



House of Commons

Business, Energy and Industrial
Strategy Committee

The impact of Brexit on the pharmaceutical sector

Ninth Report of Session 2017–19



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

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Business, Energy and Industrial Strategy Committee

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Contents

Summary	3
1 Introduction	5
The pharmaceutical sector	5
Our inquiry	6
2 Tariff barriers	8
Impact of No Deal	8
3 Non-tariff barriers	11
Border delays	11
Other non-tariff barriers	13
4 Regulatory alignment	15
Approval of Medicines	15
EU Medicines Approval Procedures	16
Manufacturing and Testing	18
Opportunities from divergence	20
Future Relationship	21
European Court of Justice	22
The Future of the European Medicines Agency	23
5 Transitional Arrangements	24
6 Trade opportunities post-Brexit	26
Intellectual Property	28
7 Skills	30
8 Research and Development	34
Clinical Trials	35
9 Conclusion	37
Conclusions and recommendations	38
Formal minutes	42
Witnesses	43
Published written evidence	43
List of Reports from the Committee during the current Parliament	44

Summary

This report is intended to inform public and parliamentary debate and to influence the Government's objectives as it conducts phase 2 of the negotiations on leaving the European Union.

The pharmaceutical sector is one of the most productive in the UK, with a turnover of £41.8 billion, providing 8.2 per cent of UK goods exports and employing more than 113,000 people, directly or in service and supply roles. The sector is a mixture of large UK-headquartered firms such as AstraZeneca and GSK, manufacturing and research sites for other global companies, and a significant proportion of SMEs and microbusinesses, researching and manufacturing branded, generic and over-the-counter medicines for UK patients and consumers and for a global market. The sector is part of heavily integrated EU supply chain that relies on the friction-free transfer of ingredients and finished products to ensure access to medicines across the continent.

Leaving the EU without a deal for pharmaceuticals would risk a hugely damaging effect on the sector in the UK, as access to markets diminish, including £11.9 billion of exports and more than 446 million potential patients and consumers in the EU. It would also risk a damaging effect on UK patients. With 73 per cent of pharmaceutical imports coming from the EU, access to pharmaceutical products could be reduced, and as only 2.3 per cent of the global market compared to the EU27's more than 22 per cent, the UK may become a less attractive location to launch new medicines. Global efforts to remove tariffs on pharmaceutical products mean that tariff costs for trading many established products in the EU would be zero, but slow progress on World Trade Organisation negotiations means many new medicines and ingredients will still be subject to tariffs. These might be funded by the taxpayer having to underwrite extra costs to the National Health Service as the main customer for pharmaceuticals.

Non-tariff barriers present a significant challenge to the industry, with any time- or temperature-sensitive products delayed at the border at risk of not reaching their destinations in a condition to be of benefit to patients. Additional costs and requirements for the processing of customs procedures will, as with tariff costs, either burden businesses or the NHS. We heard no evidence of a potential for the UK to replace the EU supply chain for products with a domestic one.

As a highly-regulated industry, the prospect of regulatory divergence from the European Medicines Agency is the deepest concern for the industry. Any divergence could lead the need for the duplication of facilities and roles across the UK and EU to enable access to products, costing companies tens of millions to establish and millions each year to run. Some large companies have already begun to implement contingency plans to ensure continued access to the market, but much of the sector has not. A divergent regime could see extra costs of £45,000 for each new medicine released in the UK, making the UK an unattractive small market for specialised medicines, and risking the loss of access entirely to some products. Without a continued relationship, there is a significant risk of the UK being a second-tier state for new and innovative medicines. We conclude that there are no benefits from regulatory divergence and no prospect of the industry being able to fully manage any divergence required in the time available for transition. The Government has indicated they wish to maintain cooperation with

the EMA, and we conclude that the EU and UK would both benefit from a continued relationship that enables mutual access to the significant capacity and expertise within Europe. We recommend the UK and EU pursue a deal that would enable a continued presence for EMA jobs and facilities in the UK.

The UK is an attractive location for skilled workers and for companies to undertake research and development. Currently, the sector is able to fill skills gaps across the sector through global recruitment, intra-company transfers and high-calibre researchers in industry and in UK research institutions. The UK has benefited disproportionately from EU funding for its research and development, leading to a significant proportion of projects and securing both public and private funding to support them. As a collaborative sector, there are benefits to both the EU and UK for continuing access to funding such as Horizon 2020 and its successor and to projects such as the Innovative Medicines Initiative. We conclude the Government must ensure the sector has urgent clarity on what support will be available to maintain international collaboration.

We have sought out any potential benefits to the UK pharmaceutical sector from Brexit, but found that any small gains would be hugely outweighed by additional costs or the loss of access to existing, successful markets. The UK is already a significant part of a global industry and there is no evidence of new trade routes from which the UK could benefit. The best potential we found for the UK to remain and grow as a world leader in the development, manufacture and regulation of pharmaceuticals is to maintain as close as possible a relationship with the EU as possible.

The pharmaceutical sector and the Government have been proactive in setting out what sort of relationship they want to see with the EU on pharmaceuticals. We support both industry and Government in securing a future relationship that is to the benefit of businesses and patients in the UK and the EU, and call on the Government to work with the European Commission to provide certainty to the pharmaceutical sector as a priority.

1 Introduction

The pharmaceutical sector

1. The pharmaceutical sector is one of the UK's most productive industries,¹ generating £41.8 billion turnover² and contributing around one per cent of the UK's output and 7.7 per cent of manufacturing GVA.³ The sector employs 62,600 people across 543 companies, supported by 1,314 service and supply companies comprising a further 51,000 people.⁴ The majority of pharmaceutical companies are SMEs, with 90 per cent of manufacturers having fewer than 250 employees⁵ and 43 per cent being micro companies with fewer than 5 employees.⁶ Pharmaceutical products represent 8.2 per cent of goods exported from the UK and 5.3 per cent of goods imported to the UK.⁷

2. The UK pharmaceutical sector is part of a global industry with high productivity and growth, in which the UK forms a global cluster and remains a leading European nation.⁸ The global sector is characterised by regional manufacturing locations serving continent-wide markets.⁹ The UK currently forms part of the European market, and as a result is heavily integrated with European Economic Area (EEA) states for supply chains and the regulation of production and distribution.¹⁰ Decisions on where to manufacture pharmaceuticals within a region are dependent on a range of factors, but there are specific, onerous regulatory requirements on development, testing and release of medicines that restrict the options for manufacturers wanting to access the EU market.¹¹

3. Pharmaceuticals are part of a wider life sciences sector that also includes medical technology and medical biotechnology, which together contribute 233,400 jobs across 5,142 companies and a turnover of £63.5 billion.¹² There has been significant support from successive Governments for the sector, including the establishment in 2014 of the Office for Life Sciences jointly by the Department for Business, Innovation and Skills and the Department of Health, and the appointment of a joint Minister for Life Sciences between 2014 and 2016.

4. In 2017, ahead of the Government's Industrial Strategy, the sector published its own Life Sciences Industrial Strategy that made long-term recommendations to Government on the support and collaboration necessary to maintain and grow the industry.¹³ The Government's subsequent Industrial Strategy White Paper was launched with an announcement of new investment from pharmaceutical manufacturer MSD and Qiagen,¹⁴ and plans for a Life Sciences Sector Deal, which was subsequently launched in December

1 Office for National Statistics, [UK Productivity Introduction: April to June 2017](#), (October 2017), p4

2 Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p10

3 Exiting the EU Committee, [HM Government Life Sciences Sector Report](#), 21 December 2017, p3

4 Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p16

5 As above, p17

6 Exiting the EU Committee, [HM Government Life Sciences Sector Report](#), 21 December 2017, p5

7 House of Commons Library, [Brexit and medicines regulation](#), Number 8148, 20 November 2017, p27

8 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

9 [Q24](#) [Mr Thompson]

10 [Q17](#) [Mr Thompson]

11 Exiting the EU Committee, [HM Government Life Sciences Sector Report](#), 21 December 2017, pp11–14

12 Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p4

13 Life Sciences Industrial Strategy Board, [Life Sciences Industrial Strategy](#), (August 2017)

14 ["Major pharma leader MSD first to endorse Government's Industrial Strategy"](#), Department for Business, Energy and Industrial Strategy press release, 27 November 2017

2017.¹⁵ The sector deal included existing and new commitments from Government and industry to increase investment, develop new programmes and grow collaboration between industry and Government.

5. As their approach to industrial strategy has shown, the life sciences industry, and the pharmaceutical sector within it, are effective at offering a coherent voice to Government and maintaining strong engagement. The creation of the industry-led, Government-supported, UK EU Life Sciences Steering Group soon after the referendum result established a network intended to consider the new relationship with the EU as the UK leaves.¹⁶ The Government too have presented a consistent and upbeat message on the need for continued cooperation with the EU for the success of both the UK and EU's pharmaceutical sectors, from Greg Clark and Jeremy Hunt's widely welcomed July 2017 open letter in the Financial Times,¹⁷ to the Prime Minister's Mansion House speech in March 2018.¹⁸

6. We welcome the Government's positive, collaborative approach so far, and trust it will continue as negotiations progress. The Government must continue to seek to preserve and build upon the success of the UK pharmaceutical sector, and the effective collaboration between industry and Government, as it undertakes negotiations on future trading arrangements with the EU.

Our inquiry

7. This is the fifth and final report in a series we are publishing on the impact of leaving the European Union on specific sectors of the economy.¹⁹ The Committee has been supported during this work by Dr Kathryn Wright, Lecturer in Law at the University of York and Parliamentary Academic Fellow, to whom we are very grateful. This report contains our assessment of the consequences for the pharmaceutical sector of different outcomes of the negotiations and seeks to establish what type of withdrawal agreement would most benefit the sector and, consequently, the UK's broader economic interests. We have sought to inform public debate and influence the Government's negotiating approach and priorities.

8. The Health and Social Care Select Committee also conducted an inquiry into the impact of Brexit on medicines, medical devices and substances of human origin between September 2017 and March 2018.²⁰ Its inquiry considered a broader range of sectors and issues than our business-focused inquiry, and its report provides an insight into these wider issues.

15 Department for Business, Energy and Industrial Strategy, [Life Sciences Sector Deal](#), 6 December 2017

16 Department for Business, Energy and Industrial Strategy, [Life Sciences: a new relationship with the European Union speech by George Freeman MP](#), 11 July 2016

17 [Letters to the Editor](#), Financial Times, 5 July 2017

18 Prime Minister's Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

19 The Committee published its [Second Report of Session 2017–19, Leaving the EU: implications for the civil nuclear sector](#), HC 378, on 13 December 2017; its [Fifth Report of Session 2017–19, The impact of Brexit on the automotive sector](#), HC 379, on 1 March 2018; its [Sixth Report of Session 2017–19, The impact of Brexit on the aerospace sector](#), HC380 on 19 March 2018; and, its [Seventh Report of Session 2017–19, The impact of Brexit on the processed food and drink sector](#), HC381 on 22 April 2018.

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

9. As part of our inquiry we received 21 submissions of written evidence from trade bodies, businesses and other stakeholders. We took evidence in public from some of them, covering UK and overseas-headquartered companies who manufacture and distribute branded, generic and over-the-counter pharmaceuticals. We have also taken evidence from the Secretary of State for Business, Energy and Industrial Strategy, Open Europe and the UK Trade Policy Observatory and seen the full, unredacted version of the life science sectoral analysis carried out by the Government. During a visit to Brussels in November 2017 we held private meetings with the UK Permanent Representation to the European Union and with the European Federation of Pharmaceutical Industries and Associations. We are grateful to all those who have contributed to our inquiry.

