Innovative regulatory framework in community pharmacy

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MARINA LANGARO

Department of Pharmacy

University of Malta

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DECLARATION OF AUTHENTICITY FOR DOCTORAL STUDENTS

Student's Code 1409616

Student's Name & Surname Marina Langaro

Course PharmD in Clinical Pharmacy

Title of Dissertation/Thesis 'Innovative regulatory framework in community pharmacy'

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Abstract

The implementation of Good Pharmacy Practice (GPP) in Malta and the evolution of pharmacy regulatory science led to an innovative patient-centred approach in regulatory audit. The aim of the research is to establish a regulatory self-audit model in community pharmacy aiming at satisfying regulatory requirements while meeting patient needs.

The methodology included (1) an analysis of the regulatory framework by a multidisciplinary focus group (n=3 patients, n=3 general practitioners, n=3 pharmacists), (2) design and validation of the self-audit protocol, (3) risk-based assessment defining regulatory criteria (N=76) as minor, major and critical and correspondingly classifying pharmacies in high (1 critical or above 5 major findings), medium (1-5 major) and low risk (only minor findings) categories, (4) competencies and regulatory self-audits and regulatory audits in 61 community pharmacies, (5) measurement of compliance agreement between regulatory and self-audits and of risk categorisation with the Kappa test, mean percentage compliance with the Wilcoxon Signed Ranks test (6) correlations between pharmacist characteristics and self-audit results with the Chi square test.

(1) The focus group analysis optimised the methodology of the research by identifying 4 risk factors (resistance for the observation of patient-pharmacist interactions, oversights of legal requirements, need for higher pharmacist competencies and pharmacist work overload), 2 weaknesses (unacceptability of proactive initiatives by the pharmacist, lack of robustness in the self-audit) and 5 strengths (optimisation of clinical service, recognition of pharmacist's role, reduction in redundant bureaucracy, meeting patient needs, personalised healthcare). (2) The self-audit protocol assessed pharmacist strengths, scientific interests, goals and opportunities for improvement, and regulatory criteria through a regulatory checklist. (3) The risk assessment identified 19 minor, 34 major and 23 critical regulatory criteria. (4) Pharmacists (34 female, mean age 43, range 25-73)

reported ‘understanding patient needs’ (57.4%) and ‘patient-orientation’ (49.2%) as the two highest strengths, ‘personalised healthcare’ (44.3%) as the major area of interest, ‘service optimisation’ (49.5%) as the main goal and ‘continuous education’ (63.9%) as an opportunity for improvement. In the self-audits pharmacies reported higher regulatory compliance (94.7% ± 4.65) and were classified in lower risk-categories (low-risk=27, medium-risk=18, high-risk pharmacies=16) than in regulatory audits (82.7% ± 8.14; low-risk=2, medium-risk=13, high-risk pharmacies=46). Agreement between regulatory and self-audits was achieved for 9 out 76 criteria (p-value<0.05). The difference on mean percentage compliance between regulatory and self-audits was statistically significant (p=0.000) while agreement on regulatory and self-audits risk categorisation was not achieved (Kappa= 0.050, p=0.395). (5) ‘Understanding patient needs’ and ‘good communication skills’ were reported as main strengths by 67.6% and 47% of the pharmacists with more than 6 years of experience (p=0.000). Pharmacists below-30 and over-60 years-old assigned a lower regulatory self-audit risk compared to intermediate age-categories (p-value=0.041).

A self-audit showed highly significant differences from the established regulatory audit. A less policing approach in audits may lead to achieve concordance between regulation and pharmacy practice. A GPP certificate based on pharmacist competencies, on regulatory compliance and on a pharmacy-risk analysis is proposed to addresses pharmacy educational needs and optimise pharmacy practice towards meeting patient needs.

Keywords

Pharmacist competencies- Regulatory self-audit- Risk assessment- Regulatory science- Patient-centred Pharmacy Practice

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Glossary

Terms related to audit adapted from the European Committee for Standardisation (CEN). Quality management systems - Fundamentals and vocabulary (EN ISO 9000:2015). Brussels: CEN; 2015

Terms related to pharmacy legislation adapted from Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.16 Pharmacy License Regulations [Online]. Malta: The Ministry; 2007 [cited 2020 May 30]. Available from: URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11256&l=1;Ministry for Justice, Culture and Local Government. Subsidiary Legislation 101.02 Internal Control of Dangerous Drugs Rules [Online]. Malta: The Ministry; 1939 [cited 2018 may 30]. Available from: URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=9261&l=1

Terms related to pharmaceutical activities in Malta adapted from the Malta Medicines Authority website and internal SOP.

Accompanying auditor

Person who accompanies the audit leader in the performance of an audit (European Committee for Standardisation, 2015).

Audit Criteria

Set of policies, procedures or requirements used as a reference against which audit objective evidence is compared (European Committee for Standardisation, 2015).

Audit Findings

Result from a process evaluating the audit evidence and compares it against audit criteria. It can show that audit criteria are being met (conformity) or not (nonconformity). Best practices or improvement opportunities can be identified through the audit (European Committee for Standardisation, 2015).

Audit Plan

Established plan for the performance of audits over a period of time for a specific purpose (European Committee for Standardisation, 2015).

Calibration certificate

Certificate issued after an instrument measures are compared and adjusted with a device of known correctness. (Allen, 2013).

Catalytic attitude

Attitude based on open discussion and education (Weske et al, 2018).

Cleaning Records Register

Register maintained to record cleaning activities of the pharmacy premises in order to comply with the standard stipulated in Subsidiary Legislation 458.16 Pharmacy Licence (Ministry for Justice, Culture and Local Government, 2007).

Coercive attitude

Attitude based on strict observation and punishment (Weske et al, 2018).

Competence

Ability to apply knowledge and skills to achieve intended results (ISO 19011: 2018).

Corrective Action

Action taken to eliminate the cause/s of a non-conformity, defect, or other undesirable situation to reactively prevent recurrence (European Committee for Standardisation, 2015).

Daily Register

Register maintained for the record of the sale of medicines dispensed against a repeat and partially dispensed prescription (Ministry for Justice, Culture and Local Government, 2007).

Dangerous Drugs Purchases Register

The DDA purchases, is used to record purchased (private DDA register) or otherwise obtained (POYC DDA register) dangerous drugs (narcotics and psychotropic drugs) (Ministry for Justice, Culture and Local Government, 1939).

Dangerous Drugs Sales Register

The DDA sales register maintains recordings about all dangerous drugs (narcotics and psychotropic drugs) supplied, including sales (private DDA sale register) and free supply (POYC DDA sale register) (Ministry for Justice, Culture and Local Government, 1939).

Deficiency

An audit finding that does not conform to the audit criteria (European Committee for Standardisation, 2015).

Gold standard

An expert rater, who is taken as a model to compare assessment (Ward et al, 2002).

Good Distribution Practice

Guidelines which ensures that medicinal products are distributed by authorised wholesalers according to conditions established at European level (Malta Medicines Authority, 2020a).

Good Manufacturing Practice

Guidelines which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation (MA) (Malta Medicines Authority, 2020b).

Good Pharmacy Practice

Practice of pharmacy to provide optimal, evidence-based care and to respond to the needs of the pharmacy customers (International Pharmaceutical Federation/World Health Organisation, 2012).

Leading Auditor

Person conducting and leading an audit (European Committee for Standardisation, 2015).

Locum Register

A record kept for documentation of pharmacists, other than the managing pharmacist, practicing at the pharmacy (Ministry for Justice, Culture and Local Government, 2007).

National Competent Authority

A medicines regulatory authority in an European Union Member State (European Medicines Agency, 2020).

Pharmacy-Of-Your-Choice scheme

National pharmaceutical service which provides patients with chronic conditions to be entitled to free medicines and pharmaceutical devices. These are provided by the Government on an 8 weeks-basis from the community pharmacy chosen by the patient (Ministry for Health, 2020).

Preventive Action

Action taken to eliminate the cause/s of a potential non-conformity, defect, or other undesirable situation to proactively prevent occurrence (European Committee for Standardisation, 2015).

Regulatory Audit

A systematic and independent procedure performed to obtain objective evidence and assess the fulfilment of the audit requirement (European Committee for Standardisation, 2015).

Regulatory Authority

A body that is responsible to regulate regulatory activities related to medicines, including the processing of marketing authorisations, monitoring of adverse drug reactions, performance of audit to assure quality, safety and efficacy of medicines. The regulatory authority in Malta is the Malta Medicines Authority (European Medicines Agency, 2020).

Regulatory science

Regulatory sciences is the discipline that supports the advance of regulation to equalise innovative progress (Wu et al., 2019).

Renewal Audit

An audit performed to renew the pharmacy licence issued by the Malta Medicines Authority. The renewal audit is not notified in advance. During this audit, a routine regulatory audit is performed against the audit checklist (Malta Medicines Authority, 2020c).

Risk

The combination of the probability of occurrence of harm and the severity of that harm **(**Wu et al., 2019).

Self-assessment

Established process used by an individual to evaluate his/her performance, while comparing it with the individual goals and job criteria (Andrade and Du, 2007).

Self-audit

Audit performed by the subject audited to assess the achievement of pre-established criteria (European Committee for Standardisation, 2015).

Temperature Register

Recording of the maximum and minimum of fridge and room temperature in the pharmacy. Temperature must be registered in all rooms and fridges where medicines are stored in order to comply with the standard in Subsidiary Legislation 458.16 Pharmacy (Ministry for Justice, Culture and Local Government, 2007).

Warning Letter

A letter which may be issued following an audit depending on findings related to the audit criteria. Pre-set criteria by the Malta Medicines Authority on which a warning letter is issued are; (1) when one audit finding can potentially affect the quality of medicines stored at the pharmacy or its licensed store(s), or (2) when one of the deficiencies was previously identified through an audits (Malta Medicines Authority, 2019).

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Malta Medicines Authority. Good Manufacturing Practice [Online]. Malta: Malta Medicines Authority; 2020 [cited 2020 May 27]. Available from: URL: http://www.medicinesauthority.gov.mt/goodmanufacturingpractice#Good%20Manufacturing%20Practice%20Guidelines

Malta Medicines Authority. Pharmacies [Online]. Malta: Malta Medicines Authority; 2020 [cited 2020 May 27]. Available from: URL: http://www.medicinesauthority.gov.mt/pharmacies

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List of Abbreviations

A/C	Air Conditioning
CAPA	Corrective Action Preventive Action
CI	Confidence Interval
DDA	Dangerous Drug Act
DPO	Data Protection Officer
EC	European Commission
FIP	International Pharmaceutical Federation
FREC	Faculty Research Ethics Committee
GMP	Good Manufacturing Practice
GP	General Practitioner
GPP	Good Pharmacy Practice
ICC	Intra-Class Correlation Coefficient
I-CVI	Item-Content Validity Index
IEC	International Electotechnical Commission
ISO	International Organisation for Standardisation
MMA	Malta Medicines Authority
NCA	National Competent Authority
PCSA	Pharmacist Competencies Self-Audit
PIC	Pharmaceutical Inspection Convention
POYC	Pharmacy Of Your Choice
R&D	Research and Development
RA	Regulatory Audit
RSA	Regulatory Self-Audit

S.L.	Subsidiary Legislation
SOP	Standard Operation Procedure
SROD	Scientific and Regulatory Operations Directorate
WHO	World Health Organisation
WPPF	Western Pacific Pharmaceutical Forum

Chapter One

Introduction

The introductory chapter consists of: (1) pharmacist evolution and Good Pharmacy Practice (GPP) standards and guidelines (2) methods of evaluation of pharmacist competencies, (3) Good Pharmacy Practice assessment performed in the world, (4) the role of risk in regulation and as applicable to pharmaceutical activities, (5) regulation of community pharmacy in Malta and implementation of Good Pharmacy Practice standards in Malta, (6) regulatory audit approach and self-assessment.

1.1. The evolution and establishment of the pharmacy profession

With the industry revolution, the production of medicines passed from being pharmacy to industry-based (Al-Shaqha et al, 2001; Coley, 2004; Pearson, 2007; Duffull et al, 2018; Hoffmann-Eubanks, 2019; Urick and Meggs, 2019) and a transition from compounding activities to dispensing and ultimately to patient-care was seen during the years (Alabid et al, 2013; Costa et al, 2017; Hoffmann-Eubanks, 2019; Urick and Meggs, 2019). The pharmacy practice and the pharmacist role within the healthcare scenario are continuously evolving to adapt to patient needs and advances in research and technology (Cruthirdsa et al, 2013; Anderson et al, 2018). The pharmacist profession had to move from a product to patient focused practice: the pharmacist is providing more and more pharmaceutical care, focusing on the patient and not on a singular medicinal product (Costa et al, 2017). Drug monitoring, identification of drug-related problems and prevention of adverse effects and events became the core skills of the pharmacist profession. The change in pharmacist roles has brought the need for the development of further competency through the adaptation of pharmacy curricula and continuous education (Urick and Meggs, 2019).

The World Health Organisation (WHO) and the International Pharmaceutical Federation (FIP) continuously study and foreseen changes in the pharmacy practice and support pharmacists with updated guidelines (Hallit et al, 2019). They strive to promote the maintenance of high pharmacy standards around the world to meet patient needs and

promote the figure of the pharmacist within the healthcare scenario (Unhurian et al, 2018).WHO provided the definition of the pharmacist role since 1986 with the Dehli meeting followed by the Tokyo meeting in 1993 (Unhurian et al, 2018). The first definition of Good Pharmacy Practice (GPP) was given by FIP together with the Swedish National Corporation of Pharmacies through the Stockholm Letter, which launched the definition of "Good pharmacy practice" and the establishment of international standards for pharmacy services (Trap et al, 2010). Good Pharmacy Practice is the delivery of the highest standards and evidence-based pharmacy services (Trap et al., 2016). Good Pharmacy Practice was also implemented in community and hospital pharmacy scenarios in 1996 by WHO. The concept of the seven star pharmacist was invented in 1997 by WHO and defined the pharmacist as a 'care-giver', 'decision-maker', 'communicator', 'leader', 'manager', 'life-longer-learner', 'teacher'. The seven-star pharmacist principle was adopted by FIP in 2000 and in the 'Good Pharmacy Practice: Joint FIP/WHO guidelines on GPP: Standards for quality of pharmacy services'.[1]

1.1.1. The Good Pharmacy Practice guidelines

The latest guidelines published in 2011[1] define standards for the community and hospital pharmacist profession for the benefit of patients and concerned stakeholders. Healthcare accessibility and quality, including medicines, services and healthcare professional as well as cost were identified barriers to good pharmacy practice.

1. International Pharmaceutical Federation. Good Pharmacy Practice: Joint FIP/WHO guidelines on GPP: Standards for quality of pharmacy services [Online]. The Hague: International Pharmaceutical Federation [cited 2020 May 27]. Available from: URL: https://www.fip.org/www/uploads/database_file.php?id=331&table_id=

The scope of these guidelines is to address barriers to good pharmacy practice and provide optimal, evidence-based healthcare services. Good pharmacy practice standards consider regulatory requirements about premises, storage, administration of bureaucracy such as maintenance of prescriptions and registers and defines the role of the pharmacist in the community and within the healthcare scenario (Tiyyagura et al, 2014).

Pharmacy practice is regulated differently between countries. This is due to a complex economic, regulatory and academic framework behind the scenes. A step-wise approach was proposed by WHO to achieve harmonisation of pharmacy practice standards within the countries. Through the guidelines, minimum standards of pharmacy practice were established and on-going optimisation of pharmacy services promoted based on national needs, capability and wealth circumstances. According to the guidelines, regulatory bodies and national organisations have the responsibility to establish the GPP standards locally and to promote optimisation of practice (Tiyyagura et al, 2014; Unhurian et al, 2018). The definition of the pharmacist profession with its functions promotes the institution of standards of pharmacy practice through the definition of the scope of pharmacy practice and pharmacist competences at a national level.[1]

The standards are described by the four roles of the pharmacist and related functions and are summarised in the 'Good Pharmacy Practice guidelines: roles and functions of the community pharmacist' table (Table 1.1).

1. International Pharmaceutical Federation. Good Pharmacy Practice: Joint FIP/WHO guidelines on GPP: Standards for quality of pharmacy services [Online]. The Hague: International Pharmaceutical Federation [cited 2020 May 27]. Available from: URL: https://www.fip.org/www/uploads/database_file.php?id=331&table_id=

Table 1.1: 'Good Pharmacy Practice guidelines: roles and function of the community pharmacist'

'Role 1: Prepare, obtain, store, secure, distribute, administer and dispose of medical products'
• Extemporaneous drug preparations • Equal access to good quality medicines and information • Good distribution practices • Drug emergency as drug recall and shortages • Appropriate storage of medicinal products • Administration of medications (when applicable) • Patient adherence to treatment • Medicines disposal
'Role 2: Provide effective medication therapy management'
• Health management, disease prevention, and healthy lifestyle • Appropriate education and use of reference material • Medicines accessibility: medicine formulary system updated to standard treatment guidelines • Access to patient data • Standard referral procedures • Continuity of care and multidisciplinary collaboration • Treatment monitoring • Assisting and educating patients • Patient-focused approach: needs, ethical, cultural and economics factor should be taken in consideration, patient involved in decision making process, patient considerations • Adherence to therapy
'Role 3: Maintain and improve professional performance'
• Update knowledge, also about alternative therapies and new technologies • Continuous education • Self-assessment and NCA assessments
'Role 4: Contribute to improve effectiveness of the health care system and public health'
• Educating patients on how to interpret information retrieved from the internet and advise • Promoting the participation to preventive programs • Abide to national legal obligations

The FIP Vision 2020 identified trends and challenges of the modern pharmacy practice. These are considered in the establishment of future strategies for the maintenance and achievement of GPP standards all over the world. It imposes social accountability of pharmacy education and competent healthcare professionals providing services in the community.[2]

1.2. Competencies related to the profession of the pharmacist

The Western Pacific Pharmaceutical Forum (WPPF) performed in 2019 a workshop to identify issues related to the implementation of GPP standards. During this meeting, the need for a competency-based professional development and self-reflection on competencies were pointed out (Jackson et al, 2019).

The quality of pharmacy services and the obtainment of patient clinical outcomes are correlated to pharmacist competencies (Coombes et al, 2010; Drzaic et al, 2018; Shah et al, 2016). Assessment of pharmacist competencies together with the assessment of pharmacy services, promotes improvement in the pharmacist service through the identification of knowledge deficiencies and needs for continuous education and establishment of goals (Sidani et al, 2014).[3]

2. International Pharmaceutical Federation. The FIP community pharmacy section. Vision 2020. [Online]. The Hague: International Pharmaceutical Federation [cited 2020 May 28]. Available from: URL:https://www.fip.org/files/content/pharmacy-practice/community-pharmacy/CPS_Vision_2020.pdf
3. Accreditation Council for Pharmacy Education. Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy [Online] Chicago: Accreditation Council for Pharmacy Education; 2015 [cited 2020 May 28] Available at: https://www.acpe-accredit.org/pdf/CPDGuidance%20ProfessionPharmacyJan2015.pdf

Different studies reported methods of evaluation for pharmacist competencies. These did not focus only on clinical knowledge but also on skills, attitudes as well as professionalism, communication and direct patient care (Alfadl et al, 2018; Austin et al, 2004; Mills et al, 2005; Saseen et al, 2017; Stojkov et al, 2016).[4]

Pharmacist competencies have been studied against particular conditions (Ibrahim et al, 2016; Netere et al, 2018), and towards pharmaceutical care orientation (Sumia et al, 2015; Udoh et al, 2018).

4. Competency Development & Evaluation Group (CoDEG). General Level Framework. A Framework for Pharmacist Development in General Pharmacy Practice [Online]. Available from: URL: http://www.codeg.org/fileadmin/codeg/pdf/glf/GLF_October_2007_Edition.pdf

1.3. Assessment of Good Pharmacy Practice

Since the 'pharmaceutical practice' term was defined and the GPP guidelines published, NCAs have started inspecting pharmacies against GPP standards (Trap et al. 2016). Studies were performed to assess GPP standards in community pharmacies, especially in developing countries (Stenson et al, 2001; Trap et al, 2010; Trap et al, 2016; Wijesinghe et al, 2007). The indicators studied were similar between the studies and regarded pharmacy system, storage of medicines, pharmaceutical services, dispensing and drug use (Trap et al, 2010; Wijesinghe et al, 2007) as well as patient counselling and therapy management (Alhusein & Watson, 2019; Petrushevska-Tozi et al, 2014). All indicators were set at different levels of standard according to the development status of the country.

Methods of assessment included observation, interviews, mystery shoppers (Netere et al, 2018), inspections (Badro et al, 2020), self-assessment (Petrushevska-Tozi et al, 2014; Tiyyagura et al, 2014), internal audits (Weske et al, 2018) and a combination of these methods (Sekaombya et al, 2019; Trap et al, 2010).

Most of the studies on GPP inspections performed by licensed auditors identified poor adherence to GPP and need for increased awareness and training to abide to standards (Badro et al, 2020; Wijesinghe et al, 2007). GPP standards were identified as poor also through self-assessment (Tiyyagura et al, 2014) and with need for improvements (Petrushevska-Tozi et al, 2014).

Inter-reliability in the assessment of GPP criteria was evaluated by Sekaombya et al. (2019). The study analysed the validity and inter-rater reliability between a gold standard inspector and eight inspectors. The inspection collected data from records, through observation and interview. The study considered the assessment of GPP standards and patient knowledge about the medicine purchased. Other pharmacist interventions, such

as medicine review, identification of interactions, pharmacist attitude, were not taken into consideration in the research performed by Sekaombya. Overall, the research identified agreement between the study inspectors more than with the gold standard inspector.

The issuance of a GPP certificate was proposed only in Uganda and was used as an instrument to motivate pharmacists in the achievement of better standards and being recognised as top quality providers (Sekaombya et al, 2019; Trap et al, 2016).

1.4. The role of risk in regulation

The assessment of GPP standards lead to identification of non-compliance with regulatory requirements. Uncompliance with regulatory criteria is likely to induce harm on patients (Weske et al, 2018) and it is assessed based on services and regulatory requirements that have a different impact on patient safety through the quality of services and medicinal products delivered.

Wu et al. (2019) reported the definition of risk used by ISO 14971 and subsequently adopted by ISO 1348 as "the combination of the probability of occurrence of harm and the severity of that harm."

On the contrary, the second edition of the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 51(7) defined safety as 'freedom from unacceptable risk '.[5]

5. International Organisation for Standardisation (ISO) and International Electrotechnical Commission (IEC). Safety aspects-guidelines for their inclusion in standards, second edition [Online]. Geneva: ISO/ICH; 1999 [cited 2020 May 28].Available from: URL: https://www. iso.org/obp/ui/#iso:std:iso-iec:guide:51:ed-2:v1:en

Safety includes an objective and a subjective risk components. These are risk assessment and risk perception, which can be both at individual or social level.

Risk has been studied to support the establishment of regulatory frameworks and includes risk assessment, risk management and risk communication. Because safety is obtained through risk assessment and perception, it can be achieved through the application of regulatory science (Muramaki, 2016).

Regulatory science is the connecting point between science and the establishment and achievement of regulatory standards (Kurtz, 2017; Woodcock, 2012). Through a scientific-based anticipation of events, it addresses and enhances the achievement of patient outcomes and needs. Regulatory science, through risk-based approach, helps predicting and achieving patient needs and support decision-making processes when there is lack of evidence.[6]

Standards are set through regulatory science which takes into account the conservative regulatory requirements, through objective risk assessment, but also the social consensus, influenced by risk social perception. Both parts of the risk, the objective and subjective, are important to maintain patient-oriented practice while achieving social satisfaction (Murakami, 2016).

Risk analysis promotes the regulatory decision process and the application of regulatory sciences in disciplines. In the pharmaceutical scenario, it is used widely in the premarketing assessments, in post-licensing vigilance as well as manufacturing (Wu et al, 2019).

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6. Pharmaceuticals and Medical Devices Agency, Japan. “Rational Medicine” Initiative <https ://www.pmda.go.jp/files/ 00021 6304. pdf> (2017). Accessed February 26, 2019.

1.4.1. The Pharmaceutical Inspection Convention recommendation

The Pharmaceutical Inspection Convention (PIC) proposed in 2012 a model for risk-based GMP inspections.[7] It included the risk assessment that manufacturers possibly impose to their stakeholders. The tool was developed in line with European quality standards (ICH Q9, Q10).

The use of the model assists National Competent Authorities (NCAs) in the establishment of inspection frequencies for Good Manufacturing Practice. The model pictures the risk as intrinsic and compliance-related risk. The intrinsic risk is defined by the characteristics and complexity of the site, such as production amount and type of processes performed, while compliance depends on the risk associated to not accomplishing regulatory requirements. The compliance-related risk is assigned based on the number and nature of the inspection findings.

The model proposes a matrix to assess both types of risk and combine them to establish inspection frequencies based on risk assessment.

7. Pharmaceutical Inspection Co-Operation Scheme. A recommended model for risk-based inspection planning in the GMP environment [Online].Geneva: Pharmaceutical Inspection Co-operation Scheme [cited 2020 May 27]. Available from: URL: https://www.gmp-compliance.org/guidelines/gmp-guideline/pic-s-recommendation-on-risk-based-inspection-planning-pi-037-1

1.5. Regulatory background of community pharmacy: the audit process

Community pharmacies in Malta are regulated by the Medicines Act 2003, Chapter 458 of the Laws of Malta and Subsidiary Legislation 458.16, 458.28, 458.49, 458.53 and 458.58. The Malta Medicines Authority, the Maltese NCA carries out renewal community pharmacy regulatory audits (RAs) to assess compliance with the established legislative standards. These are unannounced and carried out on a two-year period to renew the community pharmacy licence.[8] Regulatory requirements are assessed against the regulatory audit checklist. Findings of the regulatory audit process leads to renewal of the pharmacy licence after Corrective Actions Preventive Actions (CAPAs) are implemented, when applicable.

When entering the pharmacy, the leading inspector identifies the pharmacist and introduces himself and the accompanying inspector to the pharmacist. The purpose of the visit is presented and the audit process starts. During the audit, the pharmacist is invited to give priority to patients entering the pharmacy. While the pharmacist is assisting patients, the inspecting team reviews all registers and certificates. The assessment of other criteria is performed with the participation of the pharmacist. At the end of the audit, the leading inspector provides a summary of positive and negative findings, explaining how corrective actions have to be implemented and the rationale behind the regulatory requirements as an additional explanation of their importance.

8. Malta Medicines Authority (MMA). Pharmacies [Online]. Malta: Malta Medicines Authority; 2019 [cited 2019 Jan 27]. Available from: URL: http://www.medicinesauthority.gov.mt/Pharmacies

Pharmacists are educated and engaged in open discussion. The inspecting team enhances the compliance with regulatory standards while taking into consideration the needs of the individual pharmacy. Concordance is reached between the pharmacist and the inspecting team.

Regulatory audits in Malta are performed every two years.[8] An audit plan is drafted based on the date of the last audit. Regulatory actions are taken according to the nature and gravity of the audit findings. A warning letter might be issued if the finding has a potential or actual impact on patient safety. Criteria to issue a warning letter are defined by an internal SOP.[9] Warning criteria are findings that can potentially affect the quality of medicines stored at the pharmacy or its licensed store(s), or deficiencies identified through a previous audits.

1.5.1. The patient-centred regulatory approach and the regulatory protocol

Regulatory requirements are assessed through the use of the regulatory audit protocol proposed by Attard (2018). The work by Attard focused on the design of a patient-oriented regulatory audit checklist and has resulted in the change in the auditors' attitude. These were changed to reflect the evolution of the pharmacist profession and to improve patient clinical outcomes through the concordance achieved on regulatory requirements. The police approach of the auditor was replaced by an educative and patient-centred approach, which aims at reaching concordance more than measuring compliance.

