LOCSU

LOC HOT BRIEF

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Private & Confidential to Optical Contractors, Performers and Dispensing Opticians

Hot Briefs contain guidance and advice from the Optical Confederation and LOCSU on important issues relevant to all ophthalmic contractors, performers and dispensing opticians, which we would like LOCs to be aware of or to take action on and to disseminate to all contractors, performers and dispensing opticians in their area as soon as possible.

Update from DoH on fax machines

Following reports in the media over the weekend, it is clear that the Department of Health are looking to accelerate their long-publicised intention to discontinue fax machines for the purpose of making referrals.

The Optical Confederation and LOCSU have been making the case for a number of years that optical practices in England need secure connectivity for referrals, rather than relying on fax machines. The issue has always been that optical practices sit outside of the Health and Social Care Network and that significant investment would be needed in order to prepare for, and facilitate, referral via non-fax means.

We believe that NHS England now understands this and are well aware of the need to put secure and effective referral routes in place for the optical sector. NHS England has been working on options for a potential solution with the OC and LOCSU being involved in these discussions. We have been advised that an announcement on NHS England's plans to achieve this is expected by January 2019 at the latest.

In the meantime, we know that fax switch offs are already causing problems for some contractors and LOCs. We are working on resolving these problems with NHS England on a case by case basis. If you experience problems locally with fax-based referrals, please let your OC membership body and/or LOCSU know so that appropriate support or escalation can be offered. We are also seeking to clarify liability in the event that something goes wrong when contactors are following local arrangements where fax machines have been switched off, both now and into the future as part of a more general solution.

Government's preparations for a no-deal Brexit

The Department of Health and Social Care has issued a letter to contractors detailing the Government's preparations for a no-deal Brexit. Please see the letter below.

Department of Health & Social Care

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07 December 2018

Government's preparations for a March 2019 'No Deal' scenario: an update

On 23 August 2018, I wrote to you to set out the Department's ongoing preparations for the United Kingdom (UK) leaving the European Union (EU), including the unlikely outcome that we leave the EU without any deal in March 2019.

As you will be aware, the Government and the EU have now agreed the basis upon which the UK will leave the EU in March 2019. This represents a significant step towards the UK's objective of securing an orderly exit from the EU. Nevertheless, as a responsible Government it is only right that we should continue to plan for all scenarios. This includes making the necessary arrangements to ensure the health and care system is prepared for the UK leaving the EU without an agreement on 29 March 2019, and this letter provides further information.

Update to cross-Government planning assumptions

In my previous letter, I advised that the cross-Government planning assumption about potential border delays would be subject to revision in light of future developments. Government departments have been working to design customs and other control arrangements at the UK border in a way which ensures goods can continue to flow into the country and won't be delayed by additional controls and checks. On the UK side, this work is proceeding well, and we have been clear we will not impose additional controls and checks.

However, the UK Government does not have control over the checks which member states impose at the EU border. The European Commission has made it clear that, in the event of a 'no deal' scenario, it will impose full third country controls on people and goods entering the EU from the UK. Whether this happens or not is in their hands, not ours.

Although we cannot know exactly what each member state will do with respect to checks on the EU border, the cross-Government planning assumptions have been revised so we can prepare for the potential impacts that the imposition of third country controls by member states could have. These impacts are likely to be felt mostly on the short straits crossings into Dover and Folkestone, where the frequent and closed loop nature of these mean that both exports and imports would be affected.

The revised cross-Government planning assumptions show that there will be significantly reduced access across the short straits, for up to six months.

This is very much a worst-case scenario; however, as a responsible Government, we have a duty to plan for all scenarios. If the UK exits the EU without a deal, we would, of course, be pressing member states hard to introduce pragmatic arrangements to ensure the continued full flow of goods which would be to their benefit as well as ours. And in areas where we cannot tolerate significant risk

to the flow of goods, such as with medicines and medical products, we need to have contingency plans in place for this worst-case planning assumption.

The Government recognises the vital importance of medicines and medical products and is working to ensure that there is sufficient roll-on, roll-off freight capacity to enable these vital products to continue to move freely in to the UK. The Government has also agreed that medicines and medical products will be prioritised on these alternative routes to ensure that the flow of all these products will continue unimpeded after 29 March 2019. This includes all medicines, including general sales list medicines.

Supply of medicines and vaccines

In August, I wrote to pharmaceutical companies that supply the UK with prescription- only or pharmacy medicines from, or via, the EU or European Economic Area (EEA). I asked companies to ensure they have a minimum of six weeks' additional supply in the UK, over and above their business as usual operational buffer stocks, by 29 March 2019 to prepare for a possible 'no deal' scenario.

I am extremely pleased by the response rate so far from industry, and my officials continue to support companies and their representative bodies, so there is no need for providers to contact suppliers directly. Our UK-wide contingency plan also contains other measures, including arrangements for the air freight of medicines with a short shelf life, such as medical radioisotopes.

