

INTRODUCTION

In the effort to ensure access to medications that are not registered on the Maltese market, the Central Procurement Unit (CPSU) within the Ministry for Health is responsible for registering medicines via Article 126a of the EU Directive 2000/83/EC. The registration process requires a pharmacovigilance (PV) framework.

AIMS

This research aimed to identify and establish a robust framework of PV for medicines registered by CPSU and propose action plans for implementation of the framework.

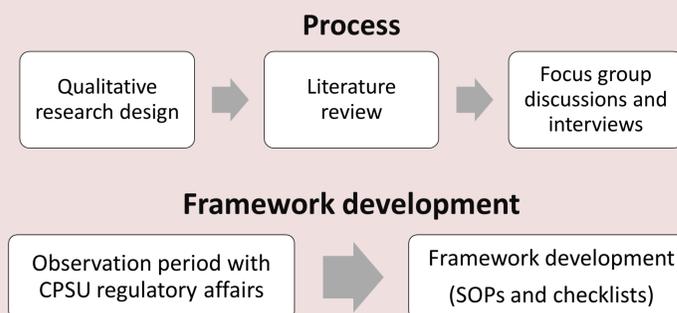
SETTING

Central Procurement and Supplies Unit (CPSU) at the Ministry for Health which is responsible for the procurement and distribution of all medicines and medical devices for the National Healthcare System

Acknowledgments: Central Procurement and Supplies Unit at Ministry for Health, Malta particularly Ing. Karl Farrugia, Managing Director

METHOD

The study employed a qualitative research design. As part of the background study, literature review, and observation sessions at CPSU were completed. Focus group discussion and interviews with CPSU, medicines regulatory agency management (Medicines Authority), and staff were undertaken. Subsequently, a framework was developed within the context of the quality management system of CPSU.



RESULTS

- ❑ The study classified five gaps in a PV system through systematic literature review namely: underreporting of adverse drug reactions (ADR) and quality of report, lack of streamlined system, weaknesses in training and awareness, moderate monitoring and evaluation, inadequate training and awareness of PV, and need for a stronger collaboration among stakeholders (Figure 1).
- ❑ The focus group discussion revealed five major themes: 1) supply and availability which include product registration and outsourcing of medicinal product, 2) pharmacovigilance and ADR reporting, 3) barriers to PV described through the impact of importation due to market size, 4) Brexit and its impact on access to medicines in Malta and 5) barriers to ADR reporting. (Figure 2).
- ❑ The framework developed identified the need to establish a Quality System that covered human resources needs, training, audit processes, optimization of documentation trail for product registration, ADR reporting and risk minimisation strategies.

Figure 1. PV Systems Weaknesses

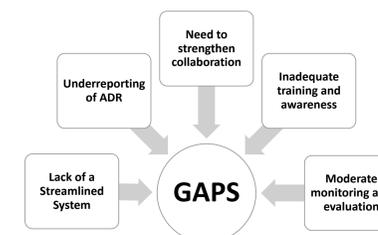


Figure 3. PV Framework for CPSU

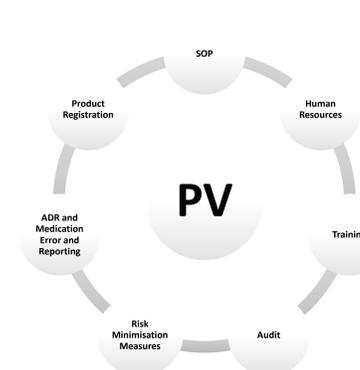


Figure 2. Thematic Analysis of the Data

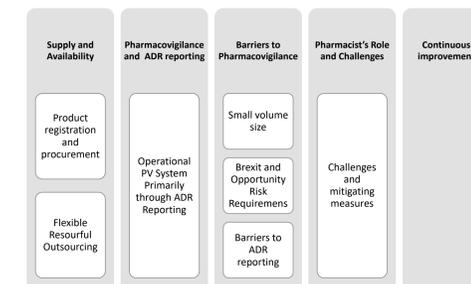


Figure 4. Standard Operating Procedures and Checklists

Standard Operating Procedure	Checklist of Documents
Adverse Drug Reaction and Medication Error Reporting	✓ ADR Reporting and Medication Error Reporting Forms
Registration of Medicinal Product under Article 126a	✓ Mock ups ✓ SPC ✓ PIL ✓ Electronic application form ✓ Signed declaration form
Risk Minimisation Measures	✓ Educational and training materials
Monitoring and Evaluation of Pharmacovigilance System in CPSU	✓ Program Goals and Objectives
Qualifications and Skills of PV Staff	✓ Diploma and Transcript of Records ✓ Candidate Evaluation form

CONCLUSION

A framework was developed based on Standard Operating Procedures and Checklists that may be adopted within CPSU. The framework is patient safety focused ensuring access to medicines for which there is shortage and which CPSU is required to register through 126A article whilst safeguarding the quality, safety and efficacy of the medicinal products.

REFERENCES

Directive 2001/83/EC of the European Parliament and Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal of the European Communities . 28 November 2001. L 311/67.