



HOUSE OF LORDS

European Union Committee

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Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care
Department of Health and Social Care
39 Victoria Street
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21 November 2018

Access to medicines in the event of ‘no deal’

Dear Minister,

The Home Affairs Sub-Committee of the House of Lords EU Committee has been reviewing the Government’s contingency preparations to ensure the UK has continued access to medicines and medical products in the event of a ‘no deal’ Brexit. On 31 October 2018 we heard evidence from Mark Dayan, Policy and Public Affairs Analyst, Nuffield Trust; Richard Freudenberg, Secretary-General, British Association of European Pharmaceutical Distributors; and Julian Maitland-Walker, Senior Partner, Maitland Walker LLP. We also received a comprehensive private briefing from DHSC officials, and are appreciative of their assistance, which has helped the Committee’s private deliberations. Nonetheless we would be grateful to receive an on the record response from you to the questions below.

Contingency planning

In August you wrote to industry advising that the supply chains for medicines from the EU and EEA to the UK “may be affected by changes to border processes and procedures” in the event of there being no deal on Brexit.¹ Given that the Healthcare Distribution Association estimates that 45% of all medicines in the UK are imported from the EU, disruption to this supply chain could be felt acutely in the UK.²

We welcome the series of technical notices for contingency planning from Government, which provide some clarity on how these disruptions will be minimised. Officials also demonstrated that significant contingency planning had been undertaken. However, evidence from witnesses

¹ Matt Hancock MP, letter to medical suppliers, 23 August 2018, <https://www.gov.uk/government/publications/letter-to-the-health-and-care-sector-preparations-for-a-potential-no-deal-brexite>

² Martin Sawyer, Executive Director of the Healthcare Distribution Association, Oral evidence, Commons Health Committee, 5 December 2017, <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/brexit-the-regulation-of-medicines-medical-devices-and-substances-of-human-origin/oral/75419.html>

suggests there is still concern that a no deal Brexit may limit the availability of medicines and medical products in the UK.

- Do you consider that the contingency planning, however extensive, will remove all risk of disruption to the supply of medicines and medical products in the event of the UK leaving the EU without a deal?

Border delays

One witness told the Committee that there was little sign to date of potential delays on the border being addressed. This concurs with the findings in the National Audit Office's report *The UK border: preparedness for EU exit*,³ which says: "The Government currently expects that, if the likelihood of a 'no deal' scenario increases over the autumn of 2018, then contingency operations could start from January or February 2019. This could include escalating planning for the priority delivery of vital supplies such as food and medicine."⁴ The report also says: "In September 2018, BDG [Border Delivery Group] assessed that 11 of the 12 systems it monitors were at risk of not being delivered on time and to acceptable quality by 29 March 2019 (rated 'amber' or above)."⁵

- What percentage of NHS-purchased medicines and medical products are imported from or via the EU?
- What work have you undertaken to ensure the import of medicines and medical products is treated as a priority at the border in the event of no deal?

We understand that industry has been asked by Government to stockpile six weeks' worth of medicines and medical products. We note that in evidence to the Commons Health and Social Care Committee you said that the six weeks was a "planning assumption for how long we will need stockpiles of medicines before we are able to resume supplies either because the blockages at the border are relieved or there are other routes in place".⁶

- What did you mean by "other routes" and what plans have you made to secure these before 29 March 2019?

³ National Audit Office, *The UK border: preparedness for EU exit*, <https://www.nao.org.uk/wp-content/uploads/2018/10/The-UK-border-preparedness-for-EU-exit.pdf>, p. 27.

⁴ National Audit Office, *The UK border: preparedness for EU exit*, <https://www.nao.org.uk/wp-content/uploads/2018/10/The-UK-border-preparedness-for-EU-exit.pdf>, p. 27.

⁵ National Audit Office, *The UK border: preparedness for EU exit*, <https://www.nao.org.uk/wp-content/uploads/2018/10/The-UK-border-preparedness-for-EU-exit.pdf>, p. 29.

⁶ Commons Health and Social Care Committee, Oral evidence: Impact of a no deal Brexit on health and social care, <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-a-no-deal-brex-it-on-health-and-social-care/oral/92043.html>

- How confident are you that the contingency measures deployed as an immediate response to secure the supply of medicines and medical products can be sustained beyond the first six weeks after Brexit, should this be required?

