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Dear Colleagues,

EU Exit – medicines supply continuity

The Department of Health and Social Care (DHSC), which has overall responsibility for medicines supply, has taken actions to help ensure medicines continue to be available and that any supply disruptions are mitigated. **This means their guidance is that it is not necessary for local providers, whether in hospitals or primary care, to stockpile medicines or for clinicians to write longer prescriptions for patients.** Unnecessary stockpiling puts more pressure on the supply chain and can risk additional pressure on the availability of medicines in other parts of the country. Prescribers and pharmacists should explain to patients that they should continue to order their prescriptions as normal.

As set out in [DHSC's recent update to industry](#), actions to protect supplies include:

- **Alternative routes** – DHSC has worked with suppliers to help ensure that they have alternative routes away from the Channel short straits crossings to mitigate against any risk of bottlenecks at ports. The Government has secured freight capacity on ferry routes for all health supplies, as well as express freight capacity. The NHS will have access to next day delivery on small consignments, including temperature-controlled or hazardous products, 48-hour delivery for larger loads, and access to specialist services, including hand-delivered courier services if needed.
- **Supporting trader readiness for the new customs and border processes** – The Government is supporting suppliers' preparation to ensure they are ready for new customs and border arrangements that will be in place from 1 January 2021.

If your pharmacy (or wider non-medicines trust procurement team) directly imports any medicines, clinical trial supplies or other products into the UK from the EU, this is a reminder that from **1 January 2021** you will need an Economic Operators Registration Identification (EORI) number to track and

register customs data, as you would do when already importing from the rest of the world. If your organisation exports from Great Britain to the EU – eg clinical trial sites – a UK EORI number must be used by the business making the export declaration and an EU EORI number must be used by the business making the import declaration on the EU side.

Please work with your procurement colleagues to review the Government's [Border Operating Model](#) and [EORI guidance](#) to develop your plans to manage customs declarations, including whether to use a customs agent or brokerage service. Please look out for forthcoming government communications in relation to clinical trials.

- **Buffer stocks of medical supplies where possible**
 - [DHSC has asked suppliers of medicines](#) from or through the EU to stockpile six weeks' total stock on UK soil where possible. This buffer stock includes unlicensed medicines and specials. For medicines that cannot be stockpiled because they have short shelf-lives, such as medical radioisotopes, suppliers must ensure they arrange alternative routes using air freight.
 - In preparation for further possible waves of COVID-19, DHSC has recently tendered for stockpiles for key critical care medicines, antibiotics and end of life care medicines using an agreed list of medicines, presentations and volumes; these have been purchased by Public Health England (PHE) on behalf of DHSC. Stocks of certain potential and confirmed therapeutic medicines for COVID-19 have similarly been purchased.

- **Regulation** – The Government is making sure that medicines, medical devices and clinical trials licensed or tested in the EU can continue to be imported and used in the UK by amending regulations. The Medicines and Healthcare products Regulatory Agency (MHRA) has published [guidance](#) for the end of the transition period and will continue to publish guidance post-transition.

The EU Falsified Medicines Directive 2011/62/EU (FMD) was published to prevent the increasing risk that falsified medicines would enter the legal supply chain and reach patients. However, as of 1 January 2021, pharmacies in Great Britain (as well as wholesalers, hospitals and others handling or

supplying medicines) will no longer be able to access the EU-based systems necessary to verify and decommission medicines. Please see the [update and guidance](#) provided by the UK FMD Working Group for Community Pharmacy, which also applies to hospital pharmacy. This includes some next steps that you and colleagues may need to take regarding local pharmacy systems and disconnecting them from the FMD systems.

- **Shortage management response** – Occasionally, the NHS experiences temporary shortages of medicines and a number of measures are in place to manage shortages and minimise the risks to patients. These are set out in the published [guidance](#), which sets out the well-established systems for the escalation and management of medicines shortages. The [Serious Shortage Protocol arrangement](#) provides an extra tool to manage and mitigate primary care medicine shortages in the exceptional and rare situation that other measures have been exhausted or are likely to be ineffective.

If a specific medicine shortage emerges at national level, prescribers and pharmacies will be quickly alerted and advised of the appropriate management plan for patients who may be affected. Please continue to report medicine shortages through the usual routes and ensure that your organisation shares the information in supply disruption emails, Central Alerting System alerts and other system communications with fellow clinicians.

I hope this information is useful in allowing you to understand the work underway and any actions you will need to take. Thank you in advance for your continued support and work on these important issues.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'K. W. Ridge', with a long horizontal flourish extending to the right.

Dr Keith Ridge CBE

Chief Pharmaceutical Officer for England