



Preparations for Brexit – guidance for healthcare providers and manufacturers of medical devices

On 21 December the Department of Health and Social Care (DHSC) published a [letter](#) and [operational readiness guidance](#) in the event of a no deal Brexit – practices and practitioners may have received copies from their NHS Area Team, or via the latest LOCSU Hot Brief.

The guidance provides advice on what Government, health care commissioners and health care providers need to consider in advance of EU exit. The Government is setting up a national Operational Response Centre, supported by regional centres, to manage and resolve any issues caused or affected by EU exit.

The guidance states that “All providers of NHS services must consider and plan for the risks that may arise due to a ‘no deal’ exit.” In reality for most eye care providers there are few risks to patient care that will need to be managed. Key points to note from the guidance are:

- DHSC has been in discussions with manufacturers and suppliers of medicines and medical devices to understand the risks to the supply chain. Medicines and medical devices will be given priority through border control.
- Health care providers and patients have been asked not to stockpile medicines or medical devices beyond what they would normally hold.
- Workforce issues – the qualifications of any regulated health care professional (e.g. optometrist, dispensing optician, contact lens optician) from an EU country that were recognised on or before 29 March will continue to be recognised after 29 March.
- Providing healthcare to EU nationals. There is no nationality requirement for eligibility for GOS, so entitlement will be unchanged. If you provide any other NHS funded eye care services to patients from EU countries, this may be affected, depending on what reciprocal healthcare arrangements the Government puts in place. This has not yet been clarified. In cases of doubt contact your NHS Area Team or Optometric Adviser.

In addition, on 3 January the Medical and Health Care Products Regulatory Authority (MHRA) published further [guidance](#) on the regulation of medicines and medical devices, if there is no deal (FODO provided a [briefing](#) on the earlier MHRA guidance). Key points to note from this update are that:

- The UK will continue to recognise prescriptions from EEA/EU countries
- For (an unspecified) time limited period, medical devices will continue to be allowed onto the UK market that are in conformity with the EU Regulations and are CE marked
- UK-based Notified Bodies (which assess and grant CE marking) will be given an ongoing legal status so that the UK continues to recognise the validity of certificates that they issued prior to 29 March 2019. This will also allow products covered by certificates issued by UK-based notified bodies to continue to be placed on the UK market after 29 March 2019.

- However, for UK manufacturers who wish to export, UK-based Notified Bodies will no longer be recognised by the EU after 29 March 2019, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive. As such these products will not be able to be placed on the EU market.
- From 30 March, the UK will have a regulatory system in place which will mirror all the key elements contained in Regulations 2017/745 on medical devices (MDR) and 2017/746 on in vitro diagnostic medical devices (IVDR) and which will be brought into force in line with the transitional timetable being followed by the EU for the full application of those two Regulations. All medical devices and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market.

We will continue to provide further briefings and updates over the coming months.

For further information contact info@fodo.com

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