8. Malta Medicines Authority. Pharmacies [Online]. Malta: Malta Medicines Authority; 2020 [cited 2020 May 27]. Available from: URL: http://www.medicinesauthority.gov.mt/pharmacies
9. Malta Medicines Authority. Standard Operating Procedure PHY003: Procedure to be followed before, during and after a pharmacy inspection. Malta; Malta Medicines Authority: 2019

This attitude, also defined by Mikkelsen et al. (2017), as the catalytic approach, stimulates discussion and suggestion between the auditor and the pharmacist, and it opposes to the coercive approach. The focus of the audit evolved from the verification of fulfilment of regulatory requirements towards the promotion and assessment of Good Pharmacy Practice (GPP) standards in community pharmacy (Attard, 2018). Before Attard, the checklist was last updated in 2012. A comparison of changes related to the checklist is reported in the tables below (Table 1.2 and Table 1.3). The full checklist and structure comparison are present in Appendix 2.

Table 1.2: Comparison of regulatory audit reports structure versions 2012 and 2018

Sections	Version 2012	Version 2018
Number of questions	15	66 questions in 7 sections (A to G)
Administrative questions	3	Five sections (A to E)
Regulatory criteria	12 questions	10 subsections with 58 ‘yes/no’ questions
Other remarks	After all questions	Next to each requirement: ‘comment’ section
Signatures and date	Last part	Last part
Assessment modality	Auditors	Auditors
Approach	Police	Educational and patient-centred

Table 1.3: Comparison of regulatory criteria in regulatory audit reports versions 2012 and 2018

Regulatory criteria	Version 2012	Version 2018
Pharmacist figure	3 (q4 to q6)	3 questions including locum register
Thermometers	1 (q8)	In 'storage of medicinal products' section with temperature records.
Fridge	1 (q9)	3 questions
Daily, DDAs, Locum registers	1 (q10)	3 separate sections: daily register (4 questions), DDA registers (7 questions between private and POYC stock) and 1 question for locum with 'pharmacist' section.
DDA cupboard key	1 (q11)	5 questions: DDA cupboard and key.
Extemporaneous preparation utensils	1 (q12)	11 questions: 9 optional only if service is carried out, 2 questions always applicable
Storage of medicines	1 (q13)	11 questions
DDA prescriptions	1 (q14)	Together with the DDA registers
Premises and other documentation	1 (q7)	12 questions
Medicines purchased by authorised suppliers	1 (q15)	Only for DDA medicines
Additional sections	-	Stock take exercise for DDA, miscellaneous (reference books, sharps bin and areas for expired medicines) sections

1.6. Regulatory audit approach and self-assessment

Frey in 1997 studied the effect of external interventions on employees' performance and motivation. While the disciplining effect seemed to improve performance, a strict and

severe external observation was found to withstand any improvement achieved. The approach adopted in the external observation is fundamental to define the outcome of the observation on performance (Mikkelsen et al, 2017). The 'motivation crowding' theory sustains that external monitoring might reduce the motivation of performing the requested behaviour (Van der Kolk et al, 2019). A study performed by Weske (2018) measured the impact of the observation attitude through a set of internal audits performed to ward leaders of a hospital in The Netherlands. The study showed that an open-discussion approach, namely catalytic, led to increased compliance with regulations. Instead an enforcing external attitude, namely coercive, generates tension and resistance to the acquisition of new skills in health professionals (Grabowski et al, 2017).

The coercive attitude is based on the assumption that non-compliance is the results of the resistance to abide to rules, while the catalytic attitude finds its foundation on lack of knowledge or missing resources to comply with the rules (Weske et al, 2018). A strict approach is driven by a feeling of distress and corrects non-compliance with enforcement, a lenient approach corrects non-compliance with education and concordance and might bring to oversights of the rules (Mascini et al, 2009).

Self-assessment is a fundamental method used for the enhancement of learning skills and the maintenance of a competent and independent professional (Gemigni, 2016; Motycka et al, 2010; Tiuraniemi et al, 2011; Ward et al, 2002) while promoting motivation in health care professionals (Motycka et al, 2010). It is described as the capability of performing personal evaluation against a set of criteria, establishing goals and strategies for the achievement of continuous competency in professionals (Andrade and Du, 2007; McMillan et al, 2008; Stevon et al, 2017). Self-assessment is compared against an external opinion, which can be of a peer or of an expert. Self-assessment differs from self-

reflection, which is an analysis of what has been achieved without comparing it against recognised standards (Andrade and Du, 2007). The identification of needs for improvement in health care professional should lead to the selection of strategies to address them (Eva and Regehr, 2005).

The variability in the self-assessment output depends on several factors. The methodology applied and the psychometrics characteristics of the self-assessment tool determine the validity of the results (Gremigni, 2016; Motycka et al, 2010; Ward, 2002). The evaluation of assessment agreement is inappropriate when the comparison with the expert is performed using the outcome of the whole group instead of the individual one. Another limitation of the self-assessment is due to the 'gold standard' used as comparison in the self-assessment. The gold standards concept affirms infallibility of the expert rating and equalise the objective criteria to which the self-assessment has to be compared to. However, disagreement between experts happens (Motycka et al, 2010). To ensure validity of the self-assessment the use of a unique expert rater is suggested as it decreases the potential disagreement between experts. Some tools have shown low validity and reliability while others demonstrated to have adequate psychometric characteristics (Symon et al, 2009; Tiuraniemi et al, 2011).

Capability to self-assess professional skills was studied in healthcare professionals (Stevon et al, 2017). Self-assessment seems to have an higher accuracy when the individual is more experienced (Scaffidi et al, 2018) while overconfidence is often associated with the least skilled (Davis et al, 2006; Dunning et al, 2004; Hodge et al, 2001).

The empowerment of pharmacists in the self-identification of deficiencies, bring to self-correction, before the regulatory audit is performed. This creates self-awareness of weaknesses and strengths (Eva and Regehr, 2005; Redwood et al, 2009; Teinila et al,

2012) and leads to the establishment of goals and strategies for the improvement of the individual (Andrade and Du, 2007; McMillan et al, 2008; Perron et al, 2015). While self-assessment can be considered as the method to achieve and maintain professional skills, it is in itself a competence (Davis et al, 2006). The external assessment should be maintained, even when high reliability and agreement is achieved within the raters. External assessment brings up knowledge to what is not known and cannot be known if external input does not occur (Motycka et al, 2010).

The performance of pharmacist self-audits is often used in the professional scenario (Motycka et al, 2009). Several Medicines Agencies world-wide have this method in place for the assessment of pharmacy standards.[10, 11]

10. Department of Consumer Affairs (DCA). Self-assessment forms. [Online]. DCA [cited 2019 Jan 28]. Available from: URL: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml
11. The pharmaceutical society of Ireland (PSI). Checklist for a pharmacy inspection by the Pharmaceutical Society in Ireland. [Online]. PSI [cited 2019 Jan 28]. Available from: URL: https://www.thepsi.ie/Libraries/I_E/Regular_PSI_Inspection_Checklist.sflb.ashx

1.7. Aim and objectives

The aim of the study is to establish a model for a self-audit in community pharmacy integrating pharmacist competencies with regulatory requirements.

The objectives of the research are to:

- Optimise the regulatory checklist, which guarantees the assessment of legal requirements while promoting user practicality.
- Design a Pharmacist Competencies Self-Audit (PCSA) tool in line with the Good Pharmacy Practice (GPP) guidelines.
- Empower managing pharmacists to perform regulatory and pharmacist competencies self-audits.
- Establish a risk-based system for pharmacy audits.
- Compare data collected through the pharmacists self-audits to data obtained from regulatory body audits.
- Evaluate pharmacists' capability in the performance of self-audits.
- Analyse pharmacists' competencies and identify educational and professional needs.

Chapter Two

Methodology

This chapter describes the methodology adopted for the performance of a focus group, the design, validation and dissemination of the audit protocol, the performance of regulatory audits. A risk assessment procedure was defined, validated and implemented to measure risk associated with pharmacy practice. The methodology of the statistical analysis performed is explained.

2.1. Research overview and design

Following a review of the literature and of the local regulatory framework, the research proposal was drafted and the design of the research delineated for the application of regulatory sciences principles in community pharmacy. The presentation of the project to a multidisciplinary focus group enabled the optimisation of the proposed regulatory framework. The regulatory checklist used for the collection of the regulatory data was updated to reflect changes in legislation and to enhance the form practicality within the users as suggested by the focus group. A Pharmacist Competencies Self-Audit (PCSA) tool was designed based on the GPP guidelines and available literature. The self-audit protocol, comprehensive of the regulatory checklist and of the PCSA tool, was validated and tested for reliability. The dissemination of the self-audit protocol to community pharmacists was followed by the pharmacist recruitment, collection of regulatory and competencies-related data and comparison of audit results. Findings of the regulatory self-audit (RSA) and of the Pharmacist Competencies Self-Audit were used to improve community pharmacy practice. The following table (Table 2.1) describes the timeline and objectives of the project.

A qualitative approach was used in the literature review of self-assessment of professionals' competencies and in the focus group analysis. The regulatory audits results were quantitatively compared to assess agreement between the pharmacists and the

regulatory authority. The competency self-audit (PCSA) enabled the qualitative identification of pharmacists' professional characteristics and needs for improvements.

Table 2.1: Timeline and objectives

Timeline	Objective
March-July 2019	Literature review
July 2019	Focus group analysis
August-September 2019	Optimisation of regulatory framework
October-November 2019	Design and validation of PCSA tool
December 2019-March 2020	Data collection and analysis
January-April 2020	Dissertation writing

2.2. Setting and approvals

The research was carried out with the Malta Medicines Authority (MMA), the NCA for the regulation of medicines and pharmaceutical activities in Malta. The research was undertaken within the Scientific and Regulatory Operations Directorate (SROD). Between the responsibilities of the Directorate, community pharmacies are regulated in accordance with the national legislation. Institutional approval was obtained from the chairman of the MMA, the SROD director and ethics approval was granted by the Faculty Research Ethics Committee (FREC).

2.3. Literature review

The legal basis for the community pharmacy regulation in Malta was revised, namely the Medicines Act Chapter 458 of the Laws of Malta and Subsidiary Legislation such as S.L. 458.16. Literature was reviewed to identify articles related to Good Pharmacy Practice assessment, evaluation of pharmacist competencies, self-assessment and risk in the

community pharmacy scenario. Articles were researched from PubMed® database and Google scholar literature. Full access studies in English language were retrieved and accessed through the University of Malta search gateway, HyDi Hybrid Discovery. Kew words for the research of relevant articles were: *regulatory science, community pharmacy, risk, risk analysis, risk assessment, pharmacy practice, pharmacy standards, pharmacist role and evolution, self-assessment, GPP, Good Pharmacy Practice.*

2.4. The focus group analysis

A total of nine participants were invited and attended the focus group. Attendees consisted of six healthcare professionals, three general practitioners (GPs) and three community pharmacists, and three laypersons. The aim of the focus group was to gather participants' perspective towards the community pharmacist's role and to analyse the current and the proposed regulatory framework.

The focus group was divided in 3 parts. During the first part, the investigator welcomed the participants and explained the purpose of the focus group session and how it was structured. During the session, open-discussion was encouraged between the participants and unanimous consent to record the session was obtained. In part 2, attendees were invited to express their perception towards the pharmacist's role in community pharmacy. During part 3, an overview of the current framework was delivered and the plan for proposed framework explained. Participants were asked to identify risk factors, weaknesses and strengths related to the project. The record of the focus group was analysed and summarised in a table. Findings were applied to optimise the methodology of the project.

2.5. Design, structure and validation of the self-audit protocol

The self- audit protocol is in English language and divided into one introductory section and two parts, namely 'Part 1: Pharmacist Competencies Self-Audit' and 'Part 2: Regulatory Self-Audit' (Appendix 3). In the first introductory part, details of pharmacist performing the self-audit, such as pharmacist's demographics, education and professional exposure are collected.

Part 1, the Pharmacist Competencies Self-Audit (PCSA) tool, was compiled to gather information of pharmacist's competencies in compliance with GPP guidelines. The PCSA consists of two sections, namely 'section A', a self-reflective list of questions and 'section B', the self-evaluation part. Section A collects the essence of the patient-centred approach by bringing up reflections on patient education and empowerment, pharmacist clinical and interpersonal skills, personalised healthcare and pharmacist perception of regulatory compliance. Section B is meant to envisage the pharmacists about their strengths, scientific interests, areas of improvement and goals.

Part 2, the Regulatory Self-Audit (RSA), consisted of the regulatory checklist used by the NCA to perform community pharmacy audits. The checklist was designed and validated by Attard (2018). The author granted consent to use and amend the checklist. The checklist consisted of seventy-six regulatory requirements. Out of the 76, fourteen criteria about domiciliary services, seven about extemporaneous preparations and three criteria about storage and dispensing of cannabis-based products assess non-mandatory services and are not applicable to all pharmacies.

For the validation process of the introductory section and Part 1 of the self-audit report, the content validity method was adopted. Validation criteria such as number of experts, number of items of the Likert scale and number of items for the concordance, I-CVI threshold were applied as per Almanasreh et al (2019). A two-round validation was

performed and involved eight experts. All experts were pharmacists with regulatory and community pharmacy expertise. Experts were asked to evaluate each item for relevance, clarity and layout and structure with a Likert scale from 1 to 5 (being 1 low relevance, clarity or structure and 5 high relevance, clarity and structure). Consensus for each item was established when at least 7 out 8 experts assigned a score of 4 or 5. The I-CVI was calculated for each item by summing the number of expert giving a score of 4 or 5 for the considered item divided by the number of expert in the validation panel. Items that did not reach an I-CVI 88% agreement were reworded and changed according to the suggestions reported. After amendments were applied, a second round validation was performed. The same criteria for consensus were applied. Each item that did not achieve the 88% I-CVI and was not identified as relevant, clear or not well structured was removed and suggestions employed.

Part 2, the regulatory checklist, was revised, updated and validated through face validity by a panel of 5 pharmacists with regulatory, community pharmacy and academic and research exposure. The face validity method was used to maintain consistency in the method previously used by Attard (2018) for the validation of the regulatory checklist.

Inter-reliability testing was performed on the tool on the regulatory part. Part 1 was not tested for reliability due to the objectivity of the responses. For the reliability exercise, nine tools were collected. The sample for the reliability was calculated through an electronic calculator after defining a 0.7% of reliability requirement (De Souza et al, 2017) and 95% confidence interval. The intra-class correlation coefficient (ICC) test was applied to assess inter-reliability and absolute agreement with a two-way mixed model. Intra-rater reliability was not tested for both parts. In part 1 changes assessed after the 10-14 days recommended period for re-test would most probably occur as the results of educational interventions. In part 2 an intra-rater reliability was not performed due to the

objectivity of the questions asked. Changes in the regulatory part are likely to occur to changes of pharmacist's compliance and not for test instability.

2.6. Pharmacies recruitment and data collection: inclusion and exclusion criteria

The Regulatory Self-Audit (RSA) report was circulated to 157 out of 229 licensed Maltese community pharmacies. Any pharmacy audited between January 2019 and January 2020 (n=72) was excluded from the study to eliminate any form of bias which could have led to the results being over optimistic. Following the regulatory audit, regulatory advice is provided and Corrective Actions Preventive Actions (CAPAs) must be implemented by the audited pharmacy to comply with legal obligations. The auditors did not have any conflict of interest with the pharmacies in the study sample.

Pharmacies were invited to participate via email. Email addresses were retrieved from the Malta Medicines Authority database for licensed pharmacies. When a pharmacy licence is granted, the licence holder gives consent to the Medicines Authority to process personal data for the purposes for which the personal data was initially collected. Being that the purpose of the project is to launch self-audit practice of community pharmacy for the assessment of GPP standards, no objection was provided by the Data Protection Officer (DPO) of the Malta Medicines Authority (Appendix 1).

Community pharmacists were initially given a 4 weeks-period to submit the Regulatory Self-Audit protocol. A reminder was sent and the submission period extended to achieve a significant study sample up to a total of 8 weeks. Pharmacies (N=61) that submitted the self-audit report were included in the study. A sample of 61 pharmacies selected from a population of 157 pharmacies (after exclusion criteria) generates a maximum margin error of 9.84% assuming a 95% confidence level.

A plan was devised to perform audits during five weekdays, from Monday to Friday, and office working-hours, from 8am to 5pm. The plan covered an 8-weeks period from

January to March 2020. Unannounced regulatory audits (RAs) were planned according to Maltese district for all the pharmacies that submitted the self-audit. The same leading auditor, accompanied by another auditor, performed the regulatory audits. Both auditors were trained and had a nine-month experience in regulatory audits. Regulatory audits for pharmacies in the same locality or district were performed in the same day for convenience purposes.

Regulatory self-audit data was registered electronically before the regulatory audit was performed. However, due to the study sample dimension, no recall bias could have affected the regulatory audit data collection.

Comparison of results was performed after the conclusion of the regulatory audit. Data was compared for each pharmacy taking into consideration the time laps and validity of findings at the time of the regulatory self-audit submission.

Pharmacist Competencies Self-Audit data were submitted together with the regulatory self-audit and processed before comparison of regulatory data was carried out. This choice was made to avoid any bias when analysing the regulatory findings.

Pharmacists' data was kept anonymous and any identification detail was removed.

2.7. Risk-assessment of regulatory audit

The panel of five-pharmacists involved in the validation of the updated regulatory checklist was invited to perform the risk-assessment exercise. Each item of the regulatory checklist was assessed to determine its impact on patient health and was assigned with a risk score from 1 to 3 (low risk or minor finding=1, medium risk or major finding=2, high risk or critical finding=3). Critical findings were items which were considered as having a high impact on patient safety and were given a score of 3 while major findings were assigned a score of 2. All other findings were assigned a score of 1, given their low impact on patient safety and medicinal products quality. The PIC's recommendation (2012)[10] was adopted and adapted to divide pharmacies in risk categories (Table 2.2). The PIC's recommendation is a model used for the risk assessment in the GMP sector. The complexity of the manufacturing scenario constitute the intrinsic risk[2]. For pharmacy regulatory audits, only the compliance risk was considered. However, to calculate the pharmacy risk, all services provided, included the one that constitute a higher risk, were considered. Regulatory self-audit and regulatory audit frequency was defined by the panel to adequately prevent and address risks in pharmacy practice (Table 2.3).

Table 2.2 Risk categories according to regulatory findings

Findings	**Risk categories**		
	High Risk	*Medium Risk*	*Low Risk*
Critical	≥1	-	-
Major	≥6	1-5	-
Minor	-	-	1-all

Table 2.3: Risk categories and audit frequencies

Risk categories	Frequency	
	RSA	*RA*
High	2 months	6-12 months
Medium	6 months	18 months
Low	12 months	36 months

The pharmacy risk is to be defined giving priority to critical, major and minor findings in this order. This means that if a pharmacy presented at least one critical finding, the audited pharmacy should be categorised into the high risk category, no matter if major or minor findings were observed as per PICs recommendation (2012).[10]

10. Pharmaceutical Inspection Co-Operation Scheme. A recommended model for risk-based inspection planning in the GMP environment [Online].Geneva: Pharmaceutical Inspection Co-operation Scheme [cited 2020 May 27]. Available from: URL: https://www.gmp-compliance.org/guidelines/gmp-guideline/pic-s-recommendation-on-risk-based-inspection-planning-pi-037-1

2.8. Statistical analysis

The statistical analysis involved data coding, descriptive statistics. Cross-tabulations were performed using the Chi- square test, Kappa test and the Wilcoxon Sign Ranks test. Graphs, tables and any type of data representation were designed using IBM SPSS Statistics® 23 software, Microsoft® 2010 Office Word and Excel.

Data was input into a spread sheet using IBM SPSS Statistics® 23 software. In the first section of the self-audit protocol, eight questions regarding demographic factors were coded in the software with nominal labels, namely 'pharmacy name', 'locality of practice', 'district of practice', 'gender', 'age', 'qualification level', 'years of experience', 'additional field of exposure'. To analyse the competencies audit, pharmacist competencies reports were reviewed by the investigator and divided in categories. Competencies categories were numbered for strengths (N=8), for scientific interests (N=15), for goals (N=6) and for opportunities for improvement (N=6).

Each regulatory criteria was coded, from question (q)1a to 76a for the self-audit and (q)1b to 76b for the regulatory audit. Compliance percentage and risk category for both audits were listed at the end of the data sheet.

2.8.1. Descriptive statistics and cross-tabulation

Descriptive statistics, including frequencies and percentages, were applied to each question of the self-audit protocol to:

- Assess demographic data and professional trends of participants.
- Identify pharmacist's strengths, goals, scientific interests and opportunities for improvement related to their practice.
- Calculate the percentage of compliance for both audits. The percentage of compliance was calculated by giving a score of 1 to each criterion accomplished

and a score of 0 to each criterion not accomplished. The sum of all points accomplished provided the compliance score. This was divided by the total number of criteria assessed and multiplied by 100 to obtain the percentage of compliance.

- Assess pharmacy associated risk. The risk assessment was performed by analysing regulatory criteria which resulted as not abided through the regulatory self-audit and regulatory audit. Pharmacies were classified into a regulatory self-audit risk category and a regulatory audit risk category independently.

Cross-tabulations were performed to identify statistical significant correlations between: strengths, goals, scientific interests, opportunities for improvement categories and demographic/professional factors with the Chi-square test.

The chi-square test is used to investigate the association between two categorical variables. The null hypothesis specifies that there is no association between the two categorical variables and it is accepted if the p-value exceeds the 0.05 level of significance. The alternate hypothesis specifies that there is a significant association between the two categorical variables and is accepted if the p-value is less than the 0.05 criterion.

The agreement between the regulatory self-audit and regulatory audit results was measured to assess the pharmacist's reliability in performing the regulatory self-audit. The Kappa test was used on all criteria. The Kappa test is used to investigate the inter-reliability in the assessment of categorical variables. The null hypothesis specifies that there is no difference in the assessment performed by two independent raters and it is accepted if the p-value is less than the 0.05 criterion. The alternate hypothesis specifies that there is a significant difference in the assessment performed by two independent

raters and it is accepted if the p-value exceeds the 0.05 level of significance. However, since in some criteria there was no variability in the raters' response, the Kappa test generated invalid results. To assess agreement on these items, the percentage of agreement on self-audit and regulatory audit was calculated for each criterion. Agreement for each pharmacy was calculated from the Kappa tables obtained. The percentage was calculated as per the below formula:

$$Percentage\ of\ agreement = \frac{Total\ number\ of\ criteria\ with\ agreement}{Total\ number\ of\ criteria}\ x\ 100$$

The total criteria assessed varied due to the applicability of the criteria to the pharmacy. Some criteria were not applicable to all pharmacies, e.g. storage of cannabis based products or domiciliary service.

Agreement on pharmacy risk categorisation between regulatory audit and regulatory self-audit was assessed with the Kappa test.

For the comparison of the mean percentage compliance between the self-audit and regulatory audit, the Wilcoxon Signed Ranks test was used. The choice of a non-parametric test was justified by the left-skewed distribution of both regulatory and self-audits. The null hypothesis specified that the mean-percentage compliance of the self-audit and regulatory audit are similar and is acceptable when the p-value exceeds the 0.05. The alternative hypothesis specifies that the mean percentage compliance differs significantly between self-audit and regulatory audit and is accepted if the p-value is less than 0.05 criterion.

Cross-tabulations were performed to identify correlations between risk category obtained through the two audits and demographic/ professional factors with the Chi-square test.

Chapter Three

Results

This chapter is structured in nine parts. Part 1 reports results of the qualitative analysis performed by the focus group. Part 2 describes updates on the regulatory checklist. In part 3, the structure and validation of the Pharmacist Competencies Self-Audit (PCSA) tool are explained. Demographic details of pharmacists participating in the study are summarised in part 4. In part 5, the PCSA data is processed and correlations with pharmacist factors studied are reported in section 6. The comparison of data collected through the Regulatory Self-Audit (RSA) and Regulatory Audit (RA) is explained in section 7. Agreement on the regulatory assessment is described in part 8. In the last part, part 9, the definition of the risk scoring and categories, the risk analysis, correlations to pharmacist factors constitute the statistical analysis related to regulatory requirements.

3.1. The focus group analysis

Participants were asked to provide their perception towards the pharmacist's role in community pharmacy. According to medical doctors, the pharmacist's work should follow a patient-centred and multidisciplinary approach for the achievement of optimal health outcomes. The pharmacist was portrayed unanimously as a knowledgeable health professional with the ability to identify patients' needs whilst supporting them in the health system services. Patients described the pharmacist as a trustworthy figure with efficient communicative skills.

The focus group performed an analysis of the project to identify risk factors, weaknesses and strengths in the proposed regulatory framework. Oversight of legal requirements was identified as a risk factor in the pharmacist's self-assessment and the experts recommended that another type of evaluation will be adopted in the study. The medical experts justified that pharmacists should have higher competencies related to regulation to be capable of performing regulatory self-audit while pharmacists supported the regulatory self-audit process. However, the robustness of the regulatory self-audit results

was considered as a weakness by both professions, being that pharmacists will be scared of legal consequences by declaring to be non-compliant with the law. The investigator recalled this as an objective of the study: assessing pharmacist's capability in the regulatory self-audit process by comparing regulatory self-audit with regulatory audit data. Since the audit process was converted from having an inspectorate to a more educative approach, the project wanted to measure the impact of this intervention in pharmacist's regulatory outcomes. Also with the new approach, pharmacists would have learnt that the regulatory body enhances concordance and open discussion with its stakeholders in order to achieve the best for the patient.

The focus group findings suggested improvements for the project. The observation of patient-pharmacist interactions was proposed in the project plan as method for data collection for the assess pharmacist's competencies. The focus group identified this method as a risk factor. Pharmacist's resistance in being observed might have reduced the number of participant and the pharmacist might have changed attitude, knowing that he/she was observed and assessed. To reduce possible biases, a self-assessment method for pharmacist's competencies was also suggested.

Other risk factors identified were related to the time constraint and pharmacist's workload which could have reduced participation to the study and time for the performance of the pharmacist regulatory self-audit.

Between the weaknesses of the study, the focus group stressed out the unacceptability of the pharmacist proactivity. This was particularly a concern of the pharmacist category. They expressed a feeling of unacceptability and refusal against their suggestions when communicating with other healthcare professionals. This was considered as a possibility by the medical category, even though the importance of inter-professional collaboration

to enhance patient healthcare outcomes was stressed out by the present general practitioners.

The increased awareness of regulatory requirements, the increased assessment level and the evaluation of pharmacist competencies were considered as activities leading to personalised healthcare, optimising clinical service and meeting patient needs through the reduction in redundant bureaucracy and promotion of the pharmacist's role for the community.

Table 3.1: Risk factors, weaknesses and strengths of the regulatory framework

Focus group analysis	
Risk factors *(n=4)*	1. Oversights of legal requirements 2. Increased need for pharmacist competencies and preparedness 3. Resistance to patient-pharmacist interaction 4. Work overload and time constraint in the pharmacy profession
Weaknesses *(n=2)*	1. Unacceptability of pharmacist's role 2. Lack of robustness in the pharmacist regulatory self-audit
Strengths *(n=5)*	1. Provision and optimisation of patient clinical service 2. Recognition of the pharmacist's role and competence 3. Reduction in redundant bureaucracy 4. Improvement in personalised healthcare 5. Providing services able to meet patient needs

3.2. Updates to the regulatory audit checklist

The update in the checklist affected few sections. Only one new section, assessing criteria related to another authority (section I), and two sub-sections related to medicinal products (sections G11 and G15) were added (Table 3.2). The order of the questions was changed. Questions related to registers and certificates were grouped to enhance the form usability and fasten the audit process.

