EU MDR: ANCILLARY DELIVERY DEVICES FACE EQUAL SCRUTINY TO STANDALONE MEDICAL DEVICES

In this article, Elizma Parry, Director, Global Clinical Practice at Maetrics, offers her expertise and practical guidance to businesses hoping to achieve a CE mark for a medical device. With new regulations being implemented this year, and little time to spare before the point of no return, pharmaceutical manufacturers must quickly embark on the first of a series of preparatory steps if they hope to achieve smooth and timely compliance.

Every medical device manufacturer placing products on the market in the EU knows the huge bearing the EU's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) are having on the EU regulatory environment. Less obvious, though, is the direct impact these regulatory changes may have on pharma companies and their products.

Although the new regulations mainly concern medical device manufacturers, pharma companies should not assume exemption from the tightening of clinical oversight sweeping across the EU. If they are manufacturing combination products or companion diagnostics, pharma businesses will need to get to grips with the exact requirements before the MDR and IVDR come into effect in May 2020 and May 2022, respectively.

In the EU, combination products are regulated as either medicinal products or medical devices, depending on which component has the ancillary function. Insulin injector pens and metered dose inhalers, for example, contain a medical device component which serves as the delivery system of the integral drug component – making its role ancillary to the drug. This kind of combination product is presently regulated as a medicinal product under the EU Medicinal Product Directive (MPD) 2001/83/EC, thereby focusing scrutiny mainly on the medicinal formulation of the product.

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NO MEDICAL DEVICE UNSCRUTINISED

Addressing the regulatory gap that existed for combination products under the previous directives, the MDR will leave no medical device unscrutinised, regardless of whether its function is central or ancillary to the product. From May 2020 onwards, combination products will need to meet the requirements as set out in Article 117 of the MDR, which amends Annex I of the MPD.

This reshuffling emanates from the growing complexity of combination products and the need to regulate ancillary device components with the same scrutiny as standalone medical devices. Crucially, not all products composed of both a medicinal and device element will constitute a combination product – only those where the manufacturer intends for it to be used together to perform effectively.

As such, the MDR will particularly impact pharma companies manufacturing combination products with ancillary medical devices, for this will represent a larger adjustment than for those manufacturing products already regulated as medical devices. Pharma companies unaccustomed to this might lack the data required to submit a clinical evaluation report and may

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need to take on the costly and time-consuming task of gathering additional clinical data for the device component. Such businesses are advised to invest in resources first time round to facilitate the continuous updating of clinical data in the future.

STRUGGLE TO KEEP UP WITH DEMAND

Similarly, combination product manufacturers might be reaching out to a medical device designated notified body for the first time. With the EU presently being short on the notified bodies required to review technical documentation, it is probable those in operation will struggle to keep up with demand. Today, there are only nine designated notified bodies under the MDR, so delays in the approval process are very likely. With the MDR deadline less than six months away, manufacturers are strongly urged to submit their documentation as soon as possible to make the cut-off date.

Companion diagnostics will equally be affected by the changing regulatory landscape – falling under the remit of IVDR. Within a newly established IVDR risk-based classification, companion diagnostics will be classified under the second-highest risk category, Class C, and will therefore be subject to a high level of clinical oversight, particularly for pharma companies developing their own companion diagnostics. Given the co-development of the IVD device with its associated medicinal product, the IVD notified body will also need to liaise with a medicinal Competent Authority (CA).

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The IVDR world is also more seriously affected by the shortage of notified bodies, with only three designated organisations currently operating. Pharma companies are therefore not only queuing to receive certification from a notified body but also for these notified bodies to be designated for companion diagnostic conformity assessments under the IVDR. In this sense, manufacturers are advised to go a step further than simply submitting their documentation on time – they may actually want to approach organisations awaiting designation from their national CA for their specific product area beforehand. Doing so will help ensure businesses secure a place at the front of the queue.

ALLOW ADDITIONAL TIME

Under the MDR and IVDR, tighter regulation of combination products and companion diagnostics will be enforced, and pharma companies will have to abide by the same requirements as medical device manufacturers with respect to the device component. But they might lack the experience that medical device companies have in collating the necessary documentation and liaising with a notified body – and should therefore allow additional time to complete these stages.

Only businesses prepared to face the negative outcomes of a missed deadline – potential removal of their products from EU markets and devastating reputational losses – should disregard the crucial importance of preparing for compliance with the new requirements.

ABOUT THE COMPANY

Founded in 1984, Maetrics is a global life sciences consulting firm focused exclusively on regulatory, quality and compliance solutions for medical device, diagnostic, pharma and biotechnology companies.

ABOUT THE AUTHOR

Elizma Parry brings more than 25 years of experience to the Maetrics team and provides clients with expert counsel in the clinical practice environment. A highly qualified industry professional, she is a proven leader with a strong track record of clinical safety, regulatory and quality management experience.