Department of Health & Social Care

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Dear Colleague,

I am writing to update you on plans and preparations ahead of the end of the Transition Period on 31 December 2020. This letter follows my previous letter to you on 3 August 2020, relating to the continuity of the supply of medicines and medical products and your vital role helping to ensure uninterrupted supply to patients right across the UK and its Crown Dependencies. The scope of the programme is:

- medicines (prescription-only, pharmacy general sales list and unlicensed medicines);
- medical devices and clinical consumables;
- supplies for clinical trials and clinical investigations;
- vaccines and countermeasures; and
- blood, tissue and transplant materials.

We are also assessing contract risks in the broader NHS and within the devolved nations and are working with suppliers to help ensure adequate mitigations are in place for non-clinical goods and services (e.g. hospital food, laundry, IT contracts etc).

The government's formal negotiations with the European Union (EU) are on-going. While the UK Government will continue its efforts to secure a free trade agreement (FTA) with the EU, we must now step up preparations for a scenario where a negotiated outcome with the EU is not reached. I must also stress that an FTA would not remove any of the requirements to act now to prepare for new customs and border processes.

As businesses and sponsors of clinical trials and investigations, please take this moment to ensure that you are doing all you can to prepare. Our plans are set out again below as they were in my letter of 3 August, along with updates on the progress made since. We have had an extremely positive response to the questionnaires and I would like to thank you for taking the time to help us understand your circumstances and enabling us to support you better where we can. If you have not already responded to questionnaires and data requests from teams in the Department of Health and Social Care (DHSC), please do so as quickly as you are able. Without this information we cannot effectively work together to mitigate the risk of delay and disruption at the short straits.

Border Planning Assumptions

At 11pm on 31 December 2020, new border and customs procedures will apply for all goods entering the UK from the EU. The UK will implement border controls in a staged approach which will help to reduce potential for disruption at the border. However, the UK Government does not have control over the checks that EU Member States impose at the EU border and

the biggest potential cause of disruption are traders not being ready for controls implemented by EU Member States on 1 January 2021. Simply put, if traders, both in the UK and EU, have not completed the right paperwork, their goods will be stopped when entering the EU and disruption will occur. Therefore, it is essential that traders act now and get ready for new formalities.

The Government's Reasonable Worst Case Scenario (RWCS) planning assumptions indicate the flow rate at the short straits could reduce to 60%-80% of normal levels after the Transition Period, with the most significant disruption occurring in the first three months of 2021. While this is not a forecast or a prediction, this emphasises the need for the Department to continue to work with you to implement the 'multi-layered approach' to mitigate against the risk of supply disruption.

Our contingency planning covers all four nations of the UK, as well as the Crown Dependencies. Our plans are joined up and considered alongside seasonal pressures on the health and care system, including the response to the coronavirus, and put patient safety at the heart of everything we do. The robust, joint multi-layered approach we are putting in place consists of the following updates against my letter of 3 August.

1. Alternative routes

a. Government-Secured Freight Capacity (GSFC)

The Department for Transport (DfT) has procured capacity from the freight framework established in 2019 for 'Category 1' goods, including all health supplies. As communicated to you recently, companies and sponsors are now able to view the routes available and register to secure capacity on the GSFC. See registration links below.

If you registered for the GSFC in 2019, you will need to re-register. This is so that you can confirm your details remain correct and up to date. Once you have re-registered a new, unique supplier access code will be sent to you. You will need to provide this access code to your logistics provider along with the GSFC handbook. Once registered, the first batch of tickets for the three-week period from 31 December 2020, will be released in late-November. Subsequent ticket release will be staged over the following weeks. Please pass this information onto your third-party logistics provider.

Freight operators' standard, business as usual terms and conditions will apply. Please note, these terms and conditions are often not as flexible as those used by port operators and freight companies at the short straits and you cannot expect to turn up and go. However, there is greater flexibility than previously, allowing for refunds and re-bookings where that is normal practice on a route.

For those companies and sponsors arranging their own alternative routes, modelling indicates that there is unlikely to be significant, sustained disruption to other high volume roll on roll off (RoRo) routes between GB and the EU, although there is a risk of some queues and delays around key ports if significant proportions of unready HGVs arrive at ports and need to be turned away. Government is working with Local Resilience Forums to ensure proportionate plans are stood up to manage any congestion.

b. Express Freight Service

DHSC has retained its Express Freight Service (EFS) arrangements with three 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 transition period as required.

All suppliers should register for the EFS. By doing so you will reduce the time it takes for us to respond to any request to use the service should you need to come the end of the Transition Period. It is the same system to register for both the GSFC and EFS. The links are below.

If you registered for EFS in 2019, your details are retained from last time and all you need to do is to check and confirm that the current details we have for your company are up to date.

Registration links for the Government Secured Freight Capacity (GSFC) and Express Freight Service (EFS):

- To register for the first time, please use this link
- To check a registration using your existing credentials, please use this link

2. Supporting trader readiness for the new customs and border processes

Many businesses and sponsors have already acted to prepare for the new customs and border processes. This is the right thing to do and is the main lever we have at our disposal to reduce disruption at the short straits and for the flow rate to remain close to normal. You now have less than two months left so it is really important that you act now. An FTA will not remove any of these requirements.

If you are planning to trade with businesses in Europe next year, you should:

- act now to appoint a specialist to deal with your customs declarations, and work with them to ensure your business is ready for 1 January
- check if you can delay your declarations and duty payments
- speak to EU businesses you trade with to check they've prepared for EU controls
- sign up for the free Trader Support Service if you plan to move goods into Northern Ireland.