Table 3.2: Comparison between versions of the regulatory audit report

	Version 2018	**Version 2020**
No. of questions	98 questions in 8 sections (A to I)	109 questions in 9 sections (A to J)
Administrative Questions	5 sections (A to F, I) 18 questions	6 sections (A to F and I, J), 12 open-ended and 14 close ended questions
Checklist: regulatory criteria	15 subsections with 80 'yes/no' questions	16 subsections, 76 'yes/no' questions

3.3. Pharmacist Competences Self- Audit tool: structure and validation

The Pharmacist Competencies Self-Audit (PCSA) tool consists of three sections: introductory, sections A and B. The below table (Table 3.3.1) shows the structure of the tool.

Table 3.3.1: Pharmacist Competencies Self-Audit tool structure

Section	Name of categories	No. of questions
Introductory	• Locality and district of practice • Pharmacist demographics: gender, age • Qualification level • Years of work experience and field of exposure	7
A	• Pharmacist patient-centred approach • Pharmacist clinical skills and interests • Patient education provided • Personalised healthcare • Medicines accessibility • Pharmacist soft skills and multidisciplinary collaboration • Pharmacist compliance with regulatory requirements	18
B	• Strengths • Scientific interests • Goals • Opportunities for improvement	4 open-ended

The validation results are divided per round 1 and 2 and assessed relevance, clarity, structure and layout for each question (N=30 for the first round, N=29 for the second round). The table below shows the number of questions which achieved agreement and comment per field for each round (Table 3.3.2). In round 1, the number of questions that

received insufficient agreement was 13. Six out of 13 did not reach the agreement level in the structure and layout validation field. In round 1 only one question did not reach the agreement level between the experts. The question was not considered relevant to the research and eliminated from the tool. The total number of questions in the PCSA tool after validation was 29. Tables with I-CVIs and comments for both rounds are in Appendix 4. The validated PCSA tool can be found in the first part of regulatory self-audit protocol in Appendix 3.

Inter-rater reliability was performed within 9 pharmacists from different pharmacies. The intraclass correlation average measure was higher than 0.7 recommended value indicating that the tool is reliable among multiple raters (Table 3.3.3).

Table 3.3.2: Number of items with sufficient agreement for both rounds (N=30)

Round	Validation field	Questions with sufficient agreement	No. of comments
Round 1	Relevance	27	5
	Clarity	26	12
	Structure and layout	24	10
Round 2	Relevance	29	0
	Clarity	30	4
	Structure and layout	30	4

Table 3.3.3: Intraclass correlation (N=9)

	Intraclass Correlation	95% CI	
		Min	Max
Average Measures	0.937[c]	0.913	0.956

3.4. Dissemination of regulatory self-audit protocol: the study population

One-hundred fifty-seven pharmacies were invited to participate in the study. The table below (Table 3.4) illustrates the number of pharmacies falling within the inclusion criteria of the study by Maltese district.

Table 3.4: Percentages and number of pharmacies per district

Maltese District	**Pharmacies**		
	Licensed	*Excluded*	*Invited*
Northern	27	11	16
Northern Harbour	75	27	48
South Eastern	29	6	23
South Harbour	49	15	34
Western	29	4	25
Gozo and Comino	20	9	11
Total	**229**	**72**	**157**

3.4.1. Characteristics of the participants

Descriptive statistics was collected to describe the study sample in terms of locality of practice, gender, age, qualification level and years of experience and additional field of exposure in pharmacy practice.

Locality of practice

The percentage of response of the pharmacies in the relative district is represented in the below table (Table 3.4.1a). The district with the highest number of pharmacies participating was the Northern Harbour district (n=18) followed by the Northern (n=11) and South Eastern districts (n=10). The Northern district presented the highest percentage of response (68.8%) followed by the Gozo and Comino district (63.6%). The total percentage of response in the study population was 38.9%, counting a study population of 61 pharmacies out of 157.

Table 3.4.1a: Percentages of pharmacies response according to district (N=61)

Maltese District	Pharmacies		
	Invited	**Enrolled**	**Response**
Northern	**16**	**11**	**68.8%**
Northern Harbour	48	18	37.5%
South Eastern	23	10	43.5%
South Harbour	34	9	26.5%
Western	25	6	24%
Gozo and Comino	**11**	**7**	**63.6%**
Total	**157**	**61**	**38.9%**

Gender

The majority of the pharmacists (n=34) participating in the study was female (Figure 3.1).

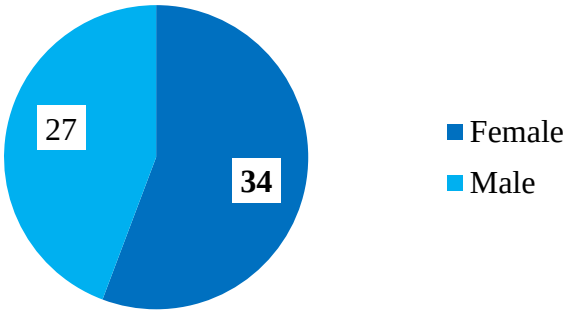

Figure 3.1: Gender (N=61)

Age

Twenty pharmacists belonged to the '41 to 50 years' category followed by the '31 to 40 years' category (n=14), with a mean age of 43 years old (ranging from 25 to 73) (Table 3.4.1b).

Table 3.4.1b: Pharmacists per age category (N=61)

Age category	Frequency	Percentage
22-30 years	13	21.3
31-40 years	14	23.0
41-50 years	22	36.1
51-60 years	6	9.8
Ove 60 years	6	9.8

Qualification level

The majority of pharmacists (n=45) had a graduate qualification level (Figure 3.2).

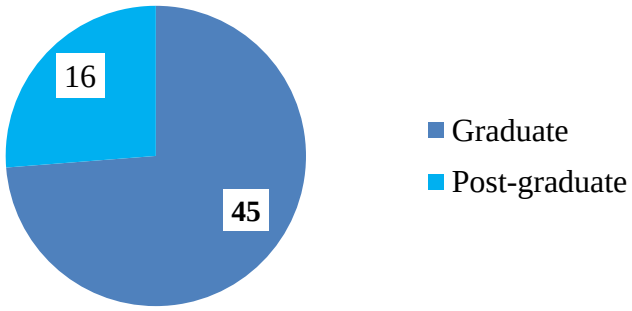

Figure 3.2: Qualification level (N=61)

Years of experience

More than 60% of the pharmacists had more than 16 years of pharmacy experience. Nineteen pharmacists were in the experience category 'between 16 and 25 year' and 18 pharmacists in the 'more than 25 years' experience category (Table 3.4.1c).

Table 3.4.1c: Participating pharmacists divided by years of experience (N=61)

Years of experience	Frequency	Percentage
Less than 1 year	2	3.3
Between 1 and 5 years	7	11.5
Between 6 and 15 years	15	24.6
Between 16 and 25 years	19	31.1
More than 25 years	18	29.5

Additional fields of exposure

Out of 61 pharmacists, 16 had been exposed to additional professional fields (Table 3.4.1d). Nine had experience in the academy sector (n=9) and 3 out of 16 were exposed to more than one additional field.

Table 3.4.1d: Pharmacist additional fields of exposure (n=16)

Years of experience	Frequency	Percentage
University	9	56.3%
Hospital pharmacy	6	37.5%
Pharmaceutical industry	5	31.3%
Regulatory	1	6.3%

3.5. Pharmacist Competencies Self-Audit

All pharmacists performed the competencies self-audit. The majority of pharmacists gave more than one answer for each question.

3.5.1. Strengths

The Pharmacist Competencies Self-Audit identified 183 strengths in the pharmacist study population. The majority of pharmacists (57.4%) considered as their strengths 'understanding patient needs'. This result was followed by being 'patient-oriented' (49.2%) and by providing complete 'patient education' (44.3%) (Table 3.5.1).

Table 3.5.1: Pharmacist Competencies Self-Audit results: strengths (N=61)

Strengths	Frequency	Percentage
Patient needs understanding	35	57.4
Patient-oriented practice	30	49.2
Patient education	27	44.3
Good communication skills	23	37.7
Problem solving skills	20	32.8
Personalised healthcare	20	32.8
Timely and efficient access to medicines	19	31.1
Continuous education	5	8.2
Sale skills	4	6.6

3.5.2. Scientific interests (N=82)

The Pharmacist Competencies Self-Audit identified 82 scientific interests in the pharmacist study population. The 44.3% of pharmacists declared of being interested in personalised healthcare, followed by the 27.9% in 'continuous education' (Table 3.5.2).

Table 3.5.2: Pharmacist Competencies Self-Audit results: scientific interests (N=61)

Scientific interests	Frequency	Percentage
Personalised healthcare	27	44.3
Continuous education	17	27.9
Pharmacology	9	14.8
Antibiotic resistance	4	6.6
Alternative medicine	3	4.9
Nutrition and healthy lifestyle	3	4.9
Sport science	3	4.9
Inter-professional collaboration	3	4.9
Gastroenterology	2	3.3
Research and drug development	2	3.3
Environmental science	2	3.3
Endocrinology	2	3.3
Respiratory conditions	2	3.3
Polytherapy management	2	3.3
Cardiology	1	1.6

3.5.3. Goals

The Pharmacist Competencies Self-Audit identified 106 goal in the pharmacist study population. The 45.9 % of pharmacists declared that one of their goal of practice is to ‘dedicate more time to patients and improve quality of service’. (Table 3.5.3).

Table 3.5.3: Pharmacist Competencies Self-Audit results: goals (N=61)

Goals	Frequency	Percentage
Time dedicated to patients and quality of service	28	45.9
Personalised healthcare	20	32.8
Reduction of medication errors	19	31.1
Patient education and empowerment	17	27.9
Continuous education	15	24.6
Reduction of bureaucratic work	7	11.5

3.5.4. Opportunity for improvement

The Pharmacist Competencies Self-Audit identified 98 opportunities for improvement in the pharmacist study population. The majority of pharmacists (63.9%) identified 'continuous education' as an opportunity for improvement related to their practice (Table 3.5.4).

Table 3.5.4: Pharmacist Competencies Self-Audit results: opportunities for improvement

Opportunities for improvement	Frequency	Percentage
Continuous education	39	63.9
Time dedicated to patients	18	29.5
Personalised healthcare and medicine review	17	27.9
Building trustworthy relationship with patients	14	22.9
Inter-professional collaboration	10	16.4

3.6. Correlations between Pharmacist Competencies Self-Audit results and other factors

Statistical analysis related to correlations between Pharmacist Competencies Self-Audit results and pharmacist characteristics was performed separately for strengths, scientific interests, goals and opportunities for improvement.

3.6.1. Correlation between strengths and participant characteristics

Eight strengths were identified through the Pharmacist Competencies Self-Audit tool and were analysed to identify correlations with pharmacist factors.

Strengths and district of practice

'Understanding patient needs' and 'patient orientation and skills' were between the most reported strengths by the pharmacist according to district (Table 3.6.1a). The correlation between district of practice and strengths was not statistically significant since the p-value exceeded the 0.05 criterion.

Table 3.6.1a: Cross-tabulation: Pharmacist district of practice and strengths (N=61)

Strengths	**District of practice**					
	Southern harbour	*Northern harbour*	*South eastern*	*Western*	*Northern*	Gozo
Good communication skills	4 (18.2%)	6 (12.5%)	1 (5.6%)	3 (15.8%)	6 (18.8%)	3 (15%)
Understanding patient needs	3 (13.6%)	12 (25%)	3 (16.6%)	5 (26.4%)	7 (21.9%)	5 (25%)
Patient orientation and skills	4 (18.2%)	9 (18.8%)	1 (5.6%)	4 (21%)	7 (21.9%)	5 (25%)
Sales skills	1 (11.4%)	1 (2%)	1 (5.6%)	0 (0%)	0 (0%)	1 (5%)
Personalised healthcare and problem solving	3 (13.6%)	7 (14.6%)	3 (16.6%)	2 (10.5%)	4 (12.5%)	1 (5%)
Patient education	3 (13.6%)	8 (16.7%)	5 (27.8%)	3 (15.8%)	5 (15.6%)	3 (15%)
Timely and efficient access to medicines	3 (13.6%)	5 (10.4%)	4 (22.2%)	2 (10.5%)	3 (9.3%)	2 (10%)
Continuous education	1 (11.4%)	0 (0%)	1 (%)	0 (%)	2 (%)	1 (%)

$X^2(40) = 32.111$, $p = 0.808$

Strengths and gender

More than 20 per cent between the reported strengths by female pharmacists (21.4%) was 'understanding patient needs' (Table 3.6.1b). The correlation between gender and strengths reported was not statistically significant as the p-value exceeded the 0.05 criterion.

Table 3.6.1b: Cross-tabulation: Pharmacist gender and strengths (N=61)

Strengths	**Gender**	
	Female	*Male*
Good communication skills	12 (11.6%)	11 (13.3%)
Understanding patient needs	22 (21.4%)	13 (15.7%)
Patient-oriented practice	16 (15.6%)	14 (16.9%)
Personalised healthcare	2 (1.9%)	2 (2.3%)
Problem solving skills	11 (10.7%)	9 (10.8%)
Patient education	14 (13.6%)	13 (15.7%)
Timely and efficient access to medicines	10 (9.7%)	9 (10.8%)
Continuous education	4 (3.9%)	1 (1.2%)
Sale skills	12 (11.6%)	11 (13.3%)

$X^2(32)=3.783$, $p=0.876$

Strengths and age category

More than 30 per cent of the reported strengths (31%) by the youngest age category of pharmacist was 'personalised healthcare and problem solving' (Table 3.6.1c). The correlation between age category and strengths reported was not statistically significant as the p-value exceeded the 0.05 level of significance.

Table 3.6.1c: Cross-tabulation: Pharmacist age category and strengths (N=61)

Strengths	**Age category**				
	22-30 years	*31-40 years*	*41-50 years*	*51-60 years*	*More than 60 years*
Good communication skills	1 (3.4%)	5 (12.5%)	12 (17.9%)	2 (14.3%)	3 (23%)
Understand patient needs	4 (13.8%)	9 (22.5%)	16 (23.9%)	4 (28.6%)	2 (15.4%)
Patient orientation and skills	5 (17.3%)	6 (15%)	15 (22.4%)	2 (14.3%)	2 (15.4%)
Sales skills	0 (0%)	1 (2.5%)	2 (3%)	0 (0%)	1 (7.7%)
Personalised healthcare and problem solving	9 (31%)	3 (7.5%)	7 (10.4%)	0 (0%)	1 (7.7%)
Patient education	5 (17.3%)	7 (17.5%)	10 (14.9%)	3 (21.4%)	2 (15.4%)
Timely and efficient access to medicines	3 (10.3%)	7 (17.5%)	4 (6%)	3 (21.4%)	2 (15.4%)
Continuous education	2 (6.9%)	2 (5%)	1 (1.5%)	0 (0%)	0 (0%)

$X^2(32) = 45.201$, $p = 0.061$

Strengths and qualification level

More than 20 per cent of the reported strengths (22%) by graduate pharmacist was 'understanding patient needs' (Table 3.6.1d). The p-value was higher than the 0.05 level of significance, indicating that there is no statistically significant correlation between pharmacist qualification level and strengths.

Table 3.6.1d: Cross-tabulation: Pharmacist qualification level and strengths (N=61)

Strengths	**Qualification level**	
	Graduate	*Post-graduate*
Good communication skills	16 (13.6%)	7 (15.5%)
Understanding patient needs	26 (22%)	9 (20%)
Patient orientation and skills	21 (17.9%)	9 (20%)
Sales skills	4 (3.4%)	0 (0%)
Personalised healthcare and problem solving	13 (11%)	7 (15.5%)
Patient education	20 (16.9%)	7 (15.5%)
Timely and efficient access to medicines	16 (13.5%)	3 (6.75%)
Continuous education	2 (1.7%)	3 (6.75%)

$X^2(8) = 8.254$, $p = 0.409$

Strengths and years of experience

Fifty per cent of the strengths identified by pharmacist having less than 1 year of experience was 'continuous education' (Table 3.6.1e). Conversely, pharmacist with more than 25 years of experience mainly reported as a strength 'patient orientation and skills' and 'understanding patient needs' with 22.9% and 20.8% respectively. The results were statistically significant as the p-value did not exceed the 0.05 criterion.

Table 3.6.1e: Cross-tabulation: Pharmacist years of experience and strengths (N=61)

Strengths	**Years of experience**				
	Less than 1 year	*Between 1 year and 5 years*	*Between 6 and 15 years*	*Between 16 and 25 years*	*More than 25 years*
Good communication skills	0 (0%)	0 (0%)	5 (12.8%)	10 (17.5%)	8 (16.7%)
Understanding patient needs	0 (0%)	2 (13.3%)	8 (20.5%)	15 (26.3%)	10 (20.8%)
Patient orientation and skills	0 (0%)	3 (20%)	6 (15.4%)	10 (17.5%)	11 (22.9%)
Sales skills	0 (0%)	0 (0%)	1 (2.6%)	1 (1.8%)	2 (4.2%)
Personalised healthcare and problem solving	1 (25%)	6 (40%)	4 (10.3%)	4 (7%)	5 (10.4%)
Patient education	0 (0%)	4 (26.7%)	7 (17.9%)	10 (17.5%)	6 (12.5%)
Timely and efficient access to medicines	1 (25%)	0 (0%)	8 (20.5%)	5 (8.9%)	5 (10.4%)
Continuous education	2 (50%)	0 (0%)	0 (0%)	2 (3.5%)	1 (2.1%)

$X^2(32)=67.719$, **p=0.000**

Strengths and field of exposure

Pharmacists with an academic professional experience reported as strengths 'patient orientation and skills' and 'personalised healthcare and problem solving' with 23.5 % each (Table 3.6.1f). No statistically significant correlation was identified between strengths and pharmacist additional exposure (p-value>0.05).

Table 3.6.1f: Cross-tabulation: Pharmacist additional exposure and strengths (n=16)

Strengths	**Additional exposure**			
	University	*Hospital pharmacy*	*Pharmaceutical industry*	*Regulatory authority*
Good communication skills	3 (17.6%)	3 (10%)	3 (21.4%)	0 (0%)
Understanding patient needs	3 (17.6%)	6 (20%)	3 (21.4%)	0 (0%)
Patient orientation and skills	4 (23.5%)	7 (23.3%)	2 (14.3%)	0 (0%)
Sales skills	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Personalised healthcare and problem solving	4 (23.5%)	5 (16.7%)	1 (7.2%)	0 (0%)
Patient education	1 (5.9%)	4 (13.3%)	3 (21.4%)	0 (0%)
Timely and efficient access to medicines	1 (5.9%)	3 (10%)	2 (14.3%)	1 (100%)
Continuous education	1 (5.9%)	2 (6.7%)	0 (0%)	0 (0%)

$X^2(28) = 31.599$, p=0.291

3.6.2. Correlation between scientific interests and participant characteristics

Fifteen scientific interests were identified through the Pharmacist Competencies Self-Audit tool and were analysed to identify correlations with pharmacist factors.

Scientific interests and district

Pharmacists from all districts mainly reported 'personalised healthcare' as a scientific interest (Table 3.6.2a). Only in the Southern Harbour district, 45.5% of the reported

interests was ‘continuous education’. No statistically significance was achieved between district of practice and scientific interest since the 0.05 level of significance was exceeded by the p-value of the correlation.

Table 3.6.2a: Cross-tabulation: Pharmacist district of practice and scientific interests (N=61)

Scientific interest	**District of practice**					
	Southern harbour	*Northern harbour*	*South eastern*	*Western*	*Northern*	Gozo
Personalised healthcare	3 (27.3%)	8 (33.2%)	5 (41.7%)	4 (40%)	4 (28.6%)	3 (33.3%)
Continuous education	5 (45.4%)	5 (20.7%)	2 (16.7%)	1 (10%)	2 (14.4%)	2 (22.2%)
Interprofessional collaboration	0 (0%)	1 (4.2%)	2 (16.7%)	0 (0%)	0 (0%)	0 (0%)
Alternative medicine	1 (9.1%)	1 (4.2%)	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)
Antibiotic resistance	0 (0%)	2 (8.4%)	0 (0%)	1 (10%)	0 (0%)	1 (11.1%)
Gastroenterology	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (14.4%)	0 (0%)
Healthy eating	0 (0%)	0 (0%)	0 (0%)	1 (10%)	1 (7.1%)	1 (11.1%)
Medicine R&D	0 (0%)	1 (4.2%)	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)
Enviromental Science	1 (9.1%)	0 (0%)	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)
Sport Science	0 (0%)	2 (8.4%)	0 (0%)	1 (10%)	0 (0%)	0 (0%)
Pharmacology	1 (9.1%)	3 (12.5%)	1 (8.3%)	2 (20%)	1 (7.1%)	1 (11.1%)
Endrocrinology	0 (0%)	0 (0%)	1 (8.3%)	0 (0%)	1 (7.1%)	0 (0%)
Cardiology	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (11.1%)
Respiratory conditions	0 (0%)	1 (4.2%)	1 (8.3%)	0 (0%)	0 (0%)	0 (0%)
Polytherapy	0 (0%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)	1 (0%)

$X^2(75)=69.342$, p=0.663

Scientific interests and gender

More than 30 per cent of the reported interest by female pharmacists (31.2%) was 'personalised healthcare' (Table 3.6.2b). The statistical association between gender and scientific interest was not significant (p-value>0.05).

Table 3.6.2b: Cross-tabulation:Pharmacist gender and scientific interests (N=61)

Scientific interest	**Gender**	
	Female	*Male*
Personalised healthcare	15 (31.2%)	12 (35.3%)
Continuous education	5 (10.3%)	12 (35.3%)
Inter-professional collaboration	2 (4.2%)	1 (2.9%)
Alternative medicine	1 (2.1%)	2 (5.9%)
Antibiotic resistance	4 (8.4%)	0 (0%)
Gastroenterology	2 (4.2%)	0 (0%)
Healthy eating	3 (6.2%)	0 (0%)
Medicine R&D	2 (4.2%)	0 (0%)
Enviromental Science	1 (2.1%)	1 (2.9%)
Sport Science	1 (2.1%)	2 (5.9%)
Pharmacology	6 (12.4%)	3 (8.7%)
Endrocrinology	2 (4.2%)	0 (0%)
Cardiology	1 (2.1%)	0 (0%)
Respiratory conditions	2 (4.2%)	0 (0%)
Polytherapy	1 (2.1%)	1 (2.9%)

$X^2(15) = 1.905$, $p = 0.110$

Scientific interests and age category

The majority of scientific interests (57.1%) reported by pharmacists older than 51 years old was 'personalised healthcare' (Table 3.6.2c). The statistical association between age and scientific interest was not significant (p-value>0.05).

Table 3.6.2c:Cross-tabulation:Pharmacist age category and scientific interests (N=61)

Scientific interests	**Age category**				
	22-30 years	*31-40 years*	*41-50 years*	*51-60 years*	*More than 60 years*
Personalised healthcare	7 (33.3%)	5 (27.7%)	7 (23.2%)	4 (57.1%)	4 (66.7%)
Continuous education	4 (19%)	3 (16.6%)	8 (26.7%)	2 (28.6%)	0 (0%)
Interprofessional collaboration	2 (9.5%)	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)
Alternative medicine	1 (4.8%)	2 (11.1%)	0 (0%)	0 (0%)	0 (0%)
Antibiotic resistance	1 (4.8%)	0 (0%)	2 (6.7%)	1 (14.3%)	0 (0%)
Gastroenterology	0 (0%)	2 (11.1%)	0 (0%)	0 (0%)	0 (0%)
Healthy eating	1 (4.8%)	1 (5.6%)	1 (3.3%)	0 (0%)	0 (0%)
Medicine R&D	0 (0%)	0 (0%)	2 (6.7%)	0 (0%)	0 (0%)
Enviromental Science	0 (0%)	0 (0%)	2 (6.7%)	0 (0%)	0 (0%)
Sport Science	3 (14.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pharmacology	2 (9.5%)	2 (11.1%)	4 (13.4%)	0 (0%)	1 (16.7%)
Endrocrinology	0 (0%)	0 (0%)	2 (6.7%)	0 (0%)	0 (0%)
Cardiology	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)
Respiratory conditions	0 (0%)	0 (0%)	1 (3.3%)	0 (0%)	1 (16.7%)
Polytherapy	0 (0%)	1 (5.6%)	1 (3.3%)	0 (0%)	0 (0%)

$X^2(60) = 61.974$, p=0.406

Scientific interests and qualification level

The 38.7% of interests reported by pharmacists with a graduate qualification level was 'personalised healthcare' (Table 3.6.2d). Statistical significance between qualification level and scientific interest was not obtained as the p-value exceeded the 0-05 level of significance.

Table 3.6.2d: Cross-tabulation:Pharmacist qualification level and scientific interests (N=61)

Scientific interest	**Qualification level**	
	Graduate	*Post-graduate*
Personalised healthcare	22 (38.7%)	5 (20%)
Continuous education	12 (21.1%)	5 (20%)
Inter-professional collaboration	2 (3.5%)	1 (4%)
Alternative medicine	2 (3.5%)	1 (4%)
Antibiotic resistance	3 (5.4%)	1 (4%)
Gastroenterology	0 (0%)	2 (8%)
Healthy eating	2 (3.5%)	1 (4%)
Medicine R&D	1 (1.7%)	1 (4%)
Enviromental Science	2 (3.5%)	0 (0%)
Sport Science	1 (1.7%)	2 (8%)
Pharmacology	4 (7.0%)	5 (20%)
Endrocrinology	1 (1.7%)	1 (4%)
Cardiology	1 (1.7%)	0 (0%)
Respiratory conditions	2 (3.5%)	0 (0%)
Polytherapy	2 (3.5%)	0 (0%)

$X^2(15) = 18.811$ $p=0.222$

Scientific interests and years of experience

The main recorded interest in pharmacists with less than one-year experience was 'personalised healthcare' (Table 3.6.2e). The association between years of experience and scientific interest was not statistically significant (p-value>0.05).

Table 3.6.2e:Cross-tabulation:Pharmacist years of experience and scientific interests (N=61)

Scientific interests	**Years of experience**				
	Less than 1 year	*Between 1 year and 5 years*	*Between 6 and 15 years*	*Between 16 and 25 years*	*More than 25 years*
Personalised healthcare	2 (66.7%)	2 (18.2%)	7 (32%)	6 (24%)	10 (47.6%)
Continuous education	1 (33.3%)	1 (9.1%)	4 (18.2%)	6 (24%)	5 (23.6%)
Inter-professional collaboration	0 (0%)	1 (9.1%)	2 (9.1%)	0 (0%)	0 (0%)
Alternative medicine	0 (0%)	1 (9.1%)	2 (9.1%)	0 (0%)	0 (0%)
Antibiotic resistance	0 (0%)	1 (9.1%)	0 (0%)	2 (8%)	1 (4.8%)
Gastroenterology	0 (0%)	0 (0%)	1 (4.5%)	1 (4%)	0 (0%)
Healthy eating	0 (0%)	1 (9.1%)	1 (4.5%)	0 (0%)	1 (4.8%)
Medicine R&D	0 (0%)	0 (0%)	0 (0%)	1 (4%)	1 (4.8%)
Enviromental Science	0 (0%)	0 (0%)	0 (0%)	1 (4%)	1 (4.8%)
Sport Science	0 (0%)	2 (18.2%)	1 (4.5%)	0 (0%)	0 (0%)
Pharmacology	0 (0%)	2 (18.2%)	2 (9.1%)	4 (16%)	1 (4.8%)
Endrocrinology	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Cardiology	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Respiratory conditions	0 (0%)	0 (0%)	0 (0%)	1 (4%)	1 (4.8%)
Polytherapy	0 (0%)	0 (0%)	1 (4.5%)	1 (4%)	0 (0%)

$X^2(60) = 51.646$ $p = 0.770$

Scientific interests and field of exposure

Between the scientific interests chosen by pharmacists with hospital exposure, 50% reported 'continuous education' (Table 3.6.2f). The association between additional field of experience and scientific interest was not statistically significant (p-value>0.05).

