse impact on UK research and development.

Research and development funding

120. In 2015, the UK contributed approximately 20% of pharmaceutical industry R&D spending in the EU.¹⁴⁸ In response, clinical medicine has received more funding from EU government bodies than any other discipline in the UK, with universities alone receiving around £120m a year (in 2014/15).¹⁴⁹ The Government has pledged to underwrite the funding for all successful bids made by UK participants for Horizon 2020 projects that are submitted before the UK’s EU exit, even when specific projects have a timeline that extends beyond March 29th 2019.¹⁵⁰ However, we received evidence that such short-term funding options do not adequately provide for the UK’s life science industry post-Brexit. For example, in written evidence to this inquiry, Quintiles IMS stated:

There needs to be long term commitment to ensuring that medical research is adequately funded and the UK can keep its status as a world leader.¹⁵¹

121. We welcome the Secretary of State’s comment in oral evidence that “We may well choose to continue to be part of European research programmes” in the longer term,¹⁵² which would allow the UK to secure at least some level of continued EU research funding. However, we heard the clear message from other evidence during our inquiry that while non-EEA countries such as Australia already participate in EU funding mechanisms such as Horizon 2020, the funding that is afforded to them is generally less than that which is offered to EEA nations, and makes up a fraction of the total that the UK currently receives.¹⁵³ We heard that only 7% of research money allocated by the European Research Council in the past decade has gone to non-member states.¹⁵⁴ While the UK could pay into the EU science budget and apply for funds (similar to Israel and Switzerland), the ‘Juste Retour’ principle traditionally means that the funding received from EU programmes by participants from a country is roughly equivalent to the amount of funding that country contributes to that programme as a whole.¹⁵⁵ The American Pharmaceutical group argued that to ensure the same degree of participation as now in future research programmes, the Government should commit to contributing funding at least equivalent to the amount currently received by UK participants in EU funding systems such as Horizon 2020, and that this should be part of a long-term approach that is also maintained in successive research partnerships.¹⁵⁶

148 “The Pharmaceutical Industry in Figures”, 2016, European Federation of Pharmaceutical Industries and Associations

149 [Quintiles IMS \(BRX0018\) p.4](#)

150 [Chancellor Philip Hammond guarantees EU funding beyond date UK leaves the EU](#)

151 [Quintiles IMS \(BRX0018\) para 19](#)

152 Q404

153 [Examining Implications of Brexit for the UK Research Base](#)

154 [Examining Implications of Brexit for the UK Research Base](#)

155 [Juste Retour—ERA-LEARN 2020](#)

156 [American Pharmaceutical Group \(BRX0035\) para 23](#)

122. The UK should also look to continue participation in the European Investment Bank (EIB) and access to the European Investment Fund (EIF), including shareholding, financial contributions and, as a result, a seat on the Board. We heard that between 2012 and 2016 alone, 11% of EIB investments in the UK were allocated to education and health initiatives, including health system infrastructure and SME support, many of which are responsible for innovation in the sector.¹⁵⁷

123. However, the text of the EU draft negotiating position which was published on 7th March states:

... regarding certain Union programmes, e.g. in the fields of research and innovation ... any participation of the UK should be subject to the relevant conditions for the participation of third countries to be established in the corresponding programmes in the next Multiannual Financial Framework.¹⁵⁸

That text suggests that participation on the same terms as currently enjoyed may not be achievable.

124. To ensure the same level of participation in future EU research programmes as the UK has currently, the Government should confirm that it is willing to contribute funding at least equivalent to the amount currently received by UK participants in EU funding systems such as Horizon 2020. Failure to do this would undermine the Juste Retour principle that has traditionally applied in EU research networks, and may jeopardise future UK involvement. However, we note that the text of the draft negotiating position from the EU suggests that participation on the same terms may be unworkable, and therefore urge the Government to publish contingency planning on how they intend to make up the resulting funding shortfall.

Access to EU pharmacovigilance systems

125. Having gone through the research and development process, the next stage in the pharmaceutical life cycle involves safety testing. Pharmacovigilance efforts in the EU are coordinated by the EMA and are conducted in each member state by the National Competent Authority or Authorities (NCAs) for that state. The MHRA is the NCA for the UK, and 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, and have sufficient staff to undertake this work. The MHRA assesses more drug applications for the EMA than any other NCA, and the UK is home to several important databases used in pharmacovigilance which are owned by the EMA.¹⁵⁹ The Drug Safety Research Unit is amongst a number of UK academic and research centres which belong to the European-wide network in pharmacovigilance: the European Network of Centres of Pharmacovigilance and Pharmacoepidemiology (ENCePP). In addition, currently, the EMA runs the Pharmacovigilance Risk Assessment Committee (PRAC), which is the committee responsible for monitoring safety issues for medicines, and undertaking assessments. PRAC has been chaired since its inception in 2012 by June Raine of the MHRA.

157 [American Pharmaceutical Group \(BRX0035\) para 24](#)

158 [European Council \(Art.50\) \(23 March 2018\) - Draft Guidelines](#)

159 [Drug Safety Research Unit \(BRX0023\) p.2](#)

126. We heard that after Brexit, the UK will no longer be represented on PRAC.¹⁶⁰ Although representatives may attend PRAC meetings as non-voting observers as Norway and Iceland currently do, we are concerned that this would effectively represent a loss in UK influence, as the UK would become a ‘taker’ rather than a ‘maker’ of pharmacovigilance decisions. We heard that the UK has, until now, been a world leader in pharmacovigilance for a number of reasons, including the concentration of highly skilled scientific staff, the availability of the NHS as a data source and the location of the EMA in London.¹⁶¹ The NHS is highly sought after by international pharmaceutical companies which need to monitor the safety and utilisation of their medicines.¹⁶² Several key databases used in pharmacovigilance are based on the NHS’s medical records. Many GP surgeries and hospitals are involved in pharmacovigilance studies, bringing in welcome income to the NHS.¹⁶³

127. We heard that after Brexit, pharmacovigilance which is conducted in the UK may not be accepted in the EU, meaning that it will need to be duplicated elsewhere in Europe.¹⁶⁴ The UK EU Life Sciences Steering Committee notes:

Patient safety may be compromised. No longer having UK involvement in the European Database of Medical Devices (EUDAMED) and integrated EU vigilance processes will impact the quality and coverage of the systems used to detect side-effects and manage safety issues. In addition, losing access to the European Centre for Disease Control could impede the UK’s ability to manage pandemics and delay vaccine supply.¹⁶⁵

128. Similarly, the British In Vitro Diagnostic Association (BIVDA) argued that:

It is not possible to move to any new arrangements immediately post-29 March 2019. For example, if the UK was to withdraw from the EudraVigilance pharmacovigilance system, there is not time to build a UK-based system by March 2019, nor would a UK system provide the same level of public safety as it would cover a much smaller population.¹⁶⁶

129. We heard that a possible solution to concerns over public health relating to the UK’s withdrawal from the EU could involve a UK agreement where it maintains membership in some capacity of the major pharmacovigilance systems and organisations. The Association of British Healthcare Industries’ written evidence said:

We strongly encourage the UK Government to consider mutual recognition agreements in relation to manufacture and distribution of pharmacovigilance services. If the UK was to withdraw from the Eudravigilance pharmacovigilance system, there is no time to build a UK-based system by March 2019, nor would a UK system provide the same level of public safety as it would cover a much smaller population. The MHRA

