Regulatory Questions for MDCC Trade Association Forum - 16/03/21

Please note that whilst we are willing to give any help and advice we can, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts. Accordingly we would always advise you to seek the views of your own professional advisors.

Questions

Healthcare Distribution Association (HDA)

Company with their own PI Range

- Will we have to register our own UK mark (CE equivalent) by submitting to the UK registering company, sending them an EU and UK pack to check they are the same?

  We are not sure what the enquirer means by this … **please could enquirer provide further information?** We will then follow up.

  Guidance on registering devices is available at: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market.

- Will we also have to register a unique number identifier (like FMD) to each pack we process? And will be able to utilise our current FMD equipment to do this or will we have to purchase new equipment?

  We are considering our future legislative requirements for medical devices, which may include a Unique Device Identifier requirement. We will consult on this later this year.

- If the imported pack already has both the CE and the UK equivalent marks, we will still need to add a UK UNI label if it does not already have it?

  A UKNI mark will only need to be affixed in cases where third party conformity assessment for the CE marking has been undertaken by a UK Notified Body for the NI market. If the device has been CE marked and an EU Notified Body has been used for third party conformity assessment, a UKNI marking will not be required.

  Our regulations state that: “No person shall supply a relevant device unless the manufacturer has affixed a UKNI indication [as required by this regulation], if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.”

  Please see our device regulation guidance for further information: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk.

- Will we have to register as a manufacturer with the MHRA prior to importation or as an importer?

  Only manufacturers* need to register with the MHRA (*or their UKRP or NI-based AR if the manufacturer is based outside the UK).

Importers must inform the relevant manufacturer, UKRP or NI-based AR of their intention to import a device – who will in turn inform the MHRA through our registration portal. Importers do not register themselves directly on the MHRA system.

Please see guidance on device registration: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market.

- Will we need to adopt the recall procedure into our systems?

  We are not sure what this is referring to – **please could the enquirer clarify?** However, as a general point, all products need to be able to be recalled if MHRA require this as part of our enforcement action.

Further questions

- Please can you provide details of the exact requirements of what by when?

  Please see our guidance documents:

  - Regulating devices: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk
  - Registering devices: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

  Summary of key changes for GB:

  - UKCA mark was introduced on 1 January 2021. It will be required for devices in GB from 1 July 2023.
  - Non-UK manufacturers are advised to appoint a UKRP as soon as possible (must be in place in line with grace periods below).
  - Devices must be registered in line with grace periods.
    - Class III and Class IIb implantables, and all active implantable medical devices and IVD List A products must be registered from 1 May 2021
    - Other Class IIb and all Class IIa devices and IVD List B products and Self-Test IVDs must be registered from 1 September 2021
    - Class I devices, custom-made devices and general IVDs (that did not need to be registered prior to 1 January 2021) must be registered from 1 January 2022.

- How will we roll out in NI – will there be a stakeholder group formed?

  We are engaging with colleagues in the Devolved Administrations on both post-transition period requirements and the development of our future regulatory framework.

- How will all distributors including corner shops be included?

  We have recently published guidance for retailers supplying devices to NI – please see links below.

- Guidance for retailers: supplying medical devices to Northern Ireland: https://www.gov.uk/guidance/guidance-for-retailers-supplying-medical-devices-to-northern-ireland
- Medical devices: EU regulations for MDR and IVDR (Northern Ireland): https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

If you have any follow-up questions after reviewing the guidance please get in touch with: devices.regulatory@mhra.gov.uk.

- Please can you clarify the rules for importation from GB, declarations and labelling?

  Please see links below to guidance documents. In NI, MDR labelling requirements will apply from May 26th 2021.

  - Guidance for retailers: supplying medical devices to Northern Ireland: https://www.gov.uk/guidance/guidance-for-retailers-supplying-medical-devices-to-northern-ireland
  - Medical devices: EU regulations for MDR and IVDR (Northern Ireland): https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

  The Trader Support Service can advise on trade between GB and NI if you have questions about exporting: https://www.gov.uk/guidance/trader-support-service.

- How will we know when products are UKCA only (ie not CE marked)?

  Products will need to have a physical UKCA marking on the device or labelling and will be registered with the MHRA. A UKCA mark will only be valid for GB and a CE marking will continue to be required for Northern Ireland.

  A UKCA mark won't be required for GB until 1 July 2023. CE marked devices can be placed on the GB market in the meantime.

- Please can you provide clarification of the unfettered access from NI –GB, how will this work?

  The UK Government has been unequivocal in its commitment for unfettered access for Northern Ireland goods moving to the rest of the UK market.

  The UK Internal Market Act 2020 put in place significant and robust protections for this regime for the long-term. NI businesses moving goods to GB face no additional process unless they are exporting a very small number of internationally controlled goods.

  The measures we have put in place are a bridge to a longer-lasting regime, which we will bring forward in the second half of 2021, which focuses the benefits of unfettered access on genuine Northern Ireland businesses.

- Who will be regulating Medical Devices in Northern Ireland? MHRA or EMA?

MHRA remains the Competent Authority for regulating devices in NI.

- For Northern Ireland, what is the definition of storage of Data for products with the UDI?

  We assume that this is a reference to Article 27, paragraphs 8 and 9 of the MDR. We are not aware that any more details of what *store and keep* actually mean have been defined by the EU, though the European regulations do go on to say that this should be achieved *preferably by electronic means*.

- Does it involve full traceability or just pure storage for use when required?