2 Tariff barriers

10. The Government's EU Exit Analysis Cross-Whitehall Briefing identifies pharmaceuticals as the sector for which UK/EU market access is the most important.²¹ In 2016, the UK exported £24.9 billion of pharmaceutical products, of which £11.9 billion (48 per cent) went to the EU,²² a market of more than 446 million potential patients and consumers.²³ At the same time, the UK imported £24.8 billion of pharmaceutical products, of which £18.2 billion (73 per cent) were from the EU, giving a trade deficit of £6.3 billion.²⁴ In oral evidence, the Association of the British Pharmaceutical Industry (ABPI) told us this reflects "45 million packs of medicines that leave the UK every month and go to Europe, and 37 million packs of medicines that leave the continent and come to the UK".²⁵

Impact of No Deal

11. Whilst the successful conclusion of phase one negotiations and further progress on the withdrawal agreement makes an orderly withdrawal from the EU more likely, the Prime Minister has asserted that "no deal for Britain is better than a bad deal for Britain."²⁶ For as long as this remains a possibility, the pharmaceutical industry in both the UK and the EU have no choice but to prepare for this scenario, and are doing so. On the UK's departure from the EU, the Government has committed to depart from the customs union and single market. In the absence of a new agreement on trade, this would mean a reversion to World Trade Organisation (WTO) tariffs. The WTO's Pharmaceutical Tariff Elimination Agreement means that for signatory states, such as Japan, the United States, Canada, Australia and member states of EU, finished pharmaceutical products and certain components are subject to zero per cent tariffs; however, for other states such as Brazil, China and Russia there are tariffs of between one and fifteen per cent.²⁷

12. Whether or not the UK becomes a signatory to the Pharmaceutical Tariff Elimination Agreement after it leaves the EU, it will still be able to trade with the EU on the basis of a zero tariff for pharmaceutical products. In written evidence to the House of Lords EU External Affairs Subcommittee in February 2017, the Government confirmed that

The Pharmaceutical Agreement is extended on a Most-Favoured Nation (MFN) basis. This means that signatories extend the tariff eliminations to all WTO members. So, all WTO members enjoy the benefits of tariff free trade to signatory countries irrespective of whether or not they themselves are members. The UK will therefore continue to

21 Exiting the European Union Committee, [EU Exit Analysis: Cross Whitehall Briefing](#), 8 March 2018, p10

22 House of Commons Library, [Brexit and medicines regulation](#), Number 8148, 20 November 2017, p27

23 'EU population up to almost 512 million at 1 January 2017', Eurostat press Release, 10 July 2017

24 House of Commons Library, [Brexit and medicines regulation](#), Number 8148, 20 November 2017, p27

25 [Q17](#) [Mr Thompson]

26 Prime Minister's Office, [PM Speech on the Government's negotiating objectives for exiting the EU](#), 17 January 2017

27 AstraZeneca, [BRP0019](#)

benefit from the tariff eliminations of negotiating parties and in line with our technical rectification approach, the UK will continue to place zero tariffs on pharmaceutical goods covered by the Agreement.²⁸

In the absence of access to free trade agreements previously negotiated by the EU or of replacements for them, the pharmaceutical sector would still face tariffs if continuing to trade with countries who are not signatories to the Pharmaceutical Tariff Elimination Agreement.

13. Not all pharmaceutical products are covered by the Pharmaceutical Tariff Elimination Agreement, which is based on a negotiated list of finished products and ingredients. The agreement included a commitment to update the list of products and ingredients every 3 years;²⁹ however, it has not been updated since 2010, which we were told was due to negotiations being held up by reservations of the USA.³⁰ It has been estimated that, as a result, up to 1,000 finished products and 700 ingredients are not currently included in the list and would therefore be subject to tariffs when traded on WTO terms.³¹ AstraZeneca, the UK's second largest pharmaceutical company, told us that for active pharmaceutical ingredients and intermediates they could still face duties of between 4 and 6.5 per cent in all countries including the EU, estimating a cost to them of \$30.5 million for exports and a \$5 million duty on exports.³² The ABPI and Bioindustry Association (BIA) indicated a tariff of 6.5 per cent for the EU, highlighting the challenges for products crossing borders three or four times during manufacture.³³

14. In the Government's written evidence to the Committee, they accept that the view of the pharmaceutical sector is that relying on WTO rules would potentially disrupt closely integrated supply chains.³⁴ We have heard the same message from industry. Swiss-based pharmaceutical company Roche expressed concerns that WTO terms may be outdated for companies that rely on the movement of medicines across multiple borders, creating serious risks for patients in cases where medicines reach them via fragile supply chains.³⁵ Johnson & Johnson, the world's largest diversified pharmaceutical company and largest foreign investor in UK life sciences,³⁶ told us

The imposition of tariffs with the EU would lead to a "double charge" being placed on imports and exports, disproportionately affecting companies that use the UK as a hub within their global supply chain. This would make it extremely challenging for business to maintain existing supply chain routes or to continue to prioritise the UK in any future supply chain planning.³⁷

28 House of Lords, Supplementary Written Evidence from Lord Bridges of Headley MBE, Parliamentary Under Secretary of State for Exiting the European Union, Department for Exiting the European Union, and Lord Price CVO, Minister of State for Trade Policy, Department for International Trade on the future trading relationship between the UK and EU in goods and services, EU External Affairs and Internal Markets subcommittee, [FTG0027](#), 24 February 2017

29 World Trade Organisation, [Trade in Pharmaceutical Products](#), 25 March 1994

30 AstraZeneca, [BRP0019](#)

31 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

32 AstraZeneca, [BRP0019](#)

33 [Q25](#) [Mr Thompson]

34 Department for Business, Energy and Industrial Strategy, [BRP0018](#)

35 Roche [BRP0004](#)

36 Johnson & Johnson, [BRP0015](#)

37 As above.

Lilly UK, a longstanding subsidiary of a US-based pharmaceutical company, told us they relied on tightly integrated supply chains, including across the Ireland-Northern Ireland border for international shipping, and that “additional customs burdens could disrupt the supply of medicines to patients across the UK and EU” as well as risking considerable costs to UK-based companies.³⁸ Merck, the world’s oldest pharmaceutical company, estimated additional annual costs of £1.59 million for their life sciences imports, based on an average tariff of 3.76 per cent, with costs expected to be borne by both the pharmaceutical industry and public institutions.³⁹

15. Access to medicines is a public good, as well as a being good for UK and EU businesses. Research by the World Health Organisation shows little benefit or justification for tariffs on pharmaceutical products, indicating that such duties generate less than 0.1 per cent of global GDP and, with a few exceptions, tariffs generally do not appear to be structured to protect local pharmaceutical industries.⁴⁰ The global nature of the industry, with complex supply chains and public and political pressure for access to new and innovative medicines, means we heard no evidence to support a protectionist approach or for any tariffs being levied on these products. For UK patients, branded and generic medicines are almost entirely subject to the purchasing decisions of the National Health Service, a body with finite resources. In 2017, the NHS spent almost £16 million on prescribed medicines, a 7 per cent increase on the previous year.⁴¹ Companies have told us that tariffs will lead to higher costs⁴² which could lead to an increasing NHS medicines bill or a reduction in access to medicines. The Government have confirmed their desire to see zero tariffs for the trade in goods,⁴³ and now must deliver on this.

16. The World Trade Organisation’s Pharmaceutical Tariff Elimination Agreement means that relying on WTO rules in the event of a ‘no deal’ scenario would not have as significant impact on the pharmaceutical sector as for other sectors that Committee has considered. However, there are still significant concerns that it could injure the UK’s position as a manufacturing base, a global supply hub and as a manufacturer and recipient of new and innovative medicines. *The Government should pursue a trade agreement with the European Union, and with other trading partners, that includes all finished and component pharmaceutical products, and is not limited to those currently listed under WTO rules.*

17. The extended delay in adding new pharmaceutical products and ingredients to the World Trade Organisation listing is already harming global access to medicines and offers no benefit to the industry or nations. It is for World Trade Organisation negotiations rather than Brexit negotiations to resolve this; however, falling back onto WTO rules could mean harmful tariffs for new and innovative medicines and components being traded between the UK and EU. *As a global leader in the pharmaceutical industry, the Government should work internationally to ensure that the WTO updates the list of pharmaceuticals and components covered by the Pharmaceutical Tariff Elimination Agreement.*

38 Lilly [BRP0013](#)

39 Merck [BRP0005](#)

40 World Health Organisation, [Pharmaceutical Tariffs: What is their effect on prices, protections of local industry and revenue generation?](#) (May 2005), p2

41 NHS England, [NHS Five Year Forward View: Funding and Efficiency](#), (accessed 17 April 2018)

42 Roche [BRP0004](#)

43 Department for Business, Energy and Industrial Strategy, [BRP0018](#)

3 Non-tariff barriers

18. Whilst the interests of both the UK and EU would benefit from an agreement that enables the avoidance of tariffs at World Trade Organisation or national levels as we continue to trade, there are challenges relating to border delays that are of greater concern to industry.⁴⁴ Alongside regulation—covered in the next chapter—the need for what the Prime Minister described in her Mansion House speech “as frictionless a border as possible” at both an administrative and physical level is of vital importance for the continued success of the sector and for continued UK and EU access to medicines.⁴⁵

19. In its policy document *‘Future customs arrangements - a future partnership paper’*, the Government has set out two options for a customs arrangement: a highly-streamlined customs arrangement that combines the maintenance of some existing arrangements combined with “new innovative facilitations” including an undefined technology-based solution; or a new customs partnership with the EU, an “unprecedented approach” that removes the need for a customs border.⁴⁶ Other committees continue to scrutinise proposals for border customs arrangements as they progress,⁴⁷ but whatever approach is followed, it is inevitable that there will be some additional costs.⁴⁸ The Draft Agreement between the EU and the UK on 19 March 2018 provides clarity on the continuation of current customs arrangements during the transition period; however, industry currently still faces significant uncertainty beyond the end of the transition period in December 2020.⁴⁹

Border delays

20. Delays at the border to and from the European Union are of significant concern to companies in the pharmaceutical sector.⁵⁰ We received evidence from companies, industry bodies and charities that highlighted the importance of rapid supply of medicines across border for the benefit of patients.⁵¹ In the most serious cases, time and temperature specific products, such as oligonucleotides, are required to be delivered to EU destinations from manufacture in the UK in as little as 24 hours, becoming unusable if delayed.⁵² Mike Thompson, Chief Executive of the ABPI confirmed that while the industry works to ensure the supply of medicines, including for urgent and emergency cases, overcoming barriers such as border friction have limited options:

44 [Q25](#) [Mr Thompson]

45 Prime Minister’s Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

46 HM Government, [Future customs arrangements - A future partnership paper](#), 15 August 2017, p2

47 Exiting the EU Committee, [The progress of the UK’s negotiations on EU withdrawal inquiry](#); Home Affairs Committee, [Home Office delivery of Brexit: customs operations inquiry](#); International Trade Select Committee, [Continuing application of EU trade agreements after Brexit inquiry](#), House of Lords, EU External Affairs sub-Committee, [Brexit Customs Arrangement inquiry](#)

48 [Q66](#) [Mr Ballard]

49 [Department for Exiting the European Union, Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community](#), 19 March 2018

50 [Q79](#) [Mr Hicken]; Johnson & Johnson, [BRP0015](#); MSD [BRP0009](#); PAGB [BRP0007](#); Roche [BRP0004](#)

51 [Q17](#) [Mr Thompson]; The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); American Pharmaceutical Group [BRP0010](#); APPG on Brain Tumours [BRP0021](#); Johnson & Johnson, [BRP0015](#)

52 Merck [BRP0005](#)

We do absolutely everything we can to get medicines to patients; I have seen us charter planes and people work thorough weekends. We do whatever we need to do to get a medicine to a patient. If we legally cannot get through borders or we are delayed in getting through, there is nothing we can do about it. We have been imploring people to understand that medicines are different.⁵³

21. Companies such as Merck have identified the specific challenges with time and temperature limited products and the potential need for new solutions if a frictionless border is not delivered:

A number of our products must be kept cold, with the refrigeration system for transportation maintained by the running engine of the vehicle in which they are transported. If delays at ports become consistent, the whole sector will have to develop new ways of transporting and storing goods and medicines to mitigate the risk of a product overheating and becoming unusable.⁵⁴

However, we heard of no appetite from the sector for either reducing the markets that they supply, which would potentially limit access to lifesaving medicines, or for developing new transport or storage solutions with associated additional costs to business.

