ISO Life Sciences

Legacy Products compliance under EU MDR

Will the demise of large numbers of legacy products be an unintended consequence of EU MDR?

As Medical Device manufacturers conclude their MDD to EU MDR gap assessments and are considering their 'Remediate, Retire or Replace' options, many are left wondering how to deal with their legacy and older products. The questions are not about the value of the EU MDR in assuring safety but about how to satisfy all compliance requirements in the form they are being requested.

The issue

The situation many Manufacturers are faced with in relation to legacy products is the real possibility that the costs of compliance under the new regulations are prohibitive. Where we are seeing significant and expensive gap remediation work is in clinical, in additional testing to support the new GSPR requirements and in consequential label and IFU updates. For legacy products many of the remediation activities required to close these gaps are having to be undertaken to evidence what is already evidenced by the historical performance record of the product in its use by HCPs to treat patients. Let me illustrate this with a recent example from a client;

> *A family of simple Class IIa medical devices that have been in use for over 80 years with a good safety record will require an expenditure equivalent to 8.5% of its annual EU revenue to undertake the various GSPR compliance remediation actions. Furthermore, this cost does not include the 2000+ hours (1.2FTEs) from various internal resources which will be required to support these remediation activities. These are low cost, low margin products, but they are products for which there is an on-going demand.*

This situation will not be uncommon and could have major repercussions where a manufacturer's portfolio is comprised of a disproportionally large number of legacy and older products.

Our intent in this discussion is not to open 'old wounds' about the removal of 'grandfathering' in the new regulations, or for that matter to create an exemption for legacy products under the new regulations. It is to pre-empt a potential 'cliff-edge' as the realities of actual remediation costs, and failure to address product rationalisation earlier in the EU MDR program, become evident as we approach the date of application of EU MDR on the 26th May 2020. Set out here are two strategies about which we are in discussion with clients as they embark on implementation. We recognise that, if there is legitimacy in our strategies, there is likely to be a need for a common agreement from the Legislators on how to proceed.

We should be clear that the products we believe fall within the scope of our discussion are legacy products where a gap assessment has concluded that the cost of remediation is prohibitive AND where historical evidence already exists to support the device's safety and performance claims.

So, what should we do about it?

1. Remediation Sufficiency.

Perhaps the choice we offered earlier for Manufacturers to 'Remediate, Retire or Replace' should be extended to include the option of 'Remediation **Sufficiency**'. This option would require the provision of evidence based on a combination of a justification for NOT performing extensive new

remediations and, if required, a prioritisation of the critical few gaps which need attention. Also, since clinical gap remediation to MEDDEV 2.7/rev 4 and EU MDR is proving to be amongst the single biggest spends for manufacturers, we would also pose the question: 'Should consideration be given for an acceptance of RWE (Real-World Evidence) similar to the FDA published guidance last year ('Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices')?'

Again, it is important to stress that asking the 'Remediation **Sufficiency**' question is not intended as a 'work around' for the application of the new EU MDR. For many Manufacturers of legacy products which have demonstrated good safety, evidenced in HCP endorsements of performance and with no serious safety events in patient use, should they be seeking to have these products assessed differently for compliance under the new Regulations? Perhaps these products could be certified under EU MDR as 'legacy products with a Proven Safety and Performance Record' designation? For these products acceptance of the use of existing patient safety and HCP performance as a basis for the justification of claims as an acceptable remediation pathway would eliminate the need to conduct extensive and costly clinical studies and testing.

2. Prospective Remediation.

An alternative strategy would be to leverage Article 56.3 & 4 Certificates of Conformity in the EU MDR Regulations with agreement from NBs to accept a 'prospective remediation' pathway. A 'prospective remediation' pathway would be applied only to those aspects of compliance which are product specific. Under this proposal a Manufacturer would have to provide evidence within their revised Technical File of EU MDR compliant Post Market Surveillance Plans (PMSP) and updated Risk Management Plans (RMP) etc., and a commitment to close all EU MDR data compliance gaps operating under a re-certified EU MDR QMS. A Manufacturer would still be required to demonstrate compliance in all aspects of the new regulations as it relates to non-product specific changes e.g. traceability, UDI labelling, vigilance and surveillance system changes etc, which will be required as a QMS compliance activity for the total portfolio.

These proposals would enable Manufacturers to prioritise resources (financial and personnel) on closing the compliance gaps on new products and those products which could not be designated with a 'legacy product with a Proven Safety and Performance Record' status.

These proposals for compliance are made as a pragmatic approach to mitigating the risks of those products which are known from performance in use to be perfectly safe from being withdrawn from the market.

What next?

We believe the industry needs to collaborate and find a way to work with the Legislators, the Competent Authorities and Notified Bodies to avoid the unintended consequence of the demise of large numbers of these proven-safe and needed legacy products. Waiting for the 'cliff-edge' is surely not an option.