Regulatory Questions for MDCC Trade Association Forum - 11/12/20

HDA

1. How will IVDR and MDR be implemented in NI

The Medical Device Regulations (2017/745) and the in vitro Diagnostic Medical Device Regulations (2017/746) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline.

2. Will there be a stakeholder group formed

MHRA may form ad hoc stakeholder groups for implementing certain aspects of the MDR and IVDR in Northern Ireland.

3. How will the UK replacement for MDRs be implemented

We will engage with stakeholders within the life sciences and healthcare sectors on our future proposed regime in 2021. As part of these discussions, we will identify and prioritise elements of international practice that promote public health and patient safety. This will be followed by a formal public consultation with the aim of delivering an attractive world-class regulatory system.

4. Status of the UKCA certification

From 1 January 2021, manufacturers will be able to voluntarily make use of the UKCA mark. It will be mandatory for placing a device on the GB market from 1 July 2023.

UKCA mark requirements will continue to be based on the requirements of the relevant Annexes to the Directives listed below, which are given effect in UK law through the UK MDR 2002:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

5. The guidance specifically states that UK will continue to recognise CE-marked goods until 30th June 2023, allowing the UK time to set up and establish a national conformity assessment system. Therefore, why cannot this also apply to parallel imported devices?

Parallel importers will be deemed importers from 1 January 2021. There will be new importer requirements from January.

From January, the responsibility for placing a device on the UK market will fall to the manufacturer. Where the manufacturer is based outside of the UK, they must designate a UK Responsible Person.

Any persons placing a device on the market who are not the manufacturer or UK Responsible Person will be required to inform the relevant UK Responsible Person of their intention to import a device. In such cases, the UK Responsible Person will be required to provide the MHRA with the name and address of the registered place of business of the person placing the devices concerned on the market.

BHTA

1. In a situation where a Class III product with a valid DoC is in the UK distribution supply chain (transferred from an EU manufacturer to a UK distributor) before 31st December, and stock will last for 12 months, is there a requirement to register this product with the MHRA?

If the manufacturer has already placed the device on the market, there is no requirement to register the device. If the manufacturer places a new stock on the market from 1 May 2021, that must be registered with MHRA before it can be placed on the GB market.

2. If an Importer is the first to place onto European or UK market from Asia, is the Importer responsible for registering the Class I medical device to the MHRA?

The responsibility for placing a device on the market in the UK falls to the manufacturer or the UK Responsible Person. Where the person placing on the market is neither of those, the importer must notify the UK Responsible Person so that their details can be registered with MHRA. The UK Responsible Person can be the importer, but the manufacturer must designate the importer as the UK Responsible Person first.

Absorbent Hygiene Products Manufacturers Association (AHPMA)

1. For NI what is the registration deadline for Class I medical devices? We understand the new registration portal does not go live until 1st Jan 2021 but we see in the guidance that class 1 medical devices should be registered by 1st January 2021

It is already a legal requirement that Class I medical devices are registered with MHRA. Therefore, where a manufacturer or its authorised representative is based in Northern Ireland, there is no ‘grace period’ for registering. They must continue to register as they normally would do. This is why the ‘deadline’ was put as 1 January 2021.

2. MHRA guidance for NI states CE mark and UKNI mark are required. If a company self certifies (and does not use a UK notified body) but has a CE mark on products is the UKNI mark also required and by what date?

A UKNI mark is only required where a UK Notified Body is used. Class I manufacturers can therefore self-certify for the CE mark and a UKNI mark is not required.

3. Can MHRA confirm that the UK responsible person may be the UK division of the company/manufacturer which places products on the UK market – rather than an individual person or an external company which manages product registration.

   The UK Responsible Person can be part of the outside UK manufacturer, so long as they are based in the UK and can fulfil the legal obligations of the UK RP.

4. Is there to be any further update on product registration process or is the detail in this link final?: https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices

   The new guidance can be found here.

5. What details will be required for product registration.

   See our guidance.

6. Which is the regulatory authority and regulation for products placed on the Gibraltar market?

   You will need to speak to the Gibraltar Health Authority about the regulation of medical devices in Gibraltar.

7. For Class I medical devices which require the UKCA mark will companies continue to self-certify or will they need to use a UK Notified Body?

   As with current requirements, Class I manufacturers will continue to be able to self-declare their conformity against the UKCA mark. A UK Approved Body is only required where the Class I device is sterile or has a measuring function.

8. Please confirm whether the registration of a responsible person is a separate additional process to the registration of companies.

   The registration process involves the UK RP or the UK manufacturer registering the devices being placed on the market. The UK RP is not required to be registered separately.

9. I would like to ask is there a grace or transition period **from the EU** for bringing packaging up to date i.e. putting the authorised representative on pack?

   Our understanding is that there is not a grace period for having the authorised representative on the pack. This needs to be done by 1 January 2021. This includes for products moving from Great Britain to Northern Ireland, as Great Britain manufacturers require an authorised representative.

10. If products already display a UK address on packaging do companies need to register a Responsible Person (company/entity)?

    If the manufacturer is based in the UK, there is no need to designate a UK RP. But a UK RP must be designated for manufacturers based outside of the UK

11. Please confirm whether companies who are already approved for the incoming MDR are also MDD approved by default and may register as such.

    An MDR certificate would continue to be accepted up until 30 June 2023. This is "deemed" to meet the necessary requirements for the UKCA mark so therefore you would be able to register your product with MHRA.

12. Is MHRA guidance available on what is included in a conformity assessment from 1st Jan 2021?

    The conformity assessment process for the purposes of a UKCA mark will mirror that of the existing Directives, which are transposed into UK law by the UK Medical Devices Regulations 2002.

13. In the document on registering as a manufacturer to sell medical devices, the summary of key requirements for placing a device on the NI market from 1 January 2021 states that if you are a manufacturer based outside the UK, you will need to have a responsible person in place who will act as a regulatory point of contact within the UK and comply with the registration requirements when these begin to apply. Does this mean that as of the 1st January 2021 you only need to have a UK responsible person in place and that registration of the products will follow the same timelines as those of GB, 1st January 2022? For our members this relates to Class I medical devices only.

    Where manufacturer is based outside of the UK (and assuming the authorised representative is also based outside of the UK), then Class I device does not need to be registered with MHRA. For example, if the manufacturer or its authorised representative is based in Germany, it would be registered in Germany and not in Northern Ireland. It would only need to be registered with MHRA (and have a UK Responsible Person appointed) by 1 January 2022 if it were to move into Great Britain.

14. For companies who have recently submitted registration as a company, how long does the MHRA process take until the registration is completed.

The timeframe for registration of devices will depend on the number of devices being registered and the amount of information that needs to be input for each device. This will vary from application to application. Please note that any registrations made prior to 1 January 2021 will need to be reviewed in line with the relevant grace periods set out in our guidance, to ensure information is up to date and that, where required, UK Responsible Person information has been provided.