Brexit: medicines, medical devices and substances of human origin: Government response to the Health and Social Care Committee's Fourth Report of Session 2017-19

Cm 9620

Brexit: medicines, medical devices and substances of human origin: Government response to the Health and Social Care Committee's Fourth Report of Session 2017-19

Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

May 2018

Cm 9620

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to us at:
Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU

ISBN 978-1-5286-0426-0

CCS0518675688 05/18

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

Government response to the recommendations of the Health and Social Care Committee's inquiry into Brexit: medicines, medical devices and substances of human origin

Fourth report of session 2017-19

INTRODUCTION

On 21 March 2018, the House of Commons Health and Social Care Select Committee published its report *Brexit: medicines, medical devices and substances of human origin.* The report included 34 conclusions and recommendations, and responses to each of these are provided in this report.

The Committee launched this inquiry to examine the regulatory arrangements needed to guarantee safe and effective supply of medicines, medical devices and products after the UK exits the EU. The Committee received over 80 pieces of written evidence from Government, as well as a broad range of organisations across the health and social care sector and pharmaceutical industry.

We welcome the Committee's report, and the important attention it brings to the issues facing the regulatory system and life sciences industry in the UK.

The Government is committed to a smooth and orderly withdrawal from the EU and recognises the importance of a close and cooperative relationship between the UK and EU in the field of medicines regulation and science and research collaboration. The Department of Health and Social Care (DHSC or "the Department") is supporting the Department for Exiting the European Union (DExEU) in negotiations with the EU with the aim of moving swiftly to the substantive discussions on our future relationship.

The Department is also working closely with its Arm's Length Bodies and other government departments to ensure robust preparations are in place for any EU exit scenario. We are clear that should we be unable to achieve our desired relationship with the EU, we will establish a regulatory system that continues to protect the interests of patients and strengthens the UK life sciences industry.

GOVERNMENT RESPONSE TO CONCLUSIONS AND RECOMMENDATIONS

Our work

1. We will be evaluating the Government's response to our letter seeking clarity about the details of a transition period and contingency planning in the event of 'no deal' and expect this to be included within the response to this report. (Paragraph 4)

The UK and EU negotiating teams have reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. During the implementation period, the UK will no longer be a Member State of the EU, but market access will continue on current terms.

To give businesses and citizens certainty, common rules will remain in place until the end of the period meaning businesses will be able to trade on the same terms as now up until the end of 2020.The agreement will be underpinned by a duty of good faith and governed by a Joint Committee to ensure the agreement is faithfully and fully implemented by both sides.

The Government has been clear on the outcome it wants to achieve for the longer term, which is to secure a strong deal and future relationship with the EU. We have always been confident that we will achieve this, and a good deal is now clearer and closer than ever. Of course, as a responsible Government we continue to plan for all scenarios, but it would not be appropriate to publish anything that would risk undermining our negotiating position. Indeed, the House of Commons voted not to disclose material that could damage the United Kingdom's position in its negotiations with the EU.

Some contingency plans have sufficiently long lead times that we need to begin now for them to remain viable, even though we hope not to need all their provisions once we have achieved a deal with the EU. We are increasingly confident that a 'no deal' scenario in March 2019 is significantly less likely.

2. We recommend that the Department of Health and Social Care produce a comprehensive list of all the issues relating to the supply of medicines, medical devices and substances of human origin which require contingency planning for the UK leaving the EU. We expect to see evidence that plans are in place to address identified risks to patients. (Paragraph 6)

In our December 2017 response to the previous Health Committee report entitled *"Brexit and health and social care – people & process"*, we were able to assure the Committee that DHSC was working to ensure the best outcome for the health and social care system. This was, is, and will continue to be, the priority for this Department throughout the process of the UK exit's from the EU and beyond.

As the Secretary of State set out in his letter to the committee in February 2018, a responsible government should prepare for all potential outcomes, including the unlikely scenario in which no mutually satisfactory agreement can be reached. To that end, teams within DHSC are progressing work to assess the impact of exiting the EU on the supply chain for all medicines and medical devices used in the NHS. A cross-Government steering group, which includes all the relevant organisations including the Medicines and Healthcare products Regulatory Agency (MHRA), NHS England (NHSE) and Public Health England (PHE), has been established to oversee and contribute to this work. Ernst and Young (EY) have been appointed to carry out this work and we expect the initial phase to be concluded in late spring 2018. DHSC will continue to engage closely with industry and other relevant stakeholders throughout this process, and the foreseeable future, to ensure that any potential mitigation required for the continuity of medicine and medical device supply for UK patients is planned in close collaboration with our industry stakeholders.

