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**Publishing Approval
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Dear colleagues,

11 April 2019

Re Preparing for the possibility of a ‘no deal’ EU exit for primary care contractors

The Department of Health and Social Care (DHSC) is leading the response to EU exit across the health and care sector. DHSC published [Operational Guidance](#) in December which set out actions needed from the NHS.

This letter is a companion to the guidance and outlines what has been done nationally to assess the potential risks to primary care, and give clear direction on the actions that contractors delivering primary care still need to take locally. It is important for everyone working in primary care to understand the actions that are needed.

Primary care contractors will not be asked to take part in the daily situation reporting that NHS England and NHS Improvement will be undertaking, however we do ask that any issues or concerns are escalated as appropriate. Details of who you should escalate issues and concerns to can be found at the end of this letter.

Contingency planning for a ‘no deal’ EU exit has focussed on the following areas:

Continuity of supply

DHSC has been working with suppliers of medicines, medical devices and clinical consumables to identify which products, ingredients or components are either made in the EU or are imported into the U.K. via the E.U.

DHSC has contacted more than 1,300 suppliers and wholesalers of medical devices and clinical consumables which has included the key suppliers to primary care. This is to understand their supply chain's, reliance on supply from the EU and proposed contingency measures for a ‘no deal’ EU exit.

Pharmacy and prescription only medicines suppliers and manufacturers have been asked to ensure that they increase their buffer stocks to hold at least an additional six weeks of stock (over and above usual buffer stock) in the UK. The vast majority of companies have confirmed stockpiling plans are in place. The intention is that these buffer stocks will be continuously replenished to ensure an uninterrupted supply to providers through their business-as-usual supply routes. For those



medicines that cannot be stockpiled because, for example, they have short shelf-lives, we have asked suppliers to use alternative routes using airfreight. The DHSC and NHS England have also reviewed general sales list medicines, specials and unlicensed products, engaging with suppliers to ensure these products are all included in government contingency plans for prioritisation.

The Department for Transport are responsible for commissioning additional ferry capacity equivalent to the total volume of supplies required by the NHS and social care, as well as alternative shipping routes dedicated for NHS use to ease pressure on the short straits crossings to Dover and Folkestone. The Government has agreed that medicines and healthcare products will be prioritised on these alternative routes.

- **Primary care contractors do not need to change their behaviour in terms of ordering stocks or engaging with suppliers, as this work has been undertaken nationally. This means contractors should not stockpile medicines, medical devices or clinical consumables and should advise patients not to do so either.**
- **However, for medical devices and clinical consumables that your practice or pharmacy orders directly from companies based in the EU on a short lead time basis (i.e. 24 to 72 hours), you should plan for lead times of around three days longer on these items only. Please note that this advice does *not* apply to medicines and does not apply to products ordered via a wholesaler.**

Serious Shortages Protocols

In early 2019, changes to legislation were made to permit the Government to issue Serious Shortage Protocols (SSPs). Serious Shortage Protocols are an additional tool to manage and mitigate medication shortages and may be used in the exceptional and rare situation when other measures have been exhausted or are likely to be ineffective.

An SSP would enable community pharmacists to supply in line with a protocol for a specific medicine rather than against a prescription, without going back to the prescriber. It would only be introduced in the case of a serious shortage if, in the opinion of Ministers, it would help manage the supply situation, if the clinicians advising Ministers think it is appropriate, and after discussion with the manufacturer and/or marketing authorisation holder.

Only if the protocol allows it, community pharmacists could supply either an alternative quantity, strength, pharmaceutical form or medicine as prescribed in the protocol. Each protocol would clearly set out what action can be taken by the community pharmacy, under what circumstances, for which patients and during which period. Pharmacists will still need to use their professional judgement and refer patients back to their prescriber if it is not appropriate to make a supply under the protocol.

Vaccines

Public Health England (PHE) manages significant stockpiles of vaccine for the national immunisation programme, as part of their business as usual planning. It is working closely with vaccine suppliers to ensure replenishment of these existing stockpiles continues in the event of supply disruption in the UK. DHSC is also working to ensure that there are sufficient stockpiles of vaccines which are not centrally procured such as those for the adult influenza vaccination programme, and for other NHS and non-NHS uses i.e. uses outside of the national vaccination programmes such as for travel and occupational health purposes within its medicines contingency programme.

Additional information

- Information on continuity of supply is available on [NHS England's website](#).
- [Supporting Q&As](#) are available which may be helpful in any discussion with patients about their medicines and medical products.
- Information for patients is also available on [nhs.uk](#).

Non-clinical goods and services

DHSC and NHS England have worked with national and local representative groups as well as providers across the four primary care contractor groups to identify key suppliers of non-clinical goods and services. These are services that would be considered critical and, if disrupted, would impact upon front-line services being delivered. We have engaged with these suppliers, including Primary Care Services England (PCSE), to ensure that they have adequate contingency plans in place to manage any disruption that may arise as a result of a 'no deal' EU exit.

