

## **Written evidence submitted by the British Pharmacological Society to the Science and Technology Select Committee inquiry on Brexit, Science and Innovation: Preparations for 'No-Deal'**

### **About us**

The British Pharmacological Society (BPS) is the primary UK learned society concerned with research into drugs and the way they work. The Society has around 4,000 members working in academia, industry, regulatory agencies and the health services, and many are medically qualified. The Society covers the whole spectrum of pharmacology, including laboratory, clinical, and toxicological aspects. Pharmacology is a key knowledge and skills base for developments in the pharmaceutical and biotech industries, and is therefore fundamental to a thriving UK industry and R&D. The Society publishes three scientific journals: the British Journal of Pharmacology, the British Journal of Clinical Pharmacology, and Pharmacology Research and Perspectives.

### **Key points**

- 1.1 This submission outlines our view that the main priorities in preparing for a potential 'no deal' scenario are to:
  - A. Secure access to research collaborations and funding
  - B. Maintain our ability to attract and retain skilled people
  - C. Ensure regulatory stability
- 1.2 In addition to the concerns we have outlined in this submission directly relating to the impact of 'no deal' on UK science and innovation, the Society would also like to highlight risks to patient care and safety. We are concerned about potential medicines shortages, the impact of any such shortages on decisions about a patient's medication and the loss of access to EudraVigilance, which is a system for reporting and analysing suspected adverse reactions to authorised medicines. We released a statement about this issue on 21 January 2019<sup>1</sup>.
- 1.3 The Society would be happy to support the inquiry going forward. For further input, please contact: Natalie Harrison, Education, Engagement and Policy Officer, e. [natalie.harrison@bps.ac.uk](mailto:natalie.harrison@bps.ac.uk), t. +44 (0)20 7843 0493.

### **A. Secure access to research collaborations and funding** **Horizon 2020**

- 2.1 Under the proposed Withdrawal Agreement, the UK will be eligible to participate in Horizon 2020 until its closure<sup>2</sup>, and this has been underwritten (subject to eligibility) by ministerial guarantees from exit day until the end of 2020. In the event of 'no deal', participation of the UK (even as a third country) is not guaranteed. If the UK were to become a third country, it would be ineligible for ERC grants, Marie Skłodowska-Curie Actions and the SME instrument (which have so far accounted for £2.13 billion of the £4.73 billion Horizon 2020 grants awarded so far) and be unable to coordinate projects. It is predicted that a 'no deal' Brexit would lose the UK some 45% of its access to high-value Horizon 2020 grants<sup>3</sup>. We join calls from UK Universities for the government to confirm that they will replace research funding sources from which the UK may be excluded at the end of March 2019<sup>1</sup>. In particular, we await explicit assurance that if the UK is unable to participate in the European Research Council and Marie Skłodowska-Curie Actions funding schemes,

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<sup>1</sup> British Pharmacological Society. Society statement on the prospect of a "no-deal" EU exit on 29 March 2019. Available at: <https://www.bps.ac.uk/news-events/news/articles/2019/society-statement-on-the-prospect-of-a-no-deal%E2%80%9D-e> (last accessed 23 January, 2019)

<sup>2</sup> UK Government. UK participation in Horizon 2020: UK government overview. Available at: <https://www.gov.uk/government/publications/uk-participation-in-horizon-2020-uk-government-overview> (last accessed 22 January, 2019)

<sup>3</sup> Wilks A. What will a no-deal Brexit cost UK science in Horizon 2020 access? Available at: [http://www.scientistsforeu.com/no\\_deal\\_brexit\\_horizon\\_2020](http://www.scientistsforeu.com/no_deal_brexit_horizon_2020) (last accessed 22 January, 2019)

that domestic alternatives will be created with the same level of funding. Further, a priority should be collecting details for all current EU research projects involving UK-based participants. It is concerning to hear that the government has not yet collected all the relevant data and does not know all current participants of Horizon 2020<sup>4</sup>. Participation in Horizon 2020 must be secured in the event of a 'no deal' scenario.