With respect to ensuring the safe supply of blood, tissues and organs, contingency planning is also underway in this area so that Government can make the necessary changes to national regulations to guarantee day one operability under any exit scenario and to support licensed establishments to put in place appropriate agreements for continued import and export, where these are necessary.

At this stage we do not have plans to publish a comprehensive list of the issues relating to medicines, medical devices and substances of human origin. We will continue to be as transparent as possible, but whilst we are engaged in on-going negotiations it is vitally important that we manage information carefully in order to not disadvantage the UK's position.

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

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

We welcome the Committee's support of the Prime Minister's Mansion House speech. As she set out in that speech, the UK wants 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 UK believes that this is achievable because it is in the EU's interests as well as ours. In particular, the Prime Minister was clear that this involves ensuring our regulators continue to work together, as they do with other international regulators, highlighting that this would be essential in continuing to get new drugs to patients quickly.

The safety of patients is of paramount importance to the Government's exit negotiations for medicines, medical devices and substances of human origin and that is why the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the European Medicines Agency (EMA). Further to recent progress in the negotiations we are increasingly confident that the prospect of a "no deal" scenario is highly unlikely and therefore we are in a strong position from which to seek to agree a mutually beneficial way forward.

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

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

As the Secretary of State said in oral evidence, planning for EU exit is a crucial part of the Department's work and is a Ministerial priority. The Government is committed to ensuring leaving the EU is a success for the health and social care sector as well as the UK as a whole. This commitment is reflected in the Single Departmental Plan (SDP) which outlines the Department's role in assuring and coordinating EU exit readiness across the health and care system, and this will continue to be featured in the 2018/19 SDP.

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

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

We recognise the importance of continuing to engage and lead on setting standards for the regulation of pharmaceuticals for human use on a global basis. The UK will continue to seek opportunities to influence through collaborations such as the International Council on Harmonisation (ICH) and similar international organisations such as the Pharmaceutical Inspection and Co-operation Scheme (PICS) and the International Medical Device Regulators Forum (IMDRF). Applications to become a full member of such organisations can take some time, and work is underway to clarify the timelines involved in these processes. The form that UK membership will take will depend on the outcome of the Future Economic Partnership negotiations with the EU.

UK's position and influence in Europe

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

We welcome the Committee's support for the Government's desire to negotiate a close relationship with the EU, including exploring with the EU the terms on which the UK could remain part of the EMA.

From the start of this process we have been clear that we want to retain a close working partnership with the EU. This was reinforced by the Prime Minister in her Mansion House speech of 2nd March.

Furthermore, the recently agreed implementation period marks a positive step in maintaining a close relationship with the EU. During this time, the EU will continue to accept UK batch testing, release and inspections, UK-based Marketing Authorisation Holders (MAH) and other regulatory actions in the UK. We will also still be able to discuss issues with EU counterparts; this is important to ensure patient and public health is maintained.

It is in the interests of both UK and EU patients for the strong relationship between the MHRA and EMA to continue. The MHRA is a strong national regulator with substantial capacity and expertise to regulate and evaluate the safety of our medicines and medical devices. The Agency is recognised globally for its expertise and as a leader within the EU regulatory framework.

UK negotiating position

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

DHSC has been allocated £21.1 million for staff to support essential EU exit preparations in 2018-19. This will include ongoing work in all relevant areas of the department, such as reciprocal healthcare, ensuring that the safety of both UK and EU patients is protected. As with all reserve funding, finalised allocations will be confirmed at Supplementary Estimates 2018-19 in early 2019.

We note the Committee's recommendation on the breakdown of DHSC funding. At this stage we are not in a position to provide this finer detail but we can offer the Committee assurance that the funding will be used effectively not only towards achieving a successful exit from the EU for the life science sector but also for the broader health sector.