Table 3.6.2f:Cross-tabulation:Pharmacist additional exposure and scientific interests (n=16)

Scientific interests	**Additional exposure**			
	University	*Hospital pharmacy*	*Pharmaceutical industry*	*Regulatory authority*
Personalised healthcare	2 (18.3%)	1 (8.3%)	2 (28.55%)	1 (50%)
Continuous education	2 (18.3%)	6 (50%)	2 (28.55%)	1 (50%)
Inter-professional collaboration	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Alternative medicine	0 (0%)	1 (8.3%)	0 (0%)	0 (0%)
Antibiotic resistance	1 (9%)	1 (8.3%)	0 (0%)	0 (0%)
Gastroenterology	1 (9%)	1 (8.3%)	1 (14.3%)	0 (0%)
Healthy eating	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Medicine R&D	1 (9%)	0 (0%)	0 (0%)	0 (0%)
Enviromental Science	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Sport Science	0 (0%)	0 (0%)	1 (14.3%)	0 (0%)
Pharmacology	3 (27.4%)	2 (16.8%)	1 (14.3%)	0 (0%)
Endrocrinology	1 (9%)	0 (0%)	0 (0%)	0 (0%)
Cardiology	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Respiratory conditions	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Polytherapy	0 (0%)	0 (0%)	0 (0%)	0 (0%)

$X^2(36) = 34.357$ p=0.547

3.6.3. Correlation between goals and participant characteristics

Six goals were identified through the Pharmacist Competencies Self-Audit tool and were analysed to identify correlations with pharmacist factors.

Goals and district

'Continuous education' was reported mainly in the Southern Harbour district (Table 3.6.3a). The correlation between district and reported goals was not statistically significant since the p-value exceeded the 0.05 criterion.

Table 3.6.3a:Cross-tabulation:Pharmacist district of practice and goals (N=61)

Goals	**District**					
	Southern harbour	*Northern harbour*	*South eastern*	*Western*	*Northern*	*Gozo*
Patient education and empowerment	*2* (18.2%)	*5* (14.3%)	*3* (16.7%)	*1* (10%)	*4* (21%)	*2* (18.2%)
Continuous education	*3* (27.2%)	*4* (11.4%)	*2* (11.1%)	*0* (0%)	*4* (21%)	*2* (18.2%)
Time spent with patient and service provided	*2* (18.2%)	*12* (34.4%)	*3* (16.7%)	*3* (30%)	*6* (31.6%)	*2* (18.2%)
Reduction of medication errors	*2* (18.2%)	*5* (14.3%)	*6* (33.3%)	*1* (10%)	*1* (5.3%)	*3* (27.2%)
Personalised healthcare and medication	*1* (9.1%)	*7* (20%)	*3* (16.7%)	*3* (30%)	*3* (15.8%)	*2* (18.2%)
Reduction of buroecratic work	*1* (9.1%)	*2* (5.7%)	*1* (5.5%)	*2* (20%)	*1* (5.3%)	*0* (0%)

$X^2(30) = 26.816$ $p = 0.633$

Goals and gender

More than 25% of the reported goals from both genders were related to 'time spent with patient and service provided' (Table 3.6.3b). No statistical significance between the goals reported and gender was achieved as the p-value exceeded the 0.05 criterion.

Table 3.6.3b: Cross-tabulation: Pharmacist gender and goals (N=61)

Goals	**Gender**	
	Female	*Male*
Patient education and empowerment	9 (16.1%)	8 (16.7%)
Continuous education	9 (16.1%)	6 (12.5%)
Time spent with patient and service provided	14 (25%)	14 (29.2%)
Reduction of medication errors	10 (17.9%)	8 (16.7%)
Personalised healthcare and medication review	10 (17.9%)	9 (18.7%)
Reduction of buroecratic work	4 (7.1%)	3 (6.2%)

$X^2(6) = 1.026$ $p=0.985$

Goals and age category

The majority of reported goals from pharmacist older than 41 years old were related to 'time spent with patient and service provided' (Table 3.6.3c). No significant difference between the age categories was identified when reporting pharmacist's goals.

Table 3.6.3c: Cross-tabulation: Pharmacist age category and goals (N=61)

Goals	**Age Category**				
	22-30 years	*31-40 years*	*41-50 years*	*51-60 years*	*More than 60 years*
Patient education and empowerment	2 (8 %)	6 (25%)	7 (18.3%)	1 (11.1%)	1 (12.5%)
Continuous education	3 (12%)	4 (16.7%)	6 (15.8%)	1 (11.1%)	1 (12.5%)
Time spent with patient and service provided	5 (20%)	4 (16.7%)	12 (31.6%)	4 (44.5%)	3 (37.5%)
Reduction of medication errors	6 (24%)	4 (16.7%)	5 (13.1%)	1 (11.1%)	2 (25%)
Personalised healthcare and medication review	8 (32%)	3 (12.45%)	7 (18.3%)	1 (11.1%)	0 (0%)
Reduction of buroecratic work	1 (4%)	3 (12.45%)	1 (2.6%)	1 (11.1%)	1 (12.5%)

$X^2(25) = 23.017$ $p=0.519$

Goals and qualification level

Pharmacists from both qualification levels have reported as main goal ‘time spent with patient and service provided’ with 27.8% for pharmacist with graduate level and 25% with pharmacist with post-graduate level (Table 3.6.3d). No significant difference between the qualification levels was identified when reporting pharmacist goals.

Table 3.6.3d: Cross-tabulation: Pharmacist qualification level and goals (N=61)

Goals	**Qualification level**	
	Graduate	*Post-graduate*
Patient education and empowerment	13 (18.1%)	4 (12.4%)
Continuous education	12 (16.6%)	3 (9.4%)
Time spent with patient and service provided	20 (27.8%)	8 (25%)
Reduction of medication errors	11 (15.3%)	7 (21.9%)
Personalised healthcare and medication review	11 (15.3%)	8 (25%)
Reduction of buroecratic work	5 (6.9%)	2 (6.3%)

$X^2(6) = 6.366$ $p = 0.383$

Goals and years of experience

The 66.7% of pharmacists with less than 1 year-experience reported as a goal the reduction of medication errors (Table 3.6.3e). The association between years of experience and goals reported was not statistically significant since the p-value exceeded the 0.05 level of significance.

Table 3.6.3e: Cross-tabulation: Pharmacist years of experience and goals (N=61)

Goals	**Years of experience**				
	Less than 1 year	*Between 1 year and 5 years*	*Between 6 and 15 years*	*Between 16 and 25 years*	*More than 25 years*
Patient education and empowerment	0 (0%)	1 (7.7%)	6 (20.7%)	6 (18.8%)	4 (14.8%)
Continuous education	1 (33.3%)	1 (7.7%)	4 (13.8%)	6 (18.8%)	3 (11.1%)
Time spent with patient and service provided	0 (0%)	3 (23.0%)	5 (17.2%)	9 (28.1%)	11 (40.7%)
Reduction of medication errors	2 (66.7%)	2 (15.4%)	6 (20.7%)	4 (12.5%)	4 (14.8%)
Personalised healthcare and medication review	0 (0%)	5 (38.5%)	6 (20.7%)	4 (12.5%)	4 (14.8%)
Reduction of buroecratic work	0 (0%)	1 (7.7%)	2 (6.9%)	3 (9.3%)	1 (3.8%)

$X^2(24) = 25.883$ $p = 0.359$

Goals and additional field of exposure

The observations reported by pharmacist with an academic work exposure with higher percentage were 'personalised healthcare' (36.4%), 'reduction of medication errors' and 'time spent with patient and service provided', both with 27.3% (Table 3.6.3f). The association between pharmacist additional professional exposure and goals was not statistically significant (p-value>0.05).

Table 3.6.3f: Cross-tabulation: Pharmacist additional exposure and goals (n=16)

Goals	**Additional exposure**			
	University	*Hospital pharmacy*	*Pharmaceutical industry*	*Regulatory authority*
Patient education and empowerment	0 (0%)	2 (11.1%)	3 (25%)	0 (0%)
Continuous education	1 (9.0%)	1 (5.5%)	2 (16.65%)	0 (0%)
Time spent with patient and service provided	3 (27.3%)	4 (22.2%)	3 (25%)	0 (0%)
Reduction of medication errors	3 (27.3%)	3 (16.7%)	2 (16.65%)	1 (50%)
Personalised healthcare and medication review	4 (36.4%)	5 (27.8%)	2 (16.65%)	1 (50%)
Reduction of buroecratic work	0 (0%)	3 (16.7%)	0 (0%)	0 (0%)

$X^2(24) = 26.654$ p=0.321

3.6.4. Opportunities for improvement

Five opportunities for improvement were identified through the Pharmacist Competencies Self-Audit tool and were analysed to identify correlations with pharmacist factors.

Opportunities for improvement and district

The opportunity for improvement reported by pharmacist that had a higher percentage was 'continuous education' across all districts (Table 3.6.4a). The association between pharmacist district and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4a:Cross-tabulation:Pharmacist district of practice and opportunities for improvement (N=61)

Opportunities for improvement	**District**					
	Southern harbour	*Northern harbour*	*South eastern*	*Western*	*Northern*	*Gozo*
Inter-professional collaboration	1 (8.3%)	1 (3.2%)	3 (21.4%)	2 (16.7%)	1 (6.3%)	2 (16.7%)
Continuous education	4 (33.3%)	11 (35.5%)	4 (28.6%)	3 (25%)	10 (62.5%)	6 (50%)
Build relationship with patients	0 (0%)	7 (22.6%)	3 (21.4%)	2 (16.7%)	1 (6.3%)	1 (8.3%)
Time spent with patient and education	4 (33.3%)	7 (22.6%)	2 (14.3%)	3 (25%)	2 (12.5%)	0 (0%)
Personalised healthcare and medical review	3 (25%)	5 (16.1%)	2 (14.3%)	2 (16.6%)	2 (12.5%)	3 (25%)

$X^2(25) = 30.935$ $p=0.191$

Opportunities for improvement and gender

The opportunity for improvement reported by pharmacist that had a higher percentage was 'continuous education' across both genders (Table 3.6.4b). The association between pharmacist gender and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4b:Cross-tabulation:Pharmacist gender and opportunities for improvement (N=61)

Opportunities for improvement	**Gender**	
	Female	*Male*
Inter-professional collaboration	4 (7.8%)	6 (13.3%)
Continuous education	19 (36.5%)	19 (42.2%)
Build relationship with patients	10 (19.2%)	4 (8.9%)
Time spent with patient and education provided	9 (17.3%)	9 (20%)
Personalised healthcare and medical review	10 (19.2%)	7 (15.6%)

$X^2(5) = 4.791 p = 0.442$

Opportunities for improvement and age category

The opportunity for improvement reported that had a higher percentage was 'continuous education' across pharmacists with less than 51 years of age (Table 3.6.4c). The association between pharmacist age and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4c:Cross-tabulation:Pharmacist age category and opportunities for improvement (N=61)

Opportunities for improvement	**Age category**				
	22-30 years	*31-40 years*	*41-50 years*	*51-60 years*	*More than 60 years*
Inter-professional collaboration	4 (17.4%)	2 (9.1%)	3 (12%)	0 (0%)	1 (11.1%)
Continuous education	9 (39.2%)	8 (36.4%)	15 (60%)	3 (37.5%)	3 (33.3%)
Build relationship with patients	1 (4.3%)	1 (4.5%)	8 (32%)	1 (12.5%)	3 (33.3%)
Time spent with patient and education provided	3 (13%)	4 (18.2%)	5 (20%)	4 (50%)	2 (22.3%)
Personalised healthcare and medical review	6 (26.1%)	7 (31.8%)	4 (16%)	0 (0%)	0 (0%)

$X^2(20) = 29.383$, p=0.08

Opportunities for improvement and qualification level

The opportunity for improvement reported that had a higher percentage was 'continuous education' across pharmacists with both qualification levels (Table 3.6.4d). The association between pharmacist qualification level and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4d:Cross-tabulation:Pharmacist qualification level and opportunities for improvement (N=61)

Opportunities for improvement	**Qualification level**	
	Graduate	*Post-graduate*
Inter-professional collaboration	8 (11.6%)	2 (7.1%)
Continuous education	25 (36.3%)	13 (46.4%)
Build relationship with patients	11 (15.9%)	3 (11.1%)
Time spent with patient and education provided	15 (21.7%)	3 (11.1%)
Personalised healthcare and medical review	10 (14.5%)	7 (25.9%)

$X^2(5) = 7.702$ p=0.173

Opportunities for improvement and years of experience

The opportunity for improvement reported that had a higher percentage was 'continuous education' across pharmacists with more than one year of experience (Table 3.6.4e). The association between pharmacist years of experience and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4e:Cross-tabulation:Pharmacist years of experience and opportunities for improvement (N=61)

Opportunities for improvement	**Years of experience**				
	Less than 1 year	*Between 1 year and 5 years*	*Between 6 and 15 years*	*Between 16 and 25 years*	*More than 25 years*
Inter-professional collaboration	1 (33.3%)	1 (7.7%)	4 (16%)	2 (7.4%)	2 (6.9%)
Continuous education	1 (33.3%)	**5 (38.6%)**	**9 (36%)**	**10 (37%)**	**13 (44.8%)**
Build relationship with patients	0 (0%)	1 (7.7%)	0 (0%)	6 (22.2%)	7 (24.1%)
Time spent with patient and education	0 (0%)	3 (23%)	4 (16%)	5 (18.5%)	6 (20.7%)
Personalised healthcare and medical review	1 (33.3%)	3 (23%)	8 (32%)	4 (14.9%)	1 (3.5%)

$X^2(20) = 27.058$ p=0.134

Opportunity for improvement and additional field of exposure

The opportunity for improvement reported that had a higher percentage was 'continuous education' for pharmacist with professional university background (Table 3.6.4f). The association between pharmacist additional field of experience and opportunities for improvement was not statistically significant (p-value>0.05).

Table 3.6.4f:Cross-tabulation:Pharmacist additional exposure and opportunities for improvement (n=16)

Opportunities for improvement	**Additional fields**			
	University	*Hospital pharmacy*	*Pharmaceutical industry*	*Regulatory authority*
Inter-professional collaboration	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Continuous education	6 (66.7%)	7 (46.7%)	4 (36.4%)	1 (50%)
Build relationship with patients	1 (11.1%)	1 (6.7%)	1 (9.1%)	0 (0%)
Time spent with patient and education provided	0 (0%)	4 (26.7%)	1 (9.1%)	0 (0%)
Personalised healthcare and medical review	2 (22.2%)	5 (33.3%)	5 (45.5%)	1 (50%)

$X^2(16) = 19.183$ p=0.259

3.7. Regulatory data

Descriptive statistics is reported below about regulatory data collected through the regulatory self-audit and regulatory audit. Each criterion of the regulatory report was analysed for both audits.

3.7.1. Storage of medicinal products

All pharmacists (N=61) declared that the pharmacy fridge was clean, of adequate capacity and dedicated to the exclusive storage of medicinal products in good condition. This was confirmed by the regulatory audit (RA) for the majority of the pharmacies (Table 3.7.1). An expiry management system was found in 95.1% of the pharmacies, while the regulatory self-audit (RSA) results stated a full compliance to the criteria (100%).

Table 3.7.1: Data comparison of criteria on storage of medicinal products (N=61)

Storage of medicinal products		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Medicines under pharmacist control	Yes	60	98.4	60	98.4
	No	1	1.6	1	1.6
Clean fridge with only medicines	Yes	61	100	57	93.4
	No	0	0	4	6.6
Fridge medicines stored in good condition	Yes	61	100	58	95.1
	No	0	0	3	4.9
Fridge of adequate capacity	Yes	61	100	57	93.4
	No	0	0	4	6.6
Expiry date management	Yes	61	100	58	95.1
	No	0	0	3	4.9

3.7.2. The pharmacist identification

The majority of pharmacists declared to wear a white coat (n=60) and the Pharmacy Council identity tag (n=59) when attending professional duties. These results were halved (31 and 38 pharmacists respectively) when compared to the one of the regulatory audit (Table 3.7.2).

Table 3.7.2: Data comparison of the pharmacist criteria (N=61)

The pharmacist		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
White coat	Yes	60	98.4	31	50.8
	No	1	1.6	30	49.2
Pharmacy Council identity tag	Yes	59	96.7	38	62.3
	No	2	3.3	23	37.7

3.7.3. Appliances and premises certificates

The regulatory self-audit reported that all pharmacies had a valid pest control certificate (100%), nearly all had a current registration (98.4%) and A/C service (96.7%) certificates. These criteria obtained a lower percentage in the regulatory audit (Table 3.7.3).

Table 3.7.3: Data comparison on appliances and premises certificates (N=61)

Certificates		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Current registration	Yes	60	98.4	38	62.3
	No	1	1.6	23	37.7
A/C service	Yes	58	96.7	33	54.1
	No	3	3.3	28	45.9
Pest control	Yes	61	100	38	62.3
	No	0	0	23	37.7

3.7.4. Pharmacy registers

The following tables collect data regarding temperature (Table 3.7.4a), housekeeping and locum (Table 3.7.4b), daily prescription (Table 3.7.4c and 3.7.4d), Dangerous Drugs registers (Table 3.7.4e).

Temperature register

In the regulatory self-audit, all pharmacies declared that thermometers were calibrated annually and that temperature registers for pharmacy fridge and store were updated daily. A lower compliance was observed in the regulatory audit (Table 3.7.4a).

Table 3.7.4a: Data comparison on calibration and temperature documentation (N=61)

Temperature register		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Thermometers calibration certificates	Yes	61	100	46	75.4
	No	0	0	15	24.6
Pharmacy fridge (daily max/ min)	Yes	61	100	38	62.3
	No	0	0	23	37.7
POYC fridge (daily max/ min)	Yes	59	96.7	36	59.0
	No	2	3.3	23	37.7
	N/A	0	0	2	3.3
Pharmacy store (daily max/ min)	Yes	61	100	39	63.9
	No	0	0	22	36.1
POYC store (daily max/ min)	Yes	58	95.1	38	62.3
	No	3	4.9	21	34.4
	N/A	0	0	2	3.3

Locum and cleaning register

According to the regulatory self-audit, pharmacies update regularly the locum register (N=61) and the cleaning register (n=60). A higher compliance was found in the regulatory audit for the locum register (93.4%) in comparison to the cleaning register (73.8%) (Table 3.7.4b).

Table 3.7.4b: Data comparison on cleaning and locum registers (N=61)

Locum and cleaning registers updated		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Locum register	Yes	61	100	57	93.4
	No	0	0	4	6.6
Cleaning register	Yes	60	98.4	45	73.8
	No	1	1.6	16	26.2

Daily register

In the regulatory self-audit, 42.6% of the pharmacies declared recording electronically dispensed medications, while during the regulatory audit only the 36.1% of the pharmacies provided electronic records (Table 3.7.4c). In both audits, the majority of the pharmacies were abiding to requirements (24 out of 26, and 18 out of 22 respectively). The regulatory self-audit highlighted that nearly all pharmacies (n=60) maintain the daily register updated daily, while the regulatory audit affirmed that only 39 out of 61 pharmacies were compliant with the legal requirement (Table 3.7.4d). Requirements regarding the daily format and the maintenance of daily prescriptions obtained similar percentages in the regulatory self-audit and in the regulatory audit.

Table 3.7.4c: Data comparison on pharmacies electronic records

Daily register		RSA (n= 26)		RA (n= 22)	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Printed, signed by pharmacist	Yes	24	92.3	18	81.8
	No	2	7.7	4	18.2

Table 3.7.4d: Data comparison on the daily register (N=61)

Daily register		RSA		RA	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Daily basis updated	Yes	60	98.4	39	63.9
	No	1	1.6	22	36.1
Printed and signed by the pharmacist	Yes	24	39.3	18	29.5
	No	2	3.3	4	6.6
	N/A	35	57.4	39	63.9
Format as per Art 6 of S.L. 458.49	Yes	60	98.4	58	95.1
	No	1	1.6	3	1.6
Prescriptions kept for 3 months	Yes	58	95.1	57	93.4
	No	3	4.9	4	6.6

Dangerous Drug Registers

The majority of pharmacies declared that Dangerous Drug Act (DDA) registers are updated within the one-month requirement. The data collected through the regulatory audit show a lower percentage of compliance with requirement (Table 3.7.4e). Two pharmacies that participated in the research do not provide the supply of medicinal products with the Pharmacy Of Your Choice (POYC) scheme. This was confirmed during the regulatory audit.

Table 3.7.4e: Data comparison on Dangerous Drug registers (N=61)

DDA register:		RSA		RA	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Sales for Pharmacy stock updated	Yes	61	100	50	82.0
	No	0	0	11	18.0
Purchases for Pharmacy stock updated	Yes	61	100	55	90.2
	No	0	0	6	9.8
Sales for POYC stock updated	Yes	58	95.1	46	75.4
	No	1	1.6	13	21.3
	N/A	2	3.3	2	3.3
Purchases for POYC stock updated	Yes	59	96.7	52	85.2
	No	0	0	7	11.5
	N/A	2	3.3	2	3.3
Available from last audit	Yes	61	100	60	95.1
	No	0	0	1	1.6
Format as per Art 11, 18, Second Schedule S.L.101.02	Yes	61	100	61	100
	No	0	0	0	0
Removed and documented expired DDAs	Yes	45	73.8	41	67.2
	No	6	9.8	8	13.1
	N/A	10	16.4	12	19.7

3.7.5. Dangerous Drug Act stock take exercise and Dangerous Drug Act cupboard

The majority of pharmacies were found compliant in both regulatory self-audit and regulatory audit with the requirements related to Dangerous Drug Act (DDA) stock take exercises and DDA cupboard. Pharmacies had a lower compliance with the DDA key criterion in the regulatory audit (44.3%) in comparison to the regulatory self-audit (98.4%) (Table 3.7.5). The 14.8% of pharmacies declared not to have expired DDA medicinal products while this percentage was higher in the regulatory audit (23.0%).

Table 3.7.5: Data comparison on DDA stock take exercise and DDA cupboard (N=61)

DDA procedures		RSA		RA	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Stock taking exercise	Yes	58	95.1	59	96.7
	No	3	4.9	2	3.3
Lockable cabinet	Yes	61	100	60	98.4
	No	0	0	1	1.6
Key on pharmacist	Yes	60	98.4	27	44.3
	No	1	1.6	34	55.7
Cupboard adequate capacity	Yes	61	100	59	96.7
	No	0	0	2	3.3
Only medicines stored in cupboard	Yes	61	100	58	95.1
	No	0	0	3	4.9
Expired DDAs labelled and stored in the cupboard	Yes	50	82.0	42	68.9
	No	2	3.3	5	8.2
	N/A	9	14.8	14	23.0

3.7.6. Cannabis-based products

According to the regulatory self-audit data, twenty-one pharmacies out of 61 stored cannabis-based products. Eighteen out of 21 pharmacies were confirmed during the regulatory audit. All pharmacies in both regulatory were abiding to the authority tamper evident label and sale of sealed products requirements (Table 3.7.6).

Table 3.7.6: Data comparison on cannabis-based products

Cannabis –based products		RSA (n=21)		RA (n=18)	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Tamper-evident label	Yes	21	100	17	94.4
	No	0	0	1	5.6
Serial number registered	Yes	20	95.2	17	94.4
	No	1	4.8	1	5.6
Sold sealed	Yes	21	100	18	100
	No	0	0	0	0

3.7.7. Extemporaneous preparations

Out of 61 pharmacies, 31 declared carrying out extemporaneous preparations in the regulatory self-audit and 30 confirmed it in the regulatory audit. Despite not carrying out extemporaneous products, all pharmacies are required by law to maintain a graduated cylinder and tablet counter at the pharmacy premises. Only one pharmacy denied having the graduated cylinder and tablet counter in the regulatory self-audit while in the results of regulatory audit three pharmacies did not have a cylinder and one the tablet counter (Table 3.7.7a).

All pharmacies delivering the service declared to label extemporaneous products, to have dedicated areas. Overall almost all pharmacies complied with the requirements for the preparation of extemporaneous preparations (Table 3.7.7b).

Table 3.7.7a: Mandatory equipment for all pharmacies (N=61)

Criteria for all pharmacies		RSA		RA	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Graduated cylinders	Yes	60	98.4	58	95.1
	No	1	1.6	3	4.9
Tablet counter	Yes	60	98.4	60	98.4
	No	1	1.6	1	1.6
Equipment clean	Yes	60	98.4	61	100
	No	1	1.6	0	0

Table 3.7.7b: Mandatory equipment only for pharmacies providing the service

Criteria only for pharmacies providing the service		RSA (n=31)		RA (n=30)	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Labelled	Yes	31	100	30	100
	No	0	0	0	0
Dedicated areas	Yes	31	100	30	100
	No	0	0	0	0
Electronic balance	Yes	28	90.3	28	93.3
	No	3	9.7	2	6.7
Ointment glass/marble slab	Yes	31	100	29	96.7
	No	0	0	1	3.3
Spatulas & stirrers	Yes	31	100	29	96.7
	No	0	0	1	3.3
Mortars and pestles	Yes	30	96.8	28	93.3
	No	1	3.2	2	6.7

3.7.8. Premises

Table 3.7.8 reports that all pharmacies (N=61) abided to nearly all requirements for pharmacy premises. The Sunday Roster criterion was the requirements with the lower percentage of compliance in both audits (85.2%).

Table 3.7.8: Data comparison regarding premises state (N=61)

Premises requirements		**RSA**		**RSA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Sunday Roster	Yes	52	85.2	52	85.2
	No	9	14.8	9	14.8
Security arrangements	Yes	61	100	60	98.4
	No	0	0	1	1.6
Good state premises	Yes	61	100	61	100
	No	0	0	0	0
Accessible entrances	Yes	61	100	61	100
	No	0	0	0	0
Pharmacy trading name	Yes	61	100	61	100
	No	0	0	0	0
Adequate dispensing bench	Yes	61	100	61	100
	No	0	0	0	0
Sink with hot and cold water	Yes	60	98.4	61	100
	No	1	1.6	0	0
Adequate lightening and ventilation	Yes	61	100	61	100
	No	0	0	0	0
Limited access to confidential documents	Yes	61	100	61	100
	No	0	0	0	0
Clean toilet	Yes	61	100	61	100
	No	0	0	0	0

3.7.9. Miscellaneous

More than 90% of pharmacies followed the miscellaneous requirements according to the regulatory self-audit reports (Table 3.7.9). The percentage of pharmacies with reference books within 2 years of issue was found of 45.9% in the regulatory audit.

Table 3.7.9: Data comparison regarding miscellaneous (N=61)

		RSA		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Reference books Within 2-years issue	Yes	55	90.2	28	45.9
	No	6	9.8	33	54.1
Sharp-objects bin	Yes	58	95.1	57	93.4
	No	3	4.9	4	6.6
Designated area for waste	Yes	60	98.4	53	86.9
	No	1	1.6	8	13.1

3.7.10. Safety Features

Compliance with criteria established by Regulation 2016/161/EU was found in both audits. Only 2 pharmacies did not have the Safety Features software in place. Beyond of these 2, in another pharmacy the verification and decommissioning of medicinal products affected by this regulation were not performed (Table 3.7.10).

