House of Commons

Business, Energy and Industrial Strategy Committee

The impact of Brexit on the pharmaceutical sector: Government Response to the Committee's Ninth Report

Eleventh Special Report of Session 2017–19

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Business, Energy and Industrial Strategy Committee

The Business, Energy and Industrial Strategy Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department for Business, Energy and Industrial Strategy.

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

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Committee staff

The current staff of the Committee are Chris Shaw (Clerk), Ben Sneddon (Second Clerk), Jeanne Delebarre (Senior Clerk), Ian Cruse and Becky Mawhood (Committee Specialists), James McQuade (Senior Committee Assistant), and Gary Calder (Media Officer).

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Eleventh Special Report

On 17 May 2018, the Business, Energy and Industrial Strategy Committee published its Ninth Report of Session 2017–19, on the impact of Brexit on the pharmaceutical sector. The response from the Government was received on 9 July 2018. The response is appended below.

In the Government response, the Committee's conclusions and recommendations appear in **bold text** and the Government's responses are in plain text.

Appendix: Government Response

The Department for Business, Energy and Industrial Strategy welcomes the report of the House of Commons Business, Energy and Industrial Strategy on 'the impact of Brexit on the pharmaceutical sector'.

The UK has one of the strongest and most productive life sciences sectors in the world. Generating turnover of around £70.3bn per annum and ranking top in major European economies for health life sciences foreign investment, with a focus on R&D and innovation. This success permeates throughout the UK with a significant regional presence in the North-West, East of England and Wales. The "Golden Triangle" between Cambridge, Oxford and London is a recognised global hub for life sciences with four of the top ten global biomedical research universities. In addition, the UK has some world-class research facilities in Scotland, including the Dundee College of Life Sciences which is one of the largest and most productive research institutes in Europe.

As we exit the EU, the Government has made clear that continued cooperation is in the best interests of UK and EU patients. By continuing to work together we can ensure quality, safety and efficacy of medicines and patients in every corner of the UK and EU are safer as a result of collaboration. There are few benefits to UK and EU patients in tearing up the sort of close working arrangements which get crucial drugs on the market as fast as possible, shares early alerts about problems with medicines, medical devices, or allows patients to benefit from new scientific discoveries earlier.

We are pleased to have agreed an Implementation Period. This agreement sets out that during the Implementation Period common rules will remain in place, meaning businesses will be able to trade on the same terms as now up until the end of 2020. Life Sciences firms will be able to continue UK batch testing, release and inspections; and Marketing Authorisation Holders (MAH) and other key roles can continue to be based in the UK. We now need to finalise this Withdrawal Agreement as a whole and we plan to do this by October, alongside the framework for the future partnership.

We want the broadest and deepest possible future partnership with the EU covering more sectors and co-operating more fully than any Free Trade Agreement anywhere in the world today. The Prime Minister set out our desire for Goods to ensure that products only need to undergo one series of approvals in one country, and also set out that the UK will explore with the EU the terms on which the UK could remain part of EU agencies, including the European Medicines Agency. We want to maintain our commitment to free trade and high standards. For goods, including medicines and medical devices, we believe the border should be as frictionless as possible.

We are committed to continuing a close working relationship with the European Medicines Agency to ensure patients continue to have timely access to safe medicines and medical innovations.

The views and recommendations expressed in the Committee's report are in many cases aligned to our approach to negotiations which places emphasis on a continued pragmatic approach to issues of trade and regulation. The remainder of this document sets out the Government response to the individual recommendations made in the report.

Recommendation Responses

Tariff Barriers

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. **Recommendation 1: 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)**

Response: The Government is seeking the broadest and deepest possible partnership with the EU following exit. The Government is keen to use this as the opportunity to build stronger trading relationships around the world and to negotiate new trade agreements. We want to maximise the ability for UK companies to trade in the EU and vice versa, so are looking for a deal that goes beyond WTO rules.

