

Regulatory Oversight of Patient Safety in Medical Devices

Project brief

Aims & objectives

The growing dependency on medical devices and *in vitro* diagnostic technologies has significantly improved healthcare outcomes, while highlighting the critical need for robust regulatory oversight to safeguard patient safety.

The aims of this study were to identify gaps in medical device regulatory sciences with particular focus on patient-centred approaches, and to develop a post-market surveillance framework to strengthen oversight of patient safety.

Methodology

The study consisted of three phases.

- Phase I involved identifying global procedures for the oversight of post-market surveillance and vigilance of medical devices. A data collection tool was developed and shared with European regulatory experts. Gaps in current regulatory landscape were identified.
- Insights gathered from Phase I were used for the development of a regulatory framework in Phase II.
- In Phase III, the framework was pilot-tested using a selection of incident reports sourced from the Malta Medicines Authority database. The findings, highlighting strengths, weaknesses, opportunities and threats, informed refinement of the framework (Figure 1).

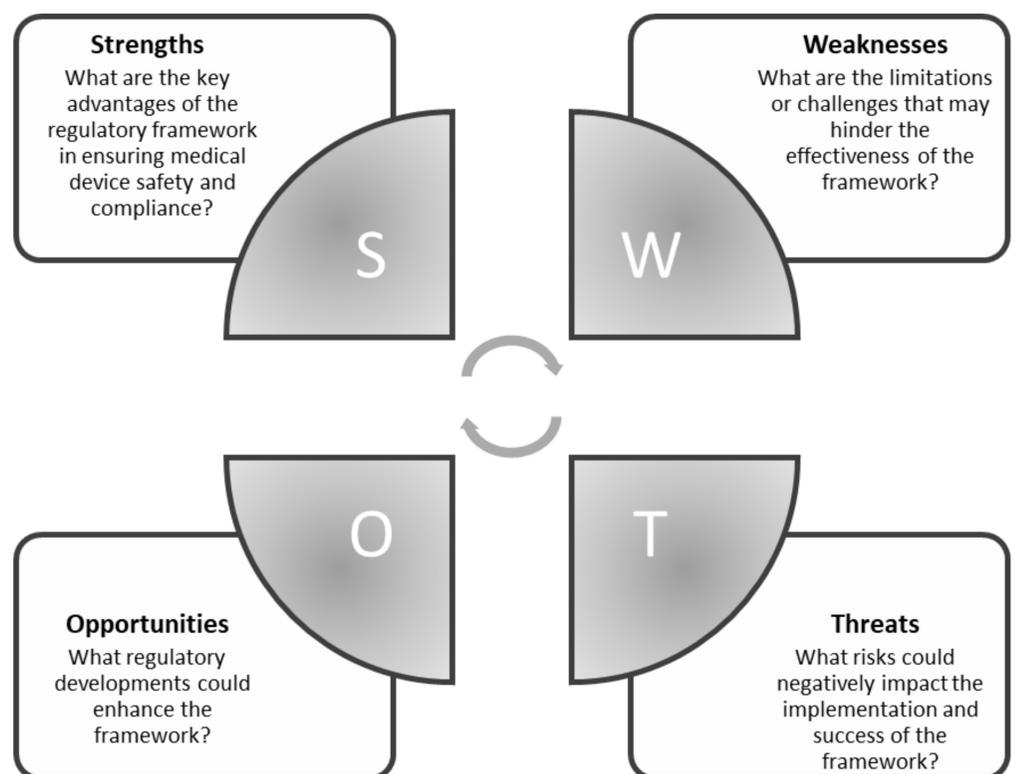


Figure 1. The Four Key Questions Guiding the SWOT Analysis

Ensuring Patient Safety through Medical Device Regulatory Science A Regulatory Framework for Competent Authorities MD-PMSV-RF01		
Aims and Scope		
Roles and Responsibilities of Stakeholders for Post-Market Surveillance [PMS] and Vigilance Activities	Manufacturers	
	Authorised Representatives	
	Importers	
	Distributors	
	Notified Bodies	
Oversight of Post-Market Surveillance Activities by the Competent Authority	Substandard and Falsified Medical Devices	
	Custom-Made Devices	
	Legacy Devices	
Vigilance	Incident Reporting	Receiving a Medical Devices Incident Form
		Receiving a Manufacturer Incident Report
	The Recall Process	Voluntary Recall by the Manufacturer
		Mandatory Recall by the Competent Authority
Monitoring Trends	Trend Analysis Strategy for Competent Authorities	
Risk Analysis and Risk Management	The Risk Matrix	
Integrating AI into Medical Device Regulatory Sciences	The AI Act and Post-Market Monitoring	
	Implementing AI in Post-Market Surveillance and Vigilance	
Training Modules on Post-Market Surveillance and Vigilance	Training for the Regulatory Personnel	
	Training for the Healthcare Professionals and other End-users	

Figure 2. Dimensions Captured in the Developed Framework

Results & Conclusions

- Phase I: Key areas where gaps were highlighted include (a) resources, (b) incident reporting, (c) legal exceptions (d) recall process, and (e) integration of artificial intelligence.
- Phase II: The developed framework maps processes that support safety and performance of devices, outlines roles of stakeholders involved in post-market surveillance and defines risk mitigation strategies (Figure 2).
- Phase III: From pilot-testing and refinement through a SWOT analysis, the framework was demonstrated to be a practical tool for competent authorities.

The framework is intended to support competent authorities in addressing challenges related to patient safety oversight within the field of medical device regulatory sciences.