## **Horizon Europe**

2.2 We welcome the government's pledge to finish paying for any British researchers whose EU grants have been approved up to the end of Horizon 2020. However, clarity is still needed about what happens from 2021 onwards, when the UK is outside the EU and the Commission's new research programme, Horizon Europe, is underway. Continuing to prioritise achieving the fullest possible association with Horizon Europe (including making appropriate financial contributions) will be critical. This may be more complex to negotiate in a 'no deal' scenario.

## ***B. Maintain our ability to attract and retain skilled people***

### **Tier 2 visas**

3.1 Doctors and nurses are now excluded from the cap on skilled worker (tier 2) visas, meaning there will be no restriction on the number of doctors and nurses who can be employed in the UK through this route. This is a welcome development, and we recommend extending this to key skills in the life science sector, including those on the shortage occupation list and those requiring a PhD. For example, the UK currently has a critical shortfall in clinical pharmacologists, with many posts being filled from Europe. To address this, we have recently called for medical and scientist clinical pharmacology roles to be represented on the shortage occupation list<sup>5</sup>. We are concerned by the white paper on the post-Brexit immigration policy<sup>6</sup> and the proposal that the UK should limit immigration to only those 'skilled' migrants who earn over £30k after Brexit; this would have serious implications for PhD students who are crucial to our university research.

### **Erasmus+ scheme**

3.2 In the event of a 'no deal' scenario, funding is available from the government to underwrite all successful bids for UK applicants submitted to the Erasmus+ programme until the end of 2020<sup>7</sup>. A priority now is reaching an agreement with the EU that UK organisations can participate in Erasmus+ projects after the UK has left the EU.

### **Uncertainty**

3.3 The Campaign for Science and Engineering have summarised the impact of uncertainty on people's attitudes and decisions<sup>8</sup>. For example, in a Prospect member survey of 650 EU nationals working in the UK, nearly 70% of respondents said they were thinking of leaving the UK because of Brexit. Major science funders, including Wellcome Trust, British Heart Foundation and Cancer Research UK, report instances

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<sup>4</sup> Kelly E. UK caught in 'Catch-22' on no deal planning for research, says science minister. Available at: <https://sciencebusiness.net/news/uk-caught-catch-22-no-deal-planning-research-says-science-minister> (last accessed 22 January, 2019)

<sup>5</sup> British Pharmacological Society. Shortage occupation list 2018: response to the Migration Advisory Committee's call for evidence. Available at: <https://www.bps.ac.uk/about/policy-positions-and-statements/consultation-responses/articles/2019/shortage-occupation-list-2018-response-to-the-mig> (last accessed 22 January, 2019)

<sup>6</sup> HM Government. The UK's future skills. Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/766465/The-UKs-future-skills-based-immigration-system-print-ready.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/766465/The-UKs-future-skills-based-immigration-system-print-ready.pdf) (last accessed 22 January, 2019)

<sup>7</sup> Department for Education. Erasmus+ in the UK if there's no Brexit deal. Available at: <https://www.gov.uk/government/publications/erasmus-in-the-uk-if-theres-no-brexit-deal/erasmus-in-the-uk-if-theres-no-brexit-deal> (last accessed 22 January, 2019)

<sup>8</sup> Campaign for Science & Engineering. Policy review: Brexit 2018. Available at: <http://www.sciencecampaign.org.uk/resource/brexit2018.html> (last accessed 22 January, 2019)

of candidates for prestigious research fellowships and funding turning down the opportunity citing uncertainty due to Brexit as a key factor. Further, in 2017 the proportion of EEA researchers applying to the Wellcome Trust's early career researcher scheme fell by 14%. In the same year, UCL had no applications from EU nationals for their Life Science and Medicines research excellence fellowships – previously these had made up around a third of applications. There must be clear communication to current and potential EU workers, working with learned societies and professional bodies to provide information through their networks.

### **Investing in UK skills**

3.5 The Society has joined together with the Association of the British Pharmaceutical Industry, Health Education England and the Faculty of Pharmaceutical Medicine to form the Clinical Pharmacology Skills Alliance<sup>9</sup>. The Alliance seeks to address critical UK clinical pharmacology skills shortages. It is vital that Government continues to work with the sector to invest in these and other key skills if the UK is to realise the ambitions of the Life Sciences Industrial Strategy regardless of developments in Brexit negotiations.