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

The life sciences industry is critical to the UK economy and UK health – with the sector supporting nearly 235,000 employees generating £64 billion turnover[1], it provides products which the NHS relies on to treat UK patients every day. The Government is committed to working in partnership with the sector to build on this success and realise the vision set out in Professor Sir John Bell's Life Sciences Industrial Strategy and in the Sector Deal: to ensure the UK is a top tier global hub for biomedical and clinical research, and medical innovation.

Good progress has already been made at pace on implementing the commitments in the Sector Deal. On 22nd January, a £70 million funding allocation for medicines manufacturing was announced, a significant step in delivering on the commitments to support leading-edge healthcare in the UK and speed up access to innovative medicines. On 12th March, £210 million of Industrial Strategy Challenge Funding was confirmed for the 'data to early diagnosis and precision medicine' challenge. This includes funding to build on our world-leading genomics assets and for a programme that will support industry collaboration with the NHS to help the UK lead the world in digital pathology and radiology, using Artificial Intelligence (AI) to analyse medical images.

Strong progress has also been made on the commitment in the Sector Deal to deliver on the vision of the Accelerated Access Review through the implementation of our response to the review, published in November 2017. The independently-chaired Accelerated Access Collaborative (AAC) met for the first time in January and is overseeing the development of the Accelerated Access Pathway (AAP), selecting the best innovations to take forward and monitoring their progress. The Pathway will streamline regulatory and market access decisions, in order to get breakthrough products that will be truly transformative to patients more quickly. We have also begun delivering the £86 million of funding announced in the

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/607193/strengthand-opportunity-2016-bioscience-technology-accessible.pdf

response, including launching an evidence gathering support scheme for Medtech small and medium-sized enterprises (SMEs) and the next wave of the Digital Health Technology Catalyst.

Regulatory alignment with the EU after Brexit

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

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

Response (9 and 10):

As the Prime Minister stated on 2nd March, the UK wants the broadest and deepest possible future partnership with the EU. In particular, the Prime Minister was clear that this includes enabling regulators to continue to work together, as they do with regulators internationally, highlighting that this would be essential in continuing to get new drugs to patients quickly.

On goods, including medicines and medical devices, a fundamental principle of the UK approach is that the UK-EU border should be as frictionless as possible and products should only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the EMA.

It is in both the UK and EU's interest to secure a good deal for both sides – one that ensures patients are not disadvantaged; that the UK will continue to play a leading role promoting and ensuring public health; and that industry are able to get their products into the UK and EU markets as quickly and simply as possible.

No matter what the outcome of the negotiations, on issues of patient safety and public health the UK will be, as it always has been, a willing and reliable partner for Europe. The EU has overseen a world leading medical science, research and medical technology development system and the UK has been a key partner in this. The UK life sciences ecosystem has much to offer in creating, developing, trialling and commercialising medicines that will benefit both UK and EU patients and economies, and strengthen the ability of both the UK and EU to compete internationally. So, throughout the negotiations we will work to ensure good ongoing collaboration, open-minded and pragmatic plans for all possible outcomes, and, should it be necessary, an orderly transition. But whatever the outcome of the negotiations we will continue to ensure that UK patients are able to access the best and most innovative medicines and be assured that their safety is protected.

With regard to substances of human origin, the current regulatory framework is well established and sets high quality and safety standards for patients in the UK. The Government's priority is to maintain the same high standards after the UK exits the EU. The current arrangements support the free movement of blood, blood components, organs, tissues and cells across the EU and continued collaboration and a close relationship between

the UK and EU would be of great benefit to patients. The current arrangements also allow for agreements to be made for imports and exports from third countries.

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

The Government will ensure that patients are not disadvantaged by the future regulatory regime. Should we not achieve our desired relationship with the EU, we will set up a regulatory system that continues to protect the interests of patients and strengthens the UK life sciences industry. However, our door will always be open to a deep and special relationship with the EU which remains the best way to promote improved patient outcomes both in Europe and globally.

We will also be ambitious in pursuing new opportunities, such as trading relationships globally, to ensure that medicines and medical devices developed and manufactured in the UK can be exported to all corners of the planet. We will support global initiatives like the Medical Devices Single Audit Programme, which aims to minimise duplicative regulatory inspections of individual manufacturers – which burden industry without providing any real additional value.

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

The UK is fully committed to continuing the close working relationship with our European partners and as part of our ambition for broad and dynamic cooperation, the UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety. The current regulatory framework is well established and sets high quality and safety standards for patients in the UK. Our priority is to maintain the same high standards for safety and quality after our exit from the EU.