Reciprocal Care

The Government is seeking to protect current reciprocal healthcare rights through transitional bilateral agreements with other member states. DHSC will provide updates and further information once the position on post EU Exit reciprocal arrangements is agreed.

Existing charging policies for dental, ophthalmic and prescriptions costs continue to apply. GP practices should continue promoting the completion of the supplementary questions section of the GMS1 form.

- **GP Practices should continue registering patients according to the [Standard Operating Principles](#). If you have any concerns about demand in your area from UK nationals returning, please escalate this through normal operational procedures.**

Additional information

- Information on how UK nationals can access healthcare in Europe can be found [here](#). This includes information on the validity of European Health Insurance Cards (EHIC) and travel and health insurance requirements.
- Information for primary care staff on providing healthcare for overseas visitors from the EEA under the current rules can be found [here](#).
- Information on the GMS1 form can be found [here](#).

Workforce

DHSC, NHS England and NHS Improvement are currently monitoring workforce levels across both the health and social care sector and are working closely with professional bodies and regulators to ensure an understanding of workforce issues which may result from a 'no deal' EU Exit.

- **Primary care contractors should publicise the [EU Settlement Scheme](#) to staff who are EU citizens.**

Data

Guidance on the actions NHS contractors need to take as part of the Government's contingency preparations for a 'no deal' EU Exit in order to ensure continuity of access to, processing and sharing of personal data has been [published and sent to NHS organisations](#).

NHS Digital, in partnership with DHSC has engaged with the national GP Principal Suppliers and also the major subsidiary suppliers under [GP System of Choice Lot 1](#) to review EU Exit planning. This work has not identified any significant risks related data flows that would be considered critical or could disrupt front-line services being delivered.

- **GP practices do not need to engage with these national software providers. If GP practices have any separate local agreements, they would need to review these. Dentists community pharmacists and optometrists should investigate their reliance on transfers of personal data from the EU/EEA to the UK, especially those that are critical to patient care and/or would have a serious impact upon the system if they were disrupted.**

Additional information

- Advice from the Department for Digital, Culture, Media and Sport and the Information Commissioner's Office (ICO) on data protection in a no deal scenario, is available on [gov.uk](#) and on the [ICO website](#), in particular to determine where to use and how to implement standard contractual clauses.
- Information on data, including frequently asked questions for primary care contractors, is available on [NHS England's website](#).

Research and clinical networks

Some primary care contractors conduct clinical trials and others identify and refer people to participating sites. These contractors should:

- Continue participating in and/or recruiting patients to clinical trials and investigations up to and from the day that the UK leaves the EU. This should occur unless you receive information to the contrary from a trial sponsor, organisation managing the trial or clinical investigation, or from formal communications advising that a clinical trial or clinical investigation is being impacted due to trial supplies.

- Follow the [government's guidance](#) on the supply of investigational medicinal products (IMPs) for clinical trials in a 'no deal' scenario, if you sponsor or lead clinical trials or clinical investigations in the UK.

Raising concerns

Established processes and systems already exist for responding to serious supply disruption.

Medicines shortages

The DHSC already works very closely with manufacturers and wholesalers of medicines to minimise the impact and manage medicines shortages which can occur for many different reasons which may or may not be related to EU exit. Intelligence from the NHS Commercial Medicines Unit, the Community Pharmacy Brexit Forum, patient groups and other sources enables this. These business as usual arrangements will continue supplemented by intelligence gathered by Regional Medicines EU Exit Panels. Actions to take regarding medicines shortages will be shared with contractors as necessary through NHS England local teams.

If you become aware of a medicines shortage, you should continue to seek to resolve supply disruption issues through your normal supply arrangements and where a medicine is not available liaise with the prescriber regarding a suitable alternative.

Issues which may cause service delivery disruption

If the issue impacting your ability to deliver services relates to supplies you should seek to resolve these issues through your normal supply arrangements. If you are unable to achieve a satisfactory resolution or if you become aware of any issues not related to supplies caused by EU exit that may impact upon service delivery, you should escalate the issue at the earliest opportunity to the organisation which commissions your service. For most GPs this would be your CCG, or for Public Health Immunisation Programmes, to NHS England local Public Health Commissioning Teams, for community pharmacists, dentists and optometrists, this would be the NHS England Primary Care Commissioning Team (pharmacy and optometry), please email england.gmtop@nhs.net. For any other issues relating to EU Exit which you believe may cause a disruption to service delivery, please raise these with the organisation that commissions your service.

Thank you for your continued support in the weeks and months ahead.

Yours sincerely,



Professor Keith Willett
EU Exit Strategic Commander

Medical Director for Acute Care & Emergency Preparedness

A handwritten signature in blue ink, appearing to read "Geddes". The signature is fluid and cursive, with a large initial "G" and a trailing flourish.

Dr David Geddes
Director of Primary Care Commissioning