"Hard Brexit" and its impact on the medical device industry

Article by Miriam Schuh

BREXIT has effects across industries, affecting medical device manufacturers, their distribution possibilities in Great Britain and the importation of medical devices into the EU 27. The answer to the question of what effects it will have on the medical devices industry and to what degree will depend to a large extent on whether BREXIT will be "hard" or "soft".

For the case of a "hard BREXIT", the British Medicines and Healthcare products Regulatory Agency (MHRA) has published new guidelines for medical devices that are to be marketed in Great Britain (and Northern Ireland and the EU) as of 1 January 2021. After a "hard BREXIT" without agreement, the United Kingdom will be considered as a third country. This means that manufacturers of medical devices based in the Great Britain will need to retain a European Authorised Representative domiciled in the EU 27. This commissioning process can be time-consuming. In addition, as of 1 January 2021, the Notified Bodies (still) based in Great Britain will no be longer allowed to issue CE markings. As of the date the MDR enters into force on 26 May 2021, co-operation with an MDR-accredited Notified Body based in the EU 27 will be required. Importation of products into the EU 27 will follow the rules of importation from a third country. Importers will be subject to the obligations of importers under the MDR, which go beyond the obligations of mere distributors.

Conversely, however, this will also apply to the access of British devices to the European market.

Manufacturers based outside the United Kingdom must designate a UK Responsible Person in connection with the new registration requirements. Cooperation with a British partner will thus be essential for the marketability of European medical devices in Great Britain in the future. A UK Responsible Person will need to have been appointed by 1 January 2021. A transitional period exists for registration at the MHRA that is aligned with the planned time frame for registration of devices in the individual risk classes. The primary responsibility of UK Responsible Persons will consist precisely in this registration of non-UK manufacturers and their devices. Further responsibilities described in the guidelines essentially correspond to those of MDR and IVDR Authorised Representatives. Examples of such responsibilities include ensuring the availability of declarations of conformity and technical documentation, and the keeping of copies of the relevant documents and certificates. After the transitional period for the validity of the CE marking in Great Britain (end: 30 June 2023),

a UK Conformity Assessed (UKCA) marking will also be required for devices. However, if a device is in compliance with both EU legislation and the new British legislation, it will likely also be acceptable after 1 July 2023 for a device to be both CE and UKCA marked. How such double markings will take place in practice, in particular what information will be affixed to the UKCA marking, remains to be worked out.

The special status for Northern Ireland negotiated thus far should be emphasised: due to the open border with the Republic of Ireland, it has been planned to date for EU regulations to continue to apply there in the future. A special arrangement has been made and a separate UK(NI) marking developed, whose joint use along with the CE marking has been envisaged. Devices with the UK(NI) marking are only to be on the market in the UK and Northern Ireland, not in the rest of the EU. In contrast, the CE marking will be recognised both in Northern Ireland and the rest of the EU, but not in Great Britain after 30 June 2023. It is impossible to foresee whether this special arrangement will actually come into force by way of the "Internal Market Bill", which was introduced into Parliament on 9 September 2020. The EU is currently preparing legal proceedings against Great Britain because it holds that the Internal Market Bill violates the jointly negotiated exit agreement.

Ultimately, after the deadlocked BREXIT negotiations, the question of whether BREXIT will be hard or soft and the consequences thereof remains open. It remains to be seen whether the recent ultimatum given by Boris Johnson for an executable trade agreement on 15 October 2020 will be enough to avert a hard BREXIT.

The text reflects the state of the debate as of 11 October 2020. We keep you updated.

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