Health and Social Care Committee

House of Commons London SW1A 0AA
Tel: 020 7219 6182 Fax 020 7219 5171 Email: hsccom@parliament.uk
Website: www.parliament.uk/healthcom Twitter: @CommonsHealth

From Dr Sarah Wollaston MP, Chair

Rt Hon Matt Hancock
Secretary of State for Health and Social Care

Letter by email to healthsofs@dh.gsi.gov.uk

21 November 2018

Dear Matt

I am writing about the impact of no-deal Brexit on the provision of medical supplies.

The Health and Social Care Committee remains concerned about several areas concerning the UK Government's preparedness for a no-deal, including patients' access to medicines and medical products and the costs and requirements of contingency planning on companies, particularly small-to-medium sized companies, in the UK life science sector.

Patient access to medicines and medical products

We are grateful to you and Sir Chris Wormald for appearing before us on 23 October 2018 to provide evidence on the Government's preparations for a no-deal scenario. This session helped us, and we hope others who tuned in or have watched the session since, to understand the plans your Department has initiated.

However, we remain concerned that the ability of UK patients to access medicines and medical products may be adversely affected in the event of a no-deal, particularly where these products are not wholly manufactured in the UK, whether because of

- the short shelf-life of some medicines and medical products, or
- the complexity of supply chains.

On behalf of the Committee, I request that you publish a list of medicines and medical products for which your Department has identified a potential supply risk, along with the steps you are taking to mitigate these risks.

A viable option in the case of some shortages is to switch patients onto another type of medicine. However, there are many medicines where this practice is not appropriate, as it presents a significant risk to patient safety. For example, in the case of drugs for the treatment of epilepsy, whilst there may be alternatives, "brand switching" may not deliver the same bioavailability of the drug thereby creating a risk of seizures. **Therefore, we request that the published list set out clearly those medicines which cannot be**

switched without creating additional risk and where careful review would be required and the alternative contingency plans that your Department is putting in place.

Costs of contingency planning

We recognise the need for preparations for a no-deal scenario. However, it is clear that the costs for companies, both large and small, are considerable. In particular, we are concerned that small and medium sized enterprises (SMEs) which are preparing for a no-deal Brexit are at risk of falling into financial difficulties due to the extra costs of contingency planning. While we are assured, as you told us on 23 October, that the Government is committed to providing support to help with the cost of contingency, for some companies stockpiling an extra 6 week's supply puts a significant pressure on their cash flow.

We are concerned that these companies may run into significant financial difficulties if they are not promptly reimbursed by your Department. **We would welcome further information from you on the arrangements that your Department is making to ensure SMEs do not suffer financially from slow or late reimbursement. We would also like to see an update on the estimated costs of no deal contingencies.**

Non-disclosure agreements

Finally, we understand that some companies engaged in contingency planning are being asked to sign non-disclosure agreements. **We would like clarification on the rationale for requesting companies to sign these agreements, and more information about the content of these agreements.** While such agreements may be appropriate to protect the commercial interests of the companies involved, we are concerned that any agreements signed must not pose a barrier to the disclosure of information, now and in the future, that may be in the public interest.

I look forward to your earliest reply.

Yours sincerely,

Dr Sarah Wollaston MP
Chair of the Committee

Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

39 Victoria Street
London
SW1H 0EU

020 7210 4850

POC_1165249

Dr Sarah Wollaston MP
Chair, Health and Social Care Committee
House of Commons
London
SW1A 0AA

31 January 2019

Dear Sarah,

I am writing to address the concerns raised by the Health and Social Care Committee with regard to the impact of a 'no deal' EU exit on the provision of medical supplies. I would like to respond to the questions posed by the Committee as to how my Department is mitigating the risks posed by a possible no-deal EU exit by providing more details of our contingency measures.

'No-deal' EU exit contingency planning and the continuity of medicines and other medical products

The Department for Health and Social Care (DHSC) is working with pharmaceutical and medical device companies, their supply chains, and the NHS to ensure patients throughout the UK continue to receive the medicines and other medical products they need if the UK leaves the EU without a deal.

In August 2018, the Government announced in technical notices its plans to secure access to medicines in the event of a 'no deal' EU exit. Firstly, to support compliance with requests to stockpile medicines, the UK will recognise batch testing from the UK, EU, EEA and third countries with whom the EU has already made arrangements from 29 March 2019. All medicines previously authorised by the European Medicines Agency (EMA) under the centralised procedure will automatically be licensed for continued use in the UK on 29 March 2019 (although the holders will have a short period of time after exit day within which to opt out of having a UK marketing authorisation).