160 [British Medical Association \(BRX0036\)](#) p.11

161 [Drug Safety Research Unit \(BRX0023\)](#) p.2

162 [Drug Safety Research Unit \(BRX0023\)](#) p.2

163 [Drug Safety Research Unit \(BRX0023\)](#) p.2

164 [Drug Safety Research Unit \(BRX0023\)](#) p.2

165 ABPI. 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.

166 [RB Reckitt Benckiser \(BRX0061\)](#) p.4

is playing an active and equal partner role on PRAC, and to ensure patient safety, the MHRA should at least have a guaranteed observer status in such committee.¹⁶⁷

130. We also heard that limitations on the use of UK pharmacovigilance in Europe would be significant not just for the UK, but also for public health in the EU. The MHRA has robust data collection which adds significant value to the data captured in EU pharmacovigilance databases, and in this way MHRA collaboration with the EMA helps to protect EU patients and continued UK access would be mutually beneficial. Lord O'Shaughnessy told us that:

The contribution that the MHRA makes to patient safety across the European Union ... is worth emphasising, I think, that it is a quarter of the centralised marketing authorisation procedures, about 40% of the decentralised procedures and 40% of safety referrals. It goes way beyond any other member state.¹⁶⁸

131. We recommend that the UK seek mutual recognition of pharmacovigilance studies by the Medicines and Healthcare products Regulatory Agency and the EMA as a priority in the next round of negotiations. In addition, the UK should seek to ensure that all UK pharmacovigilance organisations continue to be members of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, as the failure to do so could affect patient safety both in the UK and the EU. The UK must also maintain membership of all of the major EU pharmacovigilance systems and databases, including the European Databank on Medical Devices (EUDAMED) and Eudravigilance.

132. The UK should also look to retain full membership of the Pharmacovigilance Risk Assessment Committee (PRAC), and if this is not possible should endeavour to be present in PRAC meetings as an observer as an absolute minimum.

133. Evidence presented to us made the point that failure to gain access to EU pharmacovigilance systems would have serious consequences for UK medicine and drug safety. It would not be possible, let alone desirable, to draw up a UK standalone system by the time the UK exits the UK. Contingency planning in this area would highlight the risks of failure to access EU pharmacovigilance systems and needs to prompt urgent action.

Trade, customs and supply chains

134. Having undergone safety monitoring and clinical testing and having been approved for use in the UK, the final stage in the life science journey involves the supply of the product to patients, either via the NHS or pharmacies. NHS care is dependent on a network of highly integrated, complex and time sensitive supply chains for the delivery of medicines, medical devices and substances of human origin. Martin Sawer, Managing Director of the Healthcare Distribution Association, expressed how:

167 [RB Reckitt Benckiser \(BRX0061\)](#) p.4

168 Q385

... quite rightly, we take the supply chain for granted. A doctor writes a prescription; the patient might go into a pharmacy in the morning and the pharmacy says, "Come back in the afternoon and the medicine will be there." We are invisible, and we should be, but I think it is important to recognise that that supply chain is there and operating all the time. A jolt to it like this could throw a lot of cogs out of a very complicated machine.¹⁶⁹

Supply chains

135. During their life-cycle, medicines, medical products and technologies cross multiple countries for material sourcing, manufacturing, packaging, sterilisation and other processes.¹⁷⁰ UK and EU supply chains for medicines and medical technologies are highly integrated, for both finished products and components. Pharmaceutical sector supply chains across the EU involve the exchange of medicines, active pharmaceutical ingredients, clinical materials—including the trade and exchange of samples—and raw materials. The delivery of NHS care also depends on the seamless flow of time-sensitive products, such as medical radioisotopes. Teva UK, a global pharmaceutical company, told us how it is reliant on its ability to move products smoothly across borders:

[Teva UK] ...imports from 17 different countries within the EU, representing a value of approximately €69m and requiring around 1,765 customs entries. Regarding exports from the UK, we are responsible for around 1,063 shipments of finished products worldwide, of which 525 go to EU countries. In value, this represents approximately €337m (around 45 million within the EU). We favour a future regulatory system as close as possible to current arrangements, with additional administrative procedures avoided.¹⁷¹

136. Bector Dickson, the largest supplier of needles and tubes for blood collection in the NHS, manufactures its products in Plymouth before they are transported to Belgium for product checking and distributed back to the UK.¹⁷² Businesses are understandably concerned about that potential introduction tariff and non-tariff will add costs into these supply chains. Tariffs would in effect add costs several times, since goods may touch several jurisdictions before they reach their destined market.¹⁷³ Warwick Smith from the British Generic Manufacturers Association explained that within the generic industry:

Once a medicine comes off patent, a dozen or 20 companies will pick it up, so there are many more generic licences out there than there are originator licences, if I can put it that way. The risk there is that, as costs go up, some companies will relinquish their licences and their marketing authorisations, so there could be fewer manufacturers in the marketplace, and that, at the moment, keeps the market, in normal times, pretty resilient. The more manufacturers there are of the same molecule, the more options we have if there are supply difficulties. That is a key objective for the generic industry in keeping that competitive multi-source market going.¹⁷⁴

169 Q61 [Martin Sawyer]

170 [ABHI \(BRX0059\)](#) p.2

171 [Teva UK Limited \(BRX0053\)](#) p.1

172 [ABHI \(BRX0059\)](#) p.2

173 [ABHI \(BRX0059\)](#) p.2

174 Q317

137. However, the Brexit Health Alliance raised concern about the more immediate impact on patient care, saying:

... if post-Brexit trading agreements make it harder to move things around, then supply could be affected. If containers cannot move freely across borders, there is a possibility that supplies for patients could be affected. These factors could make the UK an unattractive market for producers and when supplies become low, the UK would not be a priority, meaning patient access to innovation is impeded.¹⁷⁵

138. The Department of Health and Social Care confirmed that there is ongoing work to prepare for scenarios including the future relationship Government hopes to negotiate with the EU through to the “very unlikely scenario in which no mutually satisfactory agreement can be reached and the UK exits without a deal.”¹⁷⁶ The Department informed us this includes an ongoing programme to monitor and manage the supply of medicines, medical devices and other ‘clinical consumables’ used by the NHS. The Department of Health and Social Care has involved suppliers and experts from across the sector to identify and mitigate risks. Lord O’Shaughnessy told us he was not able to share details of the Government’s contingency plans in order “to make sure that we do not prejudice negotiations and make sure that we are in lockstep with the rest of Government.”¹⁷⁷ In his oral evidence to us on 23 January 2018, Lord O’Shaughnessy stated that the Government had commissioned Ernst and Young to conduct an external analysis of the supply chain, in which they will be speaking to companies to gather their insights and concerns. He was unable to tell us whether this work was underway or whether it was about to start, but suggested that, even though the publication would be restricted, the Committee could see a summary.¹⁷⁸

175 [Brexit Health Alliance \(BRX0031\)](#) para 2.4

176 [Department of Health: Brexit:Written question - 111211 - UK Parliament](#)