  We have checked with our technical leads but are not clear what is meant by "full traceability or just pure storage for use when required." **Please could the enquirer provide further clarification?**

- Storage of Data is mandatory for Class III implantable devices and the other classes are left to each member state to decide whether to store it or not.

  Again – our technical leads have looked at this question and note that this is what MDR Article 27, paragraphs 8 and 9 say. We are at an early stage in the development of our future regulatory regime for GB – so it is not yet clear whether the position for GB will be the same.

- Will the MHRA be seeking for storage of data for all devices or only Class III implantable devices in Northern Ireland?

  MHRA will issue guidance on this in due course.

- Will the MHRA be looking to establish a database of devices and classes in the UK in future?

  MHRA already has a registration database of devices. This was recently expanded to capture all risk classes of device, following the end of the transition period.

  Further information on device registration is available at: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market.

British Healthcare Trades Association (BHTA)

Re: British manufacturers shipping to Northern Ireland – under Article 13 (General Obligations of Importers), specifically section 3, EU importers are to *"indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer."*.

We have contacted our Dublin distributor re: this issue, but they have let us know that they do not have the capacity to affix this importer label on our products upon receipt of goods. They are in discussion with the Irish competent authorities (HPRA) in order to clarify what constitutes accompanying documentation, as it would be a

logistical nightmare if we, the legal manufacturer, needed to affix the importer label ourselves on all of the products destined to be distributed by Dublin.

In parallel, we have directly contacted the HPRA to get more clarification and guidelines on how to proceed, but they simply answered that *"We [HPRA] are currently discussing this issue at an EU level with the Commission and hope to be able to provide guidance on this point shortly.".* This was on February 1st.

As an alternative, we have asked our EC Representative if they can become our importer, but they cannot.

We need clear guidance on what constitutes accompanying documents – whether a simple statement accompanying our shipment is sufficient evidence enough (like a certificate of conformance), or whether we need to include a separate statement with each single product (like an additional label). This issue is becoming urgent and we are sure we are not the only British manufacturers currently experiencing this issue for importing into the EU.

We will need to follow up separately on this question.

Urology Trade Association

When are the MHRA going to consult on the UKCA/UKNI, and will it take the form of a public or closed consultation?

For our future regulatory regime in GB, including the use of the UKCA mark for medical devices, we are engaging informally with industry at the moment and plan to consult on proposals. This will be an open, public consultation - we will provide further details in due course.

Absorbent Hygiene Product Manufacturers Association (AHPMA)

- Can MHRA help clarify the position on CE and CA marks. We have read that the UK will accept dual labelled products i.e. product can contain both CE and UKCA mark. However the EU will not accept such packaging and our understanding is that only the CE mark can appear. If this is correct this will mean that there will have to be two versions of each product, one for sale in Europe and one specific for the UK which will increase costs significantly. Can MHRA offer any clarification or solution?

  Our understanding is that the EU will accept dual marked devices (e.g. devices that bear both the CE and UKCA marks) so long as relevant requirements are met and the UKCA mark does not impede the visibility of the CE marking.

  If there are specific examples of companies having issues here, **please could they contact the device regulation mailbox** (devices.regulatory@mhra.gov.uk). It would be helpful to know where the companies in question have seen this information.

- Is the MHRA system to register products as product importers available yet? Companies report they are waiting to register products etc but have been unable to do so.

  The device registration system has been live since 1 January 2021 and manufacturers, UKRPs and NI ARs are able to add importers to the system. Note that importers can't register themselves directly on the system.

  If companies are experiencing difficulties with registering devices, we would advise that they contact the MHRA device registrations team (device.registrations@mhra.gov.uk).

- Does MHRA specify
  - any specific place on the packaging where manufacturers must place the UKCA mark
    - Requirements for affixing the UKCA mark need to meet the requirements set out in UK Medical Devices Regulations 2002 (UK MDR 2002) (as amended).
    - The UKCA mark needs to be affixed in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the UKCA mark must also appear on the sales packaging. We don't specify where on the packaging the UKCA mark should appear.
  - if the name and address of the UK Responsible Person must be placed beside the mark or can it be placed somewhere else on the packaging?
    - We have not specified where on the packaging UKRP details need to appear.
  - Rather than place company addresses on packaging is it permissible for companies to place a website address which gives names and addresses of their companies in each market. This would avoid specific packaging for the UK and associated increased cost.

    The UK Medical Device Regulations 2002 (as amended) specify that manufacturer details need to be included on the label.

    Please note that rules on Electronic-IFUs will continue to apply in GB. The MHRA has previously issued guidance on this, which will continue to apply. To comply with this guidance the device must be regulated as a medical device or an active implantable medical device. It also must be intended to be specifically used by healthcare professionals, have an adequate risk assessment conducted for electronic format, be available in paper copy if requested, and have the same content as the normal paper version.

- Rather than place UK Responsible Person name and address on packaging, is it permissible to place a website address which gives name and address?

  The UK regulations specify that UKRP name and address details must appear on the labelling. This is only required where a UKCA mark has been affixed.

  Please note that rules on Electronic-IFUs will continue to apply in GB. The MHRA has previously issued guidance on this, which will continue to apply. To comply with this guidance the device must be regulated as a medical device or an active implantable medical device. It also must be intended to be specifically used by healthcare professionals, have an adequate risk assessment conducted for electronic format, be available in paper copy if requested, and have the same content as the normal paper version.