Table 3.7.10: Data comparison on Safety Features Regulation requirements (N=61)

Regulation 2016/161/EU		**RSA**		**RA**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Software	Yes	59	96.7	59	96.7
	No	2	3.3	2	3.3
Verification decommission	Yes	58	95.1	58	95.1
	No	3	4.9	3	4.9

3.7.11. Domiciliary services

Nineteen out of 61 pharmacies declared providing the domiciliary services in the regulatory self-audit. During the regulatory audit, only 15 pharmacies confirmed providing these services. Disagreement on results was found for the majority of the criteria (Table 3.7.11).

Table 3.7.11: Data comparison on criteria for the provision of domiciliary services

Records		**RSA (n=19)**		**RA (n=15)**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Prescriptions are kept	Yes	19	100	15	100
	No	0	0	0	0
Temperature records	Yes	11	57.9	3	20
	No	8	42.1	12	80
Order log is kept	Yes	13	68.4	5	33.3
	No	6	31.6	10	66.7
Delivery log is kept	Yes	14	73.7	5	33.3
	No	5	26.3	10	66.7
Process		**RSA (n=19)**		**RA (n=15)**	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Specific software in place	Yes	1	5.6	0	0
	No	18	94.7	15	100
Area for the preparation	Yes	19	100	15	100
	No	0	0	0	0
Labelled medications	Yes	19	100	15	100
	No	0	0	0	0

Table 3.7.11: Data comparison on criteria for the provision of domiciliary services (continued)

Delivery Procedure		RSA (n=19)		RA (n=15)	
		Frequency	*Percentage*	*Frequency*	*Percentage*
Validated cool box for cold storage items	Yes	12	63.2	7	46.7
	No	2	10.6	2	13.3
	N/A	5	26.2	6	40
Vehicle of acceptable conditions	Yes	18	94.7	14	93.3
	No	1	5.6	1	6.7
Acceptable delivery bags/boxes	Yes	19	100	15	100
	No	0	0	0	0
Temperature loggers for delivery	Yes	10	52.6	6	40
	No	9	47.4	9	60
Thermometer calibration certificate	Yes	6	31.6	6	40
	No	13	68.4	9	60
Recording of distances covered	Yes	8	42.1	3	20
	No	11	57.9	12	80
Pharmacist performing deliveries	Yes	18	94.7	13	86.7
	No	1	5.6	2	13.3

3.8. Agreement on regulatory assessment

The Kappa test was performed to assess agreement between the regulatory self-audit and regulatory audit results over all regulatory criteria. Out of 76 criteria, the number of

criteria for which the Kappa test was applicable was 34. For the remaining 42 criteria, the test was not applicable since no variability was found in the pharmacist or regulatory auditor response.

3.8.1. The pharmacist identification

The pharmacists and the regulatory auditor agreed in the assessment of 32 criteria regarding the white coat and 40 regarding the pharmacy identity tag (Table 3.8.1). Their assessment was not comparable as the p value exceeded the 0.05 criterion of significance for both white coat (p-value= 0.305) and pharmacy council tag (p-value= 0.065).

Table 3.8.1: Regulatory self-audit and regulatory audit agreement on the pharmacist identification criteria (N=61)

White coat		**RA**	
		Yes	No
SA	Yes	31	29
	No	0	1
Kappa= 0.034, p=0.305			
Pharmacy Council identity tag		**RA**	
		Yes	No
SA	Yes	38	21
	No	0	2
Kappa= 0.106, p=0.065			

3.8.2. Appliances and premises certificates

Agreement was achieved in the assessment of 39 and 35 pharmacies for the current pharmacy certificate and the A/C service certificate respectively (Table 3.8.2). Agreement in the assessment was not statistically significant (p-value= 0.195 and 0.112 respectively).

Table 3.8.2: Regulatory self-audit and regulatory audit agreement on appliances and premises certificate criteria (N=61)

Current registration certificate		**RA**	
		Yes	No
SA	Yes	38	22
	No	0	1
Kappa= 0.054, p=0.195			
A/C service certificate		**RA**	
		Yes	No
SA	Yes	33	25
	No	0	2
Kappa= 0.081, p=0.112			

3.8.3. Pharmacy registers

Daily register

Agreement in the assessment of criteria related to the daily register was not achieved since the p-value exceeded the 0.05 level of significance (Table 3.8.3a).

Table 3.8.3a: Regulatory self-audit and regulatory audit agreement on Daily register criteria

Daily register updated on a daily basis		**RA**	
		Yes	No
SA	Yes	39	21
	No	0	1
Kappa= 0.057, p=0.179			
Printed and signed by pharmacist daily report		**RA**	
		Yes	No
SA	Yes	15	1
	No	1	1
Kappa= 0.437, p=0.063			
Format as per Art 6 of S.L. 458.49		**RA**	
		Yes	No
SA	Yes	57	3
	No	1	0
Kappa= -0.025, p=0.819			
Prescription kept for 3 months		**RA**	
		Yes	No
SA	Yes	55	3
	No	2	1
Kappa= 0.243, p=0.055			

Dangerous Drug Act registers

The criteria related to the updates of the Dangerous Drug Act (DDA) sales register for POYC and documentation about expired DDAs were assessed differently between the two raters since the p-value exceeded the 0.05 level of significance (Table 3.8.3b).

Table 3.8.3b: Regulatory self-audit and regulatory audit agreement on DDA registers criteria

Dangerous Drug Act Sales register for POYC updated		**RA**	
		Yes	No
SA	Yes	46	12
	No	0	1
Kappa= 0.115, p=0.058			
Removed and documented expired DDAs		**RA**	
		Yes	No
SA	Yes	55	6
	No	4	1
Kappa= 0.039, p=0.791			

3.8.4. Dangerous Drug Act stock take and cupboard

The pharmacist group and the regulatory rater agreed in the assessment of the Dangerous Drug Act stock taking exercise (Table 3.8.4). This result was statistically significant (p-value= 0.000). Criteria related to key of Dangerous Drug Act cupboard and labelled expired DDAs were not assessed equally between the groups since the p value exceeded the 0.05 level of significance.

Table 3.8.4: Regulatory self-audit and regulatory audit agreement on Dangerous Drug Act stock take and cupboard (N=61)

Dangerous Drug Act stock taking exercise		**RA**	
		Yes	No
SA	Yes	58	0
	No	1	2
Kappa= 0.792, **p=0.000**			
Key on pharmacist of Dangerous Drug Act cupboard		**RA**	
		Yes	No
SA	Yes	26	34
	No	1	0
Kappa= -0.033, p=0.258			
Expired DDAs labelled and stored in the cupboard		**RA**	
		Yes	No
SA	Yes	36	4
	No	2	0
Kappa= -0.068, p=0.638			

3.8.5. Cannabis-based products

Both rater groups agreed in the assessment of the registration of serial numbers for cannabis-based products (Table 3.8.5). The assessment was not different as the p-value did not exceed the 0.05 criterion (p-value= 0.000).

Table 3.8.5: Regulatory self-audit and regulatory audit agreement on cannabis-based products criteria (n=17)

Serial number registered		**RA**	
		Yes	No
SA	Yes	16	0
	No	0	1
Kappa= 1.000, **p=0.000**			

3.8.6. Extemporaneous preparations

With regards to extemporaneous preparations, agreement between the two audits was statistically significant (p=0.000) (Table 3.8.6).

Table 3.8.6: Regulatory self-audit and regulatory audit agreement on extemporaneous preparation criteria

Performance of extemporaneous preparations		**RA**	
		Yes	No
SA	Yes	27	4
	No	1	27
Kappa= 1.000, **p=0.000**			
Electronic balance		**RA**	
		Yes	No
SA	Yes	23	2
	No	2	0
Kappa= -0.080, p=0.678			
Graduated cylinder		**RA**	
		Yes	No
SA	Yes	57	3
	No	1	0
Kappa= -0.025, p=0.819			
Tablet counter		**RA**	
		Yes	No
SA	Yes	59	1
	No	1	0
Kappa= -0.017, p=0.896			
Equipment clean		**RA**	
		Yes	No
SA	Yes	59	1
	No	1	0
Kappa= -0.017, p=0.896			

3.8.7. Premises

Agreement in the assessment of Sunday Roster criteria was achieved between the two raters (Table 3.8.7). This was statistically significant (p-value=0.000).

Table 3.8.7: Regulatory self-audit and regulatory audit agreement on premises criteria (N=61)

Sunday roster		**RA**	
		Yes	No
SA	Yes	49	3
	No	3	6
Kappa= 0.609, **p=0.000**			

3.8.8. Miscellaneous

Statistically significant agreement (p-value=0.017) in the assessment of reference books within 2 years of issue was achieved (Table 3.8.8).

Table 3.8.8: Regulatory self-audit and regulatory audit agreement on miscellaneous criteria (N=61)

Reference books within 2-years issue		**RA**	
		Yes	No
SA	Yes	28	27
	No	0	6
Kappa= -0.169, **p=0.017**			
Sharp-objects bin		**RA**	
		Yes	No
SA	Yes	55	3
	No	2	1
Kappa= 0.243, p=0.055			
Designated area for waste		**RA**	
		Yes	No
SA	Yes	53	7
	No	0	1
Kappa= 0.199, p=0.009			

3.8.9. Safety Features

Agreement on the assessment of safety features requirements was obtained since both p-value did not exceed the 0.05 level of significance (Table 3.8.9).

Table 3.8.9: Regulatory self-audit and regulatory audit agreement on Safety Features criteria (N=61)

Software		**RA**	
		Yes	No
SA	Yes	58	1
	No	1	1
Kappa= 0.483, **p=0.000**			
Verification Decommission		**RA**	
		Yes	No
SA	Yes	56	2
	No	2	1
Kappa= 0.299, **p=0.020**			

3.8.10. Domiciliary services

Agreement was achieved only for two criteria regarding the presence of a validated cool-box for cold chain items and the adequacy of the delivery vehicle (Table 3.8.10). For both criteria, p-value did not exceed the 0.05 criterion.

Table 3.8.10: Regulatory self-audit and regulatory audit agreement on domiciliary services criteria

Temperature records		**RA**	
		Yes	No
SA	Yes	3	4
	No	0	7
Kappa= 0.429, p=0.051			
Order log is kept		**RA**	
		Yes	No
SA	Yes	4	5
	No	1	4
Kappa= 0.208, p=0.360			
Delivery log is kept		**RA**	**RA**
		Yes	Yes
SA	Yes	5	5
	No	0	4
Kappa= 0.364, p=0.078			
Validated cool box for cold storage items		**RA**	
		Yes	No
SA	Yes	7	1
	No	0	1
Kappa= 0.609, **p=0.047**			
Vehicle of acceptable conditions		**RA**	
		Yes	No
SA	Yes	13	0
	No	0	1
Kappa= 1.000, **p=0.000**			

Table 3.8.10: Regulatory self-audit and regulatory audit agreement on domiciliary services criteria (continued)			
Temperature loggers for delivery		**RA**	
		Yes	No
SA	Yes	4	2
	No	2	6
Kappa= 0.417, p=0.119			
Thermometers calibration certificate		**RA**	
		Yes	No
SA	Yes	2	2
	No	1	9
Kappa= 0.432, p=0.099			
Recording of distances covered		**RA**	
		Yes	No
SA	Yes	2	2
	No	0	10
Kappa= 0.588, p=0.016			
Pharmacist performing deliveries		**RA**	
		Yes	No
SA	Yes	12	1
	No	1	0
Kappa=-0.077, p=0.773			

3.8.11. Percentage agreement on regulatory compliance

Percentage agreement was calculated on the criteria which could not be assessed through the Kappa test (Table 3.8.11).

Table 3.8.11: Criteria with invalid Kappa test results

Section	Criteria	Percentage agreement
Storage of medicinal products	Medicines under the pharmacist	98.4%
	Clean fridge storing only medicines	93.4%
	Fridge with medicines stored in	95.1%
	Fridge of adequate capacity	93.4%
	Expiry date management system	95.1%
Premises certificates	Pest control certificate	62.3%
Temperature register	Thermometers calibration	75.4%
	Pharmacy fridge (daily max/min)	62.3%
	POYC fridge (daily max/min)	61.0%
	Pharmacy store (daily max/min)	63.9%
	POYC store (daily max/min)	63.8%
Other registers	Locum register	93.4%
	Cleaning register	75%
Dangerous Drug Registers	DDA sales register for pharmacy	81.9%
	DDA purchases register for	90.2%
	DDA purchases register for POYC	88.1%
	DDA registers available from last	98.4%
	DDA registers format	100%
DDA cupboard	Lockable cabinet	98.4%
	Cupboard of adequate capacity	96.7%
	Only medicines stored inside	95.1%

Table 3.8.11: Criteria with invalid Kappa test results (continued)

Section	Criteria	Percentage
Cannabis-based products	Tamper-evident label	94.1%
	Sold sealed	100%
Extemporaneous preparations	Labelled	100%
	Dedicated areas	100%
	Ointment glass/marble slab	96.3%
	Spatulas & stirrers	96.3%
	Mortars and pestles	96.2%
Premises	Security arrangements	100%
	Good state premises	100%
	Premises accessibility	100%
	Pharmacy trading name	100%
	Adequate dispensing bench	100%
	Sink with hot and cold water	98.4%
	Adequate lightening and ventilation	100%
	Limited access to confidential	100%
	Clean toilet	100%
Domiciliary services	Prescription are kept	100%
	Specific software in place	92.9%
	Area for the preparation	100%
	Labelled medications	100%
	Acceptable delivery bags/boxes	100%

3.8.12. Regulatory audits comparison: regulatory self-audit compliance vs. regulatory audit compliance

Compliance with regulatory requirements was identified higher when obtained through the regulatory self-audit than through the regulatory audit performed by the NCA (Table 3.8.12). The mean regulatory self-audit percentage compliance was measured as 94.7% (95% CI ±4.65), while the mean regulatory audit percentage compliance was 82.7% (95% CI ± 8.14). The difference between the two means was statistically significant (p-value= 0.000).

Table 3.8.12: Comparison of the regulatory self-audit and regulatory audit mean percentage compliance (N=61)

	Mean	*Standard deviation*	*Minimum*	*Maximum*
Regulatory self-audit Percentage compliance	94.7	4.65	80.8	100
Regulatory audit Percentage compliance	82.7	8.14	51.9	100

Z= -6.571, **p=0.000**

The Error bar graph (Figure 3.3) displays the 95% confidence interval of the actual percentage compliance of regulatory self-audit and regulatory audit. The fact that these two confidence intervals do not overlap indicates that the two percentage compliance differ significantly. This result compliments the results of the Wilcoxon Sign Rank test.

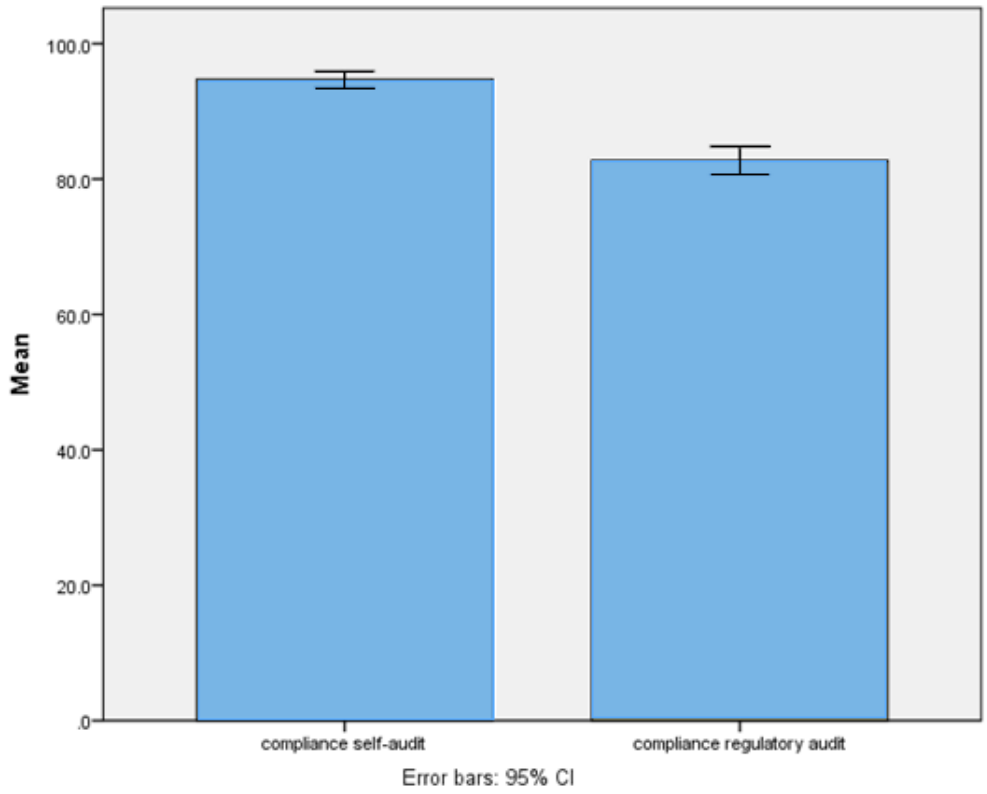

Figure 3.3: Error bar graphs of the regulatory self-audit and regulatory audit percentage compliance

3.9. Risk assessment and correlation with participants characteristics

The validation exercise performed by the 5 experts led to the establishment of criteria for the evaluation of pharmacies risk.

Out of 76 criteria considered as bearing a risk for patients, 34 were considered as major findings (Table 3.9).

Table 3.9: Number of criteria per finding category (N=61)

Findings	Questions
Critical	23
Major	34
Minor	19

Questions considered as critical findings regarded temperature control, maintenance of DDA registers, presence of a pharmacist during pharmacy opening hours, etc. The comprehensive grid of risk score is available in Appendix 5.

The risk assessment was performed on both regulatory self-audit and regulatory audit to measure risk categories established through the regulatory self-audit compliance and the regulatory audit compliance itself.

Regulatory self-audit results determined the pharmacies categorisation as per Table (Table 3.9a). Following the regulatory audit, pharmacies were divided in risk categories (Table 3.9b).

In the regulatory self-audit, 16 pharmacies belonged to the high risk category and 18 in the medium. A higher risk was identified during the regulatory audit, where 46 pharmacies belonged to the high risk and 2 in the medium risk categories.

Table 3.9a: Risk classification as per regulatory self-audit results (N=61)

Risk category*	Number of pharmacies and percentage
High	16 (26.2%)
Medium	18 (29.5%)
Low	27 (44.3%)

*High defined as at least one critical or more than 5 major findings, Medium as between 1 and 5 major findings, Low defined as no critical and/or major findings

Table 3.9b: Risk classification as per regulatory audit results (N=61)

Risk category*	Number of pharmacies and percentage
High	46 (75.4%)
Medium	13 (21.3%)
Low	2 (3.3%)

*High defined as at least one critical or more than 5 major findings, Medium as between 1 and 5 major findings, Low defined as no critical and/or major findings

3.9.1. Agreement between regulatory self-audit and regulatory audit risk categories

Table 3.9.1 illustrates changes in number of pharmacies in the risk categories in the regulatory self-audit and regulatory audit. Regulatory self-audit data categorised pharmacies as a lower risk in comparison to data collected during the regulatory audit. Agreement in the risk categorisation between regulatory self-audit risk category and regulatory audit risk category was not achieved, since the p-value exceeded the level of significance (p=0.395).

Table 3.9.1: Risk categorisation as per regulatory self-audit and regulatory audit (N=61)

	Regulatory Audit Risk category		
Regulatory Self-Audit Risk category	*Low risk*	*Medium risk*	*High risk*
Low risk	2 (3.3%)	8 (13.1%)	17 (27.9%)
Medium risk	0 (0%)	3 (4.9%)	15 (24.6%)
High risk	0 (0%)	2 (3.3%)	14 (22.9%)

Kappa= 0.050, p=0.395

3.9.2. Correlations between regulatory self-audit risk category and other factors

Statistical analysis is reported to identify correlations between regulatory self-audit risk category and pharmacists factors such as district of practice, gender, age, qualification level, years of experience and additional fields of exposure.

District of practice

The majority of pharmacies in the South Eastern district obtained a low risk from the regulatory self-audit results. No pharmacies of the Western district fell in the high risk category. No significant statistical correlation was found when considering the pharmacy risk category and the pharmacist district of practice (Table 3.9.2a).

Table 3.9.2a: Cross-tabulation: District of practice and pharmacy risk category (N=61)

District of practice	Regulatory self-audit risk category		
	Low risk	*Medium risk*	*High risk*
Northern	5 (45.5%)	1 (9.1%)	5 (45.5%)
Northern Harbour	8 (44.4%)	6 (33.4%)	4 (22.2%)
South Eastern	6 (60%)	3 (30%)	1 (10%)
Southern Harbour	2 (22.2%)	3 (33.4%)	4 (44.4%)
Western	3 (50%)	3 (50%)	0 (0%)
Gozo and Comino	3 (42.8%)	2 (28.6%)	2 (28.6%)

$X^2(10)= 9.535$, p=0.482

Gender

The majority of male pharmacists (55.6%) assigned a lower risk to their pharmacy while female pharmacists equally assigned the largest percentage to the low and medium risk categories (35.3%) (Table 3.9.2b). The p-value (0.278) exceeded the 0.05 level of significance implying that the difference between percentages is not statistically significant.

Table3.9.2b: Cross-tabulation: Pharmacist gender and pharmacy risk category (N=61)

Gender	Regulatory self-audit risk category		
	Low risk	*Medium risk*	*High risk*
Female	12 (35.3%)	12 (35.3%)	10 (29.4%)
Male	15 (55.6%)	6 (22.2%)	6 (22.2%)

$X^2(2)= 2.564$, p=0.278

Age category

Pharmacists of the youngest age category did not classify any pharmacy as high risk while only one pharmacist in the oldest age category categorised their pharmacy as high risk (Table 3.9.2c). Pharmacists between '22-30 years' of age and 'older than 60 years' considered their pharmacies as having a lower risk in comparison to pharmacists belonging to the intermediate age categories. This correlation resulted statistically significant (p=0.041).

Table 3.9.2c: Cross-tabulation: Pharmacist age category and pharmacy risk category (N=61)

Age category	Regulatory self-audit risk category		
	Low risk	*Medium risk*	*High risk*
22-30 years	6 (46.2%)	7 (53.8%)	0 (0%)
31-40 years	4 (28.6%)	6 (42.8%)	4(28.6%)
41-50 years	9 (40.9%)	5 (22.7%)	8 (36.4%)
51-60 years	3 (50%)	0 (0%)	3 (50%)
Older than 60 years	5 (83.3%)	0 (0%)	1 (16.7%)

$X^2(8)= 16.100$, p=**0.041**

Qualification level

Regulatory self-audit results classify the 50% of pharmacies with a managing pharmacist with higher qualification level in the low risk category. A higher percentage of pharmacists (33.3%) with graduate level had their pharmacy with a higher risk in comparison to post graduate pharmacists (6.2%) (Table 3.9.2d). However, the correlation between qualification level and pharmacy risk category was not found significant (p-value>0.05).

Table 3.9.2d: Cross-tabulation: Pharmacist qualification level and pharmacy risk category (N=61)

Qualification level	Regulatory self-audit risk category		
	Low risk	*Medium risk*	*High risk*
Graduate	19 (42.2%)	11 (24.4%)	15(33.3%)
Post-graduate	8(50%)	7(43.8%)	1(6.2%)

$X^2(2)= 4.953$, p=0.084

Years of experience

Pharmacists with 'more than 16 years' of experience had a higher pharmacy risk (31.6 % for the '16 to 25 years' category and 38.8% for the eldest year category) in comparison to pharmacists with lower experience (Table 3.9.2e). No pharmacies managed by pharmacists with 'less than 5-years' experience were classified in the high risk category. Pharmacists belonging to the intermediate years of experience category had the majority of their pharmacies (66.7%) in the medium risk category. The correlation between years of experience and risk category was not found significant (p-value 0.115).

Table 3.9.2e: Cross-tabulation: Pharmacist years of experience and pharmacy risk category (N=61)

Age category	Regulatory self-audit risk category		
	Low risk	*Medium risk*	*High risk*
< 1 year	1 (50%)	1 (50%)	0 (0%)
1 to 5 years	4 (57.1%)	3 (42.9%)	0 (0%)
6 to 15 years	1 (8.3%)	8 (66.7%)	3 (25%)
16 to 25 years	8 (42.1%)	5 (26.3%)	6 (31.6%)
> 25 years	10 (55.5%)	1 (5.5%)	7 (38.8%)

$X^2(8)= 12.913$, p=0.115

Additional field of exposure

The majority of pharmacists (60%) with pharmaceutical industry exposure belonged to the medium risk category in the regulatory self-audit. Only one pharmacist had regulatory exposure and belonged to the medium risk category in the regulatory self-audit (Table 3.9.2f). There was no statistically correlation between the field of exposure and the regulatory self-audit risk category (p=0.916).

Table 3.9.2f: Cross-tabulation: Additional fields of exposure and pharmacy risk category (N=16)

Fields of exposure	**Regulatory self-audit risk category**		
	Low risk	*Medium risk*	*High risk*
University	3 (33.3%)	3 (50%)	1 (16.7%)
Hospital pharmacy	4 (44.4%)	4 (44.4%)	1 (11.1%)
Pharmaceutical	2 (40%)	3 (60.0%)	0 (0%)
Regulatory authority	0 (0 %)	1 (100 %)	0 (0%)

$X^2(6)=2.036$, p=0.916

3.9.3. Correlations between regulatory audit risk category and other factors

Statistical analysis is reported to identify correlations between regulatory audit risk category and pharmacists factors such as district of practice, gender, age, qualification level, years of experience and additional fields of exposure.

Districts of practice

Pharmacies in the Northern, South Eastern, Western and Gozo and Comino districts were classified only in the medium and high risk categories (Table 3.9.3a). The higher percentage (11.1%) of pharmacies in the low risk category were in the Southern Harbour district.

The correlation between risk categories and pharmacist district of practice was not significant since the p-value exceeded the 0.05 level of significance.

Table 3.9.3a: Cross-tabulation: District of practice and pharmacy risk category (N=61)

District of practice	Regulatory audit risk category		
	Low risk	*Medium risk*	*High risk*
Northern	0 (0%)	3 (27.3%)	8 (72.7%)
Northern Harbour	1 (5.6%)	5 (27.8%)	12 (66.6%)
South Eastern	0 (0%)	2 (20%)	8 (80%)
Southern Harbour	1 (11.1%)	1 (11.1%)	7 (77.8%)
Western	0 (0%)	1 (16.7%)	5 (83.3%)
Gozo and Comino	0 (0%)	1 (14.3%)	6 (85.7%)

$X^2(10)= 4.666$, p=0.912

Gender

Pharmacies with a female managing pharmacist were categorised as high (82.4%) and medium (17.6%) risk (Table 3.9.3b). The correlation between managing pharmacist gender and pharmacy risk category was not significant (p-value>0.05).

Table 3.9.3b: Cross-tabulation: Pharmacist gender and pharmacy risk category (N=61)

Gender	Regulatory audit risk category		
	Low risk	*Medium risk*	*High risk*
Female	0 (0%)	6 (17.6%)	28 (82.4%)
Male	2 (7.4%)	7 (25.9%)	18 (66.7%)

$X^2(2)= 3.494$, p=0.174

Age category

The higher percentage of pharmacies (40%) with medium risk was registered for pharmacists within the '51 to 60 years' category (Table 3.9.3c). Pharmacies with low risk were associated with managing pharmacists younger than 41 years and within the '51 to 60 years' category. The correlation between age and pharmacy risk categories was not significant (p-value=0.08).