177 Q344

178 Q344

Box 3: Case study: Imports of plasma

The European Scrutiny Committee's 2016 report into the Blood and Human Tissues Directive from the EU in 2016 pointed out that the UK's CJD mitigation strategy depends on the ability to import plasma, which in cases of emergency can be required in short time frames. Creutzfeldt-Jakob disease (CJD) is one of a group of diseases called Transmissible Spongiform Encephalopathies (TSE) or prion diseases, which have long incubation periods and cause severe and irreversible damage to the central nervous system resulting in death. UK cases of Variant Creutzfeldt-Jakob disease (vCJD), a form of CJD which predominately affects younger people, are mainly believed to have resulted from the consumption of BSE contaminated meat products. We heard that the UK currently cannot use domestically sourced plasma for its health needs because of variant CJD,¹⁷⁹ meaning some plasma used in the UK is brought from the US, and the NHS Blood and Transplant Authority also relies on arrangements with Austria for its supply.¹⁸⁰ Following Brexit, Austrian suppliers would not be able to export to the UK unless it could be shown that the users of plasma here abided by certain conditions. As the Blood and Transplant Authority does currently comply with relevant directives, this should be possible with some relevant paperwork and planning—but if Brexit saw a collapse in talks, there would be the risk of the UK experiencing a lack of plasma. At the European level, numerous initiatives related to the blood and plasma sectors have been undertaken since 1989. Directives on standards were developed with regard to quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, including traceability requirements and notification of serious adverse reactions and events were also addressed.

Plasma derivatives follow mainly pharmaceutical regulations. Nevertheless, as blood components are used to produce plasma derivatives as starting material, the requirements on collection and testing and the relevant implementing Directives apply. In addition, guidance is provided for the interpretation of the principles and guidelines of Good Manufacturing Practice (GMP) 9, for the requirements on the scientific data for a Plasma Master File (PMF)¹⁰ and on Epidemiological Data on Blood Transmissible Infections. The UK's arrangements for the safe supply of plasma are thus crucially reliant on European-wide arrangements such as GMP and GDP, and regulations.

Following Brexit, major efforts will need to be undertaken, starting with a comprehensive understanding of a number of challenges that stakeholders and the MHRA as the UK national competent authority are facing today, to comply with requirements on safety and availability of plasma and blood products.¹⁸¹

179 Q64 [Liz Carroll]

180 [NHS Blood and Transplant NHSBT \(BRX0081\)](#)

181 [An EU-wide overview of the market of blood, blood components and plasma derivatives focusing on their availability for patients](#), accessed 8th March

Box 4: Dialysis tubing

Dialysis is a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly, and often involves diverting blood to a machine to be cleaned. We heard in evidence that no dialysis equipment for treatment is manufactured in the UK. Instead, they are imported from EU, with many manufactured in plants based on the continent. It was pointed out to us that currently, these material travel without financial or logistical restrictions, and that any change to these arrangements after Brexit would immediately be of great concern to industry, the NHS and patients.¹⁸²

In 2011 an earthquake which struck Northern Italy led to a disruption in the supply of dialysis tubing to the UK after the factories which made the tubing were badly damaged. The two factories, which were based in northern Italy, were both damaged by the Emilia Romagna earthquake in May 2011 leading to a disruption in production. Only limited numbers of the tubes remained useable after the earthquake, and as they could not be re-used, the US-based company in charge of manufacturing the product rationed supplies to prevent panic buying until it could dispatch fresh products after October of the same year. The shortages affected any hospital which used the Baxter dialysis machines, with no other companies producing compatible tubes which can only be used for 72 hours at a time. An inventory of stock, coordinated by the Department of Health, showed some hospitals feared their supplies would run out well before new supplies were received, and the situation was managed through a combination of extensive stock management and contingency planning. This example demonstrated the fragility of the UK's supply of dialysis tubing, and underscores the necessity of the UK ensuring that, following Brexit, there are robust arrangements and stockpiling of such products to ensure a reliable supply.¹⁸³

Stockpiling and time-sensitive supply chains

139. After Brexit, due to potential risks to the supply chain the need to ensure sufficient stock is on the UK market could mean stockpiling of those products that allow for it. Manufacturers may not supply certain products to the UK until only a few weeks before they are needed.¹⁸⁴ Distributors of medicines in the UK usually keep 10 days' worth of stock, but many manufacturers stock medicines for up to four months' in huge pre-wholesaler warehouses.¹⁸⁵ Leslie Galloway from the Ethical Medicines Industry Group described how:

... one concern that companies will have is how much stock is transported which way, how much you have on the market, because a medicine usually has a two-year shelf life. A wholesaler will not take it into stock unless it has a minimum of six months. Even if you reach the six months, you've got problems. This issue of holding more stock because of the shelf life and so on will be an issue. Transporting across, it is going to be making more sense

182 Q107

183 ['Shortage of dialysis tubes' after earthquake hits factories](#), The Telegraph, accessed 9th March

184 Q9

185 Q9

for companies to manufacture in mainland Europe and export to a smaller country—essentially, the UK—than manufacture in the UK and export to the EU.¹⁸⁶

140. Hugo Fry from Sanofi, a large pharmaceutical company, described how life science businesses compete for warehouse space because they may need to stockpile medicines. He explained how some medicines and medical products are difficult to stockpile, for instance:

... certain complex biologicals, where we are already too late because they have lead times, or certain vaccines have massive lead times. Again, we are right at the edge of the window of opportunity for thinking about stockpiling.¹⁸⁷

141. Judging how much to have on the market at any one time is a difficult decision and distributors will often import products quickly when UK provisions are in short supply. We heard that for time-sensitive supply chains, delays in supply could have knock-on effects for patient care and the cost of NHS care. The most newsworthy example, which has attracted attention over recent months, is the supply of medical radioisotopes (see box 5).

142. The Government has recognised customs as a significant problem on a disorderly, no-deal Brexit. According to the Institute for Government:

On the day of exit from the EU, the UK authorities will need to perform new functions or face disruption at the border. There will be new document checks and fiscal requirements, which is the primary focus of the Government's view of customs, but also a number of other key activities that regulate goods crossing borders.¹⁸⁸

Medical radioisotopes and Euratom

143. The supply of medical radioisotopes is an example of a time-sensitive supply chain. Radioisotopes are used in around 700,000 diagnostic or therapeutic procedures each year in the UK.¹⁸⁹ These materials help diagnose coronary heart disease, detect the spread of cancer to bones and treat thyroid cancer. If the supply of medical radioisotopes is affected by problems with supply arising from Brexit Day, a significant proportion of patients may not have rapid access to, amongst other things, diagnostic imaging to inform them of developments in their cancer.¹⁹⁰ We also heard that for treatment radioisotopes from unsealed sources—medical radioisotopes that are ingested or injected—a lack of an assured supply would mean a reduction in the rate of cure in the UK, meaning more people will die of conditions such as thyroid cancers.¹⁹¹

186 Q177

187 Q303

188 [Implementing Brexit: Customs](#), Institute for Government, accessed 8th March 2018

189 Parliamentary Office of Science and Technology, [POSTNOTE: Supply of Medical Radioisotopes](#), Number 558 July 2017

190 Q4

191 Q4

144. Technetium-99m (^{99m}Tc), the most commonly used radioisotope accounting for over 80% of diagnostic nuclear medicine procedures, is not produced in the UK.¹⁹² Technetium-99m decays rapidly and therefore it is not possible to stock. In 2009, medical operations and procedures in the UK were delayed or cancelled due to a global shortage of Technetium-99m, brought on by the temporary closure of two reactors, and some have speculated that similar outcomes could be expected after Brexit. Obtaining supplies from outside the EU is a possibility, but the rapid decay of these isotopes means less of the isotope will be left by the time it reaches its destination.¹⁹³

