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RISKS IN MEDICAL DEVICE VIGILANCE

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INTRODUCTION

Medical devices are products that vary from simple bandages to artificial bones, and intensive security measures are adopted from the approval up to the release of the device to the market for the safety of its users. [1]

Medical Device Compliance Exchange Form (CEF) is a communication tool used for data exchange about medical devices between Competent Authorities (CA) and Designating Authorities (DA), in specific cases including Notified Bodies (NB), within the European Union (EU). In Malta, the Medicines Authority (MMA) is the CA for ensuring medical devices' safety, incident reports and investigation.

AIMS

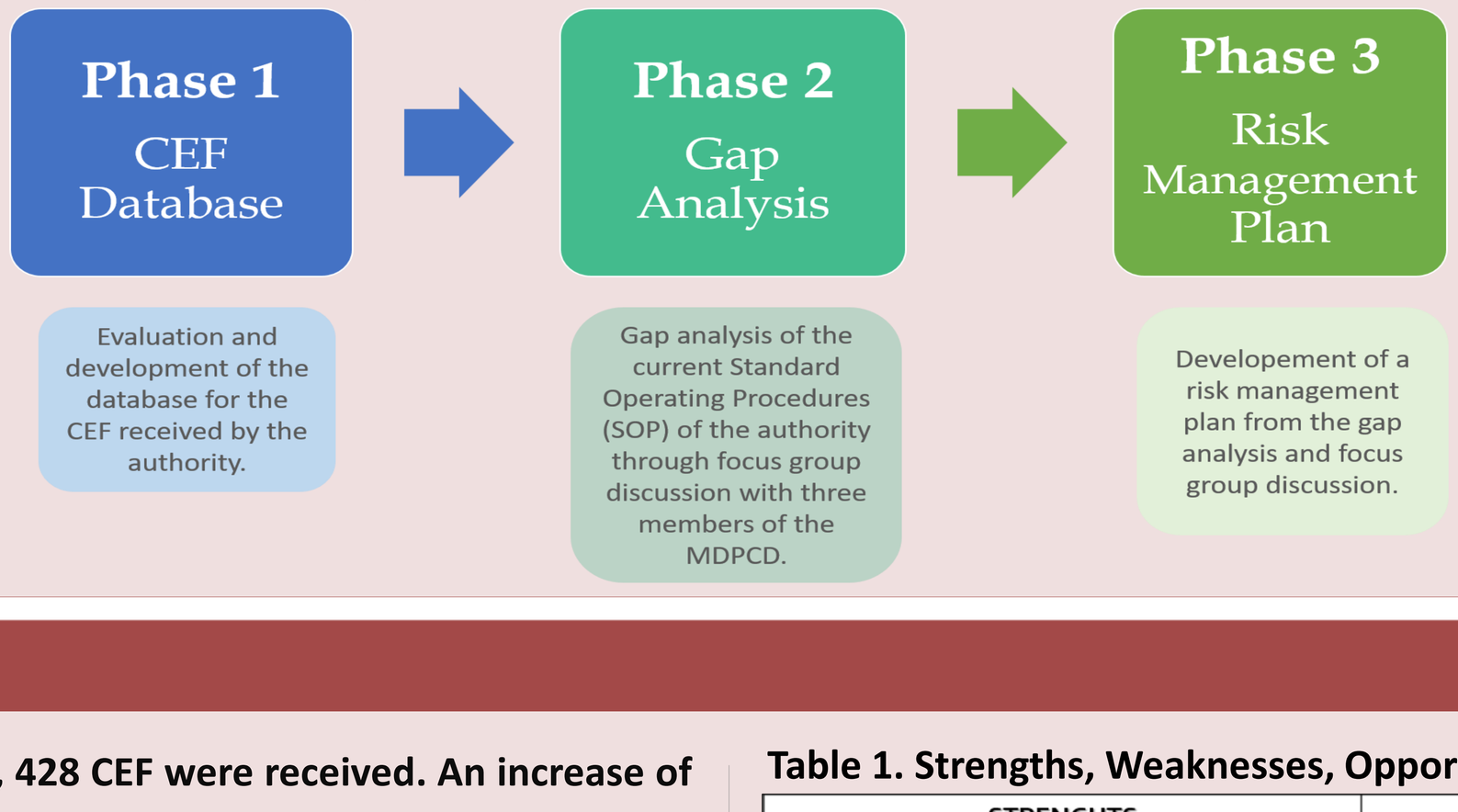
1) Evaluate the medical devices CEF received by the Authority from other EU member states, including countries under the European Free Trade Association (EFTA) and EU candidate countries which contains dissemination of information and/or injury about medical devices' functions, approval and legal standing;

2) Assess the procedures used by the Authority in handling incident reports for medical devices; and

3) Develop a risk management plan for the mitigation of risks.

METHOD

The qualitative study is divided into three phases:



RESULTS

1) From 2021 to 2022, 428 CEF were received. An increase of CEF from 2021 (N=192) to 2022 (N=236) was observed which could be connected to the rise of medical device use during the height of the COVID-19 pandemic.

2) The focus group discussion identified gaps in vigilance within the Medical Devices and Pharmaceutical Collaboration Directorate (MDPCD) as shown in Table 1.

3) A risk management plan was developed, and approved by the head of the MDPCD. A pilot implementation was performed to assess the usability of the risk management plan.

Table 1. Strengths, Weaknesses, Opportunities, Threats

STRENGHTS	WEAKNESSES
QUALITY. Well-developed and tailored SOP that fits current practice **ADAPTIVE**. Adapts a process that works for a smaller state like Malta. Adapts to changes whenever needed. **STRAIGHTFORWARD**. Direct communication with stakeholders which results to quicker response, investigation, and resolution of issues. **HARMONIZED**. Advisory committee is present and is available for consultation. Good relationship with other stakeholders. **COMPLIANT**. Excellent compliance with the standards required by the legislation and regulation **INNOVATIVE**. Current action timelines follow a quicker pace versus that of the MDR.	**IN DEVELOPMENT**. SOP and its risk analysis are currently at the drafting stage **FREQUENCY OF CHANGES**. Small and frequent changes with parts of the process algorithm might result to pending incident reports **UNFILTERED**. All types of reports are received, including procurement-related reports
OPPORTUNITIES	**THREATS**
TIMEFRAME. Specific timeframe may be added in each step of the SOP to improve overall turn-around time. **TRIAGE SYSTEM**. Solidification of a triage system with an active filtering of emails may contribute to reduction of unrelated reports **PROMOTION**. Encouragement of incident reporting and educating end-users of when, how and where to report incidents related to medical devices to reduce risk of harm.	**UNDER REPORTING**. Under reporting and lack of awareness about the reporting system might result to patient harm.

CONCLUSION

The incorporation of the risk management plan with the current practices of the Authority solidifies the goal of safety and reduces the risks in vigilance as it proposes visual steps on handling reports. Further improvement with the risk identification and reporting system awareness can contribute to the continuous improvement of medical device vigilance.

REFERENCES

1. World Health Organization (WHO) [Internet]. Medical Devices; 2022 [cited 2023 Jan 08]. Available from: https://www.who.int/health-topics/medical-devices#tab=tab_2