Table 3.9.3c: Cross-tabulation: Pharmacist age category and pharmacy risk category (N=61)

Age category	Regulatory audit risk category		
	Low risk	*Medium risk*	*High risk*
22-30 years	0 (0%)	2 (13.3%)	13 (86.7%)
31-40 years	0 (0%)	1 (6.7%)	14 (93.3%)
41-50 years	1 (3.5%)	5 (17.8%)	22 (78.6%)
51-60 years	0 (0%)	4 (40%)	6 (60%)
Older than 60 years	1 (12.5%)	1 (12.5%)	6 (75%)

$X^2(8)= 14.077$, p=0.080

Qualification level

The majority of pharmacies was classified in the high risk category independently from the qualification level of the managing pharmacist taking care of it (Table 3.9.3d). The correlation between qualification level and pharmacy risk category was not found significant (p-value>0.05).

Table 3.9.3d: Cross-tabulation: Pharmacist qualification level and pharmacy risk category (N=61)

Qualification level	Regulatory audit risk category		
	Low risk	*Medium risk*	*High risk*
Graduate	2 (4.5%)	10 (22.2%)	33 (73.3%)
Post-graduate	0 (0%)	3 (18.7%)	13 (81.3%)

$X^2(2)= 0.876$, p=0.645

Years of experience

All pharmacists (n=15) within the '6 and 15 years' of experience category had a pharmacy in the high risk category (Table 3.9.3e). Pharmacists having less than one year of experience were divided equally between the medium and high risk category. No statistical significant association (p-value=0.346) was found between years of experience and risk category identified by the regulatory audit.

Table 3.9.3e: Cross-tabulation: Pharmacist years of experience and pharmacy risk category (N=61)

Years of experience	Regulatory audit risk category		
	Low risk	*Medium risk*	*High risk*
< 1 year	0 (0%)	1 (50%)	1 (50%)
1 to 5 years	0 (0%)	1 (14.3%)	6 (85.7%)
6 to 15 years	0 (0%)	0 (0%)	15 (100%)
16 to 25 years	1 (5.3%)	5 (26.3%)	13 (68.4%)
> 25 years	1 (5.6%)	6 (33.3%)	11 (61.1%)

$X^2(8)= 8.959$, p=0.346

Additional field of exposure

The majority of pharmacists was assigned to the highest risk category through the regulatory audit independently from the additional fields of exposure (Table 3.9.3f). The result was not statistically significant since the p value exceeded the 0.05 level of significance (p=0.711).

Table 3.9.3f: Cross-tabulation: Additional fields of exposure and pharmacy risk category (N=16)

Fields of exposure	**Regulatory audit risk category**		
	Low risk	*Medium risk*	*High risk*
University	0 (0%)	1 (16.7%)	5 (83.3%)
Hospital pharmacy	0 (0%)	2 (22.2%)	7 (77.8%)
Pharmaceutical	1 (20%)	1 (20%)	3 (60%)
Regulatory	0 (0 %)	0 (0 %)	1 (100 %)

$X^2(6)=3.748$, p=0.711

Chapter Four

Discussion

Regulatory sciences is the discipline that supports the advance of regulation to equalise innovative progress (Wu et al, 2019). As innovation provides a valuable contribution to processes and services for the consumer (Taylor, 2017), regulatory bodies have to adapt regulation according to progress. Regulation has to enhance timely access to safe and innovative medicines[12] without imposing barriers to progress (Blind et al, 2017; Grabowski and Vernon, 1978). The evolution of legislative standards towards regulatory science promotes regulatory flexibility while providing timely access to safe, effective and quality standards in pharmaceutical practice (Kurtz, 2017; Rouse et al, 2018).

4.1.The focus group contribution to the research

Clinical service has evolved towards the involvement of patients in health-related choices (Longtin et al, 2010; Swartwout et al, 2016). This concept of patient's empowerment is translated in this research in the pharmacist performance of regulatory self-audits. The research explored pharmacists' reliability when self-evaluating compliance with regulatory requirements.

The risk analysis leads to a higher patient-centred approach for the assessment of regulatory criteria and it was meant to identify pharmacies with an increased need for follow-up and education.

This research aimed at enhancing the achievement of GPP standards through the self-evaluation of pharmacist's competencies while promoting the recognition of the pharmacist's role within the community and the healthcare professions.

12. HMA.eu [Internet]. EU-Innovation Network. [Cited 2020 May 25]. Available from: https://www.hma.eu/495.html

In community pharmacy, the pharmacist has seen a change in its role from being products centred to patient-oriented (Costa et al, 2017; Duffill et al, 2018). The pharmacist activities evolved from being compounding and dispensing related to being more focused on the provision of pharmaceutical services (Costa et al, 2017; Hoffmann-Eubanks, 2019; Urick and Meggs, 2019). The definition of pharmaceutical care (Hepler and Strand, 2001) translated the pharmacy practice towards the provision of patient-oriented pharmacy services (Duffill et al, 2018). The perception of the focus group reflected this approach, supporting patient-centred assistance and promoting multidisciplinary collaboration for the accomplishment of patient health outcomes.

The focus group remarked some of the characteristics of the seven stars pharmacist (Tramby et al, 2014). It portrayed the pharmacist as a knowledge health care professional with communicative skills and able to provide patients with care. Patients who participated in the focus group reported the trust associated with the pharmacist figure.

As part of a competent professional, self-assessment is a fundamental skill for the development and maintenance of competency (Gemigni 2016; Motycka et al, 2010; Tiuraniemi et al, 2011). The self-assessment method was proposed for the analysis of pharmacist competencies by the focus-group but was identified as a risk factor leading to oversight of legal requirements when applied to the regulatory assessment. The proposed assessment of pharmacist competencies through the observation of patient-pharmacist interactions was discouraged by the focus group. It was suggested that an observational method, it may have reduced the number of pharmacists willing to participate in the study as well as induced changes in pharmacist behaviour and attitude when observed. On the other side, self-assessment should be complemented with external observation (Motycka et al, 2010; Stenov et al, 2017).

The research proposed to assess pharmacist's reliability in the performance of the regulatory self-audit. Regulatory audits were seen as an educative support for pharmacist and as a tool to reduce the gap between regulation and community pharmacy practice (Attard, 2018). The data collected was compared. Inadequate regulatory competency was supported by medical practitioners while pharmacists in the focus group declared to feel competent enough to perform regulatory self-audits. However, the robustness of the self-audit results was considered as a weakness by both professions, being that pharmacists will be scared of legal consequences by declaring to be non-compliant with the law. This can be justified by the severe inspectorate approach that is associated with the regulatory authority. Through the self-assessment, the pharmacist is educated about regulatory requirements and questions himself on the importance of each criteria for the ultimate achievement of patients' outcomes. An increase of pharmacist motivation towards the provision of GPP services might be incentivised by educational activities (Hallit et al, 2019; Petrushevska-Tozi et al, 2014) such as continuous education, financial incentives (Chuc et al, 2002; Hermansyah et al, 2018; Schumock et al,2003) as well as recognition of the pharmacist's role and pharmacy accreditations (Hermansyah et al, 2018).

The educative approach proposed by Attard (2018) enhanced concordance and open discussion with community pharmacists as a standard of practice in regulatory audits. The new attitude brought back the attention of both regulator and pharmacist to comply with a regulation in order to address patient needs. This approach substituted the strict enforcement and police attitude of the regulators towards a constructive discussion between the two parts (Weske et al, 2018).

The focus group reflections brought to the optimisation of the project methodology and regulatory checklist. After revision, order of sections was changed to reduce the time for the audit process for both pharmacist and regulatory body. Being that time constraint and pharmacist work overload were identified in the focus group as risk factors, the grouping of questions into new sections (Appendix 2) might have increased pharmacist participation in the study and performance of self-audit at a pharmacy level. Other changes were implemented to include area of assessment required by new regulations or new areas of competence. A self-audit was recommended to be performed on a risk-based frequency and was considered as an educational tool to achieve regulatory compliance and GPP standards.

4.2.The implementation of the self-audit project

The study population was selected to avoid overoptimistic results by inviting pharmacies that have not been audited for at least one year, in view of the fact that the majority of pharmacies certificates have a one-year validity. Pharmacies audited recently (n=72), are requested to implement and produce evidence of CAPAs within 15 days post-regulatory audit. The inclusion of these pharmacies would have constituted a selection bias.

Demographic and professional details of pharmacists were collected to measure significance of correlations with the pharmacist self-assessment. District of practice and locality were inserted as previous studies found statistical associations between belonging to specific districts and degree of compliance with GPP standards (Trap et al, 2016) and professional competency (Chonsilapawit et al, 2016). Demographic criteria as well as qualification level (Bizri and Dimassi, 2019), years and area of experience were considered significant related to GPP compliance and professional competency (Brando et al, 2020; Chonsilapawit et al, 2016; Gremigni et al, 2016, Walasek et al, 2018).

The percentage of response was higher for the Northern (68.8%) and Gozo and Comino (63.6%) districts, despite being the regions with the lowest percentages of pharmacies invited (59.3% and 55% respectively). The study population is not geographically equally distributed but presented similar characteristics in terms of pharmacist gender. The majority of pharmacists was younger than 51 years (n=49) with a graduate qualification level (n=45) and a community pharmacy experience of more than 16 years (n=37). Almost 74% of the pharmacists participating in the study did not have any other professional exposure. The gender and education level characteristics of the population were similar to the population of the study recently performed in the Lebanese community pharmacy scenario (Badro et al, 2020).

The inclusion of the assessment of pharmacist competencies in the regulatory audit, ensured that the regulatory audit moved from focusing on product quality to focusing on quality of pharmaceutical care. The Pharmacist Competencies Self-Audit tool was the result of a literature review focused on pharmacist competencies and based on GPP principles related to the pharmacist's behaviours and attitude. Section A of the tool reflected principles of GPP guidelines and relatively new trends in the pharmacist profession. These vary from personalised healthcare and clinical skills to multidisciplinary collaboration. In this section, the pharmacist was provided with a list of questions to encourage competencies self-reflection. Section A was meant as guiding the pharmacist in the self-evaluation and in the completion of section B. Only section B was set to be completed due to the pharmacist's time constraint and to encourage the participation and performance of the self-audit. The provision of a set of questions for self-reflection (as per section A) ensured the tool interpretability and the quality of the exercise. The choice of the qualitative analysis of competencies was in view of promoting pharmacist's expressivity and identifying preferences and educational needs.

Pharmacists described their practice as being patient-oriented. Understanding patient needs, providing education and personalised healthcare with good communication and managerial skills were the main strengths reported. The findings were in line with the focus group perception towards the pharmacist's role as well as with the defined roles in the Joint GPP guidelines.[1] A positive attitude towards the provision of pharmaceutical care was reported by a study performed in 2015 in Sudanese community pharmacies. However, their practice was found to still be product-focused due to low clinical knowledge (Sumia et al, 2015).

Pharmacist's scientific interests together with goals and opportunities for improvement were collected to identify needs for education and to provide them with educational activities aiming at improving their preparedness and practice, while stimulating interest in participating. Pharmacists reported personalised healthcare and continuous education as main interests. The most reported goal was increase the time dedicated to patients and improve quality of service. Between the opportunities for improvement, continuous education was reported in larger amount in comparison to other opportunities for improvement. Lack of education and need for clinical training were identified as barriers to strengthening of pharmacy practice and were recommended by the pharmacy category (Sumia et al, 2015).

A statistically significant correlation was identified between strengths and years of experience. Continuous education was reported as a strength in pharmacist with less than 1 year of experience, while this strength reduced when the years of experience increased.

Pharmacists with more than 6 years of experience reported between their strengths understanding patient needs and the provision of timely and efficient accessibility to medicines. Having more than 25 years of experience was associated with being more

patient-oriented. Conversely, a study in Moldovia (2008) reported that younger pharmacist resulted more oriented to the provision of pharmaceutical care in comparison to their older colleagues. Another study highlighted a higher interests in managerial activities than assistance on health services (Cordina et al, 2008).

Other correlations between other strengths, scientific interests, goals and opportunities for improvement and pharmacist factors did not achieve statistical significance.

While in other studies GPP compliance was low (Badro et al, 2020), GPP standard compliance recorded a high percentage on both regulatory self-audit and regulatory audit (94.7% and 82.7% respectively). Overall, percentage of regulatory compliance was calculated and compared for both regulatory self-audit and regulatory audit. Pharmacists perceived themselves to be more complaint with regulatory requirements in comparison to what was measured in the regulatory audit. The difference in the mean percentage compliance was statistically significant (p-value=0.000).

1. International Pharmaceutical Federation. Good Pharmacy Practice: Joint FIP/WHO guidelines on GPP: Standards for quality of pharmacy services [Online]. The Hague: International Pharmaceutical Federation [cited 2020 May 27]. Available from: URL: https://www.fip.org/www/uploads/database_file.php?id=331&table_id=

Literature describes that the assessment of compliance with GPP is mainly performed through inspections (Badro et al, 2020; Trap et al, 2016; Wijesinghe et al, 2007).

The majority of the studies reported low compliance with GPP standards (Badro et al, 2020; Wijesinghe et al, 2007). In the compliance studies, unaccomplished GPP criteria were not assessed to quantify the risk that they are imposing on patients. In our study, we performed a risk analysis to quantify the impact of the findings on patient safety and to address them with a risk-based audit frequency. Correlations between GPP compliance and pharmacist factors were not performed as they were studied in the risk analysis.

The conduction of regulatory audits assists the NCA in the correction of pharmacies deficiencies with risk prioritisation. Despite being the overall compliance high also in the regulatory audit, a lot of pharmacies were categories as bearing a high risk. Having few findings does not impede the pharmacy to be categorised as high risk. While compliance percentage takes into consideration number of criteria accomplished, it is the risk assessment which defines the risk that the pharmacy might impose to patients. In high-risk pharmacies, the overview of findings performed at the last stage of the audit is fundamental. Discussing both positive and negative findings, understanding the reason behind the non-compliance is essential to build concordance and support the pharmacist while reinforcing the rationale behind regulation.

The risk assessment assigned high risk to criteria related to temperature control, presence of a pharmacist supervising the pharmacy during all opening hours, management of expired medicinal stock and DDAs, dispensing of non-counterfeited medicines. All the criteria that ensures the dispensation of good quality and safe medicinal products.

Risk classification appeared more lenient in the regulatory self-audit in comparison to the regulatory audit. This reflected the higher compliance identified through the regulatory self-audit. When comparing regulatory self-audit and regulatory audit risk categorisation, agreement was not achieved since the p-value exceeded the level of significance.

Correlations between the risk categories and pharmacist demographic and professional factors were studied and statistical significance was found between the regulatory self-audit risk category and the age category of the pharmacist performing it. The majority of pharmacists older than 60 years old (83.3%) considered their pharmacy as more compliant and with a lower risk category than pharmacists belonging to other age-categories. Conversely, in a study performed by Scaffidi et al (2018), older professionals with higher experience were more accurate in the self-assessment in comparison to the youngest and least experienced. Highest levels of competence is associated with over criticism, reflecting in a more severe and underestimated self-assessment (Stojkov et al, 2016). No other statistically significant correlations between regulatory audit risk category and pharmacist factors were found.

Data collected through the regulatory self-audit and regulatory audit was analysed to assess agreement between the two parts. Concordance of regulatory data was assessed with the Kappa test for few items: where the variability of the rater response allowed it. The Kappa test provided statistical agreement for DDA stock taking exercise, registration of serial numbers of cannabis-based products, pharmacies carrying out extemporaneous preparations, display of Sunday roster, presence of up-to-date reference books, criteria related to the Safety Features Regulation (Regulation 2016/161/EC) and vehicles and cool box for the domiciliary services. In addition, agreement on other criteria was identified with the percentage agreement on DDA register format, sale of sealed cannabis-based products, labelling and areas dedicated to the preparation of extemporaneous medications,

premises state, security and conditions, domiciliary services labelled medications, area for preparation and bags for delivery.

Despite the change in attitude of the new regulatory auditor approach, audits data did not result comparable. Different reasons might be identified: fear on legal consequences as the old inspectorate approach imposed, missing criticism skills in the pharmacist, or inaccuracy in the performance of regulatory self-audit. Another reason for incomparable results could be related to lack in education of pharmacists regarding regulatory requirements. This resulted from the open discussion during the regulatory audit: some pharmacists declared not to be aware of the requirements or the potential risk associated with non-compliance. The number of optional services provided by the pharmacies was reduced after the regulatory self-audit. This means that the regulatory self-audit increased pharmacist's awareness about requirements and led to abandon the provision of a service due to the high level of regulation required. Services affected were domiciliary services, cannabis-based products, extemporaneous preparations, electronic records. These findings could also be associated with the presence of a locum pharmacist when the regulatory audit was performed. Locum pharmacist are not always aware of the services provided by the pharmacy being that they occasionally work in that pharmacy.

4.3.Strengths and limitations of the research

Pharmacies and pharmacists were selected between the population according to inclusion criteria and based on the submission of the pharmacy self-report. Since pharmacy regulatory audits are unannounced, findings at the pharmacy can be considered representative of the real pharmacy status. Reliability of data collected was ensured by the presence of an accompanying auditor counterchecking the leading auditor. The two auditors were well-trained in the performance of pharmacy audit, with a nine-month

experience. Conversely, the majority of the studies had a limited training for the investigators (Badro et al, 2020).

The tool was validated with the content validity method and inter-rater reliability was obtained. This ensured stability and equivalence of the tool and of the data measured.

The sample selection can be considered both a strength and limitation of the study. On purpose, pharmacies that underwent a regulatory audit in the last year were excluded from the study. The reason was to avoid overoptimistic results due to the post-audit follow-up. However, pharmacies that underwent regulatory audits with the new approach would be aware of the educational intention of the audit and would be willing to discuss and achieve concordance with the regulator. This would lead pharmacists in putting aside fear and enhance a regulatory self-audit reflective of the reality.

The majority of pharmacies participating in the studies belonged to the Northern and Gozo and Comino districts, meaning that the pharmacies selected were not equally distributed between the Maltese districts. The selection of pharmacies between the one that expressed their interest in participating to obtain a randomised sample would have reduced the number of participants, leading to increase the margin error associated with the sample.

Pharmacists participating in the risk-assessment panel were selected on purpose to reflect and academia and research, regulatory and community pharmacy background. A selection bias is identified, however, it enhanced the performance of the risk-assessment by pharmacists with a broad competency in the major pharmaceutical sectors related to pharmacy practice.

4.4.Recommendations and future studies

It is recommended to deliver an educational seminar, to develop GPP guidelines for the establishment of pharmacy standards in Malta and SOPs to support and enhance the achievement of GPP standards in community pharmacy. Findings obtained through the project should be addressed through the development of courses and activities to target educational needs and promote improvement to pharmacy practice.

The rewarding of pharmacies with a GPP certificate was implemented in Uganda (Trap et al, 2016). As manufacturers and wholesalers in the pharmaceutical industry must comply with GMP and GDP guidelines and be certified to operate within Europe, compliance with pharmacy standards should be awarded with a GPP certification. The issuance of a GPP certificate could encourage the achievement of high-standards in pharmacy while increasing pharmacists' competitiveness and competency in the community pharmacy sector. The entitlement of pharmacies with the GPP certificate should be the result of high-standard services and of regular regulatory self-assessment. Pharmacists should be aiming at maintaining competency and professionalism.

Risk assessment was based on the PICs recommendation published in 2012, 'A model for risk-based GMP inspections'. The model was transposed to reflect the risk associated to pharmacy practice. The GMP model considers two types of risk: compliance risk and intrinsic risk. While the compliance risk is related to the satisfaction of regulatory criteria, the intrinsic risk considers the complexity and criticality of the site.[7]

7. Pharmaceutical Inspection Co-Operation Scheme. A recommended model for risk-based inspection planning in the GMP environment [Online].Geneva: Pharmaceutical Inspection Co-operation Scheme [cited 2020 May 27]. Available from: URL: https://www.gmp-compliance.org/guidelines/gmp-guideline/pic-s-recommendation-on-risk-based-inspection-planning-pi-037-1

The model was adapted to consider only the compliance risk. Further studies may consider the implementation of the intrinsic risk as applicable to community pharmacy. Complexity and criticality concepts for pharmacies could be defined by number of patients and additional services provided such as domiciliary services or extemporaneous preparations, etc. In the current study, all services were taken into consideration when performing the risk-assessment.

Further studies could assess the implementation of self-audit and evaluation of pharmacist competency in hospital pharmacies. In this case, the Pharmacist Competencies Self-Audit tool should be tailored to measure services provided and a clinical-oriented pharmacist interventions.

Monitoring of pharmacist competencies and regulatory assessment is recommended to evaluate improvement over time after continuous education, training, regulatory assistance are performed.

4.5.The self-audit reflection

In a metaphorical scenario, the regulatory audit process can be considered as a mirror. When a person is standing in front of a mirror the reflection of the person appears on it. In the same way, the pharmacy standards and the pharmacist's performance are depicted through the regulatory audit process. When the pharmacist performs the regulatory self-audit, the attention and accuracy which he dedicates to it will make him see the real scenario or what he wants to see. The pharmacist can perform the regulatory self-audit with inaccuracy and indifference in the same way that a person looks at the mirror elusively. Conversely, he can use the regulatory self-audit process as an educative and critical exercise as a person gets closer to the mirror to observe carefully each detail of

the image reflected. As the image is seen by the pharmacist through the mirror, his figure is seen by the patients and influences their health outcomes like our image has an impact on the world we live in.

When the regulatory audit is performed by the regulator, the auditor is the support of the mirror and enhances the pharmacist's reflection on his performance. The role of the auditor is to help the pharmacist through the audit process, to see what the pharmacist achieved and to assist his improvement.

Whether the auditor is present or not, the image reflected on the mirror will be the same. It is the pharmacist's attitude and his interest in providing a better service that will make the difference. The pharmacist's attitude and criticism will reflect back the outcomes of his practice through the regulatory audit. While standing in front a mirror, a person can see the real reflection, or be overconfident or have low self-esteem, a person can be aware that improvement is needed but not know how to do so. In these scenario, the regulator will guide and educate the pharmacist to achieve better outcomes through the regulatory audit.

The new regulatory self-audit process wants to highlight the importance of the process itself and that there is no improvement if there is no willingness and patient orientation in the pharmacist. The audit report, either performed as a regulatory self-audit or a regulatory audit, increases the knowledge of the rules, like a mirror shows the reality to the person observing the reflection. The difference between the regulatory self-audit and the regulatory audit lays in the pharmacist's attitude and competence.

Could the regulatory audit be replaced by the regulatory self-audit? Despite the results of the study highlighting the need for more pharmacist's education and training, it is important to maintain an external observation which support pharmacy practice through

regulation. The regulatory audit is an instrument for the auditor to dialogue with the pharmacist and achieve concordance. In this way, the auditor's attitude plays a role: an open discussion and catalytic approach has been reported as increasing motivation in the person observed, and leading to improvement in the individual performance. However, some studies reported that the dialogue-oriented approach does not always result in compliance and that enforcement is sometimes needed (Weske et al, 2018). The lenient approach of the regulator needs to adapt to the pharmacist's attitude. When assessing the reasons for non-compliance, the auditor's attitude should become educative or strict based on the willingness of pharmacist to cooperate and provide a good quality service for the patient. Ultimately, it is in the role of the regulator, as well as of the pharmacist, to ensure that the patient can benefit of good pharmacy practice. This can be achieved through the cooperation of the two parts. If one of the two is not collaborating the goal is not achieved. When deficiencies are addressed through education and training, it is still important to assess at which level they have been addressed and their impact on the perceived competency (Gremigni, 2016). Self-assessment should be a continuous exercise (Walsh, 2016) for both regulatory and competency audits. It promotes continuous education and improvement (Andrade and Du, 2007; McMillan et al, 2008).

4.6.Conclusion

The evolution of the pharmacist role should reflect in the adaption of regulatory processes through the application of regulatory science. The regulatory audit should be used as an instrument of self-assessment and of education for both pharmacist and regulator. Through the regulatory self-audit, the pharmacist identifies strengths and opportunities for improvement leading to self-correction, increased regulatory preparedness and ultimately leading to better pharmacy services. The role of the regulator is to support the

pharmacist through the regulatory process towards the improvement of pharmacy practice.

The project evolved the regulatory process from the verification of legal requirements towards a patient-centred approach, which promotes pharmacist's competitiveness and self-assessment. The research empowered pharmacists in the performance of self-audit and competencies audits to acknowledge the pharmacist's role within the community and the healthcare scenario. The study proposes the awarding of pharmacists with a GPP certificate which will increase pharmacist's motivation, recognition and increase competitiveness between pharmacies and will bring a higher level of pharmacy standards.

The innovation of the project lays in the inclusion of competencies in the self-audit and in the promotion of pharmacist self-assessment. This study measured the agreement between regulator and pharmacist on regulatory compliance while evaluating the achievement of GPP standards with a pharmacy-risk analysis on patients. The risk-assessment enables prioritisation of pharmacy audits, it addresses pharmacy educational needs and optimise pharmacy practice towards meeting patient needs.

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Appendix 1

Approvals for the study

Ethics approval

L-Università ta' Malta

Marina Langaro <marina.langaro.17@um.edu.mt>

Ethics application form

Christabel Gauci <christabel.gauci@um.edu.mt> 4 December 2019 at 07:05
To: Marina Langaro <marina.langaro.17@um.edu.mt>
Cc: Serracino Inglott Anthony at Medicines Authority <anthony.serracino-inglott@gov.mt>

Dear Ms Langaro,

Thank you for your email.

Documentation received with thanks.

Since your application states you have no self-assessment issues, FREC will keep your application for filing and it will not review your application.

You may proceed with your study.

Any ethical and legal issues including data protection issues are your responsibility and that of the supervisor.

I will include these documents with the documents you had already sent.

This means your application will not be reviewed in the next meeting since it is no self-assessment issues.

Thank you.

Kind regards,
Christabel Gauci
Administrator II
University of Malta
Medical School,
Block A, Level 0,
Mater Dei Hospital
Tal-Qroqq, MSD 2090
Malta
Tel: (+00356) 2340 1891
E-Mail: christabel.gauci@um.edu.mt

Chairman and Scientific and Regulatory Operations Directorate Director approvals

Letter granting institutional approval to carry out the research study

Malta Medicines Authority
Life Science Park
Sir Temi Zammit,
San Gwann.
28 November 2019

Dear Professor Anthony Serracino-Inglott,

I am a student reading for the Doctorate in Pharmacy at the Department of Pharmacy, University of Malta. In partial fulfilment of the degree requirements, I will be presenting a dissertation entitled 'Innovative regulatory framework in community pharmacy' to aim the establishment of a model for a self-audit in community pharmacy practice integrating pharmacist competencies with regulatory requirements. The project will shed light on whether self-audit would encourage pharmacists to improve their practice and to feel empowered to lead a self-regulated peer reviewed compliance without the need of a recriminating policing while at the same time ensuring patient safety.
Your kind permission is sought to conduct the research study at the Malta Medicines Authority and to use data related to pharmacy inspections. Data will be used only for the study and all information will be kept anonymous.

Sincerely,

Marina Langaro

Approved by:

Professor Anthony Serracino-Inglott
Chairperson, Malta Medicines Authority

Letter granting institutional approval to carry out the Research Project

San Gwann, 19 December 2018

Dear Dr. Annalise Attard,

I am writing to request permission to conduct a research study at the Malta Medicines Authority, within the Scientific and Regulatory Operations Directorate. I am a third-year student reading for the PharmD, Doctorate in Clinical Pharmacy, and am in the process of writing my PharmD thesis. The study is entitled 'Innovative regulatory framework in community pharmacy'

Your approval to conduct this study will be greatly appreciated.