22. For more routine customs transactions, there is still significant concern from the sector, due to complex supply chains with multiple border crossings for materials, part-finished components and finished medicines as they are manufactured and released.⁵⁵ Roche expressed concerns that “all goods due to be moved between the UK and EU could be held either at border checks, in warehouses or manufacturing”.⁵⁶ With efficient European-wide supply chains there is limited need for warehousing on either side of the UK-EU border at present. Any changes to this would lead to increased costs for companies, or the potential for supply disruptions, which Roche argue can only be solved by prioritising frictionless trade.⁵⁷ AstraZeneca, responsible for the export of £4.7 billion of goods from the UK in 2015, have been less optimistic about the opportunity for fully frictionless trade.⁵⁸ Instead they support mitigations to reduce border delays, such as the use of Authorised Economic Operator status to fast-track shipments, or following UK proposals for an advance shipping authorisation system, albeit aware of the challenges with other systems current in use.⁵⁹

23. Much of the evidence submitted to the Committee focused on the branded pharmaceuticals market. We also received written and oral evidence from industry groups representing generic products, which account for around 75 per cent of medicines used in the National Health Service, and from over-the-counter manufacturers responsible for consumer healthcare products. Their views on tariff and non-tariff barriers were broadly aligned with the branded medicines industry, but acknowledged specific risks to their parts of the sector. For consumer products, border friction has the potential to reduce the

53 [Q17](#) [Mr Thompson]

54 Merck [BRP0005](#)

55 AstraZeneca, [BRP0019](#); Johnson & Johnson, [BRP0015](#)

56 Roche [BRP0004](#)

57 As above.

58 AstraZeneca [BRP0019](#)

59 As above.

number of new over-the-counter medicines manufactured overseas being made available in the UK, or being reclassified from being prescription medicine.⁶⁰ For generic products, increased costs and border delays would also risk the attractiveness of the UK for the launch of new generic medicines in the UK, “putting at risk the onset of NHS securing the savings it achieves from generic medicines as soon as the originator loses its patent protections.”⁶¹

Other non-tariff barriers

24. All witnesses sought an approach to frictionless trade that ensured a deal as close as possible to the status quo.⁶² In both oral and written evidence, we received concerns about customs clearance costs, the requirement for new IT and administrative systems to manage any new processes, and the delays that will be caused by any potential lack of harmonisation across the UK and EU.⁶³ Johnson and Johnson told us that these non-tariff barriers were likely to have the most significant impact on their businesses,⁶⁴ while the American Pharmaceutical Group, the trade body for US pharmaceutical businesses in the UK, warned of “extremely high restructuring costs aimed at accommodating a new regulatory and trade framework that restricts trade in practice, especially in the short- and mid-term.”⁶⁵

25. While some UK businesses, such as AstraZeneca and GSK, are beginning to build new sites in EU states to ensure that they can continue to operate in Europe following the UK leaving the EU,⁶⁶ we have received no evidence of EU based companies undertaking the reverse. We explored with the ABPI the potential for increased manufacturing in the UK to reduce the need for cross-border working and supply chains; however, their view was that this did not make economic sense, noting

We do not have the process capability in the UK to manufacture all medicines in the UK. We do not have the plants. These plants cost tens, sometimes hundreds, of millions of pounds to invest in. Nobody is going to build it in the UK; at current values, with the devaluation of the pound, the UK is 2.3 per cent of the global market. People are not going to build manufacturing plants to supply all of the medicines for the UK.⁶⁷

26. With any significant friction at the border, it is possible that the UK could become a ‘second tier’ state for pharmaceutical imports, reducing access to new and innovative medicines.⁶⁸ The Office of Health Economics have estimated that should the UK lose its free trade agreements and in the absence of customs arrangements with the EU, a typical

60 PAGB [BRP0007](#)

61 British Generic Manufacturers Association (BGMA) [BRP0008](#)

62 American Pharmaceutical Group [BRP0010](#); The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); British Generic Manufacturers Association (BGMA) [BRP0008](#); PAGB [BRP0007](#)

63 [Q20](#) [Mr Thompson]; American Pharmaceutical Group [BRP0010](#); Johnson & Johnson [BRP0015](#)

64 Johnson & Johnson [BRP0015](#)

65 American Pharmaceutical Group [BRP0010](#);

66 [Qq11-12](#) [Mr Thompson]

67 [Q20](#) [Mr Thompson]

68 “[The pharmaceutical industry is at risk from Brexit](#)” London School of Economics Brexit Blog, 17 July 2017 (accessed 17 April 2018)

pharmaceutical company could expect estimated costs of £23.5 million per year to cover changes to the supply chain, tariff and non-tariffs measures costs, irrecoverable value added tax, and brokers' fees.⁶⁹

27. Burdensome customs procedures would diminish the highly productive nature of the pharmaceutical industry, act as a disincentive for further investment for manufacturing facilities in the UK, and diminish access to medicines for patients in the UK and the EU. *We support the Government in seeking as frictionless a border as possible; they must prioritise the absolute minimum additional costs and bureaucracy for the pharmaceutical sector.*

28. *The Government should ensure that, in addition to achieving as frictionless border as possible to protect the competitiveness of British pharmaceutical businesses, arrangements are put in place to ensure the cross-border transfer of short-life pharmaceutical products for emergency treatments and public health cases, in the mutual interest to patients in the UK and the EU.*

69 Office of Health Economics, [Public Health and Economic Implications of the United Kingdom Exiting the EU and the Single Market](#), November 2017, p3

4 Regulatory alignment

29. The pharmaceutical sector is subject to wide-ranging and stringent regulation throughout the development, manufacture and distribution of products.⁷⁰ Of all the barriers to trade that we have considered, it is regulatory divergence that causes the most concern for all those from whom we have received evidence. It is also an issue the Government has yet to give a clear indication of how it intends to resolve in negotiations with the EU, although the Prime Minister has set out options

There will be some areas where we have the same goals—the same objectives in terms of regulation—but wish to achieve them by different means. There will be other areas where we have the same goals and accept that they should be achieved by the same means.⁷¹

In her March 2018 Mansion House speech, the Prime Minister further indicated a willingness for close cooperation with the EU on regulation, setting out

[w]e will want to make sure our regulators continue to work together; as they do with regulators internationally. This will be essential for everything from getting new drugs to patients quickly to maintaining financial stability. We start from the place where our regulators already have deep and long-standing relationships. So the task is maintaining that trust; not building it in the first place.⁷²

In this context, we have sought to examine the advantages of the current regulatory environment, the opportunities for a future relationship and the potential for divergence.

Approval of Medicines

30. The UK has been an influential part of the EU system for the approval of medicines for release to patients, including the development of the European Medicines Agency ('EMA') in 1995 and the decision for it to be located in London.⁷³ The EMA is the decentralised EU agency responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, in conjunction with national medicine regulatory authorities (competent authorities), including the UK's Medicines and Healthcare products Regulatory Agency ('MHRA').⁷⁴ Medicines for use in one or more EU Member State(s) are required to go through one of four procedures for market authorisation set out by the EMA, depending on the product being approved and the level of availability across the EU required.

70 Exiting the EU Committee, [HM Government Life Sciences Sector Report](#), 21 December 2017, pp11–14

71 Oral evidence taken before the Liaison Committee on 20 December 2017, HC 637 (2017–19), [Q13](#) [Prime Minister]

72 Prime Minister's Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

73 Exiting the EU Committee, [HM Government Life Sciences Sector Report](#), 21 December 2017, p15

74 European Medicines Agency, [About Us](#) (accessed 17 April 2018)

EU Medicines Approval Procedures

National procedure: Medicines for use in only a single Member State are assessed only by the relevant Competent Authority of that Member State (the MHRA for the UK).

Mutual recognition procedure: Medicines that have previously been licensed for use in at least one Member State may be submitted to a further ‘reference Member State’ to assess the application to licence the product for use in other ‘concerned Member States.’

Decentralised procedure: Medicines which have yet to be approved for use in any Member State may be submitted to multiple Member States for approval together, with one Competent Authority acting as the reference Member State and any others being concerned Member States. The evaluation procedure is carried out by the reference Member State in consultation with the other states.

Centralised procedure: Medicines to be approved for use across the entire EU are submitted to the EMA who conduct the approvals process using national Competent Authorities as rapporteurs and co-rapporteurs. If approved, the medicine is cleared for use across the entire EU and EEA without the requirement for further decisions by Member States. The centralised procedure is compulsory for medicines containing new active substances to treat specific conditions, biotechnology products and advanced therapies, and optional for other new active substances and products with significant innovation or public health impacts. The majority of new, innovative medicines are subject to the centralised procedure.⁷⁵

31. The MHRA, an executive agency of the Department of Health and Social Care, plays a major role in the approval of medicines across the EU. In 2016 it was a rapporteur or co-rapporteur in 15.4 per cent of centralised procedures and scientific advice co-ordinator in 21 per cent of cases. In decentralised procedures, when involved the UK was the reference Member State in 45 per cent of cases for a medicine’s approval.⁷⁶ Companies and industry bodies have repeatedly told us that the MHRA is an influential, outstanding and globally respected organisation, a reputation that the Government should ensure it retains.⁷⁷ For over-the-counter medicines, we heard that the MHRA are “pragmatic and forward-thinking” in enabling non-prescription access to medicines, reducing demand on the National Health Service.⁷⁸

32. Should the UK leave the EU without an agreement to continue as part of a regulatory system with the EMA or recognising its decisions, applications for marketing authorisation for new medicines would need to be submitted both to the EU following one of the approval routes, and separately to the MHRA for authorisation for use in the UK. As a result, the MHRA, which currently benefits from the shared expertise and workloads of the distributed model of the EMA’s approvals process, would require increased resources to manage a significantly higher workload. The ABPI expressed concerns that as the MHRA’s approvals process is largely industry-funded by fees paid for the review of medicines, the industry “would not be able to sustain the level of fees required for

75 European Medicines Agency, [Authorisation of Medicines](#) (accessed 17 April 2018)

76 Office for Life Sciences, [Life Science Competitiveness Indicators](#), April 2017, p27

77 [Q29](#) [Mr Thompson]; American Pharmaceutical Group [BRP0010](#)

78 [Q32](#) [Mr Smith]

them to build up an authority that could review all new medicines.”⁷⁹ On this basis, the MHRA could expect to see a reduction in the number of authorisations that it is capable of granting or would require additional funding, either through the existing health budget or new public funding.

33. The UK represents less than three per cent of the global pharmaceutical market, compared to the EU’s 25 per cent.⁸⁰ The industry-led Life Sciences Industrial Strategy said in August 2017 that “a wholly free-standing system would likely be high cost—both in terms of efficiency and attractiveness to companies who typically apply to the largest markets first”.⁸¹ The evidence we received from industry bodies and companies since then supports this argument. Global pharmaceutical company Johnson and Johnson told us the UK is a market struggling to maintain its priority status and it is “unlikely whether globally-minded businesses would see it as a viable option to make this investment for a UK-only market authorisation.”⁸² US-based companies Lilly and MSD both told us that companies will focus on larger markets, with the UK becoming a less attractive proposition.⁸³ Where companies do not feel the UK is a priority market for their product, there is a risk that this will lead to delays or unavailability of new and innovative medicines in the UK, as set out in Chapters 2 and 3.⁸⁴ Charities such as Cancer Research UK are supporting the need for a continued relationship with the EMA to ensure the UK is an attractive market that enables access to innovative medicines.⁸⁵ The All-Party Parliamentary Group on Brain Tumours have expressed concerns that if the UK is not able to participate in the EMA work, such as its Committee for Advanced Therapies, UK patients may not be able to access specific forthcoming treatments currently being assessed.⁸⁶

34. Should the UK no longer be part of the EMA, marketing authorisations already held by companies in the UK to sell medicines in the EU would no longer be valid, and would need to be transferred to an entity in a Member State,⁸⁷ including at least 1,000 central authorisations.⁸⁸ Pharmaceutical company Lilly has described this as “both costly and administratively challenging” and has expressed concerns that national medicine regulatory agencies in remaining Member States may be overwhelmed by applications closer to the Brexit deadline.⁸⁹ These concerns have led the EMA’s Brexit guidance to encourage companies to transfer marketing authority in good time ahead of the UK leaving the EU.⁹⁰ Peter Ballard, Managing Director of Xiromed, told the Committee that companies are already applying for marketing authorisations without using the UK as

79 [Q42](#) [Mr Thompson]

80 Nuffield Trust, [General Election 2017: Getting a Brexit deal that works for the NHS](#), May 2017, p11

81 Life Sciences Industrial Strategy Board, [Life Sciences Industrial Strategy](#), (August 2017), p67

82 Johnson & Johnson [BRP0015](#)

83 Lilly [BRP0013](#); MSD [BRP0009](#)

84 [Q34](#) [Mr Smith]; The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); Lilly [BRP0013](#); MSD [BRP0009](#); Roche [BRP0004](#)

85 Cancer Research UK [BRP0020](#)

86 APPG on Brain Tumours [BRP0021](#)

87 European Commission and European Medicines Agency, [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](#), 29 January 2018, p2

88 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

89 Lilly [BRP0013](#)

90 European Commission and European Medicines Agency, [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](#), 29 January 2018, p1

reference member, with a result that “work that was being done in London is now being sent elsewhere, and there are not always available slots, which is causing some delays already.”⁹¹

35. If the UK leaves the EMA at the same time it leaves the EU, there is a significant risk that we will become a less attractive destination for innovative medicines, and cannot expect to be an early recipient of new medicines through our approvals process. At an estimated extra cost of £45,000 for marketing authorisation for each new medicine, the UK’s comparatively small market compared to the EU risks us losing out entirely on access to new specialised medicines.⁹² Manufacturers in the UK and EU would suffer, as the MHRA’s expertise and capacity as part of the approvals processes would be lost. The Prime Minister set out this challenge clearly in her Mansion House speech:

[M]embership 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.⁹³

36. We welcome and support the Government’s recognition of the benefits to the UK and EU of our continued membership of the EMA to ensure the UK and the EU can access the fullest possible range of new and innovative medicines and support the UK pharmaceutical sector accessing this market.