My officials are also considering how to support manufacturers taking part in the contingency planning. Part of this support will include funding to provide additional capacity for the storage of medicines. A bidding process to apply for such funding has been undertaken in recent weeks and contract agreements are imminent.

Whilst the six-week medicines stockpiling activities remain a critical part of our UK- wide contingency plan, it is clear that in light of the changed border assumptions described above this will now need to be supplemented with additional actions. I am writing in parallel to pharmaceutical companies, and my officials will continue to work closely with these companies to develop our plans.

Even though the planning assumption has been revised, the Department will continue to develop the UK-wide contingency plan with pharmaceutical companies. May I therefore take this opportunity to restate my message from August: UK health and social care providers – including hospitals, care homes, GPs and community pharmacies – should not stockpile additional medicines beyond their business as usual stock levels. There is also no need for clinicians to write longer NHS prescriptions.

Local stockpiling by UK health and social care providers is unnecessary and could cause shortages in other areas, which would put patient care at risk. Any incidences involving the overordering of medicines will be investigated and followed up with the relevant Chief or Responsible Pharmacist directly. The Department and the NHS will implement monitoring mechanisms to ensure Trusts are not stockpiling locally. NHS organisations should continue to manage shortage issues through existing communication channels.

Furthermore, if asked, clinicians should advise patients that the Government is working with industry to ensure a continued supply of medicines from the moment we leave the EU; patients should not store additional medicines at home.

Our plans are kept under review as new information becomes available, and we will communicate further guidance if necessary.

Vaccines

Officials in Public Health England are leading a separate programme to ensure the continuity of supply for centrally-procured vaccines and other products that are distributed to the NHS for the UK National Immunisation Programme or used for urgent public health use.

Supply of medical devices and clinical consumables

On 23 October 2018, I wrote to suppliers of these products, explaining the contingency measures the Department is taking to increase national stock levels of medical devices and clinical consumables.

NHS Supply Chain officials are contacting suppliers who routinely import products from the EU to establish the action required to achieve this. In parallel, my officials are requesting all suppliers that source products from the EU to review their supply chains so that the health and care system has access to the products it needs.

The Department is also developing national plans to ensure the continued movement of medical devices and clinical consumables that are supplied from the EU directly to organisations delivering NHS services. In conjunction with representatives from industry and trade associations, my officials have established a working group to test and refine our contingency plans and there will be further announcements made later this month.

Despite the planning assumption being revised, there is currently no need for UK health and social care providers to stockpile additional medical devices and clinical consumables beyond their business as usual stock levels. My officials will continually review the situation and issue further advice should this change.

If you have any questions relating to the supply of medical devices and clinical consumables, please contact mdcc-contingencyplanning@dhsc.gov.uk.

Supply of blood and other products of human origin

On 23 August 2018, the Government issued two pieces of guidance on ensuring the quality and safety of blood and blood components, and of, organs, tissues and cells in a 'no deal' scenario.

If the UK leaves the EU without a deal, the EU Blood Directives, the EU Organ Directives and EU Tissues and Cells Directives would no longer apply to the UK. The UK already implements these EU directives, so the safety and quality standards would not change after EU Exit. The UK would, however, become a 'third country' and the law will be amended under the EU (Withdrawal) Act to reflect this change. Furthermore, the EU (Withdrawal) Act will enable the Government to update the provisions in the UK to respond to emerging threats, changing safety and quality standards, and technological advances.

Blood and blood components

Whilst the planning assumptions have been revised, the UK is largely self-sufficient in the supply of blood and blood components. Nevertheless, my officials will continue to engage with the health and care sector and industry bodies to prepare for any possible disruption. NHS Blood and Transplant (NHSBT), the organisation that provides blood and transplantation services to the NHS, is leading the contingency planning work to ensure a safe supply of blood and blood components after EU Exit.

It is advised that you consult with the Medicines and Healthcare products Regulatory Agency prior to importing or exporting blood or blood components to or from the EU, and officials can be contacted at gmpinspectorate@mhra.gov.uk.

Organs

NHSBT is also responsible for organ donation and transplantation in the UK. Officials in NHSBT are working with the regulator for organs, the Human Tissue Authority (HTA), to ensure that appropriate written agreements are in place with EU organisations to allow organ exchange to continue after 29 March 2019. Transplant centres do not need to take any further action.

If you have any queries regarding organs for transplantation, please contact HTA officials.

Tissues and cells (including reproductive cells)

Licensed UK establishments that import or export tissues or cells will need written agreements with the relevant EU licensed establishments to continue importing and exporting. My officials are working with regulators – the HTA and the Human Fertilisation and Embryology Authority (HFEA) – to ensure licensed UK establishments are prepared for EU Exit so that the import of tissues and cells from the EU can continue.

Please direct any queries regarding non-reproductive tissues and cells to the HTA. For queries regarding reproductive cells, HFEA officials can be contacted at enquiriesteam@hfea.gov.uk.