Also in August 2018, the Department asked industry to stockpile a minimum of six weeks' additional supply in the UK, over and above their business as usual stocks, of all prescription-only and pharmacy medicines and other medical products which enter

the UK from or via the EU or EEA, by 29 March 2019. Additionally, a tender process to procure additional warehouse space for stockpiled medicines, including ambient, refrigerated and controlled drug storage, was undertaken in October 2018.
As the Committee has highlighted, there are certain medicines with short shelf lives, including medical radioisotopes, which cannot be reasonably stockpiled. Where these medicines are imported from the EU or EEA, we have asked that suppliers ensure in advance plans to air freight these medicines from the EU in the event of a 'no deal' exit. For other certain medical devices and clinical consumables, steps have been taken to increase stock holding within national procurement and logistics operations to complement suppliers' own measures, and to establish dedicated shipment routes for products supplied directly. Public Health England maintains significant stockpiles of vaccines (including its procurement for around 25 vaccines for the national immunisation programme) for continuous and ongoing supply to the NHS, and has worked closely with the pharmaceutical industry to assure this continues in the event of 'no deal'.

Furthermore, alternative supply routes are being opened up, on which all medicines and other medical products will be prioritised on roll-on, roll-off ferry routes away from the short straits, to maintain continuity of supply in a no-deal scenario. Last month, we wrote to pharmaceutical companies that supply licensed medicines to the UK from or via the EU or EEA, and/or manufacture medicines in the UK, and suppliers of medical devices informing them of the latest reasonable worst-case scenario border disruption planning assumptions and asking them about their current transportation routes and their ability to re-route their supply chains if they currently rely on Dover and/or Folkestone, both of which may be subject to significantly reduced flow of goods for at least six months, rather than the previous estimate of six weeks.

The Department has received very good engagement from industry who share our aims of ensuring continuity of supply of medicines and medical products is maintained and able to cope with any potential delays at the border that may arise in the short term in the event of a 'no deal' EU exit. In light of this engagement the Department is currently developing the processes by which industry can access the additional contingency arrangements we have procured.

A list of medicines in scope of the medicines supply contingency programme

The Department is unable to provide the Committee with a published list of medicines and medical products with an EU or EEA touchpoint in their supply chain for which we have identified a potential supply risk, including those where there is no identical substitute, as this information is commercially sensitive. We are working

closely with suppliers and clinicians to establish the need and scope for use of alternative products and substances on a product by product basis.

The Department does not expect to see significant changes to existing medicine supply chains or capacity; however, we will be monitoring this closely. It is important to make clear to the Committee that there are already pharmacists and others within the Department that deal with medicine supply issues arising both in the community and hospitals. We have well established operational levers and channels we use between ourselves and the Medicines and Healthcare products Regulatory Agency (MHRA) or the NHS to mitigate supply issues.

However, I can assure the Committee that steps are being taken to mitigate the risk of serious shortages. On 18 January, the Government laid a statutory instrument before Parliament enabling Ministers to issue Serious Shortage Protocols (SSPs) that, where appropriate, enable community pharmacies to dispense against am SSP instead of a prescription without going back to the prescriber first. Any SSP will be developed with input from clinicians and could cover dispensing
a different quantity, pharmaceutical form, strength or a generic or therapeutic equivalent.

SSPs for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, they would not be suitable for treatments for epilepsy or treatments requiring biosimilar products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

The estimated costs of 'no deal' EU exit contingency planning

Like other government departments, my Department has been given a ringfenced allocation to be utilised against EU exit preparations; DHSC was allocated £21.1m in 18/19 and £50m for 19/20. At the point of writing, the 2018/19 allocation is fully committed and we continue to monitor future spend closely, in line with the Accounting Officer's duties.

In response to the Committee's concerns regarding the impact of 'no deal' contingency planning for small- and medium-sized enterprises, the Department is currently considering how best it may support medicine suppliers taking part in the contingency programme. The Department has provided funding for the provision of warehouse capacity in which to stockpile medicines. We are working closely with industry to support companies in implementing their contingency plans.

The European Medicines Agency

I acknowledge that there have been concerns raised following the EMA's transferral of its headquarters to Amsterdam and the future of licensing in the context of a 'no deal' EU exit. I can confirm that in any exit outcome, if an application for a UK Marketing Authorisation is received at the same time as an application is made to the EMA, the MHRA's streamlined approach will ensure that patients can access new and innovative medicines at the same time as EU patients.

Non-Disclosure Agreements

I recognise your concern regarding the use of non-disclosure agreements (NDAs) in our consultations with suppliers as part of our no-deal supply contingency programme**.** However, NDAs are crucial in enabling us to talk to the industry in confidence, and to ensure that when we issue our final advice to the rest of the industry, our requests of them are clear, appropriate and deliverable. It is not uncommon for NDAs to be used when engaging in sensitive commercial discussions.

I hope this has served to provide the Committee with a degree of assurance as to the progress of the Department's no-deal EU exit contingency planning.

Yours ever,

MATT HANCOCK