BIVDA
British In Vitro Diagnostics Association

UK Government no-deal Brexit advice for the IVD sector - Q&A document

Introduction

Following the webinars run by BIVDA for its members on Tuesday 8 October and Monday 14 October, as part of the Government's no deal planning preparations, this document is a collation of the questions asked. The answers provided below are grouped by theme and taken from the Government's no-deal Brexit guidance with links to the respective documents.

Contents

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Regulation of IVDs in a no-deal Brexit

Legislation

Q: Will the in vitro diagnostics medical devices and associated timelines still stand following a no-deal Brexit?

A: The EU Directives on in vitro diagnostics medical devices (IVDD), active implantable medical devices (AIMDD) and medical devices (MDD) will continue to apply to the UK through the UK Medical Devices Regulations 2002.

Further Government guidance on this is available here.

Q: Will the EU REACH Regulation still stand following a no-deal Brexit?

In the event of a no-deal Brexit, the EU REACH Regulation will be brought into UK law by the European Union (Withdrawal) Act 2018.

Further information on this is available here.

The role of the MHRA

Q: Who will undertake required market surveillance of IVDs following a no-deal Brexit?

A: The MHRA will continue to perform market surveillance of IVDs on the UK market and be able to take a decision over the marketing and supplying of a device in the UK, regardless of the position of the European regulatory network, or any post-exit decision of the European Court of Justice.

Further Government guidance on this is available here.

Q: What is the limit to the number of devices that can be registered with MHRA ie could 100 devices be uploaded at a time?

A: The guidance does not reference a limit to the number of devices that can be registered. It states that you will be charged a statutory fee of £100 per registration application. Depending on the number of devices you have, you may be able to register all of these in one application however, groups of similar products can come under a single registration since the MHRA requires most products to be registered at the level of Global Medical Device Nomenclature (GMDN) code.

Further Government guidance on this is available here.

Q: How will IVD labelling look following a no-deal Brexit?

A: The UK regulatory system put in place on 1 November 2019 will mirror all key elements contained in the IVDR and MDR including that relevant labelling requirements will continue to apply including the requirement for products to carry a CE mark and devices which currently require conformity assessment by a Notified Body (NB) must have a valid CE certificate. The UK will continue to accept labelling in the English language, which includes information from other jurisdictions (such as Ireland), on condition that information complies with all UK requirements.

Further Government guidance on this is available here.

UK Responsible Person

Q: Who will be responsible for registering a new device with the MHRA?

A: The new role of the UK Responsible Person will act on behalf of a manufacturer if they are established outside of the UK and will carry out specified tasks in relation to the manufacturer's obligations, including registering with the MHRA before the device reaches the UK market. Only a manufacturer or a designated UK Responsible Person can legally place a device on the UK market. This means that a single manufacturer may have several designated UK Responsible Persons.

Further Government guidance on this is available here.

Q: Will the required UK Responsible Person role include liability?

A: Regulation 60 of the UK MDR 2002 (as amended by the UK MDR 2019) sets out that a UK Responsible Person can be proceeded against as a person placing the device on the market for the purposes of the Regulations. As the UK MDR 2002 (as amended by the UK MDR 2019) are safety regulations for the purposes of the Consumer Protection Act, it is possible that a UK Responsible Person may be proceeded against under the Regulations or under the Consumer Protection Act 1987 if they fail to perform any of their obligations. It is also possible that an individual could be held liable. Whilst not a requirement until Part VIII of the UK MDR 2019 fully applies in May 2020, the manufacturer may already have insurance in place. The UK Responsible Person may wish to include in its mandate whether it has the benefit of that insurance, or an indemnity based on the existence of that insurance, from the manufacturer.

Further Government guidance on this is available here.

Q: Can the UK Responsible Person be an importer?

A: If you are a UK-based importer and you wish to place a device on the market, you must have the authority from the manufacturer before doing so. This means that you will become a UK Responsible Person. Whilst there is no existing list of UK Responsible Persons, you may wish to speak to existing EU Authorised Representatives to determine whether they will be offering services as a UK Responsible Person.

Further Government guidance on this is available here.

Q: Could you provide further guidance on what is required to proceed with registering the UK Responsible person?

A: The UK Responsible Person must be established in the UK and acts on behalf of a manufacturer established outside the UK, to carry out specified tasks in relation to the manufacturer's obligations. This includes registering with the MHRA before the device is placed on the UK market. The requirement for a manufacturer to have in place a UK Responsible Person is in line with the grace period for registering your devices with the MHRA. Manufacturers may wish to appoint a UK Responsible Person before the end of the grace period

for post-market surveillance purposes. Manufacturers will also need to take into consideration that they might need some time to establish a UK Responsible Person and draw up a mandate.

Further Government guidance on this is available here.

Q: Does the UK Responsible Person need to be based in the UK?

A: You must provide a registered place of business in the UK at which service of any document relating in any way to the person's placing of the relevant device on the market will be effective. This address will be used for official communications, and you must be contactable at the address provided at all times. Although you may make use of resources based outside of the UK, there must always be someone physically located within the UK for the MHRA to communicate with. This is to ensure that you can fulfil your obligations as a UK Responsible Person.

Further Government guidance on this is available here.

Q: If a manufacturer already has arrangements in place for a UK Responsible Person for their products, do we, as a distributor of these products, also need to have a UK Responsible Person in order to sell them in the UK?