145. Lord O’Shaughnessy told us that the UK will be leaving Euratom as it withdraws from the European Union because the legal arrangements of the two are so intertwined.¹⁹⁴ There has been debate about to what extent leaving Euratom will impact the supply of medical radioisotopes. The Government’s stated position is that leaving the Euratom treaty will not prevent trade in medical radioisotopes with the EU, meaning it is not an issue about whether the UK can trade with Europe, but rather on what terms this trading will take place.¹⁹⁵ The UK Government’s desire is to have as free and frictionless trade with the European Union as possible through a free trade agreement. So far as radioisotopes are concerned, this agreement will need to include customs arrangements that can process these materials very quickly.¹⁹⁶ Lord O’Shaughnessy, recognising concerns about the half-lives of medical radioisotopes, explained that, currently, 96% of imports outside the EU were cleared by HMRC within seconds, and there is a two-hour clearance commitment for urgent goods.¹⁹⁷ Customs arrangements are already in place for goods outside the EU, and these arrangements would need to apply for goods coming from the EU if the UK does not secure a free trade agreement.¹⁹⁸ He also made the point that the Department of Health and Social Care has had discussions with many of the relevant UK bodies, including the British Nuclear Medicine Society, the Royal College of Radiologists, and the Society and College of Radiographers, to reassure them that some of the popular perceptions about what the Euratom treaty means for medical radioisotopes may not be accurate: that trade is possible and that we do have customs arrangements that are capable of dealing with it.¹⁹⁹

146. Nevertheless, concerns continue to be raised on Euratom. The Government’s Nuclear Safeguards Bill is intended to establish a UK nuclear safeguards regime after leaving Euratom and delegates responsibility for this to the Office for Nuclear Regulation.²⁰⁰ While the bill addresses certain functions of Euratom—such as ensuring that “civil nuclear material is not diverted from their intended use”—it does not address other functions such as access to expertise and capital to develop and operate nuclear technology. The Nuclear Safeguards Bill does not specify how the UK will guarantee a supply of nuclear material for energy production and medical use.²⁰¹

192 Parliamentary Office of Science and Technology, [POSTNOTE: Supply of Medical Radioisotopes](#), Number 558 July 2017

193 Parliamentary Office of Science and Technology, [POSTNOTE: Supply of Medical Radioisotopes](#), Number 558 July 2017

194 Q347

195 Q347

196 Q347

197 Q347

198 Q347

199 Q348

200 [Euratom | The Institute for Government](#)

201 [Euratom | The Institute for Government](#)

147. The Business, Energy and Industrial Strategy Committee has warned that the impacts of leaving Euratom will be “profound”,²⁰² putting the UK in a much weaker position to drive regulatory standards at a European level.²⁰³ They argue the Government should retain as close as possible a relationship with Euratom, and that this should include accepting its delivery of existing safeguards requirements in the UK.²⁰⁴ Throughout their inquiry, “no-one”²⁰⁵ advocated the UK leaving Euratom, but they noted that the UK is now facing the prospect of setting-up its own nuclear safeguarding regime, a regime which will fall short of the Euratom standards.²⁰⁶ This requires the UK to set up its own bureaucracy, which comes at a cost of millions, with very real doubts that it will be ready in time. The committee said it was “highly doubtful” that the UK could deliver safeguards to Euratom standards by the date of the UK’s departure from the EU in March 2019.²⁰⁷

Supply chains: conclusions

148. We are encouraged that both sides of the negotiations are now discussing the terms of a transition period. However, we reiterate the point we made in our letter to the Secretary of State, that if the announcement, and details, of a transition period are delayed beyond March 2018, more businesses will be forced to invest money in contingency plans at the expense of this funding going towards advancing patient care.²⁰⁸ This is an unnecessary cost and distraction, which should be avoided. We continue to believe that far from undermining the Government’s negotiating position, clarity about contingency planning to guarantee patient safety and continued health supplies will strengthen the UK’s hand, demonstrating we have a credible fall-back position.

149. We note and support the conclusions of the Business, Energy and Industrial Strategy Committee, and we call on the Government to keep under review its position on leaving Euratom when the UK exits the European Union. We recognise the significant difficulties which arise from the fact that the legal arrangements of the European Union and Euratom are significantly intertwined, but consider that concerted efforts need to be made to overcome them. We heard evidence that the UK’s continued membership of Euratom would be beneficial to both the UK and the European Union. If the Government is unable to ensure continued membership, we strongly believe that the Government should retain as close as possible a relationship with Euratom, and that this should include accepting its delivery of existing safeguards requirements in the UK.

150. We call on the Government to publish a summary of the external analysis of supply chain issues and to set out their contingency planning to ensure the safe supply of medicines, medical devices and substances of human origin after the UK leaves the EU.

202 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

203 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

204 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

205 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

206 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

207 [Leaving the EU: implications for the civil nuclear sector](#) HC378 p.25

208 Q285, [Johnson Johnson \(BRX0063\)](#) p.8

World Trade Organisation (WTO) rules

151. As part of the single market and the customs union the UK benefits from frictionless, tariff-free trade with other Member States in medicines, medical devices and substances of human origin.²⁰⁹ The UK's withdrawal presents two important issues here. The first is the extent to which the UK's exit from the European Union affects the status of the terms of trade the UK currently enjoys with other WTO members. The second is that current WTO rules do not cover trade of certain products and need to be updated.

152. Much of global trade in pharmaceuticals happens on a zero-tariff basis. A zero-tariff rule for the trade of pharmaceutical products, including active ingredients, has been in place since the Uruguay Round of the WTO Pharmaceutical Agreement in 1994.²¹⁰ The UK is a member of the WTO in its own right, but currently the terms of trade between the UK and the rest of the world are set by the EU. After 29 March 2019, the UK may need to re-establish its independent schedules at the WTO, which will determine the UK's terms of trade.²¹¹ It is uncertain whether the UK's actions will be viewed by other signatory countries as a modification rather than a rectification of the EU's schedules. This decision could impact whether the UK trade in pharmaceuticals, once outside the EU, on a zero-tariff basis.

