Financial Impact Of EU MDR Compliance: A Cost Mapping Assessment For Manufacturers

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INTRODUCTION

The transition from MDD to MDR in the EU has created significant challenges for medical device manufacturers.[2,3,4] Since its full implementation in 2021, MDR has introduced stricter requirements for the design, production, and post-market surveillance of medical devices, making it considerably more costly to bring products to EU markets.[1]

OBJECTIVE

The study is conducting a cost-mapping assessment of the MDR framework for manufacturers, to highlight the overall financial burden and evaluate the specific costs associated with the transition.

METHOD

A combination of descriptive and exploratory approaches was used.

- A comprehensive literature review provided an overview of the MDR transition process steps.
- To enhance the study, an interview with regulatory experts offered deeper insights, identified cost areas underrepresented in the literature, and provided real-world data on the impact on daily work.

RESULTS

The research identified various costs associated with the transition to MDR. Although some cost elements existed under MDD, MDR introduced additional and more complex requirements.

AUDIT COSTS

Initial & surveillance MDR audits: *The audit costs range from €5,000 to €50,000.[5]*

Additional special audits: *Includes targeted reviews such as clinical processes, sterilization & packaging and unannounced audits.[6,7,8]*

ADDITIONAL CLINICAL DATA GENERATION COSTS

New clinical evaluation for existing products: *Additional studies may be required to meet MDR, costing €50,000–€500,000.[5,6]*

Higher clinical trial & evaluation costs for new launches: *Stricter MDR testing significantly raises expenses for new products.[3,6,9,11,12]*

REGULATORY COMPLIANCE COSTS

Technical documentation: *Increased MDR technical documentation effort and Notified Body reviews, with costs up to €100,000 per review.[9]*

Notified Body fees & up-classification: *Stricter rules move some devices into higher-risk categories, increasing certification requirements.[2,5,10]*

GENERAL COSTS

Additional personnel & training: *MDR transition requires larger workforce and specialized expertise.[6,13,14]*

Supply chain disruptions: *Certification delays impact supply chain elements, increasing costs.[6]*

Market delays for existing & new products: *Lengthy approval timelines slow market entry, extend R&D, raise costs.[3]*

Switching to MDR is estimated to cost manufacturers about 3.5% to 5% of their total revenue in Europe.[15]

CONCLUSIONS

The MDR sets higher standards that improve patient safety and the quality of medical devices in the EU.

While the transition process has increased the cost and complexity of bringing products to market, the significant benefits to patient health and the resulting improvements in safety and regulatory oversight outweigh these financial challenges.

However, there needs to be a public debate on how those higher costs for manufacturer‘s can be at least partially be recouped to maintain an innovation-friendly EU healthcare market space and wide patient access.

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