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Correspondence

Letter to medicine suppliers: 3 August 2020

Updated 13 August 2020

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Dear colleague,

I am writing to share with you some information on the end of the transition period (TP) on 31 December 2020 as it relates to the continuity of the supply of medicines and medical products to the UK. This follows the government's recent confirmation that the TP will cease as planned on 31 December 2020 and there will be no extension

(<https://www.gov.uk/government/news/government-accelerates-border-planning-for-the-end-of-the-transition-period>).

First, I would like to thank you for the continued, crucial, role you play in helping ensure continuity of medical supplies. This has already been a challenging year due to the global impact of COVID-19 and we know many of your supply chains remain under severe strain. The ongoing pandemic, gradual resumption of NHS activity, and seasonal pressures mean we must prepare thoroughly for the end of the TP. It's imperative that we maintain our excellent working relationships and lines of communication: to this end, I am writing to you to indicate how we propose we should work together to deliver our shared goal of continuity of safe patient care.

Context and border assumptions

At 11pm on 31 December 2020, the UK will leave the EU Single Market and Customs Union. This will mean new border and customs procedures apply, regardless of whether the UK and EU agree the ambitious free trade agreement that the government is seeking to negotiate. The government has already announced it will implement new border controls in 3 stages (<https://www.gov.uk/government/news/government-accelerates-border-planning-for-the-end-of-the->

transition-period) leading up to full implementation in July 2021 with further detail set out in the Border Operating Model (<https://www.gov.uk/government/publications/the-border-operating-model>), published on 13 July.

The staged implementation of border controls by the government will help to reduce the potential for disruption at the border. However, traders will still need to be ready for controls implemented by member states on 1 January 2021, and it is anticipated that there could be border disruption if significant volumes of freight arrive at the border without completing the correct formalities. Government must plan for all scenarios, including reduced traffic flow at the short straits in a reasonable worst case scenario (ie between Calais/Dunkirk/Coquelles and Dover/Folkestone).

Our shared focus should be on mitigating any potential disruption to supply into the UK across all categories of medical supplies, including, but not limited to:

- medicines
- medical devices and clinical consumables
- clinical trials supplies
- products of human origin (blood and transplant items)
- vaccines and countermeasures
- non-clinical goods and services (NCGS) in support of health and social care providers

Our contingency planning covers all 4 nations of the UK as well as the Crown Dependencies. You will recall that during the past 2 years, we have developed robust joint plans to mitigate any such possible disruption based on a 'multi-layered approach', and in principle propose to do the same for the end of the TP.

We're asking suppliers to put in place flexible mitigation and readiness plans in preparation for new border and customs procedures.

1. Alternative routes

The cross-government reasonable worst case scenario (RWCS) for our contingency planning indicates a risk of significant disruption across the short straits for 6 months following the end of the transition period, with a particular risk during the first 3 months. As a large percentage of medical supplies come from the EU or have a supply touchpoint there, the first priority of any contingency should be to maintain replenishment rates at necessary levels including by securing capacity to reroute freight away from potential disruption, especially during the first 3 months following 1 January 2021 when, under the government's RWCS, the most significant disruption is anticipated. Companies are encouraged to review their own logistics arrangements and consider the appropriateness of using existing supply chain routes during this period as a matter of priority.

In 2019, the Department for Transport (DfT) put in place a 4-year procurement framework for freight capacity for 'Category 1' goods, which includes all health supplies. This framework is still in place. DHSC is seeking to secure capacity on the government secured freight capacity

(GSFC) to support the health and social care sector. More information will be provided when possible, including updates on the procurement timescales and when companies can expect to be able to register and access the service.

In addition, DHSC has retained its express freight service arrangements with 3 specialist logistics providers to support the urgent movement of medicines and medical products to care providers and patients if other measures experience difficulties. This service will be in place for deployment at the end of the TP as required.

2. Supporting ‘trader readiness’ for the new customs and border arrangements

As the UK leaves the EU Single Market and Customs Union, businesses will need to prepare for life outside both at the end of 2020, and many have already acted.

The government has published the Border Operating Model and launched a targeted ‘trader readiness’ communication campaign throughout the remainder of 2020. DHSC will support and supplement these to help businesses prepare for the changes at the border that will happen at the end of the year.

As part of this, we will seek information from suppliers to understand their general needs and help identify those who may need more support, for example, with controlled drugs and cold-chain logistics.

In the meantime, companies are encouraged to consult government websites, and work with their usual logistics providers to discuss what preparations may be needed to ensure compliance with customs requirements.

3. Buffer stocks of medical supplies where possible

Holding additional stock in the UK provides a further buffer against some disruption and we believe, where it’s possible, it’s a valuable part of a robust contingency plan. To build upon past work and ensure a co-ordinated approach, we will be asking suppliers to confirm their contingency plans for the end of the TP, and in particular the balance between stock-holding in the UK, re-routing away from potential disruption and readiness for new customs and border arrangements.