153. The WTO Pharmaceutical Tariff Elimination Agreement, which facilitates zero-tariff trade between WTO members, was last updated in 2010. This agreement does not cover all finished products or component products. Written evidence from the Association of the British Pharmaceutical Industry (ABPI) and BioIndustry Association (BIA) identified a significant number of products and component products awaiting introduction onto this list. The ABPI and the BIA argue that if UK-EU trade relies on WTO arrangements: "it will be critical that the agreement reflects all completed and component pharmaceutical products".²¹²

Parallel trade

154. Parallel trade is a process whereby right holders under the 'exhaustion of intellectual property rights' cannot prevent the free movement of medicines across the EEA once a product is in circulation within the area.²¹³ As governments in many cases agree prices for medicines with manufacturers, supplies of some medicines are cheaper elsewhere in the EEA. Parallel distributors buy medicines in other EU Member States then transport, repackage and sell these products below the standard local price. The existence of parallel trade benefits the UK by enabling local pharmacies to buy medicines from elsewhere in the EEA for a cheaper price.²¹⁴ According to the British Association of European Pharmaceutical Distributors (BAEPD), without the option of parallel trade, the financial viability of local pharmacies is at risk. Parallel Trade also provides an element of price competition for branded medicines, which supports the NHS to negotiate cheaper prices.²¹⁵

209 [Policy - Trade - European Commission](#)

210 [WTO | Understanding the WTO - The Uruguay Round](#)

211 [UK trade options beyond 2019, House of Commons International Trade Committee, HC817](#) p.9

212 [The Association of the British Pharmaceutical Industry and the BioIndustry Association \(BRX0022\)](#) p.5

213 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.3

214 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.3

215 Q5

155. Parallel trade is estimated to have saved the NHS €986.2million between 2004 and 2009.²¹⁶ The Department of Health and the Treasury deduct a percentage of the assumed margin from parallel trade from payments to pharmacies. These deductions currently amount to £100m per year.²¹⁷ Calculating the extent of indirect savings through the existence of parallel trade is difficult. However, the University of York in 2003 estimated that list prices for drugs are at least 3% less than they would have been without parallel trade.²¹⁸ Some medicines are currently only available in the UK through parallel trade and shifting the manufacture of these products to the UK could take time, meaning that the future supply could be affected by Brexit.²¹⁹

156. We support the Government's intention to negotiate continued free and frictionless trade with the EU. To prepare for the scenario in which continued free and frictionless trade is not possible, we recommend the Government clarify in its response whether the UK can participate in the WTO Pharmaceutical Tariff Elimination Agreement in its own right. The Government should also seek clarity on when the WTO Pharmaceutical Tariff Elimination Agreement will be updated. If the agreement is not updated before the UK leaves, we recommend the Government estimate the cost of tariff barriers to trade for the products affected. We also recommend the Government seek to agree as part of the future EU-UK trade agreement arrangements to maintain parallel trade in medicines with Member States.

157. In the meantime, we recommend the Government consider in its contingency planning those medicines used in the NHS that are only available through parallel trade. The Government should also assess the impact of loss of parallel trade to the UK, including the NHS, and should make that analysis available to us.

158. Ultimately, we heard that the effects of Brexit, and of different Brexit models, will be keenly felt across every stage in the life sciences, from early stage research and development, through safety testing and clinical trials, to supply of the product and timely patient access. We heard consistent and repeated evidence during our inquiry that to minimise the risks to all stages of the life sciences sector from Brexit, it is in the interests of patients in both the UK and EU-27 for the closest possible regulatory alignment to continue alongside associate membership of the EMA.

159. The Government should publish contingency planning for the possibility that the UK may exit the EU without a deal. In the technical areas around the safety monitoring and regulation of pharmaceutical products with complex supply chains, public scrutiny of any contingency planning will help to ensure all relevant aspects are covered.

216 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.4

217 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.4

218 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.4

219 [Healthcare Distribution Association HDA UK \(BRX0049\)](#) p.4

Conclusions and recommendations

Our work

1. We will be evaluating the Government's response to our letter seeking clarity about the details of a transition period and contingency planning in the event of 'no deal' and expect this to be included within the response to this report. (Paragraph 4)
2. We recommend that the Department of Health and Social Care produce a comprehensive list of all the issues relating to the supply of medicines, medical devices and substances of human origin which require contingency planning for the UK leaving the EU. We expect to see evidence that plans are in place to address identified risks to patients. (Paragraph 6)

Existing models of trade with the EU: Options for the UK

3. We urge the EU to look closely at the proposals for a sectoral approach to regulatory alignment set out by the Prime Minister in March 2018. We also expect both sides to consider first and foremost the implications of 'no deal' for individuals, the life sciences and the wider health and social care sector across the whole EU as well as the UK. We note that Article 9 of the Treaty on the Functioning of the European Union obliges the EU, in defining and implementing its activities and policies, to take into account requirements linked to a high level of protection of human health. (Paragraph 17)

Brexit and the Department for Health and Social Care's Single Departmental Plan

4. We are concerned about the lack of reference to Brexit in the single Departmental Plan for the Department of Health and Social Care. Brexit poses huge challenges to the life science sector and carries a number of unintended consequences for patients and the NHS. We trust that the Government's response to the recommendations of this report will reflect that and set out the department's preparation in greater detail. (Paragraph 26)

Protecting and enhancing the UK's position in Europe and globally

5. The UK should aim to have a seat at the International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) in its own right. We call on the Government to confirm that it will apply for full membership of the ICH at the earliest possible opportunity and to set out its timeline for doing so. (Paragraph 35)

UK's position and influence in Europe

6. We support the Government's intention to negotiate a close relationship with the European Union, including associate membership of the EMA. The UK, with the expertise and capacity of the MHRA, has a great deal to offer its European partners.

We believe this is in the interests of citizens and governments on both sides of the negotiations and should be prioritised in the next phase. Failure to achieve an ongoing collaboration would signal the triumph of political ideology over patient care. In the context of continued collaboration with the EMA and maintaining regulatory alignment, it will be in the interests of both sides for the EMA to benefit from the expertise of the MHRA and to continue to allow participation of UK representatives in decision making. (Paragraph 45)

UK negotiating position

7. We are encouraged that the UK Government has stated that it is seeking to ensure the UK plays a leading role in public health and preventing patients and innovators from being disadvantaged by Brexit. However, we, industry, and patients need tangible measures against which to evaluate these commitments. A detailed breakdown of the funding allocation for the DHSC from the Brexit funding should be published, and this should be accompanied by specific, detailed action points that look to explain how, and on what timeframe, the Government is looking to deliver on its commitments to the life science sector. (Paragraph 56)
8. Following Brexit, the life sciences sector will need a highly supportive domestic agenda. The Government should implement the Life Sciences Industrial Strategy in full and at pace, with a final deadline of 2023. This should be supported with commitment to other domestic measures such as the Accelerated Access Review. (Paragraph 57)

Regulatory alignment with the EU after Brexit

9. The overriding message from almost all of the evidence received in this inquiry is that the UK should continue to align with the EU regulatory regimes for medicines, medical devices and substances of human origin both during any transition period and afterwards. Evidence submitted from large pharmaceutical companies, SMEs, academics, healthcare and workforce charities was all almost unanimous in the view that regulatory alignment with the EU would be the best post-Brexit option for the NHS, for patients, and for the UK life sciences industry. (Paragraph 61)
10. The UK must look to secure, as a priority in the next round of negotiations, the closest possible regulatory alignment with the EU. The continued supply of safe and effective medical devices, medicines and substances of human origin currently on the UK market will depend on continued alignment with European regulations. (Paragraph 71)
11. At the same time, the UK Government should also be open to exploring other potential trade and regulatory agreements with the wider international life sciences community. If full regulatory alignment with the EU is not secured, then a distant second-best option for the life science industry and patients in the UK would be alignment with another large market such as the Federal Drugs Agency in the USA. While this form of alignment would raise significant financial and patient safety issues, it remains preferable to the UK endeavouring to create a standalone regulatory system after leaving the EU. (Paragraph 72)