A: If a person places a product on the market under Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), a number of additional obligations will apply to distributors, which will include, but are not limited to, verifying that:

- the device has been CE marked
- the device is accompanied relevant information to be supplied by the manufacturer
- the importer has complied with their general obligations
- a UDI has been assigned to the device

Further Government guidance on this is available here.

Q: Who should register products that are distributed in the UK and imported from the US?

A: Registration of a device with the MHRA must be undertaken by a designated UK Responsible Person established in the UK and with a UK registered address who will take responsibility for the device in the UK.

Further Government guidance on this is available here.

Q: Will there be labelling changes to reflect the role of the Responsible Person?

A: There will be no labelling changes required to reflect the role of UK Responsible Person.

Further Government guidance on this is available here.

Classification

Q: What are the timelines for manufacturers to register a new device with the MHRA/ how do I know which grace period our device falls under?

A: 4 months: IVD List A, Class III medical devices, Class IIb implantable medical devices, Active Implantable Medical Devices (AIMD).

8 months: Self-test IVDs, Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B

12 months: Class A IVDs, Class I medical devices, Self-certified IVDs

When you established your product is a general medical device, you will need to decide which class your device falls under. The categories are:

- Class I – generally regarded as low risk
- Class IIa – generally regarded as medium risk
- Class IIb – generally regarded as medium risk
- Class III – generally regarded as high risk

How a medical device is classified will depend on factors including the intended purpose of the device, how long it's intended to be in use for and if the device:

- is invasive/ surgically invasive
- is implantable or active
- contains a substance, which in its own right is considered to be a medicinal substance

Further Government guidance on this is available here.

Conformity assessment

Q: Does the UK Responsible Person check for a valid UK or EU Declaration of Conformity

A: Manufacturers of low risk devices can self-declare conformity to the legislation before affixing the CE mark. Higher-risk devices medical devices and IVDs must be certified by an independent Conformity Assessment Body, called a Notified Body, before the CE mark can be affixed.

Further Government guidance on this is available here.

Public sector procurement

Q: When will the new public sector procurement tending process be open for use and how can organisations register?

A: Suppliers wishing to access UK contract opportunities from the UK public sector will need to access the new UK e-notification service, Find a Tender, instead of OJEU/TED. This new service called Find a Tender (FTS) will be deployed at 11pm GMT on 31st October in the event that the UK leaves the EU without a deal.

Further Government guidance on this is available here.

Q: Can organisations view non-UK procurement/tending opportunities through Find a Tender?

A: The guidance states that suppliers can continue to access the relevant domestic portal, such as Contracts Finer, MOD Defence Contracts Online, Public Contracts Scotland, Sell2Wales and eTendersNI. Information on non-UK procurement /tendering is not included within the guidance.

Further Government guidance on this is available here.

Changes to customs authorisations

Q: Will parallel importing still be possible?

A: Parallel importing from the EU to the UK will not be possible following EU exit. Any device placed on the UK market will be treated as new and all relevant manufacturer requirements will apply, including those mentioned in the above answer.

Further Government guidance on this is available here.

Patents

Q: Will UK businesses be able to open litigation within the United Patent Court?

A: UK business will still be open to litigation within the Unified Patent Court based on actions they undertake within the contracting EU countries if they infringe existing rights.

Further Government guidance on this is available here.

Horizon 2020 funding

Q: Will Horizon 2020 funding continue after no-deal Brexit?
A: The government has committed to guarantee funding for all successful competitive UK bids to Horizon 2020 that are submitted before we leave the EU, if there's a no-deal Brexit. The guarantee also covers all successful competitive UK bids to Horizon 2020 calls open to third-country participation submitted between Brexit and the end of 2020. Both the guarantee and extension commit funding to UK Horizon 2020 participants for the lifetime of projects.

Further Government guidance on this is available here.

Q: I currently am a recipient of Horizon 2020 funding. How can I ensure this funding is retained?

A: Current UK recipients of Horizon 2020 funding need to provide initial information about their projects on the UKRI portal.

Full Government guidance on this is available here.

Employing EU citizens

Q: How will the rights of my EEA citizen employee living in the UK be affected?

A: There will be no change to the right to work of EU, EEA and Swiss citizens and their family members living in the UK until 31 December 2020 if the UK leaves the EU without a deal. Employers will need to check a job applicant's right to work in the same way as now until 1 January 2021. EU, EEA or Swiss citizens and their family members who are living in the UK before the UK leaves the EU can apply to the EU Settlement Scheme to continue living in the UK after 31 December 2020. If EU, EEA and Swiss citizens arrive in the UK after the UK leaves the EU and before 1 January 2021, they can apply for European temporary leave to remain. The deadline for applications is 31 December 2020.

Full Government guidance on this is available here.

Q: Will there be a new immigration system and how will this affect my employees?

A: A new immigration system will apply to people arriving on or after 1 January 2021. Details on this are yet to be confirmed by the Government. You will not be required to undertake retrospective checks on existing EU, EEA or Swiss employees.

Full Government guidance on this is available here.

Using personal data

Q: Will there be any changes to the General Data Protection Regulation system currently in place?

A: There will be no immediate change to the UK's data protection standards. The General Data Protection Regulation (GDPR) will be brought into UK law and the Information Commissioner would remain the UK's independent supervisory authority on data protection.

Full Government guidance on using personal data in your business or organisation if there's no Brexit deal is available here.

Further information

In addition to reviewing the above answers, we would recommend that you consult the full guidance document with relevant information for the IVD sector.

Additional Government guidance is available here and if you have any further questions the Business Support Helpline may be worth contacting at enquiries@businesssupporthelpline.org.

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