DOES THE NEW EU MDR SPELL THE END OF GRANDFATHERING?

Here, Helen Simons, Quality Specialist, and Stephanie Ward, Quality Assurance Engineer, both of Cambridge Design Partnership, describe how the new EU Medical Devices Regulation will impact on "grandfathered" devices that were approved under old regulation and are currently on the market, but do not necessarily comply with current/updated regulatory standards, and explain the potential implications for device manufacturers.

The new European Medical Devices Regulation (MDR), introduced by the European Commission to replace the Medical Device Directive (MDD), has led to a lot of discussion about the implications for products on the European market.

It is worth remembering that the CE marking of medical devices under the MDD was actually optional, as with all EU directives (such as the Low Voltage Directive or the Machinery Directive). However, we all followed it closely as it provided an effective framework to demonstrate to EU authorities that our products were safe and effective. Now, under the MDR, these guidelines have become law, and all manufacturers, distributors, importers and notified bodies must follow them if they wish to sell medical devices in the EU.

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With the regulation being a weighty 175-page document (compared with the 43 pages of the MDD), it can be easy to miss details in the text that may have significant impact. One such detail is only two sentences long, yet has wide-ranging implications:

"Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of the regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner." Article 10, Part 9.

In short, the MDR is enforcing continual improvement. Manufacturers must ensure that all their products on the market meet the most up-to-date safety and performance requirements, as well as updates to harmonised standards used within the product submission to show conformity to the regulation.

HISTORY OF MEDICAL DEVICE SUBMISSIONS

To understand the implication of this enforcement of continual improvement, let's take a step back and look at how devices have been treated in the past.

Previously, when devices were put on the market there was no requirement to follow up on changes in standards or regulation on existing products. There was a requirement for companies to carry out "vigilance" during product development so that a device was developed to the applicable requirements at that time but, once submitted, the design was frozen.

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Future changes were required to be managed through change control, with consideration of current regulatory requirements as part of the impact assessment. But if the design remained the same, how could an impact assessment be triggered?

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Such products, known as "grandfathered" devices, pre-date a now applicable standard, directive or regulation. For example, under the 1993 MDD, previously marketed devices were exempt from meeting the new directive and allowed to continue being marketed. The devices were sold on the basis that they were compliant before any new releases of requirements and had proven their safety by not having any reportable incidents. Therefore it was deemed acceptable for the devices to continue being on the market, without the added strain on manufacturers to conform to the new directive.

In addition to specific changes in regulatory requirements, best practice when it comes to developing medical devices has changed over time – each subsequent generation of regulation brings with it new requirements which need to be met. In recent times, the focus on human factors has been increased through the issuance of many US FDA guidelines. Similarly, the EU MDR now puts more focus on risk management and post-market surveillance, looking to ensure that data from complaints or reportable incidents is used to update the probability/occurrence scores in the risk analysis. The risk analysis is then reviewed to determine if the new information has affected the benefit-risk profile of the device – or even dictates a change of class of the device. The risk management process is now iterative throughout the lifetime of the product, rather than a static file compiled at the time of submission.

THE IMPACT ON DEVICES

In addition to regulations updates, harmonised standards, to which devices may conform, are regularly reviewed and updated to be in line with cutting-edge practices and thinking within the industry. So what does an update to a harmonised standard mean in terms of what would have to be done to make sure a product is compliant with the MDR?

To demonstrate this, let's use a drug delivery device which conforms to the current version of ISO11608-1 as an example. A hypothetical update is made to this standard which introduces new requirements for testing of the needle-based injection system. The device would then need to be tested against the new version of the standard to ensure it conforms to the new requirements. If any out-of-specification results arise from this testing, the design will require review and, perhaps, updating to bring the factors back in line with the new standard. Any design changes would then require a further impact assessment and would likely require, at minimum, an update to the risk management file to assess any new or changed risks. Other documents, such as the design inputs, would also need to be updated to reflect the requirements of the new standard.

On closer inspection, the activities that are required to comply with Article 10, Part 9 are beginning to sound much like a product development iteration. Many companies already have robust change control processes in place, as required by ISO13485 and current good manufacturing practice (cGMP), which would handle this. These just need to be expanded upon to integrate vigilance for existing products and ensure that they are updated as required.

It is important that companies have someone responsible for vigilance, who can be aware of upcoming relevant publications, and also the timescales required for any applicable changes. If any complex changes are required, considering both the design and any related aspects of the manufacturing processes, planning and implementing these changes in a timely manner is essential.

THE DEADLINES

Every device available on the market must comply with the MDR by the date of application (May 26, 2020). However, as with all legal documents, tucked away at the back there are provisions that allow manufacturers time to get their devices compliant with the MDR beyond the three-year transition period.

Article 120 details all the exemptions for medical devices with a valid MDD or Active Implantable Medical Device Directive (AIMDD) CE-mark certificate that expires after the May 26, 2020 deadline (Figure 1).