Sincerely,

Marina Langaro,

Approved by:

Annalise Attard

Director of Scientific and Regulatory Operations Directorate,

Malta Medicines Authority

Director and Data Protection Officer approvals

From: Attard Annalise at Medicines Authority <annalise.a.attard@gov.mt>

Sent: Tuesday, 10 December 2019 14:14

To: Langaro Marina at Medicines Authority <marina.langaro@gov.mt>

Cc: Said Dylan at Medicines Authority <dylan.said@gov.mt>

Subject: Re: Self-audit initiative

Approved

Sent from my iPhone

On 10 Dec 2019, at 13:57, Langaro Marina at Medicines Authority <marina.langaro@gov.mt> wrote:

Dear Annalise,

I am kindly asking if I can proceed with contacting pharmacy licence holders for the purpose of disseminating the regulatory checklist and encouraging the performance of the self-audit.

Please note that, as per DPO approval (email below), this will be in compliance with Data Protection principles.

For your kind feedback.

Best regards,

Marina

From: Said Dylan at Medicines Authority <dylan.said@gov.mt>

Sent: Tuesday, 10 December 2019 13:50

To: Langaro Marina at Medicines Authority <marina.langaro@gov.mt>

Cc: Attard Annalise at Medicines Authority <annalise.a.attard@gov.mt>

Subject: RE: Self-audit initiative

Dear Marina,

Reference is made to Article 5(1)(b) of the GDPR which highlights the principle of 'purpose limitation' by stipulating that "personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes." Recital 50 of the same Regulation explains further what is deemed compatible by stating that "The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required."

On this legal basis, and given the explanation provided hereunder, you may proceed with using the MMA mailing list for pharmacy licence holders since the activities related with this initiatives are considered compatible with the initial purpose for which the licence holders provided their contact details.

Regards,

Dylan

From: Langaro Marina at Medicines Authority <marina.langaro@gov.mt>

Sent: Tuesday, 10 December 2019 13:48

To: Said Dylan at Medicines Authority <dylan.said@gov.mt>

cc: Attard Annalise at Medicines Authority annalise.a.attard@gov.mt>

Subject: Self-audit initiative

Dear Dylan,

The Malta Medicines Authority is launching an initiatives to promote the practice of self-auditing of community pharmacists against regulatory requirements.

The analysis of the self-audit model will assist the National Competent Authority to perform a risk-based assessment of the validity of introducing self-audit as part of the regulatory on of community pharmacies. This innovative method will also serve to identify the need for continuous education and to design advanced practical courses relevant to today's progress in pharmacy practice. The project will shed light on whether self-regulated regulatory compliance would empower and encourage pharmacists to improve their practice while ensuring patient safety. These results might be used for academic and research purposes.

Please advise if as Medicines Authority, we are allowed to use email contacts of pharmacy licence holders for the purpose of this project.

Thank you and best regards,

Marina

Appendix 2

Audit checklist comparison

Comparison of audit checklists

	Version 2012	**Version 2018**	**Version 2020**
Number of questions	15	66 questions in 7 sections (A to G)	71 questions in 7 sections (A to G)
Administrative questions	3	Five sections (A to F)	
Checklist: regulatory criteria	12 questions	10 subsection with 58 ‘yes/no’ questions	
Pharmacist appearance	3 (q4 to q6)	3 including locum register	
Premises and cleaning and temperature records, pest control	1 (q7)	12 questions about premises, cleaning register and pest control.	
Thermometers and fridge	1 (q8) and 1 (q9)	In the ‘storage of medicinal products’ section with temperature records.	
Daily, DDAs, Locum registers	1 (q10)	Separate sections for each register: daily register includes 4 questions, DDA registers divided in private and POYC DDAs with 7 questions.	
DDA cupboard key	1 (q11)	5 questions regarding the DDA cupboard and key	
Extemporaneous preparation utensils	1 (q12)	A total of 11 questions: nine optional questions only if service is carried out, 2 questions are always applicable	
Storage of medicines	1 (q13)	11	
DDA prescriptions	1 (q14)	Together with the DDA registers	
Medicines purchased by authorised wholesale dealers	1 (q15)	Only for DDA medicines	
Additional sections		Addition of Stock take for DDA, Addition of miscellaneous section	

		regarding reference books, sharps bin and designated segregated areas for expired medicines	
Other remarks	Last section	Remarks can be listed next to each requirement in the 'comment' section	
Auditors and pharmacist signatures	At the end of the checklist	At the end of the checklist	
Assessment modality	Auditor	Auditor	Auditor and pharmacist through self-assessment

Audit checklist (Version 2018)

Requirements for the Evaluation of Pharmacy - by The Medicines Authority

Section A: Dispensary Details:

i. **Name:**
ii. **Locality:**
iii. **Email address:**
iv. **Telephone number:**

Section B:

	YES	NO
Any change in pharmacy address? **If yes, enter details;**		
Any change in license holder/ address? **If yes, enter details;**		

Section C: Name, registration number and contact details of the managing pharmacist*:

i. **Name:**
ii. **Registration number:**
iii. **Mobile number:**

***If the managing pharmacist is not present, what is the name and registration number of the locum pharmacist present at the inspection?**

i. **Name:**
ii. **Registration number:**

Section D: Managing/ locum pharmacist signature: _____

Section E: as per Chapter 343Employment and Training Services Act

1	**Employees**	**Number**
1.1	How many people are employed at the pharmacy?	
1.1.1	-On full time basis?	
1.1.2	-On part time basis?	

2. *List Name, Surname and ID number for each*

Name and Surname	**ID number**

Section F: as per Chapter 378 Consumer Affairs Act Subsidiary Legislation 378.09

1	**Price Regulation**	**YES**	**NO**	**Comments** *(if applicable)*
1.1	Is the price indicated on or near all products sold?			

Section G: as per Chapter 458 The Medicines Act

1	**REGISTRATION CERTIFICATES**	**YES**	**NO**	**COMMENTS** *(where applicable)*
1.1	Is the current certificate of registration for the pharmacy available at the pharmacy and is it displayed such that it is legible from the public pharmacy area? *Medicines Act Chapter 458 Article 66 (1)*			
2	**STORAGE OF MEDICINAL PRODUCTS** *Medicines Act Chapter 458 Article 85 (1) and (2) Medicines Act Chapter 458 Article 86*	**YES**	**NO**	**COMMENTS** *(where applicable)*
2.1	Are all medicines stored in an area of the pharmacy under the control of the pharmacist?			
2.2	Is the fridge clean with only medicinal products stored within?			
2.3	Are all medicines stored in the fridge in good condition?			
2.4	Is the fridge of an adequate capacity to permit the orderly storage of medicines? *Comment: pharmaceutical grade fridges recommended*			
2.5	Are the thermometers calibrated annually? **Certificate number:** _____			
2.6	Is the air conditioner serviced annually? **Certificate number:** _____			
2.7	Is the maximum/minimum **fridge temperature for the pharmacy stock** monitored, recorded and reviewed, on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.8	Is the maximum/minimum **fridge temperature for the POYC stock** (if applicable) monitored, recorded and reviewed, on a daily basis, as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.9	Is the maximum/minimum **temperature in the dispensary and any additional**	**YES**	**NO**	**N/A**

	storage areas for pharmacy stock monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?			
2.10	Is the maximum/minimum **temperature in the dispensary and any additional storage areas for POYC stock** (if applicable) monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.11	Are all medicines stored in the pharmacy in date and is there an active documented expiry date management system in place? *Medicines Act Chapter 458 Article 84 (b)*			
3	**DUTY REGISTER AND THE PHARMACIST**	**YES**	**NO**	**COMMENTS** *(where applicable)*
3.1	Is there a pharmacist supervising the pharmacy for all hours of opening and is this recorded in the locum register? *Medicines Act Chapter 458 Article 74 (g)* *Medicines Act Chapter 458 Article 75(2)(b)*			
3.2	Is the pharmacist wearing a white coat while attending to his professional duties? *Medicines Act Subsidiary Legislation 458.16 Article 13 (3)*			
3.3	Does the pharmacist have the identity tag issued by the Pharmacy Council attached to his coat? *Medicines Act Chapter 458 Subsidiary Legislation 16 Article 13 (3)*			
4	**DAILY DISPENSING REGISTERS** *Medicines Act Chapter 458 Article 86*	**YES**	**NO**	**COMMENTS** *(where applicable)*
4.1	Is the prescription register/ daily dispensing report recorded on a daily basis?			
4.2	Daily dispensing report printed (if applicable) and signed by the pharmacist? *Medicines Act Chapter 458 Subsidiary Legislation 49 Article 6 (2)*			
4.3	Is the prescription register/ daily dispensing report completed in the correct format in accordance with the requirements of Article 6 of the Subsidiary Legislation 458.49 (Prescription and Dispensing Requirements Rules) (as amended)?			

	(date on which the prescription is dispensed, name, quantity and the pharmaceutical form and strength of the product, full name of the prescriber and his registration number, date of the prescription, in the case of medicinal products dispensed incompliance with rule 4(3), the date on which the prescription is received)			
4.4	Are all prescriptions for the previous three months available for review at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 12 (2)*			
5	**DANGEROUS DRUG REGISTERS** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11*	**YES**	**NO**	**COMMENTS** *(where applicable)*
5.1	Is the **Dangerous Drug Sales register for pharmacy stock** kept updated? (Within one-month limit)			
5.2	Is the **Dangerous Drug Purchases register for pharmacy stock** kept updated? (Within one-month limit)			
5.3	Is **Dangerous Drug Sales register for POYC** kept updated? (Within one-month limit)			
5.4	Is the **Dangerous Drug Purchases register kept updated and are invoices kept in an orderly manner for POYC**? (Within one-month limit)			
5.5	Are both dangerous drugs registers from the last inspection available for review?			
5.6	Is the Dangerous Drug Sales Register completed in the correct format in accordance with the requirements of Article 11, 18 and Second Schedule of the Subsidiary Legislation 101.02 (Internal Control of Dangerous Drug Rules) (as amended)? *(name of substance, date on which the prescription is received/ dispensed, name of person from which is obtained/ to which is supplied, quantity and the pharmaceutical form and strength of the product, address of person or entity from which it was obtained/ to whom is dispensed)*			
5.7	Where dangerous drugs have been removed from the active balance, either because they are expired or destroyed is there documentation available?			

6	DANGEROUS DRUG STOCK TAKE	YES	NO	COMMENTS *(where applicable)*
6.1	Is a stock taking exercise carried out yearly and report sent to Medicines Authority? Stock take report headings minimum requirement: Stock level of previous year, Quantity Procured, Quantity Dispensed, Quantity, Quantity Expected and Actual Stock Level *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11 (g)*			
7	**DANGEROUS DRUG CUPBOARD** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 12 (2)*	**YES**	**NO**	**COMMENTS** *(where applicable)*
7.1	Is there a lockable cabinet for the storage of narcotic and psychotropic substances and cannabis-based products in place in the dispensary?			
7.2	Is the key kept solely and all the time by the managing pharmacist?			
7.3	Does the Dangerous Drug cabinet have sufficient capacity to permit the orderly storage of all dangerous drugs and cannabis-based products?			
7.4	Are all narcotic and psychotropic substances and cannabis-based products stored in the dangerous drug safe? Is the cabinet reserved solely for the storage of medicines?			
7.5	Are expired/ patient returned dangerous drugs and cannabis-based products stored in a designated part of the DDA cupboard and appropriately labelled? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
8	**CANNABIS-BASED PRODUCTS** Drug Dependence (Treatment Not Imprisonment) Act, CAP 537, Article 10.	**YES**	**NO**	**COMMENTS** *(where applicable)*
8.1	Do all the cannabis-based products have a Medicines Authority tamper-evident label?			
8.2	Are the serial numbers on the tamper-evident labels being recorded in the DDA register? *Note: Cannabis-based products are considered as DDAs*			

8.3	Are the cannabis-based products sealed and sold sealed?			
9	**EXTEMPORANEOUS PREPARATIONS**	**YES**	**NO**	**COMMENTS** *(where applicable)*
9.1	Are extemporaneous preparations carried out at the pharmacy?			
	If yes, go to 9.2, if not go to 9.9			
9.2	Are preparations labeled with all information required in accordance with regulations or rules made under the Medicines Act? *Comment: Expiry date of 4 weeks for all extemporaneous preparations* *Medicines Act Chapter 458 Article 83* *Medicines Act Chapter 458 Article 87*			
9.3	Are dedicated areas for preparing Extemporaneous Products in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (e)*			
9.4	Is all required equipment available in the pharmacy? *Medicines Act Chapter 458 Article 86* *Medicines Act Chapter 458 Article 87*			
9.5	Electronic balance (accurately measures 0.1g to 200g)			
9.6	Ointment glass/marble slab			
9.7	Spatulas & stirrers			
9.8	Mortars and pestles			
9.9	Graduated cylinders			
9.10	Tablet counter			
9.11	Is all equipment kept in a clean state?			
10	**PREMISES**	**YES**	**NO**	**COMMENTS** *(where applicable)*
10.1	Display box available for displaying Sunday roster? *Medicines Act Subsidiary Legislation 458.16 Article 13 (4)*			
10.2	Are there adequate security arrangements in place, e.g. alarm, shutters, CCTV, glass thickness (minimum 10mm), iron bars as applicable? *Medicines Act Subsidiary Legislation 458.16 Article 9 (i)*			

10.3	Are the **external and internal** premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard? *Medicines Act Subsidiary Legislation 458.16 Article 10*			
10.4	Are all entrances to the premises well maintained, clear and accessible? *Medicines Act Subsidiary Legislation 458.16 Article 9 (a)*			
10.5	Is the trading name of the pharmacy displayed at all entrances to the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*			
10.6	Is a dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (c)*			
10.7	Is there a dedicated dispensary sink/dispenser with access to hot and cold (potable) water? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*			
10.8	Is adequate lighting/ ventilation provided in the dispensary? *Medicines Act Subsidiary Legislation 458.16 Article 9 (g)*			
10.9	Is access to the dispensary and all areas where medicines or confidential records are stored restricted to authorised personnel?			
10.10	Is there a clean and well-maintained toilet and wash hand basin provided at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (j)*			
10.11	Is housekeeping in all areas of the pharmacy maintained at an acceptable standard and is a register countersigned by the managing pharmacist kept in an orderly manner? *Medicines Act Subsidiary Legislation 458.16 Article 9 (d)*			
10.12	Is pest control done annually to all areas of the pharmacy? **Certificate number:** _____			

11	MISCELLANEOUS	YES	NO	COMMENTS *(where applicable)*
11.1	Does the pharmacy have appropriate and up to date reference books? (Recommended BNF within 2 year of issue and Maltese Medicine Handbook) *Medicines Act Subsidiary Legislation 458.16 Article 11* Specify title and issue date:			
11.2	Does the pharmacy have a medicinal product waste bin, and sharp objects bin? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
11.3	Is all waste and patient returned medication stored in a designated area of the pharmacy segregated from active stock pending timely processing? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
12	**VERIFICATION AND DECOMMISSIONING OF MEDICINAL PRODUCTS affected by Regulation 2016/161/EU**	**YES**	**NO**	**COMMENTS** *(where applicable)*
12.1	Do you have a software in place for the verification and decommissioning of Safety Features? *Regulation 2016/161/EU art. 25(3)*			
12.2	Is the verification and decommissioning of the unique identifier performed for the supply to the public of medicinal product affected by the Regulation 2016/161/EU? *Regulation 2016/161/EU art. 25(1)*			

Section H: Extension of the Pharmacy Inspection for Pharmacies carrying out Domiciliary Services (fill in only if service is being carried out)

1	**POLICIES AND STANDARD OPERATING PROCEDURES**	**YES**	**NO**	**COMMENTS** *(where applicable)*
1.1	Is the pharmacy equipped with procedures for all processes carried out for delivery of medicines?			
1.1.1	At a minimum, the following procedures should be in place:			
1.1.1a	National Domiciliary Service 70+ Scheme (as provided by the Chamber of Pharmacists)			
1.1.1 b	Extension of the Delivery of Medicine Service (To include cold chain items and Narcotics and Psychotropic)			
1.1.1c	Training of staff involved in this service			
1.1.1 d	Handling of errors and/or complaints			
2	**SERVICES**	**YES**	**NO**	**COMMENTS** *(where applicable)*
2.1	National Domiciliary 70+ Service			
2.2	Extension of the Delivery of Medicine Service *Please specify:* _____			
2.3	Others *Please specify:* _____			
3	**RECORDS**	**YES**	**NO**	**COMMENTS** *(where applicable)*
3.1	Are prescriptions being kept? *If soft copies are kept, back-up system required* *Please specify:* _____			
3.2	Are temperature records being kept, during transportation of medicinal products? *Temperature logs with Min/ Max records of*			

	vehicle and delivery container for cold chain medicinal products during transport should be available			
3.3	Is an order preparation log being kept? *Order preparation log should consist of 'prepared by' and 'checked by'(pharmacist)*			
3.4	Is a delivery log being kept? *Delivery log should consist of name and address of patient, delivery location, patient and pharmacist signature*			
4	**PROCESS**	**YES**	**NO**	**COMMENTS** *(where applicable)*
4.1	**Order Receipt and Preparation**			
4.1.2	Is there a specific software being used to receive orders and deliver this service? *Please specify and describe role of software:* _____ _____ _____ ____			
4.1.3	Is there a specific area designated for the preparation of medicinal products? *This must be temperature monitored and recorded*			
4.1.4	Are prepared medications labelled appropriately? *At minimum, name and surname, ID card number,* ***contact number*** *and address*			
4.2	**Delivery Procedure**			
4.2.1	Are the cold storage medicines being kept in a validated cool box? *Specify brand:* _____			
4.2.2	Is the vehicle of adequate capacity and of acceptable condition to carry out this service? *Vehicle needs to have a functioning air conditioner system*			
4.2.3	Are boxes and/or bags used to deliver medicine of acceptable condition?			

4.2.4	Are temperature loggers available, for the duration of the delivery?			
4.2.5	Are calibration records available for the temperature loggers used during the delivery process? **Certificate number:** **_____**			
4.2.6	Are distances and areas covered being recorded on the delivery sheets?			
4.2.7	Are deliveries being carried out by a pharmacist? *Only pharmacists can deliver medicines to patients*			

Section J: Inspectors signatures and date:

_____

_

Appendix 3

Self-audit report

Details of pharmacist performing the self-audit

1.1 Locality of practice: _____
(If more than one, please choose the one where you practice the most)

1.2 District of practice:

- ☐ Southern Harbour District
- ☐ Northern Harbour District
- ☐ South Eastern District
- ☐ Western District
- ☐ Northern District
- ☐ Gozo and Comino District

Pharmacist demographics:

1.3 Gender:

- ☐ Female
- ☐ Male
- ☐ X

1.4 Age:

- ☐ 22-30
- ☐ 31-40
- ☐ 41-50
- ☐ 51-60
- ☐ 60+

1.5 Level of education:

- ☐ Graduate
- ☐ Post graduate

1.6 Years of working experience in community pharmacy:

- ☐ Less than 1 year
- ☐ Between 1 year and 5 years
- ☐ Between 6 and 15 years
- ☐ Between 16 and 25 years
- ☐ More than 25 years

1.7 Additional fields of exposure, if applicable:
(more than one answer may be selected)

- ☐ University
- ☐ Hospital pharmacy
- ☐ Pharmaceutical industry
- ☐ Regulatory authority

Part 1: Competencies self-audit

Pharmacist Competencies Self-Audit (PCSA) Tool

Please consider section A as a list of questions provided to help you reflect about your competencies. Then, proceed with completing section B of the PCSA Tool.

Section A

Pharmacist patient-centred approach
2.1 In my practice, am I more concerned about how to help patient or do I tend to hurry up?
2.2 As a pharmacist, do I ensure accessibility for the patient by choosing a cheaper alternative medicine?
Pharmacist clinical skills and interests
2.3 Am I entirely focused on the patient or do I tend to just follow the dispensing process? Do I consider patient medication history and allergies?
2.4 Do I refer to scientific literature when I am unsure about information related to medications and its uses?
2.5 Do I use reliable scientific resources (e.g. latest versions of the British National Formulary, recent scientific articles) to find information related to medicines?
2.6 Do I maintain my knowledge up to date and address my knowledge gaps?
Patient education provided
2.7 Do I ensure that I am understood by patients (e.g. using the most appropriate jargon or ensuring the patient is understanding the therapy)?
2.8 Do I provide both verbal and written information?
Personalised healthcare
2.9 Do I perform medication review (assessment and identification of drug interactions, side effects, consistency in treatment about medications prescribed and dosage regimen), with POYC and/or private patients?
2.10 Do I educate patients and ensure that all medications are taken as prescribed?
2.11 Do I safeguard patient empowerment by considering the patients' opinions in the decision-making process?
Medicines accessibility
2.12 Do I ensure timely access to medicines by contacting agents or other pharmacies?
Pharmacist soft skills and multidisciplinary collaboration
2.13 Do I listen carefully what the patient has to say?
2.14 How do I welcome the patients? Are patients comfortable when interacting with me?

2.15 Am I inclined to build a relationship of trust with patients? 2.16 Do I collaborate with other healthcare professionals, when necessary (e.g. telephone conversations discussing therapeutic strategies, referring patient to healthcare professionals, etc.)? 2.17 When an incongruity arises (e.g. disagreement of pharmacist with therapeutic regimen/therapeutic agent/pharmaceutical form/etc...), do I communicate with other healthcare professionals?
Pharmacist compliance with regulatory requirements 2.18 Do I make sure that medicines are stored safely and do I ensure that the quality of medicines is maintained?

Section B

Please list how you can apply your strengths and personal interests in your daily practice. Specify strategies for your goals and areas for improvement.

Strengths and how do you apply them in your daily practice

_____

_____

_____

Scientific interests and their application during your daily practice

_____

_____

_____

Goals and achievement plan

_____

_____

_____

What would you be willing to do to improve your job performance?

_____

_____

_____

Part 2: Regulatory Self-Audit (RSA)

Date of Self-audit: _____

Section A: Dispensary Details:

i. **Name:**
ii. **Locality:**
iii. **Email address:**
iv. **Telephone number:**

Section B:

	YES	NO
Any change in pharmacy address? **If yes, enter details;**		
Any change in license holder/ address? **If yes, enter details;**		

Section C: Name, registration number and contact details of the managing pharmacist*:

i. **Name:**
ii. **Registration number:**
iii. **Mobile number:**

***If the managing pharmacist is not present, what is the name and registration number of the locum pharmacist present at the inspection?**

1. **Name:**
2. **Registration number:**

Section D: Managing/ locum pharmacist signature: _____

Section E: as per Chapter 343 Employment and Training Services Act

1	**Employees**	**Number**
1.1	How many people are employed at the pharmacy?	
1.1.1	-On full time basis?	
1.1.2	-On part time basis?	

2. *List Name, Surname and ID number for each*

Name and Surname	**ID number**

Section F: as per Chapter 378 Consumer Affairs Act Subsidiary Legislation 378.09

1	**Price Regulation**	**YES**	**NO**	**Comments** *(if applicable)*
1.1	Is the price indicated on or near all products sold?			

Section G: as per Chapter 458 The Medicines Act

1	**REGISTRATION CERTIFICATES**	**YES**	**NO**	**COMMENTS** *(if applicable)*
1.1	Is the current certificate of registration for the pharmacy available at the pharmacy and is it displayed such that it is legible from the public pharmacy area? *Medicines Act Chapter 458 Article 66 (1)*			
2	**STORAGE OF MEDICINAL PRODUCTS** *Medicines Act Chapter 458 Article 85 (1) and (2) Medicines Act Chapter 458 Article 86*	**YES**	**NO**	**COMMENTS** *(if applicable)*
2.1	Are all medicines stored in an area of the pharmacy under the control of the pharmacist?			
2.2	Is the fridge clean with only medicinal products stored within?			
2.3	Are all medicines stored in the fridge in good condition?			
2.4	Is the fridge of an adequate capacity to permit the orderly storage of medicines? *Comment: pharmaceutical grade fridges recommended*			
2.5	Are the thermometers calibrated annually? **Certificate number:_____**			
2.6	Is the air conditioner serviced annually? **Certificate number: _____**			
2.7	Is the maximum/minimum **fridge temperature for the pharmacy stock** monitored, recorded and reviewed, on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.8	Is the maximum/minimum **fridge temperature for the POYC stock** (if applicable) monitored, recorded and reviewed, on a daily basis, as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.9	Is the maximum/minimum **temperature in the dispensary and any additional storage areas for pharmacy stock** monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.10	Is the maximum/minimum **temperature in the dispensary and any additional storage areas for POYC stock** (if applicable) monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**YES**	**NO**	**N/A**
2.11	Are all medicines stored in the pharmacy in date and is there an active documented expiry date management system in place? *Medicines Act Chapter 458 Article 84 (b)*			

3	**DUTY REGISTER AND THE PHARMACIST IDENTIFICATION**	**YES**	**NO**	**COMMENTS** *(if applicable)*
3.1	Is there a pharmacist supervising the pharmacy for all hours of opening and is this recorded in the locum register? *Medicines Act Chapter 458 Article 74 (g) Medicines Act Chapter 458 Article 75(2)(b)*			
3.2	Is the pharmacist wearing a white coat while attending to his professional duties? *Medicines Act Subsidiary Legislation 458.16 Article 13 (3)*			
3.3	Does the pharmacist have the identity tag issued by the Pharmacy Council attached to his coat? *Medicines Act Chapter 458 Subsidiary Legislation 16 Article 13 (3)*			
4	**DAILY DISPENSING REGISTERS** *Medicines Act Chapter 458 Article 86*	**YES**	**NO**	**COMMENTS** *(if applicable)*
4.1	Is the prescription register/ daily dispensing report recorded on a daily basis?			
4.2	Daily dispensing report printed (if applicable) and signed by the pharmacist? *Medicines Act Chapter 458 Subsidiary Legislation 49 Article 6 (2)*			
4.3	Is the prescription register/ daily dispensing report completed in the correct format in accordance with the requirements of Article 6 of the Subsidiary Legislation 458.49 (Prescription and Dispensing Requirements Rules) (as amended)? *(date on which the prescription is dispensed, name, quantity and the pharmaceutical form and strength of the product, full name of the prescriber and his registration number, date of the prescription, in the case of medicinal products dispensed incompliance with rule 4(3), the date on which the prescription is received)*			
4.4	Are all prescriptions for the previous three months available for review at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 12 (2)*			

5	**DANGEROUS DRUG REGISTERS** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11*	**YES**	**NO**	**COMMENTS** *(if applicable)*
5.1	Is the **Dangerous Drug Sales register for pharmacy stock** kept updated? (Within one-month limit)			
5.2	Is the **Dangerous Drug Purchases register for pharmacy stock** kept updated? (Within one-month limit)			
5.3	Is **Dangerous Drug Sales register for POYC** kept updated? (Within one-month limit)			
5.4	Is the **Dangerous Drug Purchases register kept updated and are invoices kept in an orderly manner for POYC**? (Within one-month limit)			
5.5	Are both dangerous drugs registers from the last inspection available for review?			
5.6	Is the Dangerous Drug Sales Register completed in the correct format in accordance with the requirements of Article 11, 18 and Second Schedule of the Subsidiary Legislation 101.02 (Internal Control of Dangerous Drug Rules) (as amended)?*(name of substance, date on which the prescription is received/ dispensed, name of person from which is obtained/ to which is supplied, quantity and the pharmaceutical form and strength of the product, address of person or entity from which it was obtained/ to whom is dispensed)*			
5.7	Where dangerous drugs have been removed from the active balance, either because they are expired or destroyed is there documentation available?			