12. We recommend that the nature and level of UK ‘regulatory drift’ in the life science sector from the EU be systematically assessed at regular intervals by current and future UK Governments, in order to prevent issues over a lack of harmonisation occurring in the future. (Paragraph 73)

‘No deal’ risk management

13. We reiterate the point made in our letter to the Secretary of State regarding Brexit transitional arrangements (15 February 2018), that rather than undermining the UK’s negotiating position, clarity about contingency planning to guarantee patient safety and continued health supplies will strengthen the UK’s negotiating position by demonstrating that we have a credible fall-back position. This contingency planning should be published as soon as possible to alleviate the concerns of businesses and patients. The European Medicines Agency has published its guidance on what is necessary for the UK to maintain continued access to medicines in a ‘no deal’ scenario, and we believe that this one-sided picture may harm confidence if it is not possible to compare it to the Government’s planned approach. Contingency planning is already taking away money that could otherwise be invested into pharmaceutical research or patient care, and calming the fears of life science companies to prevent them from investing in a ‘no deal’ scenario should be considered a priority in the next round of negotiations with the EU. (Paragraph 77)

Batch testing, QPs and Good Manufacturing and Distribution Practices

14. To allay fears within the life science sector, and to prevent the relocation of Qualified Persons (QPs) from the UK to the EU-27, the Government must seek agreement with the EU for those QPs currently working in the UK to continue to have their work recognised in EEA countries, ideally in the Withdrawal Agreement for the short to medium term and in regulatory cooperation or a mutual recognition agreement for the longer term. (Paragraph 85)
15. At the same time, as any Brexit deal, and the agreements proposed within it, could collapse, we recommend that the Government publish its contingency planning as soon as possible for a situation in which no mutual recognition of QPs in the UK and EU is agreed. This should include proposals to prevent the exodus of UK QPs, and contingency planning around the training and recruitment of new QPs to fill any vacancies. (Paragraph 86)
16. Furthermore, as regulatory divergence over Good Manufacturing Practice and Good Distribution Practice will place financial burdens on UK businesses and make the UK less desirable as a market, we recommend that the UK should transpose these regulations into UK law in the EU (Withdrawal) Bill. (Paragraph 87)

The UK’s relationship with the EMA

17. We welcome the Government’s announcement that it will seek associate membership of the European Medicines Agency (EMA). We call on negotiators from both sides to put the needs of patients first and foremost as negotiations on this matter progress. However, the EU’s draft negotiating position appears to suggest that continued UK

EMA membership may be rejected. We therefore recommend that the Government publish any contingency planning it has undertaken for a situation in which associate membership of the EMA is not achieved. (Paragraph 92)

Continued participation in clinical trials

18. The Government should recognise that while a commitment to transferring the Clinical Trials Regulation into UK law is a positive starting point for patient safety in the UK, this is insufficient to guarantee continued UK access to EU clinical trials. This will demand co-operation and willingness from other stakeholders in the EU. The Government should make public its contingency planning for the possibility that the UK is unable to secure continued participation in these trials, both for current participants in trials and for the future of UK clinical trials. (Paragraph 104)
19. We welcome the Government's aim to play a full part in new clinical trials regulations and medical devices regulations. We would like to see much more detail of what this will entail in practice, and we expect to see that detail in the Government's response to this report. (Paragraph 105)
20. We urge the Government to commit to adopting the new Clinical Trials Regulation into UK law following Brexit and to secure a joint statement with the EU committing to continued collaboration on clinical trials following the UK's exit from the EU. (Paragraph 106)
21. We recommend that the Government provide urgent confirmation of the status of UK citizens currently engaged in ongoing clinical trials. It is critical that this is covered in the Withdrawal Agreement that the UK strikes with the EU, ideally in the provisions on citizens' rights. (Paragraph 107)

Regulatory alignment over EU rules for data protection

22. We strongly support the UK Government's desire to seek 'more than just an adequacy agreement' under Article 45 of the General Data Protection Regulation with the EU so as to secure lawful data flow, including of personal data for health research, between the EU and the UK. We look forward to seeing further detail of the arrangements which the Government is seeking to achieve. We note the Council's preparedness to reconsider its offer should the UK position evolve. We urge the Government to be ready to be flexible, should detailed proposals of arrangements for lawful data flow require such flexibility. The Government should clarify whether it will look to secure these arrangements with the EU from UK 'Exit Day' or at the end of any transitional period. (Paragraph 111)

Research and collaboration networks

23. The UK should continue to be a member of EU research and development funding and research mechanisms such as Horizon 2020 and the Innovative Medicines Initiative after leaving the EU, if possible on the same terms as they currently enjoy. If

the same relationship is not possible, we still advocate membership of these funding and research systems in order for UK R&D to enjoy the collaborative opportunities they provide. (Paragraph 116)

Free movement of researchers

24. We welcome the Government's statements of their desire to have a future immigration policy that recognises the value that life science researchers bring to the UK, but would like to see further details about what this policy would look like. The failure to achieve an immigration policy post-Brexit that helps the UK to retain and attract the highest-quality researchers could have a significant adverse impact on UK research and development. (Paragraph 119)

Research and development funding

25. To ensure the same level of participation in future EU research programmes as the UK has currently, the Government should confirm that it is willing to contribute funding at least equivalent to the amount currently received by UK participants in EU funding systems such as Horizon 2020. Failure to do this would undermine the Juste Retour principle that has traditionally applied in EU research networks, and may jeopardise future UK involvement. However, we note that the text of the draft negotiating position from the EU suggests that participation on the same terms may be unworkable, and therefore urge the Government to publish contingency planning on how they intend to make up the resulting funding shortfall. (Paragraph 124)

Access to EU pharmacovigilance systems

26. We recommend that the UK seek mutual recognition of pharmacovigilance studies by the Medicines and Healthcare products Regulatory Agency and the EMA as a priority in the next round of negotiations. In addition, the UK should seek to ensure that all UK pharmacovigilance organisations continue to be members of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, as the failure to do so could affect patient safety both in the UK and the EU. The UK must also maintain membership of all of the major EU pharmacovigilance systems and databases, including the European Databank on Medical Devices (EUDAMED) and Eudravigilance. (Paragraph 131)
27. The UK should also look to retain full membership of the Pharmacovigilance Risk Assessment Committee (PRAC), and if this is not possible should endeavour to be present in PRAC meetings as an observer as an absolute minimum. (Paragraph 132)
28. Evidence presented to us made the point that failure to gain access to EU pharmacovigilance systems would have serious consequences for UK medicine and drug safety. It would not be possible, let alone desirable, to draw up a UK standalone system by the time the UK exits the UK. Contingency planning in this area would highlight the risks of failure to access EU pharmacovigilance systems and needs to prompt urgent action. (Paragraph 133)