The Government's objective is to ensure that the whole of the UK can take full advantage of the opportunities that trade offers and trade and investment is a core tenet of the Government's industrial strategy. We have committed to building a global economy that works for everyone and to ensure that the benefits of trade deliver wealth and opportunity across the country. The Life Sciences Industrial Strategy was a sector-led vision to promote the best outcomes for the life sciences sector. As a response to this strategy the Government and the life sciences sector agreed and published a transformative Sector Deal in August 2017, supporting the ambition to ensure the UK continues to be the global hub for clinical research and medical innovation. The Government will continue to work closely with industry to implement this deal and ensure we deliver a trade policy that works for the sector.

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. **Recommendation 2: 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)**

Response: Our vision is for the broadest and deepest possible future partnership with the EU, covering more sectors and co-operating more fully than any Free Trade Agreement anywhere in the world today. We believe this is achievable because it is in the EU's interests as well ours.

We recognise that the UK life sciences sector is concerned that the annex to the WTO Pharmaceutical Tariff Elimination Agreement has not been updated. The Government champions free trade, including in pharmaceutical products and their components. Our objective is to develop an ambitious agenda at the WTO once we have left the EU. We will continue to work closely with the life sciences sector to develop this agenda, and to pursue the most appropriate policy tools available to us to deliver the best possible outcomes for the sector.

Non-Tariff Barriers

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.
Recommendation 3: 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)

Response: We welcome the Committee's view of negotiating as frictionless a border as possible between the UK and the EU following exit. The Government recognises the importance of minimising friction and additional burden at the border to all sectors, including the life sciences sector. The Government remains committed to achieving this ambition in our ongoing negotiations with the EU.

The Government set out two options for a customs arrangement in the policy paper 'Future customs arrangements – a future partnership paper'. Both options will allow the Government to seek as free and frictionless trade as possible, in goods between the UK and the EU, and allow the UK to forge new trading relationships with partners around the world. How post-EU exit customs arrangements will work remains dependent on the outcome of UK-EU negotiations. We are planning for various options that may be presented by the outcome of these negotiations. However, the UK will protect public health and the safe, timely trade of treatments between this country and the EU.

Recommendation 4: 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)

Response: We recognise the importance of a border that's as frictionless as possible, particularly for patients, as medical products with a short shelf-life can become unusable if delayed. The Department for Health and Social Care is continuing to progress work to assess the impact of EU exit on the supply chains for all medical products used in the NHS, including those with a short-shelf life. Our objective is to ensure the continuity of

medicine supply and patient safety following EU exit. This analysis, along with input from industry and clinical stakeholders will help to inform any contingency planning required to ensure supply of all products, including those with a short shelf-life.

Regulatory Alignment

Recommednations 5 and 6: ***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)** ***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)**

Response: We welcome the Committee's view on the positive impact the MHRA has had on the regulatory landscape with the EU. The Government has made clear that continued cooperation is in the best interests of EU and UK patients and the Prime Minister was clear that this involves making sure our regulators continue to work together, as they do with regulators internationally. Beyond that, the Government would like to explore the terms on which the UK could remain part of the European Medicines Agency.

The Government has also set out the ambition to agree a comprehensive system of mutual recognition for the trade of goods between the EU and UK, including medicines and medical devices. This approach would ensure that, as now, products only need to undergo one series of approvals, in one country, to show that they meet the required regulatory standards. We cannot pre-judge the outcome of the negotiations, however we have been clear that our driving principles for negotiation are to ensure that patients are not disadvantaged; products should be able to get onto the market as quickly and simply as possible and that the UK should continue to play a leading role in promoting public health. Patients must have confidence that their safety is protected through the strongest regulatory framework and continued sharing of data.

Recommendation 7: 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)

Response: The Prime Minister has stated that EU law and the decisions of the ECJ will continue to affect the UK even after we have left the jurisdiction of the European Court of Justice. More specifically, if the UK does continue to participate in any EU agency, the UK would have to abide by the rules of those agencies. But just as importantly – the UK Parliament would remain ultimately sovereign. It could decide not to accept these rules, but with consequences for our membership of the relevant agency and linked market access rights.