Manufacturing and Testing

37. Once a product has been granted marketing authorisation, it is still subject to a range of rigorous regulatory requirements for the testing and release of batches of each product, overseen by the EMA and supported by national medicine regulatory authorities. The batch testing and release of products may take place in any EEA Member State and be valid for the sale and use of the product in any Member State. Guidance on Brexit issued by the EMA to marketing authorisation holders sets out a clear requirement that, without an alternative agreed in negotiations, after the UK has left the EU all active substances produced in the UK will be treated as imported products and required to be certified by the MHRA as having manufacturing processes equivalent to the EU’s existing Good Manufacturing Practices (GMP) standards.⁹⁴ For finished products manufactured in the UK, these too will be treated as imported products and will be required to be subject to batch control testing and batch release from a site within the EEA.⁹⁵ Without any reciprocal arrangements, products manufactured in the UK for release in the UK would still be required to complete batch control testing and batch release in the UK, regardless of any testing undertaken within the EEA.

91 [Q101](#) [Mr Ballard]

92 Confederation of British Industry, [Smooth operations: an A-Z of the EU rules that matter for the economy](#), April 2018, p83

93 Prime Minister’s Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

94 European Commission and European Medicines Agency, [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](#), 29 January 2018, p3

95 As above, p4

38. Since the announcement of the EMA's post-Brexit requirements, large companies such as GSK have already announced their intention to build batch release sites in the EU, at a "cost of tens of millions of pounds".⁹⁶ In written evidence to the Committee, they told us that their process for setting up a new facility will take up to 3 years.⁹⁷ Lilly, as a global company, told us that they do not currently have any batch release sites in the UK, and that if they were required would lead to increased costs due to "new infrastructure and facilities; regulatory submissions for additional testing and release facilities; and regulatory inspections of testing and release facilities."⁹⁸ While Lilly are also considering the use of contract laboratories, which could be a solution for companies on both sides of the Channel, they were concerned that there is limited capacity in laboratories and high competition from manufacturers.⁹⁹

39. Manufacture and batch release also require the appointment of specific statutory roles. Qualified Persons (QPs) are trained quality assurance professionals responsible for ensuring every batch release complies with its specification and has been made according to good manufacturing practice¹⁰⁰ Qualified Persons for Pharmacovigilance (QPPVs) are required to ensure the Marketing Authorisation holder has an appropriate pharmacovigilance system in place, to have an overview of a safety profile for the manufacturers products and be the point of contact with the competent authorities.¹⁰¹ As with the physical testing and release of products, the EMA's Brexit guidance requires that both QPs and QPPVs are present and resident in the EEA.¹⁰² The availability of QPs and QPPVs is already of concern to the sector. Peter Ballard of Xiromed told us:

Good QPs have been at a premium for many years, to my certain knowledge, having tried to recruit replacements when people have retired. I have worked with some decidedly superannuated QPs who have carried on, out of goodwill, into their 70s. We had one chap who was absolutely first class but we just could not replace him, so he stayed on. It is already difficult to recruit good QPs.¹⁰³

With a finite number of QPs and QPPVs available, increased demand and no indication of a significant increase in the number of people seeking qualification, there is a risk of relocation from the UK to the EU of appropriately qualified staff.¹⁰⁴

40. The EMA has set out its requirements for testing and for the appointment of qualified persons following the UK leaving the EU. Without a continued or new formal relationship with the EMA, manufacturers will need to have manufacturing and testing sites with relevant qualified persons both in the UK and the EU to continue to operate in both jurisdictions and to release products for use. Cost estimates vary, but industry representatives we heard from put the cost into the millions, some of which is already

96 [Q11](#) [Mr Thompson]

97 [AstraZeneca BRP0019](#)

98 [Lilly BRP0013](#)

99 As above.

100 [Pharmaceutical Journal, How does one become a qualified person?](#) (accessed 17 April 2018)

101 [Pharmafile, The roles and responsibilities of an EEA qualified person for pharmacovigilance \(QPPV\)](#) (accessed 17 April 2018)

102 [European Commission and European Medicines Agency, 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, 29 January 2018, p3](#)

103 [Q94](#) [Mr Ballard]

104 [Johnson & Johnson BRP0015](#)

being spent.¹⁰⁵ In the event of no cooperation with the EMA after leaving the EU, analysis by the Office of Healthcare Economics puts the potential cost to a large UK pharmaceutical company of £49.6 million in implementation and £36.4 million in annual costs.¹⁰⁶

Opportunities from divergence

41. Were the UK to diverge from the regulatory requirements of the EMA, there was scant evidence of any potential benefits to the sector. Companies and industry groups identified that there may be the chance for increased flexibility on the amount of time it takes for new products to be approved; but accepted that this would be offset by the need for separate EU and UK approvals for market access.¹⁰⁷ The Propriety Association of Great Britain, the trade body for over-the-counter medicines, mooted in written and oral evidence the possibility of greater self-regulation for their industry to increase “availability, access and choice for people in the UK” with “more user-friendly language, more comprehensible names and more people-centred labelling for these products”¹⁰⁸ but they told us these benefits would be outweighed by the cost from regulation and loss of trade.¹⁰⁹ We also received evidence on the potential for a relationship with other pharmaceutical regulators, such as the US’s Food and Drug Administration, Health Canada or Swissmedic.¹¹⁰ We heard from the ABPI that with 75 per cent of the value in the medicine market coming from the EU and US, any movement away from either of these regulatory regimes would diminish the UK industry.¹¹¹ Emily Lydgate, Lecturer in Law at the UK Trade Policy Observatory, told the Committee in a session covering all of the Committees’ sectoral inquiries, that the EU and US were “basically the two games in town.”¹¹² In considering the US as a market, a previous European Commission impact assessment of the Transatlantic Trade and Investment Partnership suggested trade equivalent costs with the US would be above 20 per cent for many sectors, with chemicals equivalent to a 25.5 per cent tariff.

42. Evidence from Roche indicated that 64 per cent of the British public supported policies that would ensure “the UK leads the world in the regulation of medicines and medical devices, ensuring that regulations are flexible enough to accommodate new and cutting-edge discoveries.”¹¹³ From the evidence we have seen and heard, to be world leading in the regulation of pharmaceuticals, the UK needs to be part of a wider, successful regulatory system. **What little benefits there may be of regulatory divergence would be greatly overshadowed by the costs and loss of markets and influence the UK would face. It makes commercial sense for the UK to remain aligned with standards in the EU market, given the significant amount of trade it provides for both the UK and EU and the access it gives both to medicines. *The Government should pursue this approach.***

105 [Q11](#) [Mr Thompson]; [Q31](#) [Mr Smith]; [Q92](#) [Mr Hicken]; [Q93](#) [Mr Ballard]

106 Office of Health Economics, [Public Health and Economic Implications of the United Kingdom Exiting the EU and the Single Market](#), November 2017, p3

107 [Q60](#) [Mr Thompson]; [Q63](#) [Mr Smith]; AstraZeneca [BRP0019](#)

108 [Q54](#) [Mr Smith]; PAGB [BRP0007](#)

109 As above.

110 Roche [BRP0004](#)

111 [Q29](#) [Mr Thompson]

112 Oral evidence taken before the Business, Energy and Industrial Strategy Committee on 31 January 2018, HC 384 (2017–19), [Q16](#) [Ms Lydgate]

113 Roche [BRP0004](#)

Future Relationship

43. In her Mansion House speech, the Prime Minister set out the Government's approach to engagement with the EMA as negotiations continue:

The UK will need to make a strong commitment that its regulatory standards will remain as high as the EU's. That commitment, in practice, will mean that UK and EU regulatory standards will remain substantially similar in the future.

We will also want to explore with the EU, the terms on which the UK could remain part of EU agencies such as those that are critical for the chemicals, medicines and aerospace industries: the European Medicines Agency, the European Chemicals Agency, and the European Aviation Safety Agency.

We would, of course, accept that this would mean abiding by the rules of those agencies and making an appropriate financial contribution.¹¹⁴

The basis of this relationship has been previously set out by Greg Clark and Jeremy Hunt in their FT letter of July 2017 and in the Department for Business, Energy and Industrial Strategy's evidence to us, as being that

patients should not be disadvantaged; innovators should be able to access the UK market as quickly and simply as possible; and we will continue to play a leading role in both Europe and the world promoting public health.¹¹⁵

We agree with and support the approach of the Prime Minister and Ministers, but believe that there needs to be greater clarity from both the UK and the EU on how this will be achieved.

44. Pharmaceutical trade bodies have been clear in their support for a continued relationship with the EMA, which delivers a regulatory cooperation agreement between the UK and EU, continued alignment of current and future regulations; and continued UK participation in EU regulatory processes and supervision of medicines, including the sharing of data.¹¹⁶ Some companies have proposed mutual recognition agreements or cooperation agreements if full alignment is not possible.¹¹⁷ We believe that the Government should work towards the closest possible arrangement, up to and including some form of membership of the EMA. As the CBI have set out in their recent report on EU regulations, the UK has the third highest number of batch testing sites, the second highest number of Good Manufacturing Practice Sites and has the highest detection rate for flaws in medicines within the EU.¹¹⁸ We agree with the CBI and the pharmaceutical sector that there is real incentive from both the UK and the EU to get this right, to maintain patient safety and a successful sector.

114 Prime Minister's Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

115 Department for Business, Energy and Industrial Strategy, [BRP0018; Letters to the Editor](#), Financial Times, 5 July 2017

116 American Pharmaceutical Group [BRP0010](#); The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); British Generic Manufacturers Association (BGMA) [BRP0008](#); PAGB [BRP0007](#)

117 Merck [BRP0005](#); MSD [BRP0009](#)

118 Confederation of British Industry, [Smooth operations: an A-Z of the EU rules that matter for the economy](#), April 2018, p83

45. The EMA currently has agreements in place with a number of third countries: USA, Canada, Japan, Switzerland, Australia, New Zealand, and Israel; and supports European Commission collaboration with China, India and Russia.¹¹⁹ The third country agreements allow for cooperation that includes, for example, the sharing of confidential information, mutual recognition of GMP standards, waiving of batch-testing, and cooperation on pharmacovigilance.¹²⁰ The Government has identified these relationships as a precedent for continued relationship,¹²¹ and they reflect the absolute minimum level of collaboration that would have some benefit to UK and EU businesses. We agree with the Prime Minister that existing models do not work, either in the interests of the UK or the EU, and this is especially true for the pharmaceutical sector. Given the MHRA's significant expertise and capacity, the Government should seek a bespoke agreement that ensures continued influence to support pan-European businesses and supply chains.