Trade, customs and supply chains

29. We note and support the conclusions of the Business, Energy and Industrial Strategy Committee, and we call on the Government to keep under review its position on leaving Euratom when the UK exits the European Union. We recognise the significant difficulties which arise from the fact that the legal arrangements of the European Union and Euratom are significantly intertwined, but consider that concerted efforts need to be made to overcome them. We heard evidence that the UK's continued membership of Euratom would be beneficial to both the UK and the European Union. If the Government is unable to ensure continued membership, we strongly believe that the Government should retain as close as possible a relationship with Euratom, and that this should include accepting its delivery of existing safeguards requirements in the UK. (Paragraph 149)
30. We call on the Government to publish a summary of the external analysis of supply chain issues and to set out their contingency planning to ensure the safe supply of medicines, medical devices and substances of human origin after the UK leaves the EU. (Paragraph 150)
31. We support the Government's intention to negotiate continued free and frictionless trade with the EU. To prepare for the scenario in which continued free and frictionless trade is not possible, we recommend the Government clarify in its response whether the UK can participate in the WTO Pharmaceutical Tariff Elimination Agreement in its own right. The Government should also seek clarity on when the WTO Pharmaceutical Tariff Elimination Agreement will be updated. If the agreement is not updated before the UK leaves, we recommend the Government estimate the cost of tariff barriers to trade for the products affected. We also recommend the Government seek to agree as part of the future EU-UK trade agreement arrangements to maintain parallel trade in medicines with Member States. (Paragraph 156)
32. In the meantime, we recommend the Government consider in its contingency planning those medicines used in the NHS that are only available through parallel trade. The Government should also assess the impact of loss of parallel trade to the UK, including the NHS, and should make that analysis available to us. (Paragraph 157)
33. Ultimately, we heard that the effects of Brexit, and of different Brexit models, will be keenly felt across every stage in the life sciences, from early stage research and development, through safety testing and clinical trials, to supply of the product and timely patient access. We heard consistent and repeated evidence during our inquiry that to minimise the risks to all stages of the life sciences sector from Brexit, it is in the interests of patients in both the UK and EU-27 for the closest possible regulatory alignment to continue alongside associate membership of the EMA. (Paragraph 158)
34. The Government should publish contingency planning for the possibility that the UK may exit the EU without a deal. In the technical areas around the safety monitoring and regulation of pharmaceutical products with complex supply chains, public scrutiny of any contingency planning will help to ensure all relevant aspects are covered. (Paragraph 159)

Formal minutes

Tuesday 13 March 2018

Members present:

Wollaston, in the Chair

Luciana Berger	Johnny Mercer
Mr Ben Bradshaw	Andrew Selous
Dr Lisa Cameron	Derek Thomas
Rosie Cooper	Martin Vickers
Diana Johnson	Dr Paul Williams

Draft Report (*Brexit: medicines, medical devices and substances of human origin*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 159 read and agreed to.

A Paper was appended to the Report as Appendix 1.

Summary agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Thursday 15th March at 9:30am.]

Appendix 1: Letter to the Secretary of State regarding Brexit transitional arrangements, 15 February 2018

Dear Jeremy,

I am writing on behalf of the Health Committee to stress the pressing need for clarity on the details of a transitional period after UK Exit day and the Government's contingency planning to protect patients, NHS services and the UK's life science industry.

The Health Committee welcomes the commitment given in your joint letter with the Secretary of State for Business, Energy and Industrial Strategy of 5 July 2017 to a continued close working relationship with the European Union after UK Exit day. Since then, as you know, our Committee has undertaken an inquiry into the impact of leaving the EU on life sciences, and we have heard compelling evidence from industry, patient groups and health professionals setting out the need for certainty.

Businesses and healthcare services need certainty on the transition arrangements as soon as possible

Patient care, both in the UK and Europe, is at risk of being compromised in the event of a disorderly Brexit. Businesses and services, like Government, need to plan for all outcomes to avoid any disruption to the supply of medical products. However, with only 13 months until the UK exits the European Union on 29 March 2019, healthcare services and businesses, including those manufacturing and distributing medicines, remain in the dark. Many businesses told us they are having to prepare for a worst-case scenario despite the cost because time is running out for a transition period to be announced. The Business Committee were told of risks that companies forced to invest in contingency plans for sites in Europe may not find those sites and associated roles returning to the UK, even if the contingency was no longer required. We are encouraged that both sides of the negotiations are now discussing the terms of a transition period. However, if the announcement, and details, of a transition period is delayed beyond March 2018, more businesses will be forced to invest money in contingency plans at the expense of this funding going towards advancing patient care. This is an unnecessary cost and distraction, which should be avoided.

Businesses and healthcare services must not be forced to transition twice. It would be unwelcome for life science businesses and the NHS to transition twice. The UK Government should seek to agree an implementation period wherein the current regulatory status quo is maintained to avoid imposing unnecessary burdens on the life science sector. The Health Committee urges the Government to reach a position by March that will enable both sides to set out detailed information on the arrangements of an implementation period for the life science sector.

Political clarity is needed on patient care

The Health Committee welcomes the commitment expressed by both sides to ensure patient safety is not compromised. Our view is that a "deep and special partnership" with

the European Union and the European Medicines Agency after Brexit is in the interests of patients in the UK and Europe and we support the UK Government's intention to negotiate a close partnership.

Despite this mutual interest, the outcome of the Brexit negotiations cannot be certain; the principle of "nothing is agreed until everything is agreed" means that a failure to reach an agreement on other sectors of the economy could jeopardise an agreement on medicines, devices and substances of human origin, and put patient care at risk. A disorderly UK exit could result in an immediate impact on the supply of essential medicines and medical products, both in the UK and the EU-27. The Health Committee calls on the UK Government and the European Commission to agree a joint public statement, setting out how both sides will protect the interests of patients in the event of a no-deal. A joint statement would allay fears of a disorderly exit and honour the commitment both sides have made to protect patient safety. Failing this, and in the event that agreement to a transition is not reached by the end of March, the Committee seeks a commitment from the Government to make its own statement about the UK's unilateral preparations for a no deal situation.

Public scrutiny of contingency planning will strengthen the Government's position and manage risks to patient care

You told the Health Committee on 23rd January that details of the Government's contingency planning would not be made public as to do so would undermine the negotiating position of the UK. However, we believe that far from undermining it, clarity about contingency planning to guarantee patient safety and continued health supplies will strengthen the UK's negotiating position by demonstrating that we have a credible fall-back position. The European Medicines Agency has published its guidance on what is necessary for the UK to maintain continued access to medicines in a 'no deal' scenario, and we believe that this one-sided picture may harm confidence if it is not possible to compare it to the Government's planned approach. The Government should also publish the contingency planning it has undertaken to ensure that the UK maintains access to medical radioisotopes after Brexit, in the event that the desired close association with Euratom is not achieved. In these highly technical areas, with complex supply chains, extensive public scrutiny of any contingency planning will ensure that all relevant aspects are covered to guarantee the health of UK patients regardless of the Brexit outcome.

I would welcome a response from your department on the points covered in this letter.

Yours sincerely,

Dr Sarah Wollaston MP

Chair of the Committee

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the [inquiry publications page](#) of the Committee's website.