As the Prime Minister stated on 2nd March, the UK wants the broadest and deepest possible future partnership with the EU. In particular, the Prime Minister was also clear that this includes ensuring our regulators continue to work together, as they do with regulators internationally, highlighting that this would be essential in continuing to get new drugs to patients quickly. On goods, including medicines, a fundamental principle of the UK approach is that the UK-EU border should be as frictionless as possible and products should only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the EMA.

During the implementation period, the UK will no longer be a Member State of the EU, but market access will continue on current terms. To give certainty to businesses and citizens, common rules will remain in place until the end of the period meaning businesses will be able to trade on the same terms as now up until the end of 2020. The agreement will be underpinned by a duty of good faith and governed by a Joint Committee to ensure the agreement is faithfully and fully implemented by both sides.

'No deal' risk management

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

To reiterate the Secretary of State's response to the Committee's letter of 15 February 2018, the Government has made significant progress in the negotiations in December and March and is increasingly confident that the prospect of a "no deal" scenario has receded significantly.

Despite this, we are continuing to prepare for all negotiation outcomes, including the unlikely scenario where the UK exits the EU without a deal. This includes working with businesses across the economy in order to provide the certainty that they need to plan ahead, understand and respond to both the challenges and opportunities they may face in the near future.

We will continue to be as transparent as possible, without compromising the UK's position in ongoing negotiations. It is essential that we manage information carefully to protect UK citizens and ensure the best possible outcome for them, and for UK businesses. As a result of this, we do not intend to publish our contingency plans at this stage but can assure the Committee that extensive preparations are underway across the Department.

We have always been confident that we will get a good deal and now that good deal is clearer and closer than ever. Of course as a responsible Government we continue to plan for all scenarios, but with increased confidence that we will leave with a deal and that a 'no deal' scenario in March 2019 is significantly less likely.

Batch testing, QPs and Good Manufacturing and Distribution Practices

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

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

Response (14 and 15):

During the Implementation Period, our access to one another's markets will remain unchanged and on the current terms. This means citizens and businesses in the UK and across the EU can plan with confidence for life after our withdrawal, on the basis that businesses can operate as now throughout the implementation period.

This means that during the IP the EU will continue to accept UK batch testing, release and inspections, UK-based Marketing Authorisation Holders (MAH) and other key roles in the UK including QP certification. We will also still be able to discuss issues with EU counterparts, which is important to ensure patient and public health is maintained.

We want to retain a close working partnership with the EU, in the interest of ensuring patients continue to have timely access to safe medicines and medical innovations. However, while negotiations are on-going it is important that we understand the implications of different scenarios in full. As a result, we are exploring a range of options for the future regulation of medicines and medical devices in the UK. We will discuss with the EU and Member States how best to continue cooperation in the field of medicines regulation in the best interests of business, citizens and patients in both the UK and the EU as part of the future partnership negotiations.

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

The Withdrawal Bill will preserve EU guidelines into UK law on exit day to ensure consistency for industry. During the implementation period, the UK will remain in step with the EU. This means that the current EU principles and guidelines of Good Manufacturing Practice and Good Distribution Practice will be preserved. Whilst there is no current policy intention for any divergence, it is important that the licensing authority has the power to update these principles and guidelines in the future so that they are not "frozen in time" and can be updated to reflect evolving best practice.

The UK's relationship with the EMA

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

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, and, as part of that, are committed to continuing a close working relationship with the EMA. This was reiterated by the Prime Minister in her Mansion House speech of 2nd March.

The Government recognises the importance of a close and cooperative relationship between the UK and EU in the field of medicines regulation. We are committed to engaging in these negotiations in good faith with the aim of moving swiftly to the substantive discussions for our future relationship.

We have always been confident that we will achieve a good deal, and now that good deal is clearer and closer than ever. Of course, as a responsible Government we continue to plan for all scenarios. Should we not achieve our desired relationship with the EU, we will set up a regulatory system that continues to protect the interests of patients and strengthens the UK life sciences industry. However, our door will always be open to a deep and special relationship with the EU which remains the best way to promote improved patient outcomes both in Europe and globally.