46. The success of EU-wide regulation of manufacturing and regulation of testing and release of medicines, with the Medicines and Healthcare products Regulatory Agency an integral and influential part, means the Government should prioritise a form of membership with the European Medicines Agency that maintains cooperation and does not require replication of manufacturing sites, testing or roles. The Government has set out its desire for continued cooperation and a form of Membership. *The Government should as a priority now seek from the European Commission an explanation as to the Commission's approach.*

European Court of Justice

47. While it is possible that, in the negotiations, the EU may require that any arrangement includes recognition of some involvement of the European Court of Justice (ECJ) in any dispute resolution, we have received evidence of only one or two challenges to decisions of the EMA, which were the result of political disagreement¹²² or controversial new products.¹²³ Pharmaceutical companies indicated a desire for a single dispute resolution mechanism alongside regulatory harmonisation, to ensure stability and legal certainty for the sector.¹²⁴

48. In her Mansion House speech, the Prime Minister set out her aspiration for an form of membership of the EMA that could permit UK firms to resolve certain challenges to agencies through UK courts rather than the ECJ, with Parliament ultimately able to override rules with the inherent risk and consequences for our continued engagement with agencies such as the EMA.¹²⁵ ***We recommend that the Government continues to take a pragmatic approach in relation to any potential continuing ECJ role in the pharmaceutical sector.***

119 European Medicines Agency, [Bilateral interactions with non-EU regulators](#) (accessed 17 April 2018)

120 European Medicines Agency, [Canada](#) (accessed 17 April 2018); European Medicines Agency, [United States](#) (accessed 17 April 2018)

121 HM Government, [Collaboration on science and Innovation: a future collaboration paper](#), September 2017, p14

122 [Q29](#) [Mr Thompson]

123 Such as Viagra; [Q38](#) [Mr Thompson]

124 Johnson & Johnson [BRP0015](#)

125 Prime Minister's Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

The Future of the European Medicines Agency

49. The EMA is one of two EU decentralised agencies currently based in the UK, both of which are due to leave the UK once it leaves the EU.¹²⁶ The EMA's departure to Amsterdam in 2019 presents a significant challenge for organisation, the EU and the UK. Of the 712 FTE staff surveyed in September 2017, before the final relocation decision was made, between 137 and 250 employees would be unlikely to remain with the agency even in the most attractive Member States.¹²⁷ Depending on the exact staff who departed the organisation, the EMA suggested that this would have a negative impact on their ability to carry out their current responsibilities, with approval of new medicines and safety monitoring largely maintained, but with possibility of delays and progress on a number of public health initiatives, such as antimicrobial resistance, moving at a slower pace.¹²⁸

50. We heard from Mike Thompson, Chief Executive of the ABPI, that while there may be some marginal opportunities for the MHRA or the UK pharmaceutical industry to recruit those EMA staff who wish to remain in the UK, there is a more significant challenge for the organisation in being able to leave the UK anywhere near as quickly as intended.¹²⁹ The current EMA headquarters at Canary Wharf are subject to a lease until 2039 for which the EU expects the UK Government to be responsible after the UK leaves the EU.¹³⁰ **While it is necessary for the European Medicines Agency to move its headquarters to a Member State once the UK leaves the EU, there is a beneficial case for both the UK and EU for the EMA to retain a residual staff in the UK to support a continued relationship between the UK's influential Medicines and Healthcare products Regulatory Agency and the EMA, and to support EMA employees who do not wish to leave the UK. We recommend that as part of a new association with the EMA, the Government should seek to retain a presence for EMA jobs and facilities in the UK where it would benefit the operation of the EMA and the MHRA, supporting UK businesses to continue to access the European market and European businesses to access the UK market.**

126 The other, the European Banking Authority, is due to relocate to Paris in 2019.

127 European Medicines Agency, [EMA business continuity planning and impact of staff retention scenarios from the EMA staff survey](#), September 2017, p4

128 As above, p5

129 [Q59](#) [Mr Thompson]

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

5 Transitional Arrangements

51. As with other sectors the Committee has considered, the consistent message we received from the pharmaceutical sector was a need for certainty on the transition period and the intended deal that the UK expects to secure with the EU. The announcement of a transition period that will last until 31 December 2020 has provided some certainty to the industry, but without further clarity on what the end state will be, decisions are being taken that may see businesses relocate or expand to the EU rather than focus on the UK.¹³¹ The evidence we received from the sector sought a transition period that would enable the industry to implement any processes that are required as a result of the new relationship that is negotiated. While some parts of the sector preferred not to give a specific timeframe for this transition, simply seeking the longest possible transition to make changes necessary,¹³² we received evidence from companies on an appropriate timescale between two and five years.¹³³ Peter Ballard, Managing Director at Xiromed, told us that anything less than two years would be “catastrophic.”¹³⁴ John Smith, Chief Executive of over-the-counter trade body PAGB, told us that while large companies will be able to cope with whatever happens, an early, fixed end date for leaving the EU could be very severe for some SMEs.¹³⁵

52. The EMA has already announced post-Brexit requirements for industry, in the event of no bespoke deal, as covered in Chapter 4. Witnesses told us that it takes at least 12 months, typically 18 and up to 24 months to move manufacturing or start a second manufacturing plant. On the basis of the March 2019 exit date and the lack of certainty on transition timings until March 2018, some companies had already started to undertake contingency planning by the time we took evidence in December 2017 or were intending do so early in 2018.¹³⁶ Large companies have already indicated they are seeking to mitigate these new requirements, with GSK already making investments of tens of millions of pounds to build sites required for testing in the EU.¹³⁷ Following the announcement of the transition period, the UK and European industry bodies have welcomed the clarity, but continue to advise members to plan for all outcomes and call for clarity in the negotiations as soon as possible.¹³⁸ Nonetheless, pharmaceutical businesses have continued to invest in the UK industry since the country voted to leave the EU.¹³⁹

53. The agreement of a 21-month transition period as the UK leaves the UK is less than the minimum amount of time we were told is required to avoid serious issues for some businesses. It is, however, a positive step in so far as it provides business with some certainty. *The UK Government must, alongside the European Commission, now*

131 [QQ11–12](#) [Mr Thompson]

132 AstraZeneca [BRP0019](#); Lilly [BRP0013](#); Roche [BRP0004](#)

133 PAGB [BRP0007](#)

134 [Q124](#) [Mr Ballard]

135 [Q63](#) [Mr Smith]

136 AstraZeneca [BRP0019](#); Johnson & Johnson [BRP0015](#)

137 [Q11](#) [Mr Thompson]

138 European Federation of Pharmaceutical Industries and Associations, [Statement in response to the EU Council ratifying the Brexit transition deal](#), 23 March 2018 (accessed 17 April 2018)

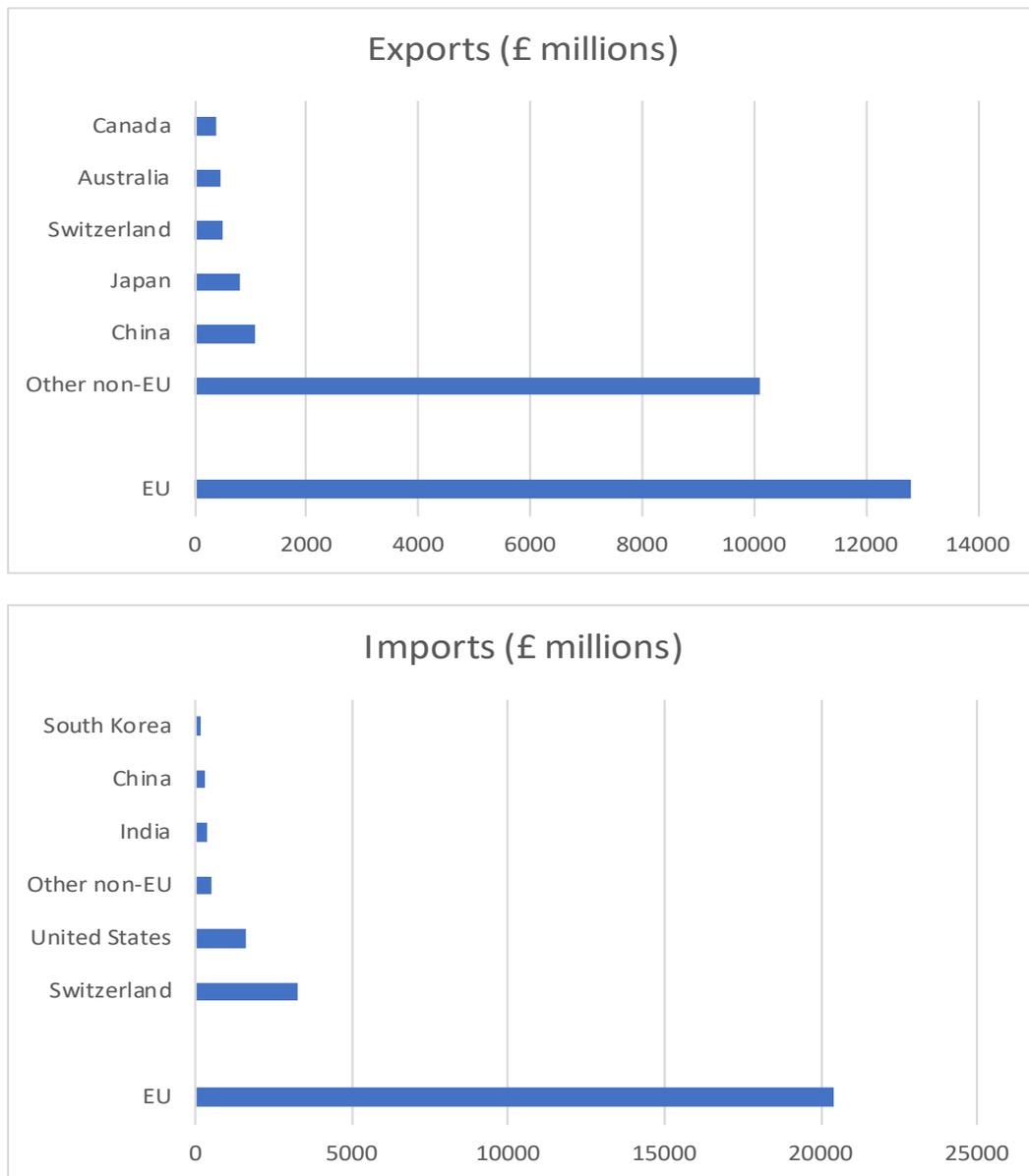
139 Department for Business, Energy and Industrial Strategy, [BRP0018](#); “Major pharma leader MSD first to endorse Government’s Industrial Strategy”, Department for Business, Energy and Industrial Strategy press release, 27 November 2017

ensure a speedy decision is taken on the new relationship for the UK and the EMA, early enough to minimise unnecessary contingency planning costs currently being borne by the pharmaceutical sector.

6 Trade opportunities post-Brexit

54. As we have established throughout the report, the pharmaceutical industry is a global one, with complex regional supply chains.¹⁴⁰ For the UK, this is reflected in UK pharmaceutical exports in 2016 worth £24.9 billion and imports £24.8 billion.¹⁴¹ 44 per cent of our exports are to the EU, while 73 per cent of imports come from the EU.¹⁴² For generic medicines, which make up around 75 per cent of the National Health Service's day-to-day medicine use, between 80 and 90 per cent of products used in the UK are imported.¹⁴³ Figure 1 below sets out the main markets overall for UK import and export of pharmaceutical products.

Figure 1: UK Trade in pharmaceutical and medical products 2017



Source: HMRC, UK Trade Info, SITC Code 54

140 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

141 House of Commons Library, [Brexit and medicines regulation](#), Number 8148, 20 November 2017, p27

142 [Q17](#) [Mr Thompson]

143 [Q1](#) [Mr Fleming]; [Q70](#) [Mr Ballard]

55. The current mix of trade in pharmaceutical products shows that membership of the EU is not a barrier to wider international trade in pharmaceutical products; however, this trade currently depends on the range of free trade agreements negotiated as part of the UK's membership of the EU. The Government has indicated its desire to secure new global trading relationships as the UK leaves the EU,¹⁴⁴ and for increased bilateral cooperation on research areas such as genomics and precision medicines, in which the UK is a global leader.¹⁴⁵ Pharmaceutical companies and trade bodies have welcomed this approach, which would benefit companies both UK-based, such as AstraZeneca, and those headquartered overseas such as Johnson and Johnson and Lilly.¹⁴⁶ However, these are not new relationships. AstraZeneca is already expanding its global manufacturing operations in the USA, Australia, Russia and the Middle East. In China, it is already the second largest international biopharmaceutical company with revenues of \$2 billion and 11,000 employees.¹⁴⁷ Johnson and Johnson, the world's largest diversified pharmaceutical company, told us that "the UK is leaving the freest and most integrated market in the world and that any future situation will be less attractive, no matter how many free trade agreements the UK signs after Brexit."¹⁴⁸

56. Despite the appetite for new markets from Government, senior executives from pharmaceutical companies and industry groups have told us that there are few new markets for which companies could compete, and while different companies have different potential for growth, the EU27—representing more than 22 per cent of global trade¹⁴⁹—will remain the largest trading partner for companies across the sector.¹⁵⁰ Looking at the potential for new markets, Mike Thompson, Chief Executive of the ABPI, told us:

At the moment, those other economies receive the same medicines out of regional supply chains in their areas, whether it is the US or the Far East. There are already manufacturing capabilities to do that, so I do not think it is the fact that they have not got these medicines and we can therefore sell them. There are supply routes that are already regionally based.¹⁵¹

Swiss-based pharmaceutical company Roche told us the same, already having affiliates for their products in most countries supplying their own markets, there would be limited opportunity for them to export outside of the EU.¹⁵² While there is evidence of the potential for expansion in some markets, such as the United States,¹⁵³ we have received no evidence that there are new trade routes or opportunities on which the UK is missing out.

