ABHI ANALYSIS

First wave of Technical Papers

ABHI

OVERVIEW

- 25 papers published in first wave, a further c.45 expected. They provide guidance in the event of a no-deal scenario.
- Of most relevance to the HealthTech Sector are:
  - How medicines, medical devices and clinical trials would be regulated
  - Submitting regulatory information on medical products
  - Horizon 2020 funding
  - Trade remedies
  - Trading with the EU
  - Classifying your goods in the UK Trade Tariff.

- Three letters sent to
  - 1.) The NHS
  - 2.) Pharmaceutical companies
  - 3.) HealthTech companies outlining government contingency plans.

ABHI

TECHNICAL PAPERS

- The following slides give the main information from the most relevant papers.
- The full list of published technical papers can be found here.
- The papers contain guidance for companies in the event of a **no deal**.

ABHI

HOW MEDICINES, MEDICAL DEVICES AND CLINICAL TRIALS WOULD BE REGULATED

The UK would unilaterally recognise the EU CE marking system

- On day one, any product with a CE mark would be eligible for registration on the UK market. The UK will comply with the MDR and IVDR.
- In the future, the UK may diverge from the MDR, but not without time given to adjust.
- Further detail on the long-term solution will be given after a consultation due in Sept/Oct 2018.
- The MHRA will no longer have a presence in EU committees.
- UK Notified bodies would no longer be able to assess for the EU.
- MHRA would carry out independent post market surveillance of devices.

ABHI

SUBMITTING REGULATORY INFORMATION ON MEDICAL PRODUCTS

Regulatory information would need to be sent to the MHRA via a national portal using EU application forms and EU standards for submission

- The following types of information would be submitted:
  - marketing authorisation (MA) applications (Pharma)
  - periodic safety update reports (PSURs) (Pharma and Devices)
  - paediatric investigation plans (PIPs) (Pharma)
  - clinical trial applications (Pharma and Devices)
  - qualified person for pharmacovigilance (QPPV) and pharmacovigilance system master file (PSMF) notifications (Pharma and potentially Devices)
  - individual case safety reports (ICSRs) and subsequent transmission of anonymised single patient reports (ASPRs) (Pharma)
  - device registration (Devices)
  - e-cigarette notifications. (Pharma)
- Systems will be up and running by March 2019, with more detail available by the end of 2018.
- Stakeholders will be consulted on the new system.

ABHI

HORIZON 2020 FUNDING

As previously announced, the government will guarantee funding for competitively bid-for EU projects submitted before we leave the EU, including Horizon 2020 projects.

- UKRI are developing systems to ensure payments.
- Current recipients will soon be invited to provide initial data about project(s).

ABHI

TRADE REMEDIES

The UK will establish an independent trade remedies system by March 2019, operated by a new arms length body: the UK Trade Remedies Authority.

- The UK TRA will be operational by exit date.
- UK businesses will need to approach the TRA instead of the European Commission with complaints.
- Legislation is underway (the Taxation/Cross-border Bill) to provide the tools permitted under WTO to tackle injury caused by unfair trading practices.

ABHI

TRADING WITH THE EU

Government has suggested a number of actions businesses' can take now to prepare, include the following:

- Understand what the likely changes to customs and excise procedures will be to their businesses in light of this technical notice.
- Take account of the volume of their trade with the EU and any potential supply chain impacts such as engaging with the other businesses in the supply chain to ensure that the necessary planning is taking place at all levels.
- Businesses should consider the impact on their role in supply chains with EU partners.
- If necessary, put steps in place to renegotiate commercial terms to reflect any changes in customs and excise procedures, and any new tariffs that may apply to UK-EU trade. Look at the existing guidance for importing and exporting outside of the EU on GOV.UK to familiarise themselves with the key processes.
- Consider how they will submit customs declarations for EU trade in a 'no deal' scenario, including whether they should engage the services of a customs broker, freight forwarder or logistics provider to help, or alternatively secure the appropriate software and authorisations.
- Register for the HMRC's EU Exit update service. On GOV.UK, search for 'HMRC videos, webinars and email alerts', click to register to get business help and education emails, enter your email and select 'EU Exit'.

ABHI

TRADING WITH THE EU

A no deal would mean that:

- Businesses would have to apply same customs and excise rules to goods going to the EU as goods going to the rest of world (ROW).
- Customs duties may be due *(0% for medical products, but could affect components)*.
- A custom declaration will be required to move goods across borders.
- A number of actions will be required if a company is exporting or importing.
- More information can be found here.

ABHI

CLASSIFYING YOUR GOOD IN THE UK TRADE TARRIF

Anyone importing goods into the UK from the EU, or exporting goods to the EU from the UK, will have to comply with customs procedures, where these were not previously necessary. This includes the potential payment of duty on UK-EU trade.

- For more information please click here.

CONTINGENCY PLANNING IN DHSC

DHSC have written three letters to advise on contingency planning. One of which has been sent to Medical Device companies. It details that:

- DHSC has undertaken analysis of supply chains for Medical Devices
- Stock holding at a national level will be increased
- Suppliers will be contacted in September to start discussing contingency plans and where necessary increasing production/stock holdings
- They have asked that for the contact details of the lead representatives in your organisation on EU Exit related matters to be sent to mdcc-contingencyplanning@dh.gsi.gov.uk.

ABHI

NEXT STEPS

More technical papers due in Sept

Consultation on regulations in autumn

Engagement with DHSC on planning

Engagement with EU27 on positions

ABHI

ABHI
HealthTech for Life

THANK YOU

E: enquiries@abhi.org.uk

T: +44 (0)20 7960 4360

@UK_ABHI

107 Gray's Inn Road, London, WC1X 8TZ

For any further information please contact eleanor.charsley@abhi.org.uk