We will continue to be as transparent as possible, without compromising the UK's position in ongoing negotiations. It is essential that we manage information carefully to protect UK citizens and ensure the best possible outcome for them, and for UK businesses. As a result of this, we do not intend to publish our contingency plans at this stage but can assure the Committee that extensive preparations are underway across the Department.

Continued participation in clinical trials

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

The UK is committed to remain one of the best places in the world for science and innovation and an important element of that will be a competitive and effective framework for clinical trials. The UK is already a preferred destination for EU and global trials and we recognise that it is essential to put measures in place to minimise the burden on those who apply so that the UK remains an attractive contributor to both EU and global trials after we exit the EU.

If the CTR comes into force during the implementation period, as it is currently expected to do in March 2020, 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 priority to taking the 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.

Currently a clinical trial being conducted in multiple EU countries requires individual national approvals in each of the countries involved, according to their national laws transposed from the Clinical Trials Directive. This will remain the case following the implementation of the CTR as Members States will still individually approve clinical trials, albeit through a harmonized application process, joint assessment, and single application point.

Indeed, the UK is already taking steps to implement a more joined up system between our regulatory and ethical approval bodies which help establish clinical trials, in advance of the EU systems that will be applied under CTR. Our national system is being designed to accept the same application package and to function similarly to the future EU system under CTR, so we will have an efficient and effective approvals system for trials, regardless of the EU exit outcome. In addition, the MHRA is working closely with the NHS more widely to ensure that our whole clinical trials system, from registration through to study set up, is efficient.

Regardless of the outcome of the negotiations, the Government will ensure that after the end of the Implementation Period, our national legislation will protect the rights, safety, dignity and well-being of research participants in the UK to the same degree as research participants in other EU Member States. Our national legislation will reflect globally acceptable standards of

good clinical practice and will help us to collaborate with regulators across the world to share information about patient safety. The Government will also continue to support patients and stakeholders with their planning.

19. **We welcome the Government's aim to play a full part in new clinical trials regulations and medical devices regulations. We would like to see much more detail of what this will entail in practice, and we expect to see that detail in the Government's response to this report. (Paragraph 105)**
20. **We urge the Government to commit to adopting the new Clinical Trials Regulation into UK law following Brexit and to secure a joint statement with the EU committing to continued collaboration on clinical trials following the UK's exit from the EU. (Paragraph 106)**

Response (19 and 20):

If the CTR comes into force during the implementation period, as it is currently expected to do in March 2020, 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 priority to taking the 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 the UK's control, and therefore not covered by this guarantee or pledge, are, first, the use of a shared central IT portal and, secondly, participation in the single assessment model, both of which require a negotiated UK-EU agreement regarding UK involvement post-EU exit. We cannot pre-empt these negotiations and we do not wish to do anything that might disadvantage the negotiating position of the UK by giving any further guarantees at this time.

The EU Medical Devices Regulation will be fully applied from May 2020, during the implementation period agreed with the EU. This would not automatically follow for the new EU Regulations for in vitro diagnostic (IVD) medical devices, which does not apply until May 2022.

However, elements of both new devices regulations have been applied directly in UK law since May 2017, meaning medical devices, including IVDs, can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements.

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

UK citizens participating in on-going trials in the UK will not be affected by either the UK's exit from the EU or the end of the implementation period. This is because under both the current system (based on the EU Clinical Trials Directive) and the new system (based on the new EU CTR), trials which take place in the UK require a UK authorisation and are subject to rules enshrined in UK legislation which protect the participants. The UK rules will continue to deliver the protections afforded to trial participants by the EU which are based on internationally recognised standards.

Being an EU citizen is not a criterion for participating in a trial conducted under either the EU Directive or the new EU Regulation, so participation of UK citizens in trials taking place in the EU27 after the UK exits the UK should not be interrupted and the protections afforded under EU rules will continue to apply to those participants.

Regulatory alignment over EU rules for data protection

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

As the Prime Minister said in her Mansion House speech, achieving a deal on data protection is one of the foundations that must underpin the UK-EU trading relationship. The UK has exceptionally high standards of data protection and recognises the need for, and is one of the leading drivers of, high data protection standards across the globe. The UK's new Data Protection Bill will further strengthen UK standards, ensuring they are up to date for the modern age, and it will implement the EU's new data protection framework in our domestic law. Our data protection laws will therefore be fully aligned with the EU's at our point of exit. We want to secure an agreement with the EU that provides stability and confidence for EU and UK business, public bodies and individuals to achieve our aims in maintaining and developing the UK's strong trading, economic and security links with the EU.