57. For the UK to continue to be one of the major global hubs for pharmaceutical innovation, it is cooperation as part of regional and global networks to develop new and innovative medicines which is likely to bring continued success. As most

144 Department for International Trade, [Preparing for our future trade policy](#), 9 October 2017; Foreign and Commonwealth Office, [‘Uniting for a Great Brexit’ speech by Rt Hon Boris Johnson MP](#), 14 February 2018

145 Department for Business, Energy and Industrial Strategy, [BRP0018](#)

146 American Pharmaceutical Group [BRP0010](#); AstraZeneca [BRP0019](#); Johnson & Johnson [BRP0015](#); Lilly [BRP0013](#)

147 AstraZeneca [BRP0019](#)

148 Johnson & Johnson [BRP0015](#)

149 Bioindustry Association and the Association of the British Pharmaceutical Industry, [Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU](#), September 2016, p4

150 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

151 [Q23](#) [Mr Thompson]

152 Roche [BRP0004](#)

153 American Pharmaceutical Group [BRP0010](#)

manufacturers are multinational with regional supply chains, any trade deals are unlikely to lead directly to a substantial increase in investment and jobs in the UK. Given that the EU represents 44 per cent of the UK's pharmaceutical exports and 73 per cent of imports, the Government should prioritise continued friction-free access to the EU market and the roll-over of existing free trade agreements over securing new third country agreements.

Intellectual Property

58. There has been a longstanding tension between the rights of pharmaceutical companies to protect their intellectual property developed through innovation and investment, and the public health benefits of wider access to medicines. The World Trade Organisation agreed a minimum standard for the setting and enforcement of intellectual property rights and resolution of disputes, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁵⁴ Bilateral trade agreements may commit parties to more stringent rules (TRIPS-plus) which have included restrictions on the sharing of test data, extensions on the length of patents and measures delaying manufacturers of generic pharmaceutical products from seeking and receiving marketing approval for their products.¹⁵⁵

59. Restrictions on intellectual property have been criticised both by public health campaigners and by generics manufacturers. In evidence to us STOPAIDS, a network of charities and campaigning organisations, highlighted the opportunities of restricting patents:

With a stricter patentability criteria, the UK government will be able to get better access and reduced costs of medicines. Stricter patentability criteria would help block the attempts of pharmaceutical companies to 'evergreen' their products (for instance changing something from a pill to a powder or re-patenting a medicine if it is proved therapeutic for another disease area) and enable the entry of generic medicines. For example, the pharmaceutical company Genzyme re-patented a drug known as Alemtuzumab used to treat leukaemia when it proved effective in treating multiple sclerosis (MS). Before the relicensing Alemtuzumab cost £2,500 per MS course, after the re-licensing the cost increased to £56,000 per course.¹⁵⁶

Generic manufacturers told us that the Government should consider enhanced incentives for the development and manufacture of generic medicines, including reviewing data exclusivity measures that restrict access to testing information for generic manufacturers and requires further clinical testing.¹⁵⁷ However, in evidence to the Committee, Paul Fleming, Technical Director at the British Generics Manufacturers Association, told us "we want to maintain regulatory alignment. Our view is that this is not the time and place

154 World Health Organisation, [Policy and Legal Framework: Intellectual property and access to medicines](#), (2012), p2

155 As above.

156 StopAids [BRP0014](#)

157 British Generic Manufacturers Association (BGMA) [BRP0008](#)

to be talking about those different elements around IP.”¹⁵⁸ John Smith of the over-the-counter manufacturer trade body PAGB said “the benefits will be outweighed by the costs involved.”¹⁵⁹

60. We also considered whether stronger intellectual property protections would benefit the UK pharmaceutical sector. The Government argue that the UK has “a world-class intellectual property regime”¹⁶⁰ and we received evidence from pharmaceutical companies and trade bodies that divergence from EU intellectual property standards would make the UK a less attractive market and be a disincentive to the development of new and innovative medicine in the UK.¹⁶¹ Any extension to intellectual property rights in the UK, with the attendant delay in the availability of cheaper generic products, would have a negative impact in terms of cost for the National Health Service and ultimately could harm patients.¹⁶²

61. The UK and EU have an intellectual property regime that effectively supports both innovation and access to medicines. Any unilateral changes to this as the UK leaves the EU would risk either the UK’s attractiveness as a base for research and development or the ability of the National Health Service to access the full range of medicines its needs. *The Government should ensure that any trade deals struck as we leave the EU do not cause us to diverge from current intellectual property rules.*

158 [Q35](#) [Mr Fleming]

159 [Q51](#) [Mr Smith]

160 Department for Business, Energy and Industrial Strategy [BRP0018](#)

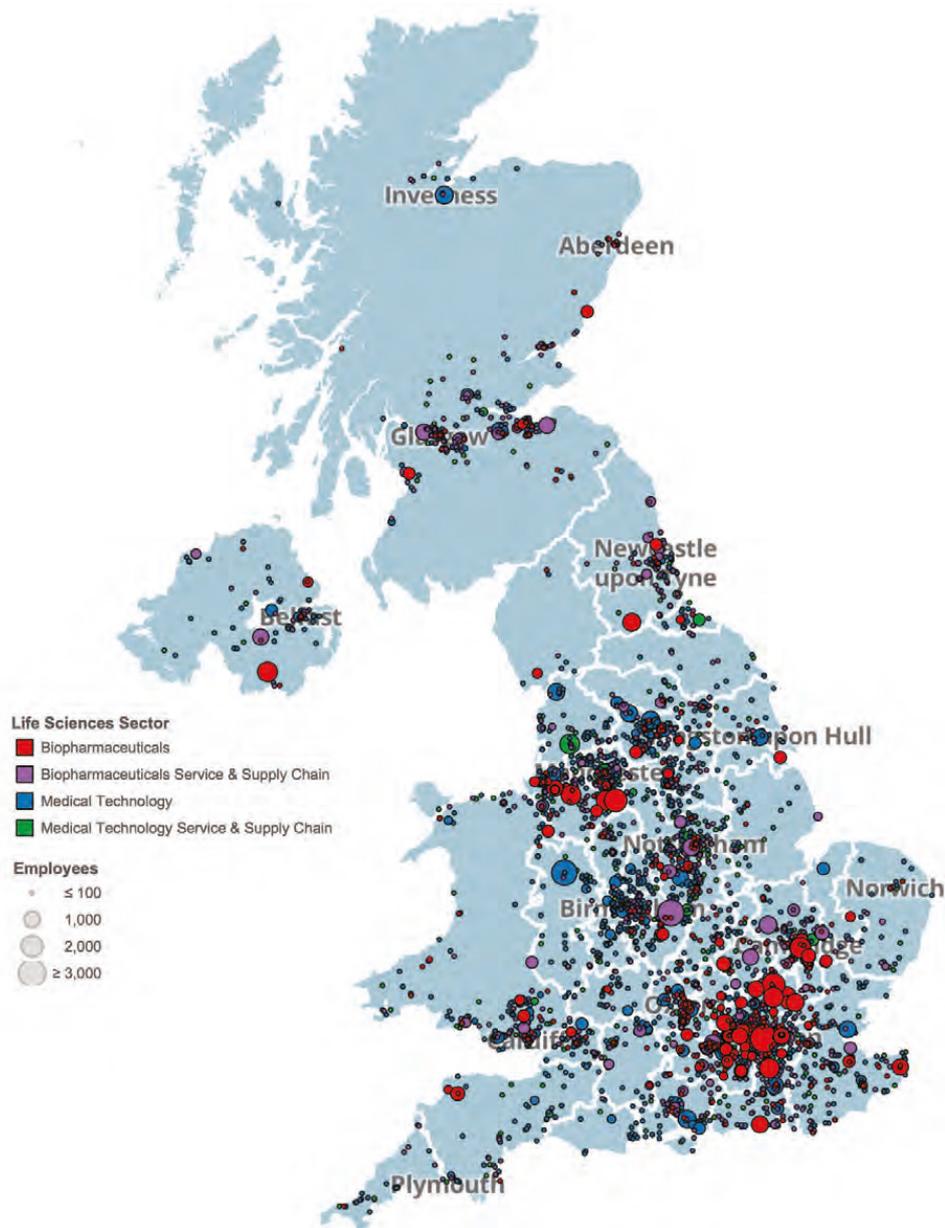
161 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); Lilly [BRP0013](#)

162 [Q105](#) [Mr Ballard]

7 Skills

62. The pharmaceutical sector, and the wider life sciences industry, are present across the UK, although there are large concentrations in the ‘golden triangle’ of London-Oxford-Cambridge and in the North West, and a significant presence close to the Northern Ireland/Ireland border. The pharmaceutical service and supply chain has a heavy presence in the South East and East of England and in Scotland.¹⁶³ Figure 2 shows the geographical spread of life sciences employment in detail, with the distribution of turnover in the sector closely aligned with the level of employment.¹⁶⁴

Figure 2: Geographical spread of UK life sciences sector employment



Source: Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p36

163 Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p35

164 Office for Life Sciences, [Strength and Opportunity 2016](#), (April 2017), p37

63. The UK is an attractive destination for skilled workers in science and research, rivalling the leading global centres of Boston and the San Francisco Bay area.¹⁶⁵ The benefits of a successful industry, with a GVA of over £330,000 per employee,¹⁶⁶ are combined with the attractiveness of the UK as what the ABPI called an “enormously attractive destination” which is attractive for families and a place where “people feel comfortable and safe in our society”¹⁶⁷ and from which the APPG on Brain Tumours noted allows the sector to thrive as the best minds from across the world work together.¹⁶⁸ Around ten per cent of employees of the companies who submitted evidence to us are from non-UK EEA states¹⁶⁹ and these are primarily recruited because they offer specific skills needed by the company. Research institutions, such as the recently established Crick Institute, see up to 40 per cent of their research base are from overseas.¹⁷⁰ As Johnson and Johnson told us in written evidence:

There are a number of advantages to employing EEA workers, including EEA language skills and understanding of EMEA markets, which are specific capabilities in short supply in the UK. Language and cultural awareness is in high demand in our regional groups and is very difficult to hire from local talent.¹⁷¹

EEA employees (and employees from the rest of the world) also provide skills that are not currently readily available from UK recruits, including shortages on translational medicine, clinical pharmacology and novel therapies.¹⁷² Specific roles such as Qualified Persons are also highly competitive, in which the UK competes against other EU states from a limited pool in recruitment processes that take up to 12 months to complete.¹⁷³ In the event of divergent regulation, these roles will become even more difficult to fill as demand increases significantly.¹⁷⁴ While companies are keen to recruit from the UK and willing the Government to do more to enable this to happen, we have received no evidence that there is likely to be any short or medium term mitigations that mean companies will no longer need to recruit from overseas to fill roles.¹⁷⁵

64. As a global industry, large pharmaceutical companies and their employees have benefited from the opportunity for intra-company transfers that enable skills and experiences to be shared and developed.¹⁷⁶ German-based Merck told us that the benefits on such transfers extend to ensuring that the parent company outside the UK has a greater understanding of the UK business environment and can encourage further investment, while US-based Johnson and Johnson highlighted the benefits of such transfers to

165 BioIndustry Association, [Building something great: UK's Global Bioscience Cluster 2016](#), May 2017, p4

166 Department for Business, Energy and Industrial Strategy, [BRP0018](#)

167 [Q58](#) [Mr Thompson]; The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

168 [Q58](#) [Mr Thompson]; APPG on Brain Tumours [BRP0021](#)

169 AstraZeneca [BRP0019](#); Johnson & Johnson [BRP0015](#); Lilly [BRP0013](#); Merck [BRP0005](#)

170 [Q56](#) [Mr Thompson]

171 Johnson & Johnson [BRP0015](#)

172 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); Merck [BRP0005](#)

173 Private meeting with the European Federation of Pharmaceutical Industries and Associations in Brussels, November 2017

174 See paragraph 39

175 Roche [BRP0004](#); Johnson & Johnson [BRP0015](#); Merck [BRP0005](#)

176 AstraZeneca [BRP0019](#); British Generic Manufacturers Association (BGMA) [BRP0008](#); Lilly [BRP0013](#); Merck [BRP0005](#)

develop future leaders.¹⁷⁷ We received some evidence that indicated such transfers, and recruitment more generally, has become more difficult since June 2016.¹⁷⁸ Businesses are deeply concerned that this will continue and any reciprocal issues could harm UK employees seeking roles overseas, especially harming those who participate in leadership development programs and other programs aimed to give international experience at an early career stage.¹⁷⁹