Recommendation 8: ***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)**

Response: Now and throughout the Implementation Period the MHRA will continue to play an active and collaborative role with the EMA and other European regulators. As the Prime Minister said in the Mansion House Speech the Government would like to explore with the EU terms on which the UK could remain part of the EMA. However, the UK life sciences sector is not just built on the location of the EMA. The UK has a world class research base, universities and businesses that mean the UK life sciences sector will continue to thrive, and the Government has been consistent in saying that a key priority through the negotiations is to ensure that the UK remains one of the best places in the world for science and innovation.

Transition Arrangements

Recommendation 9: ***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)**

Response: Continued cooperation is in the best interests of EU and UK patients. We want to retain a close working partnership with the EU to ensure patients continue to have timely access to safe medicines and medical innovations. Beyond that, the UK would like to explore the terms on which the UK could remain part of the European Medicines Agency. The Prime Minister also set out our desire to ensure that products only need to undergo one series of approvals in one country with her highlighting that this would be essential in continuing to get new drugs and devices to patients quickly.

Trade opportunities post-Brexit

Recommendation 10: ***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)

Response: The Government's priorities on trade are guided by its commitment to keep trade with the EU as frictionless as possible and to establish an independent international trade policy.

Therefore, the Government is pursuing a bold and ambitious free trade agreement with the European Union that allows for the freest possible trade in goods and services between the UK and the EU's member states, whilst forging new trade relationships with our partners around the world. The UK and EU have agreed that we will be able to negotiate, sign and ratify new trade agreements during the Implementation Period, to enter into force after the conclusion of the Implementation Period. Our priority for new trade deals is to be in a position to begin formal negotiations with key partners immediately after we leave the EU, and to then make progress towards substantive deals during the Implementation Period, ensuring such deals work for the whole of the UK.

The Government is also committed to ensuring continuity of its international agreements with third countries as we leave the European Union. We reached agreement with the EU at March European Council that the UK is to be treated as a Member State for the purposes of international agreements, including trade agreements, for the duration of the implementation period. The EU will notify other parties of this approach. This provides certainty and confidence that there will be no disruption to existing relationships underpinned by international agreements as we move into the Implementation Period. It will also ensure an orderly transition. We are also engaging with partner countries to ensure continuity of existing arrangements beyond the Implementation Period.

Recommendation 11: ***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)**

Response: The UK's intellectual property regime is consistently rated as one of the best in the world. As we leave the EU, in line with our WTO commitments, the Government will continue to maintain our high level of protections of intellectual property. The Industrial Strategy recognises the importance of intellectual property and the Government is determined that the UK continues to properly support innovation and business, including the pharmaceutical industry.

The UK has long been, and remains, a strong supporter of an open, rules-based international trading system. The WTO's agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) sets out the minimum standards for trade and intellectual property across all WTO member nations. As the UK updates the terms of its WTO membership, we will also be making sure that we remain compliant with the TRIPS agreement. Where appropriate, UK intellectual property trade policy will further build on TRIPS to maximise trade and investment opportunities in our future trade agreements with global partners.

As we develop our trading relationships with other countries getting the right outcome for UK inventors, creators, consumers, and public services, will be key. Our approach to developing our future trade policy must be flexible, transparent and inclusive, and we will be working closely with a wide range of stakeholders to develop our priorities around trade and intellectual property, including Devolved Administrations, industry and consumers.

Skills

Recommendation 12: 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)

Response: The Government acknowledges the international nature of scientific endeavour and values the vital contribution of workers and international collaboration to the success of the UK pharmaceutical sector. In light of our exit from the EU, we remain committed to ensuring that the UK pharmaceutical sector has the opportunity to become more global and continues to have access to the best global scientific talent.

