ENTERING THE UK MARKET: A GUIDE FOR US MEDICAL DEVICES COMPANIES

In this article, Matthew Burton, Strategic Development Director at IMed Consultancy, discusses the new EU Medical Device Registration and offers a guide for the UK Responsible Person within companies.

Europe is in full regulatory transition, and with the new EU Medical Device Registration (MDR) causing delays and complications for businesses wanting to place a new device on the European market, many US businesses are understandably starting to turn towards the UK.

In contrast with the EU, in fact, the UK continues to operate with consolidated regulations for the time being and is positioning itself as an ideal market for products that are novel and niche while trying to enhance the medtech sector and develop it as a pillar of industry with the declared objective of attracting innovative products. Specifically, the UK government has recently launched a medtech strategy, to ensure social care systems can reliably access safe, effective and innovative medical technologies.[1] The document states the vital importance of medtech within the UK health and care system, as recently highlighted by the covid-19 pandemic, and the critical role medtech devices will have in shaping the future of the UK health and care system.

Another reason the UK market is appealing to US businesses is its "one provider, one payer" model provided by the NHS, with tenders every four years that increase the chance of successfully positioning medical devices within the NHS framework. In addition, the UK market does not normally require translation and localisation of instructions for use, technical documents and even advertising, as would be the norm for access into non-English-speaking European countries, further speeding up processes without the need for additional investments.

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First and foremost, however, US businesses wanting to enter the UK market in this time of regulatory transition need to understand the UK regulatory landscape and to get familiar with acronyms such as MHRA and UKRP.

UK OR GREAT BRITAIN?

The first important distinction to make is between the UK and Great Britain (England, Scotland and Wales), due to Northern Ireland's unique current regulatory status. Under the Northern Ireland Protocol, in fact, different rules apply in Northern Ireland and in Great Britain.[2]

As of January 2021, businesses wishing to enter the market in **Great Britain** are required to:

- Register with the MHRA
- Appoint a single UK Responsible Person (UKRP) for all of their devices, who will act on their behalf to carry out specified tasks, such as registration
- Comply with relevant product marking and conformity assessment requirements for medical devices.

Requirements for placing devices on the **Northern Ireland market** can instead be summarised as follows:

- The EU MDR and EU IVDR have applied in Northern Ireland since May 2021 and May 2022, respectively
- CE marking is required in Northern Ireland. In addition, the UKNI indication is required if a UK Notified Body undertakes mandatory third-party conformity assessment

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- Certain devices will require registration with the UK MHRA, including *in vitro* diagnostic medical devices (IVDs), which need to be registered with the MHRA when placed on the Northern Ireland market.

THE MHRA

The MHRA is the entity responsible for regulating the UK medical devices market. Specifically, the MHRA performs market surveillance and can take decisions over the marketing and supply of devices in the UK.

Failure to meet the above requirements will preclude manufacturers from lawfully placing their devices on the UK market.

What is a UKRP?

A UKRP acts on behalf of businesses based outside the UK to carry out all tasks needed to successfully place their device on the UK market and liaise with entities such as the MHRA.

UKRPs need to be physically located in the UK, and their name and address must be included on the product labelling or the outer packaging, or the instructions for use in cases where the UK Conformity Assessed (UKCA) marking has been affixed.[2] They are legally responsible on a par with manufacturers.

A UKRP's responsibilities are detailed in the UK MDR 2002,[3] but can be summarised as follows:

- Liaising and collaborating with the MHRA
- Ensuring the declaration on conformity and all technical documentation have been drawn up
- Keeping available a copy of all relevant documentation, including a copy of the declaration of conformity and relevant certificates
- Immediately informing the manufacturer about complaints and reports from healthcare professionals, patients and users.

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Choosing the right UKRP, especially when placing a device on the UK market for the first time, can definitely make a difference for medical device manufacturers that need to be at least familiar with all the UKRP requirements and responsibilities, as set out in the UK MDR 2002, to ensure they are getting the support required from an eligible UKRP.

Since appointing a single UKRP to act on their behalf is the first, most important thing businesses based outside the UK need to do to place a device on the Great Britain market, choosing the right partner can be the make or break of success in entering the market for medical device manufacturers.

Manufacturers should also be aware that, although there is nothing to prevent an importer or distributor also acting as a UKRP, the newly defined responsibilities of the UKRP require an in-depth understanding of the regulatory landscape for medical devices. Manufacturers should appoint their UKRP carefully and would be well advised to consider UKRP providers that offer experience in dealing with institutions and volatile regulatory environments. US businesses wishing to place one or more devices on the UK market may even decide to rely on not just one expert but on a consultancy to make sure of being assisted by a whole team of experts with broad knowledge and wide access to relevant resources, which can support them in all their regulatory needs.

ABOUT THE COMPANY

Founded in 2012, IMed Consultancy offers a wide range of regulatory and compliance services to the medtech industry, supporting medical device manufacturers through all stages of the product lifecycle from concept and design consultancy through to post-market surveillance activities. IMed Consultancy's team of skilled and experienced medical regulatory professionals offers an outstanding yet flexible service covering regulatory affairs, UKRP and EU Authorised Representative (EUAR) services, PRRC, and quality assurance in medical devices, including Class III active and implantables, companion diagnostics, software as a medical device (SaMD) and IVDs. With extensive hands-on problem-solving expertise, IMed Consultancy's remit is truly global, ensuring that client devices are successfully launched and maintained in total compliance in the UK, EU, US and internationally.

REFERENCES

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ABOUT THE AUTHOR

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