The UK and EU negotiating teams have reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. The UK will no longer be a Member State of the EU, but market access will continue on current terms. To give certainty to businesses and citizens, common rules will remain in place until the end of the transition period. This will be the case for data protection.

Research and collaboration networks

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

As set out in the Prime Minister's speech on the 2 March, the UK is committed to establishing a far-reaching Science and Innovation pact with the EU, facilitating the exchange of ideas and researchers. This should enable the UK to continue to participate in key programmes alongside our EU partners.

The UK has a strong history of collaborating with European partners through EU, pan-European and other multilateral and bilateral initiatives and has been a highly active and valued participant in the Research and Innovation Framework Programmes to date. As outlined in our future partnership paper, *Collaboration on Science and Innovation*, published on 6th September 2017, the UK will seek an ambitious agreement that promotes Science and Innovation across Europe now and in the future. We would welcome a full and open discussion with the EU about all of the options for continued collaboration.

The Government recognises the UK and EU's shared interest in maintaining and strengthening research collaboration between researchers and businesses across Europe. The withdrawal agreement ensures that UK entities' right to participate in EU programmes will be unaffected by the UK's withdrawal from the EU for the lifetime of projects financed by the current Multiannual Financial Framework. This includes the eligibility of UK entities to participate in Horizon 2020 actions, including the Innovative Medicines Initiative, and apply for Horizon 2020 funding up until the end of the programme in 2020. This settlement, once agreed as part of the Withdrawal Treaty, will supersede the requirement for the domestic guarantee announced by the Government in 2016. UK organisations can continue to bid for EU funding, including that delivered through the Innovative Medicines Initiative, with the assurance that payments will continue after our departure from the EU.

Free movement of researchers

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

The Government will be considering its long-term arrangements covering the migration of EU citizens, and wants to ensure that these are based on evidence and engagement with all interested parties. The Home Secretary has commissioned the Migration Advisory Committee (MAC) to advise on the economic and social impacts of the UK's exit from the EU and also on how the UK's immigration system should be aligned with a modern industrial strategy. DHSC has responded to that call, and continues to work in close alignment with the Department for Business, Energy and Industrial Strategy (BEIS) and Office for Life Sciences to feed into the process.

We recognise that a significant number of EU nationals are vital to the country's health research landscape in universities and the NHS. These include academic clinicians working at all levels from doctoral researchers to professorial and across all research disciplines, and research support and delivery staff.

Through funding training in National Institute for Health Research, DHSC will continue to support and enable researchers and support staff to lead the way in applied clinical research. In conjunction with BEIS, DHSC are working closely with Home Office to represent the interests of the medical and health research delivery workforce in the future immigration system, to ensure continued access to, and mobility of research talent.

Research and development funding

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

As the Prime Minister set out in her speech on 2 March at Mansion House, the UK is committed to establishing a far-reaching Science and Innovation pact with the EU, facilitating the exchange of ideas and researchers. We want to assure the EU of our commitment to ongoing collaboration in Science and Innovation, and to work together on a mutually beneficial outcome. To that end, we would like to ensure Framework Programme 9 remains open to our association. We recognise that such an association would necessarily involve an appropriate financial contribution in line with other associates, and would like to discuss the details with the EU.

While we remain focussed on achieving a far-reaching Science and Innovation pact, the Prime Minister has been clear that we are preparing for every scenario, including making sure that we are ready to support the continued excellence of UK Science and Innovation if we should leave the EU without our preferred deal. As the Committee's report highlights, the UK Government's commitment to underwrite Horizon 2020 funding provides reassurance to UK businesses and universities. Through this guarantee, any successful bid submitted before the UK leaves the EU will be funded for the lifetime of the project. This ensures businesses and universities can feel confident bidding for Horizon 2020 funds while the UK remains a member of the EU.

Once we have left the EU, decisions on spending taxpayers' money will be made in the UK, based on our own domestic priorities and considering the economic environment, the fiscal position and the negotiated outcome. As the Prime Minister said in her speech at Mansion House, the UK is also committed to establishing a far-reaching science and innovation pact with the EU which could enable the UK to participate in key programmes alongside our EU partners - this will be a matter for the negotiations. Any future spending decisions will be made in the round at the next Spending Review in 2019.