Supply of non-clinical consumables, goods and services

For NHS Provider Trusts, the Department has identified categories of national suppliers for non-clinical goods and services that it is reviewing and managing at a national level. An example of such a category is food, for which the Department is engaging with both suppliers and health experts to identify and plan for any food items that might suffer supply disruption in the event of the UK exiting the EU without a deal. My officials are also working closely with their counterparts at the Department for Environment, Food & Rural Affairs in analysing this area, and standard guidelines will be developed for health and social care providers on suitable substitutions arrangements for any at risk food items identified.

In October, I wrote to the Chief Executives of NHS Provider Trusts outlining the scope of the Department's work and advising on the steps Trusts need to take to assess their remaining supply chains for a 'no deal' scenario. This included a self-assessment tool for Trusts to use to assess their supply chains that are not covered by the Department, such as 'hotel services', 'office solutions' and services carried out abroad.

I am pleased by the engagement from Trusts so far, and I would urge Trusts that have not yet completed their self-assessment to identify contracts that may be impacted in a 'no deal' EU Exit, alongside planned mitigating activities, and return the results to contractreview@dhsc.gov.uk.

The Department is analysing the self-assessment review data received from Trusts, and my officials will advise further on any changes and recommendations at a local level. This will be communicated to Trusts later this month.

The supply chain reviews conducted by my Department cover all areas of the health and care system, and work is in progress to identify risk areas specific to health and care providers in the primary care and social care sectors. Where necessary, we will be writing to social care commissioners and providers to outline the scope of the Department's work in these areas and advising on actions that need to be taken locally.

Workforce

EU nationals play a crucial role in our health and care system, and I want them to know that they have a secure future here after the UK leaves the EU. As the Prime Minister reiterated recently, regardless of whether we leave the EU with or without a deal, the rights of EU citizens will be protected here.

EU Settlement Scheme

Through the EU Settlement Scheme, which will launch in early 2019, EU nationals will be able to register for settled status if they have been here for five years, or pre- settled status if they have been here for less than five years. The process to register is simple and largely digital, and will cost £65 per adult and £32.50 per child. I am aware that some employers are planning to meet this cost, and this is something that you may wish to consider.

To test the system prior to wider launch, the Home Office has opened it up to health and care staff for a period of three weeks initially, until Friday, 21 December 2018. NHS Employers recently wrote to HR directors in the NHS, and members of the Cavendish Coalition, with full details of the scheme and an update on plans to further test it in the healthcare sector. My officials have also conducted webinars for organisations in the health and social care sectors to explain, in detail, the process for registering for the EU Settlement Scheme. Organisations have also been provided with an online toolkit to help promote the scheme to the EU nationals in their workforce. There is no obligation for EU nationals to register early; however, **it is an opportunity for many to get this certainty earlier, and I would strongly encourage you to publicise this to your health and care staff who are EU nationals.**

We have tried to ensure as many EU nationals as possible can take part in the pilot. The full list of those that are eligible to take part in the pilot scheme can be found in the Immigration Rules. This includes any EU national who is employed by an organisation that delivers health and care services and is registered with the Care Quality Commission, whether that is an NHS organisation or an independent health and care employer.

Research and clinical trials

The UK is committed to a competitive service for clinical trial assessments after EU Exit, regardless of the outcome of negotiations.

Clinical Trials and Clinical Investigations

On 12 October 2018, the Government issued guidance on the supply of investigational medicinal products (IMPs) for clinical trials in a 'no deal' scenario.

My officials continue to engage with the life sciences industry regarding contract research trials of IMPs. However, your organisation may also be involved in running investigator-initiated trials, other industry collaborative clinical trials, or non-commercially funded trials of IMPs; or clinical trials or clinical investigations using medical devices. Reiterating the Government's guidance, I encourage all organisations running these clinical trials or clinical investigations in the UK to liaise with trial and study sponsors to understand their arrangements for ensuring continuity of supply chains for clinical trial of IMPs and medical devices which come from, or via, the EU or EEA are guaranteed in the event of border delays. If you have further queries concerning IMPs or clinical devices, please contact officials at imp@dhsc.gov.uk.

Business continuity plans

The health and care system should continue to prepare for a 'no deal' scenario, and this will form part of existing local business continuity plans. These plans should continue to be updated to factor a 'no deal' scenario, and organisations should adopt a 'reasonable worst case' mindset. You will need to continue to make links across health and social care, and while organisations are responsible for their own business continuity plans, you may choose to develop your EU Exit contingency plans in collaboration with other providers and commissioners across your Sustainability and Transformation Partnership or region.

At a local level, Local Resilience Forums are coordinating efforts to assess the broader impacts of EU Exit using a template provided by the Ministry for Housing, Communities and Local Government. I strongly encourage all organisations in the local health and care economy to input to this work and inform the assessment.

Further information

I will continue to issue guidance prior to 29 March 2019 to support the health and care system prepare for EU Exit. All information published by the Department – and other parts of Government – on EU Exit can be viewed here, and my officials will update this regularly so that the health and care system can be aware of ongoing preparation and actions to undertake. For any other queries, I would again encourage you to use your established points of contact in national organisations to assist on specific areas.

Yours ever,

MATT HANCOCK