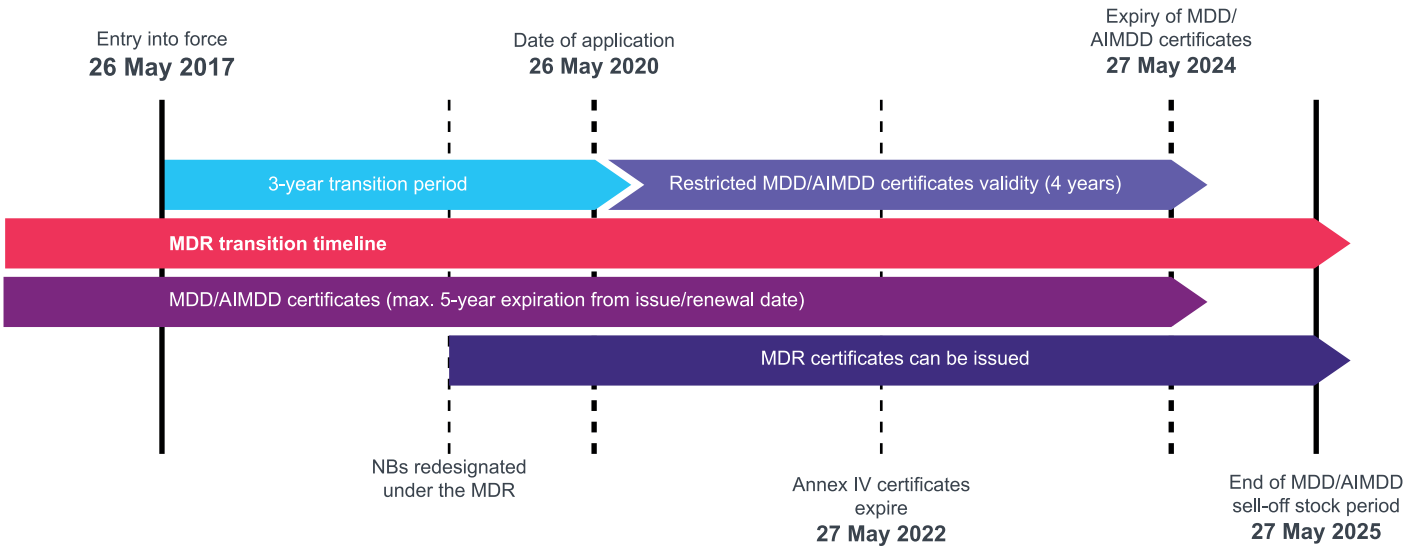

Figure 1: Article 120 transition timescales.

It outlines that a certificate issued prior to May 25, 2017 shall remain valid until the end of the period indicated on the certificate, unless it exceeds May 27, 2024, by which point all MDD/AIMDD certificates will become void (unless the certificate was issued in accordance with Annex IV of the directives, in which case it will become void, at the latest, by May 27 2022).

A manufacturer can continue to distribute CE-marked devices for five years beyond the date of application deadline if the device was placed on the market prior to May 26, 2020, or placed on the market after May 26, 2020 if a valid certificate is in place (as previously mentioned). This would mean a manufacturer generating stock under a MDD/AIMDD certificate prior to May 26, 2020 and placing on the market with a declaration of conformity to the applicable directive. Any remaining stock will be required to be removed from the market by May 27, 2025.

A manufacturer can also continue to manufacture and distribute a CE-marked product that complies with the MDD/AIMDD until May 27, 2024 (four years after the date of application) providing the following apply:

- The manufacture has a valid MDD/AIMDD certificate
- The product continues to comply with either of those directives
- There have been no significant changes in design and intended purpose
- The manufacturer complies with the new MDR requirements for post-market surveillance, market surveillance, vigilance, registration of economic operators, and registration of devices, whilst not making any significant changes to the device design (as per the previous point).

The challenges of manufacturing and distributing medical devices under a MDD/AIMDD certificate after May 26, 2020 mean it is not "carry on as normal", and manufacturers should be planning for the MDR transition in earnest to meet the three-year implementation deadline. A thorough transitional plan allows for any additional time given by Article 120 to be used to sell pre-MDR stock.

IN CONCLUSION

For some companies, the new MDR will not mean a massive change – they will already have procedures in place that ensure they continue to meet the regulatory requirements. But many organisations with grandfathered devices face a huge jump from potentially pre-MDD to MDR, and they are unlikely to have the sound groundwork of the MDD on which to base the additional requirements of the MDR. These companies will not only have to ensure they comply with the new MDR, they also face the task of updating or creating processes, procedures and documents to comply with the vigilance and surveillance requirements to make sure their products meet the new standards.

How well companies adapt to these challenges will be seen in how many products are removed from the market due to non-compliance with the MDR. It could even mean the loss of small medical device manufacturers who find the cost of compliance is too high.