To ensure that the UK continues to protect skills we are ensuring that the sector (and wider economy) has access to the best scientists and researchers worldwide. We have increased the number of Tier 1 Exceptional Talent visas available annually from 1000 to 2000 and streamlined the endorsement process, reducing time and paperwork commitments for applicants. The Government recognises that ensuring access to global talent is a priority for the sector and pharmaceuticals companies have been invited to make their views known to the Migration Advisory Committee (MAC). The MAC will be reporting in September and the Government will take account of their advice when making any final decisions about our future immigration system, which would not be implemented until 2021.

Recommendation 13: *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)

Response: The Government recognises the importance of growing the number of people with suitable science, technology, engineering and mathematics (STEM) skills, and is committed to growing these skills to deliver a dynamic economy as set out in the Industrial Strategy. This includes developing the skills young people need for careers in sectors such as the pharmaceutical sector. As such, we committed £406m in the 2017 Autumn Budget to improve skills, particularly STEM skills.

The Government is committed to raising both the standard of and pupil participation in STEM education, at all stages of the education pipeline. There are a number of existing programmes specifically addressing skills in the sciences at school level. One such project, project Enthuse, jointly funded with the Wellcome Trust and industry partners provides bursaries for science teachers to attend a CPD course at the National STEM Learning Centre in York, which together with the Science Learning Partnerships forms the National

STEM Learning Network. To improve the development of technical STEM skills, 3 of the 15 technical routes will focus on core STEM occupations, of which Health and Science is one.

We will bring forward proposals for our future immigration system in due course.

Research and Development

Recommendation 14: *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)

Response: Life Science, research and innovation are vital to our country's prosperity, security and wellbeing, and are at the heart of our Industrial Strategy. In particular the UK's excellence in life sciences means better outcomes for patients and the important work being done by our researchers, universities and innovative businesses must continue.

The UK recognises the need to provide certainty to all stakeholders wherever possible. To this end, the Withdrawal Agreement ensures that UK entities' right to participate in EU science and innovation programmes, including Horizon 2020, will be unaffected by the UK's withdrawal from the EU for the lifetime of projects financed by the current MFF.

With respect to the future relationship with the EU, the UK has been clear in its desire for continued collaboration on science, research and innovation. To this end, the Prime Minister set out in her speech on science and modern Industrial Strategy that the UK would like the option to fully associate to the excellence-based European science and innovation programmes including the successor to Horizon 2020.

To further inform the development of the future framework, the Government published its 'Framework for the UK-EU partnership: Science, research and innovation' on 23 May, setting out proposals for a far-reaching Science and Innovation Pact with the EU.

Recommendation 15: 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)

Response: The new Clinical Trials Regulation, agreed in 2014, is a major step forward. It will enable a streamlined application process, harmonised assessment procedure, single portal for all EU clinical trials and simplified reporting procedures, including for multi-Member State trials. The UK has been involved in developing the new regulation and this has been widely welcomed by the research sector, including medical research charities and industry.

The timing of the application date of the new regulation is yet to be determined by the European Commission. The current regulatory approval legislation will stay in place until such time as any changes are needed so there will be no interruption in UK clinical trials approval.

If the Clinical Trials Regulation comes into force during the Implementation Period, as it is currently expected to in March 2020, then it will apply to the UK. The Withdrawal Agreement and Implementation Bill will give effect to the Implementation Period in domestic law and will allow regulations to continue to apply in the UK for this time-limited period.

If this opportunity does not come to pass, we will give high priority to taking steps necessary to bring into UK law, without delay, all relevant parts of the EU regulation that are within the UK's control, so that those planning clinical research can do so with certainty. The two key elements of the regulation that are outside of the UK's control, and this does not therefore cover, are (i) the use of a shared central IT portal and (ii) participation in the single assessment model, both of which require a negotiated UK/EU agreement regarding UK involvement post-Brexit.

We cannot pre-empt these negotiations, nor can we disadvantage the UK's position in these negotiations by giving any further guarantees at this time. The Government has always been clear on its preference for close cooperation across all aspects of medicines regulations, as it is in the interest of both patients and the life sciences sector.