Access to EU pharmacovigilance systems

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

As a leader in the area of pharmacovigilance, the UK already makes a substantial contribution to the work of the European network across this area; we are active participants in pharmacovigilance organisations, projects such as SCOPE and WEB-RADR and databases such as Eudravigilance. As such, we believe a continued close relationship will be of significant benefit to not just UK patients, but also EU patients for whom the UK makes a significant public health contribution.

Our commitment to that priority of public health and protecting patient safety is reflected in our main aims for the negotiations. As the Prime Minister said on 2nd March, the UK wants the broadest and deepest possible future partnership with the EU. In particular, the Prime Minister was also clear that this includes enabling our regulators to continue to work together, as they do with other international regulators, to continue to get new drugs to patients quickly. On goods, including medicines, a fundamental principle of the UK approach is that the UK-EU border should be as frictionless as possible and products should only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the EMA. We are seeking a comprehensive system of mutual recognition to ensure that, as now,

pharmaceutical products and medical devices only need undergo one series of approvals in one country.

In the event that the UK and EU do not agree to the most desired outcome from these negotiations, the UK's strength in the area of pharmacovigilance will enable it to continue to protect public health and support the UK life sciences industry. The MHRA is working on contingency plans for all possible scenarios with this and the current implementation period terms in mind.

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

As the Prime Minister said on 2nd March, the UK wants the broadest and deepest possible future partnership with the EU. In particular, the Prime Minister was also clear that this includes enabling our regulators to continue to work together, as they do with other international regulators, to continue to get new drugs to patients quickly. On goods, including medicines, a fundamental principle of the UK approach is that the UK-EU border should be as frictionless as possible and products should only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the EMA. The UK's level of participation at PRAC meetings will depend on the outcome of the negotiations.

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

Part of the UK's negotiations with the EU over a future relationship on medicines regulation will involve discussions over how the UK can continue to work together with the EU on pharmacovigilance. One of our key priorities is to ensure that UK and EU patients are protected by a strong regulatory system that maintains patient safety. Our objective is to continue co-operation and the sharing of expertise and experience on pharmacovigilance with the EU.

The UK is a leader in pharmacovigilance and has provided around a fifth of the EU network's capacity on pharmacovigilance. As stated in the Committee's report, the MHRA assesses more drug applications for the EMA than any other National Competent Authority, and its combination of a skilled workforce and accessibility to the NHS and clinical researchers make it a world leader in pharmacovigilance.

The UK's strengths in pharmacovigilance mean that if our desired agreement with the EU cannot be agreed, or in the event of a scenario where the UK no longer has the same level of access to EU pharmacovigilance systems, the UK would nonetheless be in a good position to put in place pharmacovigilance activities that continue to protect public health and sustain the competitiveness of the UK life sciences industry. It should also be noted that EU pharmacovigilance systems are not the only source of multinational drug safety data (for example, the UK will continue to have access to the international WHO VigiBase database). The MHRA is working on contingency plans for all possible scenarios. These activities have identified the critical systems that would need to be in place in the event of loss of access to EU systems and the MHRA is considering options for delivery to the necessary time frames should this situation arise.

Trade, customs and supply chains

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

In the Written Ministerial Statement laid by the Secretary of State for Business, Energy and Industrial Strategy on 11 January 2018, the Government set out its ambition for a close and effective association with Euratom.

The Government confirmed that it is seeking a close association with Euratom in the future, including the possibility of future co-operation on nuclear non-proliferation and safeguards, and any potential role for Euratom in supporting the establishment of the UK's own domestic safeguards regime. The exact nature of the relationship will be subject to further negotiations with the EU, although the European Commission has made clear that, whatever the future relationship between the UK and the EU, it will be on a different legal basis to the current relationship, as the UK will no longer be a Member State.

In a further Written Ministerial Statement laid by the Secretary of State for Business, Energy and Industrial Strategy on 26 March, the Government confirmed that it will be taking legal responsibility for its nuclear safeguards in the future. This will enable the UK to continue to meet international obligations from day one of exit, while not precluding continued involvement by Euratom with nuclear safeguards in the UK.