### **C. Ensure regulatory stability**

#### **Medicines supply**

4.1 Reliance on the free movement of goods throughout the EU is a central part of how the medicines supply chain (from factory, to wholesaler, distribution to hospitals and pharmacies, and dispensing) works. If the UK is no longer able to benefit from this, there is a real risk that border delays from customs checks could delay medicines getting to the patients who need them. Companies such as Merck have identified the specific challenges with time and temperature limited products and the potential need for new solutions if a frictionless border is not delivered<sup>10</sup>. However, in the event of 'no deal' there could be sudden and serious impact on medicines supply, which has been recognised by the government<sup>11</sup>.

4.2 As we have outlined in our statement of 21 January 2019<sup>12</sup>, we are concerned that serious shortages of medicines may have a significant impact on the treatment of patients and expose them to increased risks. We would like to stress that it is critical that decisions about changes to a patient's medication are made with appropriate clinical input. We are concerned that current plans for a protocol to address medicines shortages are not sufficiently advanced. Further, we are concerned at the reported increases in generic drug prices amid Brexit planning and stockpiling<sup>13</sup>

4.3 Further, in the event of 'no deal', the UK would likely revert to WTO tariffs. In this scenario, the cost of importing many medicines could rise due to not all pharmaceutical products being covered by the Pharmaceutical Tariff Elimination Agreement, which was last updated in 2010. It has been estimated that up to 1000

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<sup>9</sup> Clinical Pharmacology Skills Alliance. Launch statement. Available at: <https://www.bps.ac.uk/news-events/news/articles/2017/clinical-pharmacology-skills-alliance-launched-to> (last accessed 22 January, 2019)

<sup>10</sup> Written evidence from Merck (BRP0005). Available at: <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/business-energy-and-industrial-strategy-committee/leaving-the-eu-implications-for-the-pharmaceuticals-industry/written/73557.pdf> (last accessed 22 January, 2019)

<sup>11</sup> Hancock M. The government's preparations for a potential no-deal Brexit: letter to health and care sector. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/735742/gvt\\_preparations\\_for\\_potential\\_no\\_deal\\_-\\_letter\\_to\\_health\\_and\\_care\\_sector.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/735742/gvt_preparations_for_potential_no_deal_-_letter_to_health_and_care_sector.pdf) (last accessed 22 January, 2019).

<sup>12</sup> British Pharmacological Society. Society statement on the prospect of a "no-deal" EU exit on 29 March 2019. <https://www.bps.ac.uk/news-events/news/articles/2019/society-statement-on-the-prospect-of-a-no-deal%E2%80%9D-e> (last accessed 23 January, 2019)

<sup>13</sup> Pharmaceutical Services Negotiating Committee. Correspondence from PSNC regarding Pharmacies and Brexit. Available at: <https://www.parliament.uk/documents/commons-committees/Health/Correspondence/2017-19/Correspondence-from-PSNC-regarding-Pharmacies-and-Brexit-07-12-18.pdf> (last accessed 22 January, 2019)

finished products and 700 ingredients are not currently included in the list and would therefore be subject to tariffs when traded on WTO terms<sup>14</sup>. The WTO Pharmaceutical Tariff Elimination Agreement list needs to be urgently updated, regardless of 'no deal' and its impact on the UK.

### **Access to EU networks**

4.5 The UK will lose access to EU networks after transition under article 7 of the Withdrawal Agreement. In a 'no deal' scenario, the UK is set to immediately lose access to EudraVigilance<sup>15</sup>, a system for reporting and analysing suspected adverse reactions to authorised medicines. The UK should seek formal assurances that its access will be retained for the benefit of patients across the UK and Europe.

### **Regulation of medicines and clinical trials**

4.6 Regulation of medicines and clinical trials is currently harmonised across the UK and Europe, through the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA), respectively. In addition to direct benefits for public health, this has also meant the streamlining of regulatory burden for industry. The MHRA has undertaken contingency planning to address immediate challenges in the event of a 'no deal' scenario<sup>16</sup> and we welcome indications (such as the amendment introducing New Clause 17 to the Brexit Trade Bill<sup>17</sup>) that securing the UK's participation in the European regulatory networks will be a priority. The UK Life Sciences Industrial Strategy aims to enhance UK clinical trial capacity by 50%<sup>18</sup>. An agile and accessible regulatory environment will underpin the UK's research and innovation environment – it must be protected and strengthened.