To support traders further, we have produced a set of more detailed guidance and held a series of webinars. This guidance and all previous webinars are available via our DHSC eXchange platform. If you are not yet a member, you can request an invite by emailing one of the teams at the email addresses near the end of this letter. On the platform, you will also find the updated Border Operating Model, setting out how the border will work from the end of the transition period.

Since August, HMRC has been contacting traders operating across the UK-EU border, as part of their 'Field Force' contact campaign. We have asked that they include many priority suppliers to the health and care system. If you should be contacted by HMRC, please take

the call so that they can understand your readiness across all relevant business areas and assist you with any specific issues you might have.

3. Buffer stocks of medical supplies where possible

We have been clear that holding additional stocks on UK soil provides a further buffer against disruption and, where it is possible, it is a valuable part of a robust contingency plan. To build upon past work and ensure a co-ordinated approach, we are asking suppliers to confirm their contingency plans for the end of the transition period, 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 continue to encourage companies to make stockpiling a key part of contingency plans and ask industry, where possible, to stockpile to a target level of six weeks' total stock on UK soil. DHSC stands ready to support companies with their plans and understands that a flexible approach to preparedness may be required – that considers a mixture of stockpiling and rerouting plans as necessary. While we have not explicitly asked sponsors of clinical trials and clinical investigations to stockpile, we are encouraged to see that many have included some stockpiling in contingency plans.

The Department continues to work with NHS Supply Chain to build up a Centralised Stock Build (CSB) of fast-moving medical devices and clinical consumables. This includes supplies vital for the NHS response to COVID-19. We are on course to achieve our target of six weeks' stocks in the CSB by the end of the transition period.

4. Regulation

On 5 November, the UK Government made a statement following the fourth meeting of the Ireland/Northern Ireland Specialised Committee between the Government and the European Commission. The Committee agreed an approach had been reached on a phased process for implementing medicines regulation in Northern Ireland up to 31 December 2021, providing the additional time needed for businesses to prepare in relation to batch testing, importation and Falsified Medicines Directive (FMD) requirements. Further guidance to business in relation to the announcement, including the steps needed to be taken to ensure compliance during 2021, and more detail of what has been agreed, will be in due course.

There will be a pragmatic 1-year time-limited approach to the implementation of FMD 'safety features' and regulatory importation requirements which will help ensure no disruption to the critical flow of medicines to Northern Ireland at the end of the transition period as we deal with the challenges of COVID-19 and give industry additional time for work on preparedness.

The Protocol will mean new requirements for businesses, but this agreement gives industry more time to adapt–supply chains to help ensure the continued supply of medicines into Northern Ireland. The EU has been clear that there will be no further extensions. Twelve months remains a challenging timescale within which to mitigate risks to supply into Northern Ireland and significant work and effort will be required by industry, with support of the Department, to be ready for 31 December 2021.

The Medicines and Healthcare products Regulatory Agency (MHRA) published guidance on 1 September on the regulation of medicines and medical devices at the end of the transition period. To help ensure continuity of supply of medicines and medical devices from 1 January 2021, especially in a non-negotiated outcome with the EU, the UK will unilaterally recognise certain EU regulatory processes for a time-limited period. This recognition is known as 'standstill'. You can find more detail on the guidance here.

In October, the MHRA published a further set of guidance relating to the movement of goods after the end of the transition period. Links to this new and updated guidance are below. As part of its role as the UK's standalone medicines and medical devices regulator, the MHRA will continue to publish post-transition guidance to support its stakeholders. All guidance published to date can be found here.

For suppliers of blood, organs, tissues and cells, new guidance was published at the beginning of November in relation to quality and safety from 1 January 2021. This guidance can be found here for organs, tissues and cells and here for blood and blood components.

5. Shortage management response

Suppliers and sponsors should continue to raise any anticipated or actual supply disruption through business as usual routes. Medicine suppliers have a statutory duty to provide early notification of supply disruption to the department and the contact details for the Medicines Supply Team are at the end of this letter. The Department is working more closely than ever with the Devolved Administrations, Crown Dependencies, NHS England and NHS Improvement, the MHRA and all operators in the supply chain to prevent and manage shortages and minimise the risks to patients.

The National Supply and Disruption Response (NSDR) service remains operational in order to assist with the response to COVID-19. NSDR will be stood up for the end of the transition period regardless of the COVID-19 situation. At present, supply issues not related to COVID-19 should be raised through business as usual routes.

Finally, we are asking NHS trusts and community pharmacies not to stockpile locally and not to alter usual prescribing or ordering patterns. Either of these actions can impact the supply chain and jeopardise national plans for continuity of supply. We are working hand-in-hand with NHS England and NHS Improvement, as well as NHS Supply Chain to ensure these messages reach the front line.

Useful links

Contact the relevant team at the department at:

- medicines contingency (for EoTP-related returns or queries): medicinescontingencyplanning@dhsc.gov.uk
- medicine shortages or discontinuations reporting: DASH@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: nhsi.eucpc@nhs.net

Or for more information on border and customs processes, visit:

- https://www.gov.uk/transition

Useful COVID-19 related links:

- all guidance and advice on COVID-19 can be found at www.gov.uk/coronavirus.

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

- Department of Health and Social Care – @DHSCgovuk
- NHS England and NHS Improvement – @NHSEngland
- Public Health England – @PHE_uk
- MHRA - @MHRAgovuk

Please remain in close contact with the teams in the department. Continued engagement with this process and effective information sharing are imperative to the success of our joint efforts.

Yours sincerely,

Steve Oldfield
Chief Commercial Officer

Department of Health and Social Care