Tuesday 5 December 2017

Dr Andrew Grainger, Assistant Professor in Logistics and Supply Chain Management, University of Nottingham, **Richard Freudenberg**, Secretary-General of the British Association of European Pharmaceutical Distributors, **Martin Sawer**, Executive Director of the Healthcare Distribution Association, and **Dr Jeanette Dickson**, Vice-President of the Faculty of Clinical Oncology, Royal College of Radiologists

[Q1–62](#)

Professor Jean McHale, Professor of Healthcare Law and Director of the Centre for Health Law, Science and Policy, University of Birmingham, **Ian Bateman**, Director of Quality at NHS Blood and Transplant, **Fiona Loud**, Policy Director, Kidney Care UK, and **Liz Carroll**, Chief Executive, The Haemophilia Society

[Q63–113](#)

Tuesday 12 December 2017

Dr Jayne Spink, Chief Executive, Genetic Alliance UK, **Dr Beth Thompson MBE**, Head of UK and EU Policy, The Wellcome Trust, and **Aisling Burnand MBE**, Chief Executive, Association of Medical Research Charities

[Q114–146](#)

Steve Bates, Chief Executive, BioIndustry Association, **Leslie Galloway**, Chairman, Ethical Medicines Industry Group, and **Suzanne Halliday**, Head of Medical Devices, British Standards Institution

[Q147–218](#)

Tuesday 19 December 2017

Professor Alan Boyd, President of Faculty of Pharmaceutical Medicine, Academy of Medical Royal Colleges, **Emma Greenwood**, Director of Policy, Cancer Research UK, **John Maingay**, Director of Policy and Public Affairs, British Heart Foundation, and **Sir Hugh Taylor**, Co-Chair, Brexit Health Alliance

[Q219–264](#)

Hugo Fry, UK General Manager, Sanofi, Warwick Smith, Director General, British Generic Manufacturers Association, **Phil Thomson**, President, Global Affairs, GlaxoSmithKline, and **John Wilkinson**, Partner, Cooley LLP

[Q265–335](#)

Tuesday 23 January 2018

Rt Hon Jeremy Hunt, Secretary of State for Health and Social Care, **Lord O'Shaughnessy**, Parliamentary Under-Secretary of State at the Department of Health and Social Care, **Dr Ian Hudson**, Chief Executive, Medicines and Healthcare products Regulatory Agency

[Q336–442](#)

Published written evidence

The following written evidence was received and can be viewed on the [inquiry publications page](#) of the Committee's website.

BRX numbers are generated by the evidence processing system and so may not be complete.

- 1 ABHI ([BRX0059](#))
- 2 Academy of Medical Royal Colleges ([BRX0041](#))
- 3 Academy of Medical Sciences ([BRX0071](#))
- 4 ACRO (Association of Clinical Research Organizations) ([BRX0004](#))
- 5 Addison's Disease Self-Help Group ([BRX0069](#))
- 6 AHPPI ([BRX0066](#))
- 7 Alan Fraser ([BRX0086](#))
- 8 Allergy UK ([BRX0044](#))
- 9 American Pharmaceutical Group ([BRX0035](#))
- 10 Association of Medical Research Charities (AMRC) ([BRX0052](#))
- 11 AstraZeneca ([BRX0087](#))
- 12 BIVDA ([BRX0015](#))
- 13 Boston Scientific ([BRX0038](#))
- 14 Brexit Health Alliance ([BRX0031](#))
- 15 British Association of European Pharmaceutical Distributors ([BRX0077](#))
- 16 British Heart Foundation ([BRX0057](#))
- 17 British Medical Association ([BRX0036](#))
- 18 British Nuclear Medicine Society ([BRX0043](#))
- 19 British Specialist Nutrition Association ([BRX0027](#))
- 20 British Standards Institution ([BRX0051](#))
- 21 BSI ([BRX0024](#))
- 22 Cancer Research UK ([BRX0076](#))
- 23 Changing Markets ([BRX0055](#))
- 24 Concordia International ([BRX0037](#))
- 25 Department of Health ([BRX0054](#))
- 26 Device-11 ([BRX0072](#))
- 27 Drug Safety Research Unit ([BRX0023](#))
- 28 Ethical Medicines Industry Group (EMIG) ([BRX0021](#))
- 29 Genetic Alliance UK ([BRX0067](#))
- 30 Glenis Willmott ([BRX0003](#))
- 31 HCA Healthcare UK ([BRX0005](#))
- 32 Health Research Authority ([BRX0062](#))
- 33 Health Tech Alliance ([BRX0058](#))

- 34 Healthcare Distribution Association (HDA UK) ([BRX0049](#))
- 35 HealthWatch UK & Universities Allied for Essential Medicines UK & TranspariMED (joint submission) ([BRX0079](#))
- 36 Human Fertilisation and Embryology Authority ([BRX0083](#))
- 37 Human Tissue Authority ([BRX0082](#))
- 38 Institute of Physics and Engineering in Medicine ([BRX0017](#))
- 39 Intuitive Surgical Ltd ([BRX0010](#))
- 40 Johnson & Johnson ([BRX0063](#))
- 41 Kidney Care UK ([BRX0006](#))
- 42 MAP BioPharma ([BRX0013](#))
- 43 MeddiQuest Limited ([BRX0028](#))
- 44 Medical Research Council ([BRX0074](#))
- 45 Medical Technology Group ([BRX0039](#))
- 46 Medilink Midlands ([BRX0078](#))
- 47 MHRA ([BRX0084](#))
- 48 MHRA ([BRX0088](#))
- 49 Mrs Ingrid Hardacre ([BRX0047](#))
- 50 MSD ([BRX0040](#))
- 51 Mukesh Patel ([BRX0011](#))
- 52 National Institute for Health and Care Excellence (NICE) ([BRX0007](#))
- 53 Newcastle University ([BRX0020](#))
- 54 NHS Blood and Transplant (NHSBT) ([BRX0081](#))
- 55 NHSBSA ([BRX0085](#))
- 56 Nuffield Council on Bioethics ([BRX0070](#))
- 57 Nuffield Trust ([BRX0075](#))
- 58 Optical Confederation ([BRX0045](#))
- 59 PAGB ([BRX0016](#))
- 60 PCI Pharma Services ([BRX0046](#))
- 61 Professor Stephen Evans ([BRX0065](#))
- 62 Quintiles IMS ([BRX0018](#))
- 63 Quotient Clinical Limited ([BRX0064](#))
- 64 RB (Reckitt Benckiser) ([BRX0061](#))
- 65 Richmond Pharmacology ([BRX0060](#))
- 66 Roche ([BRX0030](#))
- 67 Royal College of Pathologists ([BRX0025](#))
- 68 Royal College of Physicians and Surgeons of Glasgow ([BRX0034](#))
- 69 Royal College of Physicians of Edinburgh ([BRX0014](#))
- 70 Royal College of Radiologists ([BRX0019](#))

- 71 SageTech Medical Equipment ([BRX0002](#))
- 72 Sanofi UK ([BRX0029](#))
- 73 Scottish Government ([BRX0033](#))
- 74 Sling The Mesh ([BRX0001](#))
- 75 STOPAIDS ([BRX0080](#))
- 76 Teva UK Limited ([BRX0053](#))
- 77 The Association of the British Pharmaceutical Industry and the Bio-Industry Association ([BRX0022](#))
- 78 The British Generic Manufacturers Association ([BRX0050](#))
- 79 The British Society for Antimicrobial Chemotherapy (BSAC) ([BRX0042](#))
- 80 The Royal Pharmaceutical Society ([BRX0026](#))
- 81 Thermo Fisher Scientific ([BRX0012](#))
- 82 TOPRA ([BRX0048](#))
- 83 Urology Trade Association ([BRX0032](#))
- 84 Wellcome Trust ([BRX0073](#))

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the [publications page](#) of the Committee's website. The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2017–19

First Report	Appointment of the Chair of NHS Improvement	HC 479
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