On 23 October 2018 you said that an invitation to tender for additional storage capacity had been made that day.⁷

- Can you provide more detail on the tender for additional storage capacity, including: the amount of funding awarded; the size of the storage obtained; and how much of that is for refrigerated storage.

You told the Commons Health Committee that medical products with short shelf-lives (which cannot be stockpiled) would be flown in.⁸ Mark Dayan told the Committee that this was sensible, but would “obviously be expensive, and potentially, logistically difficult”.

- What plans has the Government made to secure and prioritise airborne routes for medical products?
- What is the expected cost of flying in medical products for a six-week period?
- Can you list which medicines and medical products will be prioritised to be flown in? If no such list exists yet, how will you prepare it, and when?

Inspections and certifications of batches for new products

You told the Commons Committee that, with effect from 29 March 2019, the Government would “unilaterally recognise EMA approvals and EMA batch testing to make sure there is no barrier in this space”.⁹ Mark Dayan warned that this was unlikely to be reciprocated by the EU, creating a strong incentive for companies to locate those processes and people to the EU. Julian Maitland-Walker agreed that companies were already “moving their licensing activities and licence applications out of the UK. Previously, quite a lot of licensing was done in the UK for the European Union. Now that is being moved primarily, I think, to Germany.”

- What analysis has the Government conducted on the impact to the UK economy and employment of companies shifting their licensing activities from the UK to the EU as a result of a unilateral recognition of EMA approvals by the UK? How many companies have already shifted their activities or have indicated their intention to do so?

⁷ Commons Health and Social Care Committee, Oral evidence: Impact of a no deal Brexit on health and social care, 23 October 2018, <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-a-no-deal-brex-it-on-health-and-social-care/oral/92043.html>

⁸ Commons Health and Social Care Committee, Oral evidence: Impact of a no deal Brexit on health and social care, 23 October 2018, <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-a-no-deal-brex-it-on-health-and-social-care/oral/92043.html>

⁹ Commons Health and Social Care Committee, Oral evidence: Impact of a no deal Brexit on health and social care, 23 October 2018, <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-a-no-deal-brex-it-on-health-and-social-care/oral/92043.html>

Introduction of new products to the UK

One witness was very concerned that pharmaceutical companies would give less priority to licensing a new drug in the UK post-Brexit, given that the UK would represent a smaller market than the EU. He cited evidence that smaller markets had slower lead times for the introduction of new drugs into those markets.

- What are the Government's plans to encourage drug companies to prioritise introducing new products to market in the UK?

The technical notice published on 14 September states that the EU is planning to implement new regulations for clinical trials but they “will not be in force in the EU at the time that the UK exits the EU and so will not be incorporated into UK law on Exit day under the terms of EUWA.”¹⁰ The notice goes on to say that the UK will “align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals.”

We note an article in the *Independent* on 3 October 2018 that UK patients have been cut from an international clinical trial to test a new heart attack drug because of uncertainties about registering new medicines after Brexit.¹¹ The article claims the drug company fears that data in the UK will no longer be acceptable to the European Medicines Agency once the UK leaves the EU.

- What action is the Government taking to resolve uncertainty about data from clinical trials conducted in the UK being accepted by the EMA?

Meeting market needs

One witness said there would be less flexibility post-Brexit for products to be redistributed to meet the needs of the market. For example, manufacturers can at present easily move products from one Member State to another to meet need. Losing this flexibility creates a risk that shortages of medicines in the UK may be harder to manage.

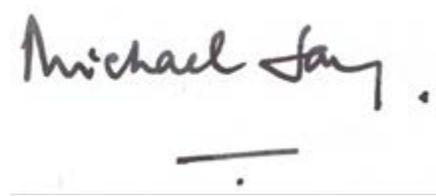
- What consideration has the Government given to the reduced flexibility of manufacturers to move products from the EU to the UK in response to market needs, and how do you plan to mitigate this risk?

I look forward to a response within ten working days.

¹⁰ HM Government, How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal, <https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal>

¹¹ Alex Matthews-King, “Brexit uncertainty sees UK patients cut from heart attack drug trial”, *Independent*, 3 October 2018, <https://www.independent.co.uk/news/health/brexit-heart-attack-drug-trial-research-european-medicines-agency-recardio-dutogliptin-a8566426.html>

Yours sincerely

A handwritten signature in black ink that reads "Michael Jay". Below the signature is a horizontal line with a small dot underneath it, serving as a signature mark.

Lord Jay of Ewelme

Chairman of the House of Lords EU Home Affairs Sub-Committee