65. The Government has commissioned the Migration Advisory Committee (MAC) to consider the impact of EEA migration on the UK. The MAC is due to report in September 2018 to inform the post-transition period migration system.¹⁸⁰ The MAC's interim report in March 2018 found that the vast majority of UK employers are in line with the pharmaceutical industry, in so far as they do not seek to deliberately fill vacancies with migrant workers, but primarily do so when they are the best or only possible candidates for a role.¹⁸¹ In its commission to the MAC, the Government asked it to consider aligning the UK immigration system with a modern industrial strategy.¹⁸² With pharmaceuticals and life sciences a vanguard of the Government's industrial strategy so far, it is vital that the immigration system does nothing to diminish the strength of the UK as a global centre for this sector. As the CBI said in their submission to the MAC:

Overseas workers bring fresh ideas, added diversity, and unique skills sets which cannot be replicated and are critical for success of the industrial strategy. Migrants often bring unique cultural understanding or specialist knowledge which British workers cannot provide, even if trained to the highest degree. British firms are operating in a global environment and if they are not able to access the world's top talent, from academia to engineering to life sciences, then they will be at a distinct competitive disadvantage.¹⁸³

The British Generic Manufacturers Association, in a survey of their members found that they shared this view and that if changes to the UK immigration system meant generic manufacturers were unable to fulfil a business function with UK candidates, a majority would consider outsourcing or relocating a function outside of the UK.¹⁸⁴

66. The Government has committed to protecting the rights of EU citizens residing in the UK, which should provide certainty to those currently living and working in the UK in support of the pharmaceutical industry.¹⁸⁵ Further clarity provided by the phase 1 Negotiations Report on EU citizens' rights and the statements from the Government that it wishes to retain access to skilled EU workers in this country are welcome, but in a global, mobile industry with visible recruitment challenges the Government needs to ensure that there is no disruption to the ability for UK pharmaceutical businesses to recruit the necessary staff. ***In the short term, the Government should ensure that the***

177 Johnson & Johnson [BRP0015](#); Merck [BRP0005](#)

178 [Q113](#) [Mr Ballard]; PAGB [BRP0007](#)

179 Johnson & Johnson [BRP0015](#)

180 Migration Advisory Committee, [EEA-workers in the UK labour market: Interim Update](#), (March 2018), p5

181 As above.

182 As above, p20

183 As above, p45

184 British Generic Manufacturers Association (BGMA) [BRP0008](#)

185 "[Migration Advisory Committee \(MAC\) commissioned by Government](#)", Migration Advisory Committee Press Release, 27 July 2017

industry can continue to have immediate access to the skills it needs, including through effective circulation of staff from around the world to meet skills shortages and to support personal and corporate development.

67. Skills shortages are already a problem in the pharmaceutical industry and could increase depending on the post-Brexit immigration approach as well as any changes to pharmaceutical regulation. *The Government must continue to work with the industry to meet its skills gap and increase the number of UK nationals working in the sector for the long term.*

8 Research and Development

68. The UK pharmaceutical industry invests £11.5 million per day in research and development, employing more than 23,000 people in research-intensive roles.¹⁸⁶ While the UK constitutes under three per cent of the global pharmaceuticals market, it typically attracts more than five per cent of research and development spending.¹⁸⁷ There has been support for the industry from successive Governments, most recently with the Government's response to the Accelerated Access Review, intended to dramatically reduce the amount of time it takes for new and innovative treatments¹⁸⁸ and the launch of the Life Sciences Sector Deal as part of the Government's Industrial Strategy White Paper. Government actions as a result of the sector deal are intended to include a growth in overall R&D spending to the current OECD average of 2.4 per cent by 2027 and further growth to the OECD target of three per cent in the longer term, investment of more than £950 million in research infrastructure and measures to speed up approvals for clinical trials.¹⁸⁹ In response, the sector has committed to a pipeline of new investment, beginning with new research centres in London and Oxford, and new research collaborations with universities and with charities including the Wellcome Trust, Bill and Melinda Gates Foundation and Cancer Research UK.¹⁹⁰ Many of the announcements made so far in relation to the Life Sciences Sector Deal and the Industrial Strategy have focused on large, established companies. We hope that as the deals progress, industry and Government are able to ensure that small and 'disruptive' companies are also supported as part of announcements, in line with the Government's criteria set out for Sector Deals.¹⁹¹

69. As a world leader in pharmaceutical research and development, the UK has benefited disproportionately from the EU's Horizon 2020 funding, receiving 13 per cent of the total grants so far, while the UK Venture Capital ecosystem is currently reliant on EU funds, such as the European Investment Bank and European Investment Fund.¹⁹² The UK also receives the most funding from, and leads the most projects in, the Innovative Medicines Initiative, the world's largest R&D public-private partnership, in which UK businesses such as AstraZeneca are significant contributors and participants.¹⁹³ Industry has welcomed the commitment from Government to maintain Horizon 2020 funding, but have expressed significant concerns about the potential for a longer-term loss of access to Horizon 2020 funding and its successors.¹⁹⁴ While there is uncertainty about what comes next for both the UK's and the EU's plans on research funding, there is precedent for non-EEA states receiving funding through Horizon 2020 Association Agreements, such as Israel and Switzerland, and there is pressure from industry to ensure that the Government secures a form of access to ensure continued collaboration.¹⁹⁵ The collaborative nature of

186 The Association of the British Pharmaceutical Industry, [Industry Achievements](#), (accessed 17 April 2018)

187 [Q69](#) [Mr Hicken]

188 Department of Health and Department for Business, Energy and Industrial Strategy, [Making a reality of the Accelerated Access Review](#), November 2017

189 Department for Business, Energy and Industrial Strategy, [Life Sciences Sector Deal](#), 6 December 2016, p10

190 As above, p11

191 Department for Business, Energy and Industrial Strategy, [Industrial Strategy: Building a Britain fit for the future](#), 27 November 2017, pp208–11

192 AstraZeneca [BRP0019](#), Department for Business, Energy and Industrial Strategy, [BRP0018](#)

193 AstraZeneca [BRP0019](#), Lilly [BRP0013](#)

194 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); Lilly [BRP0013](#); Merck [BRP0005](#); Roche [BRP0004](#)

195 The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#)

EU programmes benefit both the EU and non-Member states. The UK's continued presence in these would ensure that, as the Prime Minister set out in her Mansion House speech "the EU would continue to access the expertise of the UK's world-leading universities"¹⁹⁶

70. The Government has committed to becoming "the fastest place in the world for the design, development and widespread adoption of medical innovations and stimulate new investment, jobs and economic growth to support the NHS."¹⁹⁷ It will only be able to do this if we remain fully engaged with EU partners and the global industry, through collaborative research, development and investment. **The Government commitment to underwriting Horizon 2020 funding and to seek continued engagement is welcome. As part of its Industrial Strategy and a commitment to take R&D spending to the OECD average, the Government should provide certainty to businesses and research institutions by setting out its approach to R&D collaboration, including whether it will seek an association agreement with the successor to Horizon 2020.**

Clinical Trials

71. The need for collaboration on the development of new medicines was most clearly outlined to us in terms of the use of clinical trials at a pan-European level. In the later stages of clinical trials for new products, we heard companies may need as many as 8,000 patients, requiring up to 40 centres to conduct them.¹⁹⁸ Should the UK have a divergent regime that makes it more difficult for these medicines to be made available for trial in the UK, or fail to negotiate the recognition of clinical trials results, we heard that it is unlikely that companies would invest in clinical trials in the UK as well as in the EU.¹⁹⁹ Estimates have suggested the UK's participation in clinical trials delivers £192 million in free medicines to the National Health Service each year, enabling welcome early access to new and innovative medicines and putting the UK as a leader or participant in the largest number of pan-EU trials for paediatric and rare cancers.²⁰⁰

72. The UK has been an influential part of the development of clinical trials in the EU, both through industry and Government leadership. Most recently, the UK has played a leading role in developing a successor to the current Clinical Trials Directive (2001/20/EC), the forthcoming EU Clinical Trial Regulation (536/2014), that will create a harmonised and highly integrated system for registering and approving clinical trials in 2019.²⁰¹ As new legislation, the EU Clinical Trial Regulation is not expected by industry to be in force before the withdrawal date, meaning it would not be transposed by the European Union (Withdrawal) Bill.²⁰² As a result, there is a need for a decision as part of the negotiations on whether the UK follows the new regulation and whether we will be able to access the collaborative portals that will enable the registration of trials and sharing of results. There is strong support from industry for this continued access and for collaboration,

196 Prime Minister's Office, [PM speech on our future economic partnership with the European Union](#), 2 March 2018

197 House of Commons Library, [Debate Pack: Implications of the Accelerated Access review on cystic fibrosis and other conditions](#), Number 2016/0242, 9 November 2016

198 [Q46](#) [Mr Thompson]

199 [Q46](#) [Mr Thompson]; American Pharmaceutical Group [BRP0010](#); The Association of the British Pharmaceutical Industry and the Bio-Industry Association [BRP0001](#); AstraZeneca [BRP0019](#); Johnson & Johnson, [BRP0015](#); Lilly [BRP0013](#); Roche [BRP0004](#)

200 KPMG, [NIHR Clinical Research Network: Impact and Value Assessment](#), (September 2016), p3; APPG on Brain Tumours [BRP0021](#); Cancer Research UK [BRP0020](#)

201 Cancer Research UK [BRP0020](#); Lilly [BRP0013](#)

202 European Commission, [Clinical trials - Regulation EU No 536/2014](#), (accessed 17 April 2018)

and we agree that it would benefit industry and patients in the UK and the EU to retain the closest possible collaboration on safe, effective and influential clinical trials.²⁰³ ***In negotiating its post-Brexit relationship with the EU, the Government should ensure that UK pharmaceutical companies can conduct effective clinical trials through continued cooperation with European institutions and with mutual recognition of results.***

9 Conclusion

73. The pharmaceutical sector in the UK is primarily a mix of UK, EU and USA-headquartered companies and one of the most productive and successful sectors in the economy. As part of the wider life sciences industry, the sector has enjoyed support from successive governments who have recognised its importance to society and the economy. The UK's pharmaceutical sector is heavily integrated into the European market, not least with a significant and influential role in an established and respected regulatory system. Although the UK has a disproportionately large role in regulation and in research and development for European medicines, the size of the European market heavily outweighs that of the UK. As a result, manufacturers are unlikely to prioritise the UK over the EU as a market, and UK manufacturers are already spending tens of millions in contingency planning to access EU markets because of uncertainty. **The UK must seek the closest possible regulatory cooperation and the minimum border friction possible to ensure the continued success of the industry. The European Commission has a responsibility to set out their position, to ensure there is no fragmentation of a closely integrated industry that is working to the benefit of patients across Europe.**

74. We sought out any potential benefits to the UK pharmaceutical sector from Brexit, but found that any small gains would be hugely outweighed by additional costs or the loss of access to existing, successful markets. **The potential for speedier approval of medicines is outweighed by the risk of no access at all to other products. The potential for weaker intellectual property regulation is outweighed by a potential loss of investment in the UK. The potential for stronger intellectual property protection is outweighed by the potentially huge costs for the NHS and harm to the generic pharmaceuticals sector. The potential for change to how we conduct clinical trials is outweighed by the loss of access to huge number of participants across Europe. The potential for new, untapped markets simply does not exist in an already global sector in which the UK is highly engaged. The best potential approach we found for the UK to grow as a world leader in the development, manufacture and regulation of pharmaceuticals is to maintain as close a relationship with the EU as possible.**

75. We found no-one involved at a senior level in the sector who was prepared to make a positive case for Brexit for pharmaceuticals. The sector has nonetheless been engaged and realistic since the decision to leave the EU was taken. They have made coherent proposals for the sustainability of an important and influential UK sector, many of which we have echoed in this report. **We welcome the positive engagement demonstrated to date from both the Secretary of State for Business, Energy and Industrial Strategy and the Secretary of State for Health and Social Care, and their departmental Ministers. In her Mansion House speech, the Prime Minister set out a positive and compelling case for continued cooperation between the UK and EU on medicines. The Government must now translate words into actions that protect the UK's status as a world leader for pharmaceuticals.**

Conclusions and recommendations

Introduction

1. We welcome the Government's positive, collaborative approach so far, and trust it will continue as negotiations progress. The Government must continue to seek to preserve and build upon the success of the UK pharmaceutical sector, and the effective collaboration between industry and Government, as it undertakes negotiations on future trading arrangements with the EU. (Paragraph 6)

