CHALLENGES FACING REGULATORY SCIENCE IN MEDICAL DEVICES

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INTRODUCTION

Medical devices play a central role in the management of diseases for a wide range of conditions.[1] In recent years, medical device regulations have evolved due to advancement in technology and increasing awareness for a more consistent and transparent approach to regulatory documentation.

AIMS

- To understand the current implemented regulatory system for medical devices.
- To identify challenges faced by the regulatory body and stakeholders in the medical device industry.

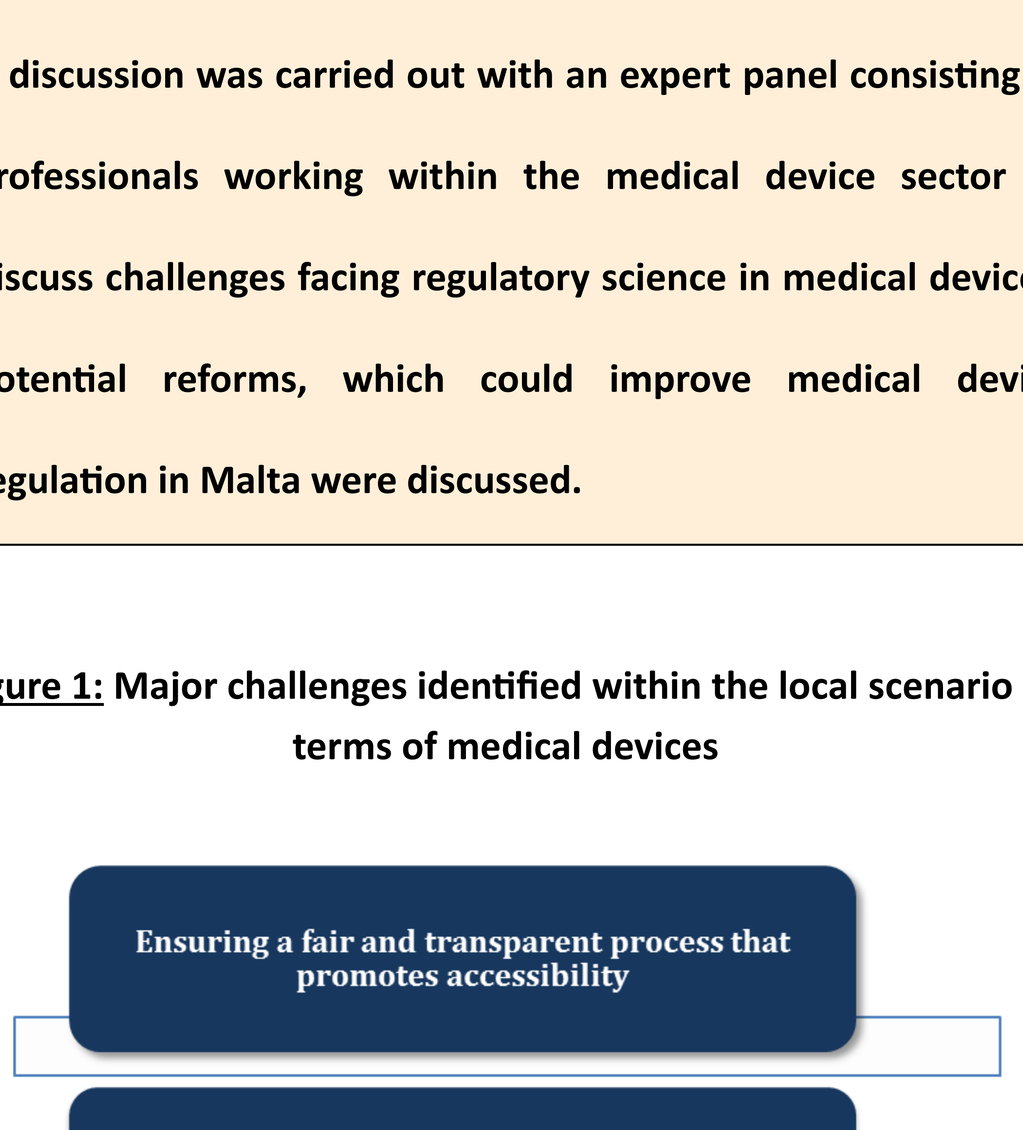
METHOD

- A systematic literature review was conducted to study and evaluate the variation in regulation between different governing states where particular reference to the regulatory system for medical devices in the United States and European Union was given.
- Qualitative research in the form of semi-structured interviews was conducted to study the current implemented medical device regulatory system in Malta. Purposive sampling and chain referral sampling were adopted for this study.
- Semi-structured interviews were carried out with the directors and employees of the national Competent Authority regulating medical devices in Malta and the Central Procurement and Supplies Unit responsible for procuring medical devices within the Governmental Health System in Malta.
- A discussion was carried out with an expert panel consisting of professionals working within the medical device sector to discuss challenges facing regulatory science in medical devices. Potential reforms, which could improve medical device regulation in Malta were discussed.

RESULTS

Challenges faced by stakeholders in the medical device industry were identified (Figure 1). The starting point for improving medical device regulations lies in the management of the challenging issues outlined. Both the national Competent Authority and procurement department believe that stakeholders should contribute in the mutual understanding of pertinent issues and accept responsibility for being actively involved in on-going discussions and shared education. Results show that current policies and regulations should be continuously reviewed and implemented in order to be in line with technology, while safeguarding the patient. Reviews should be based more on clinical effectiveness rather than on device performance. This patient-centred approach will ensure that only medical devices of good quality, safety and performance are available on the market.

Figure 1: Major challenges identified within the local scenario in terms of medical devices



CONCLUSION

A more effective notification and enforcement system similar to what is done in the area of medicinal products will encourage the cost-effective availability of appropriately certified medical devices. A forward-looking regulatory system, in which pre-marketing and post-marketing frameworks are integrated, is recommended.

Reference:

[1] Sorenson C, Drummond M. Improving Medical Device regulations: The United States and Europe in Perspective. *The Milbank Quarterly* 2014; 92(1):114-150.