We recognise that global supply chains are under significant pressure, exacerbated by recent events with COVID-19. However, we encourage companies to make stockpiling a key part of contingency plans, and ask industry, where possible, to stockpile to a target level of 6 weeks’ total stock on UK soil. DHSC stands ready to support companies with their plans if required and understands that a flexible approach to preparedness may be required that considers a mixture of stockpiling and rerouting plans as necessary.

Centralised stock build

In the run-up to EU Exit, the department, working with NHS Supply Chain, built up a centralised stock build (CSB) of fast-moving medical devices and clinical consumables. Some of this stock remains and accounting for likely demand trends for the time of year, we plan to build these levels back up to a target level of 6 weeks' total stock. It's important to note that the devolved nations of the UK may, in addition, choose to build their own stockpiles.

4. Warehousing

Previous EU Exit preparations by government included securing dedicated warehouse capacity for suppliers of medicines to stockpile in the UK. However, during 2019, utilisation of this space was extremely low. Given that the government is continuing to advocate a multi-layered approach to contingency planning and the additional preparation time companies have had before the confirmed exit date, we do not propose to intervene in this market at this time. However, we will keep this under review.

5. Regulatory flexibility

You have been clear and consistent on your asks around regulatory clarity from 1 January 2021. In negotiations with the EU, the government put forward a proposal that minimises trade barriers and bolsters the resilience of medicines supply chains. We have entered a new, intensified stage of the negotiations and are ready and willing to reach an agreement. We will communicate to you more detail in the coming weeks. At this stage, we want to reassure you that we fully understand your requests and are working hard across government to ensure that the needs of the health and social care sector are met.

6. Shortage management response

Suppliers should in the first instance raise any anticipated or actual supply disruption through business as usual routes. For suppliers of medicines, the department's Medicine Supply Team has well established procedures to deal with actual or potential medicine shortages and works closely with the Medicines and Healthcare products Regulatory Agency (MHRA), the pharmaceutical industry, NHS England and NHS Improvement, the devolved administrations and others operating in the supply chain to help prevent shortages and minimise the risks to patients. By way of reminder, medicines suppliers have a statutory duty to provide early notification of supply disruptions to the department and contact details for the Medicines Supply Team are at the end of this letter. All other suppliers should raise supply issues through usual routes or the National Supply Disruption Response.

National Supply Disruption Response

The National Supply Disruption Response (NSDR) is the service for suppliers of all categories experiencing supply and logistics challenges. The NSDR is currently stood up in order to assist with the demands on supply across the workstreams as part of our response to COVID-19.

Regardless of the COVID-19 situation, NSDR will be stood up for the end of the TP as a contingency measure. At present, supply issues not related to COVID-19 should be raised through business as usual routes.

We will continue to ask health and social care service providers to avoid local stockpiling over and above business as usual ahead of 31 December as it is unnecessary and could cause shortages in other areas, which could put patient care at risk. Nor do patients need to stockpile medicines.

Northern Ireland Protocol

A 'command paper' setting out the UK's approach to the Northern Ireland Protocol (NIP) (<https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol>) has been published. This sets out the basis of the government's approach to implementing the protocol. Further guidance relating to the detailed workings of the NIP will be provided in the coming weeks.

Useful links

Contact the relevant team at the department at:

- medicines contingency: medicinescontingencyplanning@dhsc.gov.uk
- MDCC contingency team: mdcc-contingencyplanning@dhsc.gov.uk
- clinical trials: ctcontingencyplanning@dhsc.gov.uk
- vaccines and countermeasures: immunisation-mb@dhsc.gov.uk
- blood and transplants: transplants@dhsc.gov.uk
- non-clinical goods and services: contractreview@dhsc.gov.uk

Useful COVID-19 related links:

- all guidance and advice on COVID-19 can be found at www.gov.uk/coronavirus (<https://www.gov.uk/coronavirus>).

You can follow these Twitter accounts to keep up to date:

- Department of Health and Social Care (<https://twitter.com/DHSCgovuk>) – @DHSCgovuk
- NHS England and NHS Improvement (<https://twitter.com/NHSEngland>) – @NHSEngland
- Public Health England (https://twitter.com/PHE_uk) – @PHE_uk

Over the coming months, traders may be contacted by HMRC as part of its campaign to support and assist trader readiness in anticipation of the change to customs and border procedures on 1 January 2021.

In addition to this letter and ongoing engagement through DHSC teams, we will be running webinars again to which you will be invited. These offer a chance to hear rapid updates and to ask questions. Your engagement and feedback are of great value in shaping our plans and joint preparations.

Please stay in close contact with the teams in the department and raise any supply issue with us as soon as possible.

Yours sincerely,

Steve Oldfield,

Chief Commercial Officer

Department of Health and Social Care