Tariff barriers

2. The World Trade Organisation's Pharmaceutical Tariff Elimination Agreement means that relying on WTO rules in the event of a 'no deal' scenario would not have as significant impact on the pharmaceutical sector as for other sectors that Committee has considered. However, there are still significant concerns that it could injure the UK's position as a manufacturing base, a global supply hub and as a manufacturer and recipient of new and innovative medicines. *The Government should pursue a trade agreement with the European Union, and with other trading partners, that includes all finished and component pharmaceutical products, and is not limited to those currently listed under WTO rules.* (Paragraph 16)
3. The extended delay in adding new pharmaceutical products and ingredients to the World Trade Organisation listing is already harming global access to medicines and offers no benefit to the industry or nations. It is for World Trade Organisation negotiations rather than Brexit negotiations to resolve this; however, falling back onto WTO rules could mean harmful tariffs for new and innovative medicines and components being traded between the UK and EU. *As a global leader in the pharmaceutical industry, the Government should work internationally to ensure that the WTO updates the list of pharmaceuticals and components covered by the Pharmaceutical Tariff Elimination Agreement.* (Paragraph 17)

Non-tariff barriers

4. Burdensome customs procedures would diminish the highly productive nature of the pharmaceutical industry, act as a disincentive for further investment for manufacturing facilities in the UK, and diminish access to medicines for patients in the UK and the EU. *We support the Government in seeking as frictionless a border as possible; they must prioritise the absolute minimum additional costs and bureaucracy for the pharmaceutical sector.* (Paragraph 27)
5. *The Government should ensure that, in addition to achieving as frictionless border as possible to protect the competitiveness of British pharmaceutical businesses, arrangements are put in place to ensure the cross-border transfer of short-life pharmaceutical products for emergency treatments and public health cases, in the mutual interest to patients in the UK and the EU.* (Paragraph 28)

Regulatory alignment

6. We welcome and support the Government's recognition of the benefits to the UK and EU of our continued membership of the EMA to ensure the UK and the EU can access the fullest possible range of new and innovative medicines and support the UK pharmaceutical sector accessing this market. (Paragraph 36)
7. What little benefits there may be of regulatory divergence would be greatly overshadowed by the costs and loss of markets and influence the UK would face. It makes commercial sense for the UK to remain aligned with standards in the EU market, given the significant amount of trade it provides for both the UK and EU and the access it gives both to medicines. *The Government should pursue this approach.* (Paragraph 42)
8. The success of EU-wide regulation of manufacturing and regulation of testing and release of medicines, with the Medicines and Healthcare products Regulatory Agency an integral and influential part, means the Government should prioritise a form of membership with the European Medicines Agency that maintains cooperation and does not require replication of manufacturing sites, testing or roles. The Government has set out its desire for continued cooperation and a form of Membership. *The Government should as a priority now seek from the European Commission an explanation as to the Commission's approach.* (Paragraph 46)
9. *We recommend that the Government continues to take a pragmatic approach in relation to any potential continuing ECJ role in the pharmaceutical sector.* (Paragraph 48)
10. While it is necessary for the European Medicines Agency to move its headquarters to a Member State once the UK leaves the EU, there is a beneficial case for both the UK and EU for the EMA to retain a residual staff in the UK to support a continued relationship between the UK's influential Medicines and Healthcare products Regulatory Agency and the EMA, and to support EMA employees who do not wish to leave the UK. *We recommend that as part of a new association with the EMA, the Government should seek to retain a presence for EMA jobs and facilities in the UK where it would benefit the operation of the EMA and the MHRA, supporting UK businesses to continue to access the European market and European businesses to access the UK market.* (Paragraph 50)

Transitional arrangements

11. The agreement of a 21-month transition period as the UK leaves the UK is less than the minimum amount of time we were told is required to avoid serious issues for some businesses. It is, however, a positive step in so far as it provides business with some certainty. *The UK Government must, alongside the European Commission, now ensure a speedy decision is taken on the new relationship for the UK and the EMA, early enough to minimise unnecessary contingency planning costs currently being borne by the pharmaceutical sector.* (Paragraph 53)

Trade opportunities post-Brexit

12. For the UK to continue to be one of the major global hubs for pharmaceutical innovation, it is cooperation as part of regional and global networks to develop new and innovative medicines which is likely to bring continued success. As most manufacturers are multinational with regional supply chains, any trade deals are unlikely to lead directly to a substantial increase in investment and jobs in the UK. *Given that the EU represents 44 per cent of the UK's pharmaceutical exports and 73 per cent of imports, the Government should prioritise continued friction-free access to the EU market and the roll-over of existing free trade agreements over securing new third country agreements.* (Paragraph 57)
13. The UK and EU have an intellectual property regime that effectively supports both innovation and access to medicines. Any unilateral changes to this as the UK leaves the EU would risk either the UK's attractiveness as a base for research and development or the ability of the National Health Service to access the full range of medicines its needs. *The Government should ensure that any trade deals struck as we leave the EU do not cause us to diverge from current intellectual property rules.* (Paragraph 61)

Skills

14. *In the short term, the Government should ensure that the industry can continue to have immediate access to the skills it needs, including through effective circulation of staff from around the world to meet skills shortages and to support personal and corporate development.* (Paragraph 66)
15. Skills shortages are already a problem in the pharmaceutical industry and could increase depending on the post-Brexit immigration approach as well as any changes to pharmaceutical regulation. *The Government must continue to work with the industry to meet its skills gap and increase the number of UK nationals working in the sector for the long term.* (Paragraph 67)

Research and development

16. The Government commitment to underwriting Horizon 2020 funding and to seek continued engagement is welcome. *As part of its Industrial Strategy and a commitment to take R&D spending to the OECD average, the Government should provide certainty to businesses and research institutions by setting out its approach to R&D collaboration, including whether it will seek an association agreement with the successor to Horizon 2020.* (Paragraph 70)
17. *In negotiating its post-Brexit relationship with the EU, the Government should ensure that UK pharmaceutical companies can conduct effective clinical trials through continued cooperation with European institutions and with mutual recognition of results.* (Paragraph 72)

Conclusion

18. The pharmaceutical sector in the UK is primarily a mix of UK, EU and USA-headquartered companies and one of the most productive and successful sectors in the economy. As part of the wider life sciences industry, the sector has enjoyed support from successive governments who have recognised its importance to society and the economy. The UK's pharmaceutical sector is heavily integrated into the European market, not least with a significant and influential role in an established and respected regulatory system. Although the UK has a disproportionately large role in regulation and in research and development for European medicines, the size of the European market heavily outweighs that of the UK. As a result, manufacturers are unlikely to prioritise the UK over the EU as a market, and UK manufacturers are already spending tens of millions in contingency planning to access EU markets because of uncertainty. The UK must seek the closest possible regulatory cooperation and the minimum border friction possible to ensure the continued success of the industry. The European Commission has a responsibility to set out their position, to ensure there is no fragmentation of a closely integrated industry that is working to the benefit of patients across Europe. (Paragraph 73)
19. We sought out any potential benefits to the UK pharmaceutical sector from Brexit, but found that any small gains would be hugely outweighed by additional costs or the loss of access to existing, successful markets. The potential for speedier approval of medicines is outweighed by the risk of no access at all to other products. The potential for weaker intellectual property regulation is outweighed by a potential loss of investment in the UK. The potential for stronger intellectual property protection is outweighed by the potentially huge costs for the NHS and harm to the generic pharmaceuticals sector. The potential for change to how we conduct clinical trials is outweighed by the loss of access to huge number of participants across Europe. The potential for new, untapped markets simply does not exist in an already global sector in which the UK is highly engaged. The best potential approach we found for the UK to grow as a world leader in the development, manufacture and regulation of pharmaceuticals is to maintain as close a relationship with the EU as possible. (Paragraph 74)
20. We found no-one involved at a senior level in the sector who was prepared to make a positive case for Brexit for pharmaceuticals. The sector has nonetheless been engaged and realistic since the decision to leave the EU was taken. They have made coherent proposals for the sustainability of an important and influential UK sector, many of which we have echoed in this report. We welcome the positive engagement demonstrated to date from both the Secretary of State for Business, Energy and Industrial Strategy and the Secretary of State for Health and Social Care, and their departmental Ministers. In her Mansion House speech, the Prime Minister set out a positive and compelling case for continued cooperation between the UK and EU on medicines. The Government must now translate words into actions that protect the UK's status as a world leader for pharmaceuticals. (Paragraph 75)

Formal minutes

Tuesday 8 May 2018

Members present:

Rachel Reeves, in the Chair

Vernon Coaker Stephen Kerr

Draft Report (*The impact of Brexit on the pharmaceutical sector*), proposed by the Chair, brought up and read.

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

Paragraphs 1 to 75 read and agreed to.

Summary agreed to.

Resolved, That the Report be the Ninth 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 Wednesday 9 May at 9.00 am

Witnesses

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

Tuesday 5 December 2017

Question number

Mike Thompson, Chief Executive, Association of the British Pharmaceutical Industry; **John Smith**, Chief Executive, Propriety Association of Great Britain; **Paul Fleming**, Technical Director, British Generic Manufacturers Association [Q1–63](#)

Mark Hicken, Managing Director, UK & Ireland for Janssen, Pharmaceutical Companies of Johnson & Johnson; **Peter Ballard**, Managing Director, Xiromed [Q64–136](#)

Published written evidence

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

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

- 1 American Pharmaceutical Group ([BRP0010](#))
- 2 APPG on Brain Tumours ([BRP0021](#))
- 3 Association of British Healthcare Industries ([BRP0011](#))
- 4 AstraZeneca ([BRP0019](#))
- 5 British Generic Manufacturers Association (BGMA) ([BRP0008](#))
- 6 British Medical Association ([BRP0002](#))
- 7 British Specialist Nutrition Association ([BRP0006](#))
- 8 Cancer Research UK ([BRP0020](#))
- 9 Department for Business, Energy and Industrial Strategy ([BRP0018](#))
- 10 GMB ([BRP0016](#))
- 11 Johnson & Johnson ([BRP0015](#))
- 12 Lilly UK ([BRP0013](#))
- 13 Merck ([BRP0005](#))
- 14 MSD ([BRP0009](#))
- 15 PAGB ([BRP0007](#))
- 16 Roche ([BRP0004](#))
- 17 STOPAIDS ([BRP0014](#))
- 18 The Association of the British Pharmaceutical Industry and the Bio-Industry Association ([BRP0001](#))
- 19 The Royal Society ([BRP0003](#))
- 20 Union of Shop, Distributive and Allied Workers (Usdaw) ([BRP0012](#))
- 21 Unite the Union ([BRP0017](#))

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	A framework for modern employment	HC 352
Second Report	Leaving the EU: implications for the civil nuclear sector	HC 378
Third Report	The safety of Electrical Goods in the UK	HC 503
Fourth Report	Pre-legislative scrutiny of the draft Domestic Gas and Electricity (Tariff Cap) Bill	HC 517
Fifth Report	The impact of Brexit on the automotive sector	HC 379
Sixth Report	The impact of Brexit on the aerospace sector	HC 380
Seventh Report	The impact of Brexit on the processed food and drink sector	HC 381
Eighth Report	Pre-appointment hearing with the Government's preferred candidate for Chair of the Competition and Markets Authority	HC 985
First Special Report	Industrial Strategy: First Review: Government Response to the Committee's Second Report of Session 2016–17	HC 337
Second Special Report	Corporate governance: Government Response to the Committee's Third Report of Session 2016–17	HC 338
Third Special Report	Apprenticeships: Government Response to the Second Joint Report of Session 2016–17	HC 450
Fourth Special Report	Leaving the EU: negotiation priorities for energy and climate change policy: Government Response to the Committee's Fourth Report of Session 2016–17	HC 550
Fifth Special Report	Pre-legislative scrutiny of the draft Domestic Gas and Electricity (Tariff Cap) Bill: Government Response to the Committee's Fourth Report	HC 865
Sixth Special Report	Leaving the EU: implications for the civil nuclear sector: Government response to the Committee's Second Report	HC 881
Seventh Special Report	The safety of Electrical Goods in the UK: Government Response to the Committee's Third Report	HC 920

Eighth Special Report	A framework for modern employment: Government response to the Second Report of the Work and Pensions Committee and First Report of the Business, Energy and Industrial Strategy Committee of Session 2017–19	HC 966
Ninth Special Report	The impact of Brexit on the automotive sector: Government Response to the Committee’s Fifth Report	HC 1018