4.7 In the event of 'no deal', UK participation in the European regulatory network would cease and the MHRA would need take on these functions. This would require changes to UK law, via the Human Medicines Regulations 2012 (HMRs) and would be a burden on resources<sup>19</sup>. The Government commitment to convert existing EU marketing authorisations to those recognised by the UK on 29 March 2019, along with the high-level overview of the process<sup>20</sup>, are welcome, but do not address the potential delays of getting new medicines to UK patients. Further, if there in the event of a 'no deal' scenario, the MHRA will lose access to the database of EU-approved products, so new generic applications would need to be based on reference

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<sup>14</sup> Written evidence from the Association of the British Pharmaceutical Industry and the BioIndustry Association (BRP0001). Available at:

<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/business-energy-and-industrial-strategy-committee/leaving-the-eu-implications-for-the-pharmaceuticals-industry/written/73078.html> (last accessed 23 January, 2019)

<sup>15</sup> European Medicines Agency. EudraVigilance. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance> (last accessed 22 January, 2019)

<sup>16</sup> Department of Health and Social Care. MHRA EU Exit no-deal contingency legislation for the regulation of medicines and medical devices. Available at: <https://consultations.dh.gov.uk/mhra/mhra-no-deal-contingency-legislation-for-the-regul/> (last accessed 23 January, 2019)

<sup>17</sup> The Public Whip. Trade Bill — New Clause 17 — UK Participation in the European Medicines Regulatory Network. Available at: <https://www.publicwhip.org.uk/division.php?date=2018-07-17&number=222&house=commons> (last accessed 22 January, 2019)

<sup>18</sup> Bell J. Life Sciences Industrial Strategy – A report to the Government from the life sciences sector. Available at:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/650447/LifeSciencesIndustrialStrategy\\_acc2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf) (last accessed 23 January, 2019)

<sup>19</sup> Department of Health & Social Care. How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal. Available at: <https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexite-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexite-deal> (last accessed 22 January, 2019)

<sup>20</sup> Medicines and Healthcare products Regulatory Agency. Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal. Available at:

<https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexite-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexite-deal> (last accessed 22 January, 2019)

products authorised in the UK. This could have large cost and productivity implications for the NHS<sup>21</sup>.

- 4.7 Proposals made in the current Withdrawal Agreement—in which manufacturers would only need to undergo one series of tests in either market, in order to place products in both markets—are welcome. However, on 2 September 2018, the EMA announced it has ceased to appoint MHRA rapporteurs<sup>22</sup>. As outlined in our response to the MHRA consultation on EU Exit ‘no deal’ contingency legislation<sup>23</sup>, rebuilding relationships with the EMA will be crucial. Currently, many questions remain—eg, it needs to be clarified whether the MHRA can request a post-authorisation safety study (PASS) when the EMA have not. The same issue applies to the review of PASS results<sup>10</sup>.
- 4.8 The Government issued an update on the Clinical Trials Regulation (CTR) during the implementation period, with a clear commitment to align where possible with the new CTR (536/2014) without delay when it does come into force in the EU. In the event of ‘no deal’, the Government should aim to quickly re-align with the parts of the EU’s CTR legislation that are within the UK’s control.

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<sup>21</sup> The King’s Fund. How much has generic prescribing and dispensing saved the NHS? Available at: <https://www.kingsfund.org.uk/blog/2015/07/how-much-has-generic-prescribing-and-dispensing-saved-nhs> (last accessed 22 January, 2019)

<sup>22</sup> The Guardian. Britain loses medicines contracts as EU body anticipates Brexit. Available at: <https://www.theguardian.com/business/2018/sep/02/britain-loses-medicines-contracts-as-eu-body-anticipates-brexite> (last accessed 22 January, 2019)

<sup>23</sup> British Pharmacology Society. Response to the MHRA’s consultation on EU Exit no-deal contingency legislation. Available at: <https://www.bps.ac.uk/about/policy-positions-and-statements/consultation-responses/articles/2018/response-to-the-mhra%E2%80%99s-consultation-on-eu-exit-no> (last accessed 22 January, 2019)