The Government is working closely with the Office for Nuclear Regulation (ONR) to ensure that it will be in a position to deliver the UK's future domestic civil nuclear safeguards regime to international safeguards and nuclear non-proliferation standards when Euratom safeguards arrangements no longer apply in the UK.

The UK and EU have agreed the implementation period running from 30 March 2019 until 31 December 2020 will include all of the Euratom acquis, including on safeguards. This means that existing Euratom arrangements will continue during this period. It should be noted that the Government has made clear that the UK's ability to import medical radioisotopes will not be affected by our withdrawal from Euratom. DHSC is leading cross-Government work with all relevant Departments to ensure continuity of supply.

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

DHSC is continuing to progress work to assess the impact of EU exit on the supply chain for all medicines, medical radioisotopes and medical devices used in the NHS. Identification of contingency measures and detailed preparedness planning is in progress to ensure continuity of supply and patient safety following EU exit, under a range of scenarios. This analysis, along with input from our industry and clinical stakeholders will help to inform any contingency planning required to ensure that supplies of these products continue to remain available for UK patients. DHSC are containing to engage closely with industry and other relevant

stakeholders throughout this process and the foreseeable future to ensure that any potential mitigation required for ensuring the continuity of medicine supply for UK patients are planned in close collaboration with all stakeholders.

Due to the large volume of commercial and sensitive information that has been shared by the industry throughout this work, DHSC will be unable to publish the final report. However, we will consider publication of an executive summary of the work.

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

How post-EU exit customs arrangements and compliance measures 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, so that we are prepared for the implications of a variety of different scenarios. However, the UK will protect public health and the safe, timely trade of treatments between this country and the EU. This is reflected in our desire to secure tariff-free trade of medicines and devices.

In the event that the UK is outside of EU frameworks, we want there to be no barriers to medicines, medical devices and research, building upon our current starting point of complete alignment with EU frameworks in a way that other countries negotiating free trade agreements are unable to replicate. If we are unable to achieve the relationship we desire, the UK will continue to protect public health and support the life science industry through its regulatory system.

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

EU exit does not mean that parallel imports of medicines will cease: under the TRIPS agreement which governs international rules around intellectual property and trade, countries may choose their own exhaustion regime which means they can determine whether to allow parallel imports or not. The Government notes that parallel imports provide a valuable source of supply diversity, which may support continuity of supply if there is an interruption in supply for products intended directly for the UK market.

When the UK leaves the EU, and following the implementation period, the UK may need to consider a future exhaustion regime: options include a national regime, a regional regime, or an international regime. The Government recognises that the NHS, patients and businesses across many sectors will have views on the choice of exhaustion regime going forward: we are therefore in the process of commissioning economic analysis to understand the consequences of different exhaustion regimes and engaging with a broad range of stakeholder groups. Any change to the UK's exhaustion regime will take account of the potential impact on the NHS, and will be communicated in good time to allow businesses to adapt their distribution models in response. It should also be noted that continuing parallel

imports of medicines would also be subject to the UK being able to obtain the necessary information about the exported product from the country of export.

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

We are committed to working together on medicines regulation, given its crucial and mutually beneficial role in improving patient outcomes, driving innovation in new medicines and supporting growth. We know the exact relationship with the EU may not be the same but are open to finding innovative solutions as we move forward.

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, and, as part of that, are committed to continuing a close working relationship with the EMA. This was reiterated by the Prime Minister in her Mansion House speech of 2nd March.

The UK wants to explore with the EU the terms on which we could remain part of EU agencies, including the EMA. The Government recognises the importance of a close and cooperative relationship between the UK and EU in the field of medicines, medical devices and substances of human origin regulation. We are committed to engaging in these negotiations in good faith with the aim of moving swiftly to the substantive discussions on our future relationship.

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

DHSC is working to ensure the best outcome for the health and social care system. Teams responsible for technical areas including safety monitoring and regulation of pharmaceutical products with complex supply chains have assessed the implications of the UK's withdrawal from the EU and are delivering detailed planning for all scenarios. There are no current plans to publish contingency planning for these issues.

Every government department, including DHSC, will be proceeding in the only responsible way possible: planning to deliver a smooth exit under any scenario, which includes preparing the UK for the future economic partnership we hope to negotiate with the EU as well as the very unlikely scenario in which no mutually satisfactory agreement can be reached and the UK exits without a deal.

CCS0518675688

978-1-5286-0426-0