RA news round-up

BREXIT SPECIAL

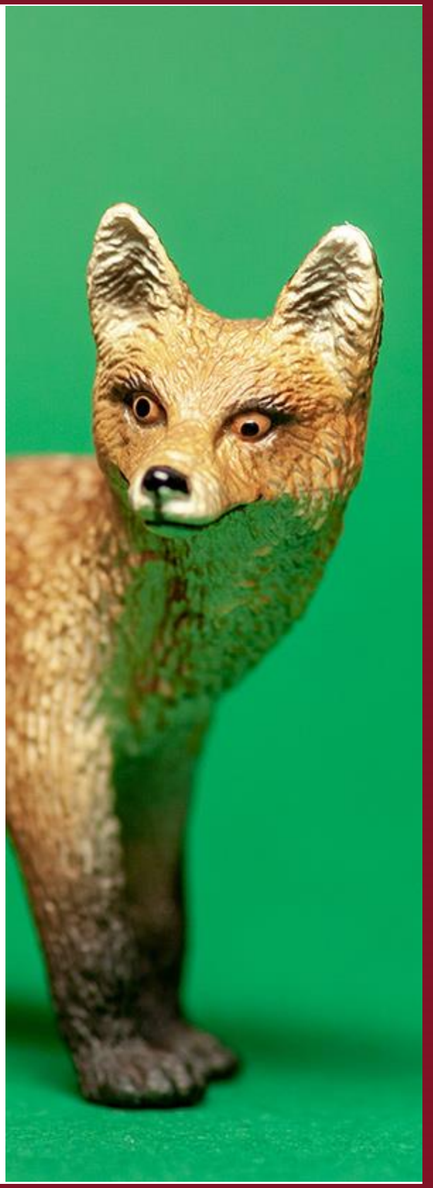
The recent guidances published by the British **Medicines and Healthcare products Regulatory Agency (MHRA)** provide relevant information for medical device manufacturers in Great Britain, Northern Ireland and the European Economic Area. They answer questions arising with the upcoming Brexit on how to place a medical device on the UK market from 1 January 2021.

It must be noticed: These guidances are not effective until parliamentary approval which is expected later this year. Some topics and requirements still need to be determined more detailed. Anyhow, companies active on the UK and the Northern Irish market need to adapt their strategy.

Beginning 1 January 2021, the **MHRA** will take on the responsibilities such as setting requirements for registration activities, conformity assessment procedures, labelling and post-market surveillance.

Summary of the most relevant changes:

- **CE marked medical devices** can be sold and put into the markets affected by the Brexit until 30 June 2023. The MHRA will establish the **UKCA mark** starting 1 January 2021. All devices need a UKCA mark from 1 July 2023.
- The **Medical Devices Regulations 2002** (SI 2002 No 618, as amended) will continue to have effect in Great Britain after the transition period.
- All manufacturers and devices must be **registered with the MHRA** from 1 January 2021. There will be a grace period for registering:
  - 4 months for Class IIIs and Class IIb implantables, and all active implantable medical devices
  - 8 months for other Class IIb and all Class IIa devices
  - 12 months for Class I devices
- For manufacturers from outside of the UK a **UK Responsible Person** must be put into place. They take responsibility for various requirements lied down by MHRA.
- Northern Ireland receives a special status



Registration with the MHRA

All devices must be **registered** with the MHRA from 1 January 2021. Grace periods from 4 to 12 months apply depending on risk class. The grace period of 12 month for class I devices does not apply to devices, which already need to be registered with the MHRA under currently applicable law (class I medical devices, class A in-vitro diagnostic devices, etc.). Medical devise not registered by these dates must not be placed on the market.

All manufacturers of medical devices, IVD and custom-made devices need to register with the MHRA before placing a device on the UK market If the manufacturer does not have a registered place of business in the UK a **UK Responsible Person** must be put into place. The registration has a grace period and the requirement is in line with the grace period for registering devices with the MHRA.

The **UK Responsible Person** will act on behalf of manufacturers based outside the UK in order to fulfil the manufacturer's obligations (as registration with MHRA, ensure the declaration of conformity has been drawn up, an appropriate conformity assessment procedure has been carried out, etc. See guidances for further information).

There are no further requirements for manufacturers based in **Northern Ireland**. Anyhow, devices to be placed on the Northern Ireland market need to be registered with the MHRA as well from 01 January 2021.

UKCA mark

Medical devices which previously required CE marking will need the new UKCA (UK Conformity Assessed) mark for legal supply in the UK. Medical devices may require both CE and UKCA marks if put into both UK and EEA markets. The UKCA mark has to be installed and the device labeled until 1 July 2023 latest.

UK Conformity Assessment Bodies / UK Approved Bodies

In order to execute conformity assessment procedures the MHRA will start to designate **UK Approved Bodies** from 1 January 2021. Previously designated UK Notified Bodies under

MDR, IVDR, MDD, IVDD or AIMDD will therefore be able to continue their work under the requirements of **Medical Devices Regulations 2002**. UK Approved Bodies will only be able to assign UKCA marks but wont be able to perform conformity assessments under the European legislatives anymore.

The CE mark of devices received under MDR, IVDR, MDD, IVDD and AIMDD by EEA notified bodies will be recognized in the UK until 30 June 2023. According to the MHRA guidance, the EU will not accept UKCA marks as equivalent to CE marks. Therefore, medical device manufacturers who want to continue to supply their products in the EEA and in the UK will need to involve two different conformity assessment bodies from 1 July 2023, one in the UK one in the EEA. Time and effort will noticeably increase for those manufacturers.

Northern Ireland's special status

Northern Ireland takes on a special role because of its land border to the EU. The requirements and procedure for Northern Ireland differ to the ones explained above and are quite more complex.

https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021

https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices

https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021