6	**DANGEROUS DRUG STOCK TAKE**	**YES**	**NO**	**COMMENTS** *(if applicable)*
6.1	Is a stock taking exercise carried out yearly and report sent to Medicines Authority? *Stock take report headings minimum requirement: Stock level of previous year, Quantity Procured, Quantity Dispensed, Quantity, Quantity Expected and Actual Stock Level* *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11 (g)*			
7	**DANGEROUS DRUG CUPBOARD** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 12 (2)*	**YES**	**NO**	**COMMENTS** *(if applicable)*
7.1	Is there a lockable cabinet for the storage of narcotic and psychotropic substances and cannabis-based products in place in the dispensary?			
7.2	Is the key kept solely and all the time by the managing pharmacist?			
7.3	Does the Dangerous Drug cabinet have sufficient capacity to permit the orderly storage of all dangerous drugs and cannabis-based products?			
7.4	Are all narcotic and psychotropic substances and cannabis-based products stored in the dangerous drug safe? Is the cabinet reserved solely for the storage of medicines?			
7.5	Are expired/ patient returned dangerous drugs and cannabis-based products stored in a designated part of the DDA cupboard and appropriately labelled? *Medicines Act Chapter 458 Article 84 Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
8	**CANNABIS-BASED PRODUCTS** *Drug Dependence (Treatment Not Imprisonment) Act, CAP 537, Article 10.*	**YES**	**NO**	**COMMENTS** *(if applicable)*
8.1	Do all the cannabis-based products have a Medicines Authority tamper-evident label?			
8.2	Are the serial numbers on the tamper-evident labels being recorded in the DDA register? *Note: Cannabis-based products are considered as DDAs*			
8.3	Are the cannabis-based products sealed and sold sealed?			

9	**EXTEMPORANEOUS PREPARATIONS**	**YES**	**NO**	**COMMENTS** *(if applicable)*
9.1	Are extemporaneous preparations carried out at the pharmacy?			
If yes, go to 9.2, if not go to 9.9				
9.2	Are preparations labeled with all information required in accordance with regulations or rules made under the Medicines Act? *Comment: Expiry date of 4 weeks for all extemporaneous preparations Medicines Act Chapter 458 Article 83 Medicines Act Chapter 458 Article 87*			
9.3	Are dedicated areas for preparing Extemporaneous Products in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (e)*			
9.4	Is all required equipment available in the pharmacy? *Medicines Act Chapter 458 Article 86 Medicines Act Chapter 458 Article 87*			
9.5	Electronic balance (accurately measures 0.1g to 200g)			
9.6	Ointment glass/marble slab			
9.7	Spatulas & stirrers			
9.8	Mortars and pestles			
9.9	Graduated cylinders			
9.10	Tablet counter			
9.11	Is all equipment kept in a clean state?			

10	PREMISES	YES	NO	COMMENTS *(if applicable)*
10.1	Display box available for displaying Sunday roster? *Medicines Act Subsidiary Legislation 458.16 Article 13 (4)*			
10.2	Are there adequate security arrangements in place, e.g. alarm, shutters, CCTV, glass thickness (minimum 10mm), iron bars as applicable? *Medicines Act Subsidiary Legislation 458.16 Article 9 (i)*			
10.3	Are the **external and internal** premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard? *Medicines Act Subsidiary Legislation 458.16 Article 10*			
10.4	Are all entrances to the premises well maintained, clear and accessible? *Medicines Act Subsidiary Legislation 458.16 Article 9 (a)*			
10.5	Is the trading name of the pharmacy displayed at all entrances to the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*			
10.6	Is a dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (c)*			
10.7	Is there a dedicated dispensary sink/dispenser with access to hot and cold (potable) water? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*			
10.8	Is adequate lighting/ ventilation provided in the dispensary? *Medicines Act Subsidiary Legislation 458.16 Article 9 (g)*			
10.9	Is access to the dispensary and all areas where medicines or confidential records are stored restricted to authorised personnel?			
10.10	Is there a clean and well-maintained toilet and wash hand basin provided at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (j)*			
10.11	Is housekeeping in all areas of the pharmacy maintained at an acceptable standard and is a register countersigned by the managing pharmacist kept in an orderly manner? *Medicines Act Subsidiary Legislation 458.16 Article 9 (d)*			
10.12	Is pest control done annually to all areas of the pharmacy? **Certificate number: _____**			

11	**MISCELLANEOUS**	**YES**	**NO**	**COMMENTS** *(if applicable)*
11.1	Does the pharmacy have appropriate and up to date reference books? (Recommended BNF within 2 year of issue and Maltese Medicine Handbook) *Medicines Act Subsidiary Legislation 458.16 Article 11* Specify title and issue date:			
11.2	Does the pharmacy have a medicinal product waste bin, and sharp objects bin? *Medicines Act Chapter 458 Article 84 Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
11.3	Is all waste and patient returned medication stored in a designated area of the pharmacy segregated from active stock pending timely processing? *Medicines Act Chapter 458 Article 84 Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*			
12	**VERIFICATION AND DECOMMISSIONING OF MEDICINAL PRODUCTS affected by Regulation 2016/161/EC**	**YES**	**NO**	**COMMENTS** *(if applicable)*
12.1	Do you have a software in place for the verification and decommissioning of Safety Features? *Regulation 2016/161/EC art. 25(3)*			
12.2	Is the verification and decommissioning of the unique identifier performed for the supply to the public of medicinal product affected by the Regulation 2016/161/EU? *Regulation 2016/161/EC art. 25(1)*			

Section H: Extension of the Pharmacy Inspection for Pharmacies carrying out Domiciliary Services (fill in only if service is being carried out)

1	**POLICIES AND STANDARD OPERATING PROCEDURES**	**YES**	**NO**	**COMMENTS** *(if applicable)*
1.1	Is the pharmacy equipped with procedures for all processes carried out for delivery of medicines?			
1.1.1	At a minimum, the following procedures should be in place:			
1.1.1a	National Domiciliary Service 70+ Scheme (as provided by the Chamber of Pharmacists)			
1.1.1b	Extension of the Delivery of Medicine Service *(To include cold chain items and Narcotics and Psychotropic)*			
1.1.1c	Training of staff involved in this service			
1.1.1d	Handling of errors and/or complaints			
2	**SERVICES**	**YES**	**NO**	**COMMENTS** *(if applicable)*
2.1	National Domiciliary 70+ Service			
2.2	Extension of the Delivery of Medicine Service *Please specify:* _____			
2.3	Others *Please specify:* _____			
3	**RECORDS**	**YES**	**NO**	**COMMENTS** *(if applicable)*
3.1	Are prescriptions being kept? *If soft copies are kept, back-up system required* *Please specify:* _____			
3.2	Are temperature records being kept, during transportation of medicinal products? *Temperature logs with Min/ Max records of vehicle and delivery container for cold chain medicinal products during transport should be available*			
3.3	Is an order preparation log being kept? *Order preparation log should consist of 'prepared by' and 'checked by'(pharmacist)*			
3.4	Is a delivery log being kept? *Delivery log should consist of name and address of patient, delivery location, patient and pharmacist signature*			

4	PROCESS	YES	NO	COMMENTS *(if applicable)*
4.1	**Order Receipt and Preparation**			
4.1.2	Is there a specific software being used to receive orders and deliver this service? *Please specify and describe role of software:_____*			
4.1.3	Is there a specific area designated for the preparation of medicinal products? *This must be temperature monitored and recorded*			
4.1.4	Are prepared medications labelled appropriately? *At minimum, name and surname, ID card number, **contact number** and address*			
4.2	**Delivery Procedure**	**YES**	**NO**	**COMMENTS** *(if applicable)*
4.2.1	Are the cold storage medicines being kept in a validated cool box? *Specify brand: _____*			
4.2.2	Is the vehicle of adequate capacity and of acceptable condition to carry out this service? *Vehicle needs to have a functioning air conditioner system*			
4.2.3	Are boxes and/or bags used to deliver medicine of acceptable condition?			
4.2.4	Are temperature loggers available, for the duration of the delivery?			
4.2.5	Are calibration records available for the temperature loggers used during the delivery process? **Certificate number: _____**			
4.2.6	Are distances and areas covered being recorded on the delivery sheets?			
4.2.7	Are deliveries being carried out by a pharmacist? *Only pharmacists can deliver medicines to patients*			

Section I: Accessibility to all as per Chapter 413 Equal Opportunities (Persons with Disability) Act

Is the main entrance accessible to all? *(at least 900mm wide and if there are steps should have a ramp)*	YES	NO
Does the building have accessible sanitary facilities?	YES	NO
Does the building have more than 1 floor?	YES	NO
Does the building have a lift?	YES	NO
Is the lift accessible to all? *(does it accommodate a wheelchair)*	YES	NO
Does the counter have a portion which is not higher than 760mm from floor level?	YES	NO
	N/A	

For further information and measurements regarding accessible environment, please refer to SM3800:2015 Accessibility for All in the Built Environment available from http://crpd.org.mt/wp-content/uploads/2016/04/Access-for-all-2011.pdf .

For matters relating to discrimination, please refer to the Equal Opportunities (Persons with Disability) Act, Chapter 413 of the Laws of Malta

http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8879&l=1

Section J: Inspectors signatures and date:

Appendix 4

Tool validation

Pharmacist Competencies Self-Assessment tool validation

Table A4.1: Round 1: I-CVIs for relevance, clarity, structure and layout

	Relevance		**Clarity**		**Structure & Layout**	
	Expert	**I-CVI**	**Expert**	**I-CVI**	**Expert**	**I-CVI**
1.1 Pharmacist name:	**6**	**0,75**	**8**	**1**	7	1
1.2 Locality of Practice (Please choose the one you spend more time in):	**6**	**0,75**	**8**	**1**	**6**	0,75
1.3 District of practice	**6**	**0,75**	**7**	**0,875**	**5**	0,625
1.4 Gender	**8**	**1**	**7**	**0,875**	8	1
1.5 Age	**8**	**1**	**8**	**1**	8	1
1.6 Qualification level	**7**	**0,875**	**8**	**1**	8	1
1.7 Years of working experience in community pharmacy	**8**	**1**	**8**	**1**	8	1
1.8 Additional fields of exposure (if applicable)	**8**	**1**	**8**	1	**6**	0,75
2.1 In my practice, am I more concerned about how to help patient or do I tend to hurry up?	**8**	**1**	**8**	**1**	8	1
2.2 Do I recommend the most appropriate alternative for the patient, by taking into consideration price accessibility?	**8**	**1**	**7**	**0,875**	7	0,875
2.3 Do I look at the patient entirely or do I just stick to the dispensing process?	**8**	**1**	**7**	**0,875**	7	0,875
2.4 When I am not sure about information which regards medications do I look up for it?	**8**	**1**	**5**	**0,625**	5	0,625
2.5 Which resources do I take into consideration? Are those reliable scientific sources?	**8**	**1**	**8**	**1**	7	0,875
2.6 Do I maintain my knowledge up to date and address my knowledge gaps?	**8**	**1**	**8**	**1**	8	1
2.7 Do I make sure that the patient understands me by using appropriate jargon and by making sure that the patient understood?	**8**	**1**	**7**	**0,875**	7	0,875
2.8 Do I provide both verbal and written information?	**8**	**1**	**8**	**1**	8	1
2.9 Do I perform medical review, especially with POYC patients?	**8**	**1**	**6**	**0,75**	7	0,875

Continued Table A4.1: Round 1	**Relevance**		**Clarity**		**Structure & Layout**	
	Expert	**I-CVI**	**Expert**	**I-CVI**	**Expert**	**I-CVI**
2.10 Do I educate patients and make sure that all medications are taken as prescribed, while ensuring patient safety and treatment effectiveness?	**8**	**1**	**8**	**1**	8	1
2.11 Do I listen to patients' opinions and involve them in decision concerning their health?	**8**	**1**	**8**	**1**	8	1
2.12 Do I make sure that the patient has timely access to medicines by contacting agents or other pharmacies nearby?	**8**	**1**	**8**	**1**	8	1
2.13 Do I listen carefully to the patient? Am I patient when dealing with clients?	**8**	**1**	**6**	**0,75**	6	0,75
2.14 How do I welcome the patients? Are patients comfortable when interacting with me?	**8**	**1**	**7**	**0,875**	7	0,875
2.15 Am I inclined to build a relationship of trust with patients?	**8**	**1**	**8**	**1**	8	1
2.16 Am I really willing to help patients or am I just interested in performing my job with the least effort possible?	**8**	**1**	**7**	**0,875**	8	1
2.17 Do I collaborate with other healthcare professionals, if necessary?	**8**	**1**	**7**	**0,875**	8	1
2.18 Do I communicate with other healthcare professionals when a non- incongruity is found?	**8**	**1**	**6**	**0,75**	6	0,75
2.19 Do I make sure that medicines are stored safely and in a way to make sure that quality is maintained?	**8**	**1**	**8**	**1**	8	1
3.1 Strengths and how do you apply them in your daily work	**8**	**1**	**8**	**1**	8	1
3.2 Personal interest and how do you apply them in your daily work	**7**	**0,875**	**8**	**1**	8	1
3.3 Goals and what is your plan to achieve them	**8**	**1**	**8**	**1**	8	1
3.4 Areas of improvement and what would you be willing to do to improve	**8**	**1**	**8**	**1**	7	0,875

Table A4.2: Round 2: I-CVIs for relevance, clarity, structure and layout

	Relevance		Clarity		Structure & Layout		Actions taken
	Expert	I-CVI	Expert	I-CVI	Expert	I-CVI	
1.1 Pharmacist initials:	5	0,625	8	1	8	1	Eliminated:
1.2 Locality of Practice (Please choose the one you spend more time in):	8	1	8	1	8	1	
1.3 District of practice	7	0,875	8	1	8	1	Kept for statistics
1.4 Gender	7	0,875	8	1	8	1	
1.5 Age	8	1	8	1	8	1	
1.6 Qualification level	8	1	8	1	8	1	
1.7 Years of working experience in community pharmacy	8	1	8	1	8	1	
1.8 Additional fields of exposure (if applicable)	8	1	8	1	8	1	
2.1 In my practice, am I more concerned about how to help patient or do I tend to hurry up?	8	1	8	1	7	0,875	
2.2 Do I recommend the most appropriate alternative for the patient, by taking into consideration price accessibility?	8	1	8	1	8	1	Implemented
2.3 Do I look at the patient entirely or do I just stick to the dispensing process?	8	1	8	1	7	0,875	changed to tend, implemented
2.4 When I am not sure about information which regards medications do I look up for it?	7	0,875	8	1	8	1	
2.5 Which resources do I take into consideration? Are those reliable scientific sources?	8	1	8	1	8	1	implemented
2.6 Do I maintain my knowledge up to date and address my knowledge gaps?	8	1	8	1	8	1	
2.7 Do I make sure that the patient understands me by using appropriate jargon and by making sure that the patient understood?	8	1	8	1	8	1	implemented

Continued Table A4.2 Round 2	**Relevance**		**Clarity**		**Structure & Layout**		**Actions taken**
	Expert	**I-CVI**	**Expert**	**I-CVI**	**Expert**	**I-CVI**	
2.8 Do I provide both verbal and written information?	**8**	**1**	**8**	**1**	**8**	**1**	
2.9 Do I perform medical review, especially with POYC patients?	**8**	**1**	**8**	**1**	**8**	**1**	Implemented
2.10 Do I educate patients and make sure that all medications are taken as prescribed, while ensuring patient safety and treatment effectiveness?	**8**	**1**	**8**	**1**	**8**	**1**	
2.11 Do I listen to patients' opinions and involve them in decision concerning their health?	**8**	**1**	**8**	**1**	**8**	**1**	
2.12 Do I make sure that the patient has timely access to medicines by contacting agents or other pharmacies nearby?	**8**	**1**	**8**	**1**	**8**	**1**	
2.13 Do I listen carefully to the patient? Am I patient when dealing with clients?	**7**	**0,875**	**8**	**1**	**8**	**1**	Implemented
2.14 How do I welcome the patients? Are patients comfortable when interacting with me?	**8**	**1**	**8**	**1**	**8**	**1**	
2.15 Am I inclined to build a relationship of trust with patients?	**8**	**1**	**8**	**1**	**8**	**1**	
2.16 Do I collaborate with other healthcare professionals, if necessary?	**8**	**1**	**8**	**1**	**8**	**1**	
2.17 Do I communicate with other healthcare professionals when a non-incongruity is found?	**8**	**1**	**8**	**1**	**8**	**1**	Implemented
2.18 Do I make sure that medicines are stored safely and in a way to make sure that quality is maintained?	**8**	**1**	**8**	**1**	**8**	**1**	implemented.
3.1 Strengths and how do you apply them in your daily work	**8**	**1**	**8**	**1**	**8**	**1**	
3.2 Scientific interest and how do you apply them in your daily work	**8**	**1**	**8**	**1**	**8**	**1**	
3.3 Goals and what is your plan to achieve them	**8**	**1**	**8**	**1**	**8**	**1**	
3.4 Areas of improvement and what would you be willing to do to improve	**8**	**1**	**8**	**1**	**8**	**1**	

Appendix 5

Risk assessment

Regulatory report: Risk assessment

Date of Self-audit: _____

Section A: Dispensary Details:

v. **Name:**
vi. **Locality:**
vii. **Email address:**
viii. **Telephone number:**

Section B:

	YES	NO
Any change in pharmacy address? **If yes, enter details;**		
Any change in license holder/ address? **If yes, enter details;**		

Section C: Name, registration number and contact details of the managing pharmacist*:

iv. **Name:**
v. **Registration number:**
vi. **Mobile number:**

***If the managing pharmacist is not present, what is the name and registration number of the locum pharmacist present at the inspection?**

3. **Name:**
4. **Registration number:**

Section D: Managing/ locum pharmacist signature: _____

Section E: as per Chapter 343 Employment and Training Services Act

1	**Employees**	**Number**
1.1	How many people are employed at the pharmacy?	
1.1.1	-On full time basis?	
1.1.2	-On part time basis?	

2. *List Name, Surname and ID number for each*

Name and Surname	**ID number**

Section F: as per Chapter 378 Consumer Affairs Act Subsidiary Legislation 378.09

1	**Price Regulation**	**YES**	**NO**	**Comments** *(if applicable)*
1.1	Is the price indicated on or near all products sold?			

Section G as per Chapter 458 The Medicines Act

1	**Storage of Medicinal Products** *Medicines Act Chapter 458 Article 85 (1) and (2)* *Medicines Act Chapter 458 Article 86*	**Average rounded**
1.1	Are all medicines stored in an area of the pharmacy under the control of the pharmacist?	**3**
1.2	Is the fridge clean with only medicinal products stored within?	**2**
1.3	Are all medicines stored in the fridge in good condition?	**3**
1.4	Is the fridge of an adequate capacity to permit the orderly storage of medicines? *Comment: pharmaceutical grade fridges recommended*	**2**
1.5	Are all medicines stored in the pharmacy in date and is there an active documented expiry date management system in place? *Medicines Act Chapter 458 Article 84 (b)*	**3**
2	**The pharmacist identification**	
2.1	Is the pharmacist wearing a white coat while attending to his professional duties? *Medicines Act Subsidiary Legislation 458.16 Article 13 (3)*	**1**
2.2	Does the pharmacist have the identity tag issued by the Pharmacy Council attached to his coat? *Medicines Act Chapter 458 Subsidiary Legislation 16 Article 13 (3)*	**2**
3	**Appliances and Premises Certificates**	
3.1	Is the current certificate of registration for the pharmacy available at the pharmacy and is it displayed such that it is legible from the public pharmacy area? *Medicines Act Chapter 458 Article 66 (1)*	**1**
3.2	Is the air conditioner serviced annually? **Certificate number:_____**	**2**
3.3	Is pest control done annually to all areas of the pharmacy? **Certificate number:_____**	**2**

4	**Temperature records and certificates**	
4.1	Are the thermometers calibrated annually? **Certificate number/s:_____**	**2**
4.2	Is the maximum/minimum **fridge temperature for the pharmacy stock** monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**3**
4.3	Is the maximum/minimum **fridge temperature for the POYC stock** (if applicable) monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**3**
4.4	Is the maximum/minimum **temperature in the dispensary and any additional storage areas for pharmacy stock** monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**3**
4.5	Is the maximum/minimum **temperature in the dispensary and any additional storage areas for POYC stock** (if applicable) monitored, recorded and reviewed on a daily basis as per the Medicines Act Guidelines on the Storage of Medicinal Products within a Pharmacy?	**3**
5	**Locum Register** *Medicines Act Chapter 458 Article 74 (g)* *Medicines Act Chapter 458 Article 75(2)(b)*	
5.1	Is there a pharmacist supervising the pharmacy for all hours of opening and is this recorded in the locum register?	**3**
6	**Cleaning register** *Medicines Act Subsidiary Legislation 458.16 Article 9 (d)*	
6.1	Is housekeeping in all areas of the pharmacy maintained at an acceptable standard and is a register countersigned by the managing pharmacist kept in an orderly manner?	**2**

7	**Daily Dispensing Registers** *Medicines Act Chapter 458 Article 86*	
7.1	Is the prescription register/ daily dispensing report recorded on a daily basis?	**2**
7.2	Daily dispensing report printed (if applicable) and signed by the pharmacist? *Medicines Act Chapter 458 Subsidiary Legislation 49 Article 6(2)*	**1**
7.3	Is the prescription register/ daily dispensing report completed in the correct format in accordance with the requirements of Article 6 of the Subsidiary Legislation 458.49 (Prescription and Dispensing Requirements Rules) (as amended)? *(date on which the prescription is dispensed, name, quantity and the pharmaceutical form and strength of the product, full name of the prescriber and his registration number, date of the prescription, in the case of medicinal products dispensed incompliance with rule 4(3), the date on which the prescription is received)*	**1**
7.4	Are all prescriptions for the previous three months available for review at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 12 (2)*	**1**
8	**Dangerous Drug Registers** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11*	
8.1	Is the **Dangerous Drug Sales register for pharmacy stock kept** updated? (Within 1 month limit)	**3**
8.2	Is the **Dangerous Drug Purchases register for pharmacy stock kept** updated? (Within 1 month limit)	**3**
8.3	Is **Dangerous Drug Sales register for POYC** kept updated? (Within 1 month limit)	**2**
8.4	Is the **Dangerous Drug Purchases register kept updated and are invoices kept in an orderly manner for POYC**? (Within 1 month limit)	**2**
8.5	Are both dangerous drugs registers from the last inspection available for review?	**1**
8.6	Is the Dangerous Drug Sales Register completed in the correct format in accordance with the requirements of Article 11, 18 and Second Schedule of the Subsidiary Legislation 101.02 (Internal Control of Dangerous Drug Rules) (as amended)? *(name of substance, date on which the prescription is received/ dispensed , name of person from which is obtained/ to which is supplied, quantity and the pharmaceutical form and strength of the product, address of person or entity from which it was obtained/ to whom is dispensed)*	**2**

8.7	Where dangerous drugs have been removed from the active balance, either because they are expired or destroyed is there documentation available?	**2**
9	**Dangerous Drug Stock Take**	
9.1	Is a stock taking exercise carried out yearly and report sent to Medicines Authority for Dangerous Drugs and cannabis- based products? *Stock take report headings minimum requirement: Stock level of previous year, Quantity Procured, Quantity Dispensed, Quantity, Quantity Expected and Actual Stock Level* *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 11 (g)*	**2**
10	**Dangerous Drug Cupboard** *Dangerous Drugs Ordinance Subsidiary Legislation 101.02 Article 12 (2)*	
10.1	Is there a lockable cabinet for the storage of narcotic and psychotropic substances and cannabis-based products in place in the dispensary?	**3**
10.2	Is the key kept solely and all the time by the managing pharmacist?	**2**
10.3	Does the Dangerous Drug cabinet have sufficient capacity to permit the orderly storage of all dangerous drugs and cannabis-based products?	**2**
10.4	Are all narcotic and psychotropic substances and cannabis-based products stored in the dangerous drug safe? Is the cabinet reserved solely for the storage of medicines?	**2**
10.5	Are expired/ patient returned dangerous drugs and cannabis-based products stored in a designated part of the DDA cupboard and appropriately labelled? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*	**3**
11	**Cannabis-based products** *Drug Dependence (Treatment Not Imprisonment) Act, CAP 537, Article 10*	
11.1	Do all the cannabis-based products have an Medicines Authority tamper-evident label?	**3**
11.2	Are the serial numbers on the tamper-evident labels being recorded in the DDA register? *Note: Cannabis-based products are considered as DDAs*	**3**
11.3	Are the cannabis-based products sealed and sold sealed?	**3**

12	**Extemporaneous Preparations**	
12.1	Are extemporaneous preparations carried out at the pharmacy?	
12.2	Are preparations labeled with all information required in accordance with regulations or rules made under the Medicines Act? *Comment:* *Expiry date of 4 weeks for all extemporaneous preparations* *Medicines Act Chapter 458 Article 83* *Medicines Act Chapter 458 Article 87*	**2**
12.3	Are dedicated areas for preparing Extemporaneous Products in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (e)*	**2**
12.4	Is all required equipment available in the pharmacy? *Medicines Act Chapter 458 Article 86* *Medicines Act Chapter 458 Article 87*	**2**
12.5	Electronic balance (accurately measures 0.1g to 200g)	**2**
12.6	Ointment glass/marble slab	**1**
12.7	Spatulas & stirrers	**1**
12.8	Mortars and pestles	**1**
12.9	Graduated cylinders	**1**
12.10	Tablet counter	**1**
12.11	Is all equipment kept in a clean state?	**2**

13	**Premises**	
13.1	Display box available for displaying Sunday roster? *Medicines Act Subsidiary Legislation 458.16 Article 13 (4)*	**2**
13.2	Are there adequate security arrangements in place, e.g. alarm, shutters, CCTV, glass thickness (minimum 10mm), iron bars as applicable? *Medicines Act Subsidiary Legislation 458.16 Article 9 (i)*	**2**
13.3	Are the **external and internal** premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard? *Medicines Act Subsidiary Legislation 458.16 Article 10*	**1**
13.4	Are all entrances to the premises well maintained, clear and accessible? *Medicines Act Subsidiary Legislation 458.16 Article 9 (a)*	**1**
13.5	Is the trading name of the pharmacy displayed at all entrances to the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*	**1**
13.6	Is a dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity in place? *Medicines Act Subsidiary Legislation 458.16 Article 9 (c)*	**1**
13.7	Is there a dedicated dispensary sink/dispenser with access to hot and cold (potable) water? *Medicines Act Subsidiary Legislation 458.16 Article 9 (b)*	**2**
13.8	Is adequate lighting/ ventilation provided in the dispensary? *Medicines Act Subsidiary Legislation 458.16 Article 9 (g)*	**1**
13.9	Is access to the dispensary and all areas where medicines or confidential records are stored restricted to authorised personnel?	**2**
13.10	Is there a clean and well maintained toilet and wash hand basin provided at the premises? *Medicines Act Subsidiary Legislation 458.16 Article 9 (j)*	**1**

14	**Miscellaneous**	
14.1	Does the pharmacy have appropriate and up to date reference books? (Recommended BNF within 2 year of issue and Maltese Medicine Handbook) *Medicines Act Subsidiary Legislation 458.16 Article 11* *Specify title and issue date:*	**2**
14.2	Does the pharmacy have a medicinal product waste bin, and sharp objects bin? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*	**2**
14.3	Is all waste and patient returned medication stored in a designated area of the pharmacy segregated from active stock pending timely processing? *Medicines Act Chapter 458 Article 84* *Medicines Act Subsidiary Legislation 458.16 Article 9 (k)*	**2**
15	**Verification and decommissioning of medicinal products affected by Regulation 2016/161/EU**	
15.1	Do you have a software in place for the verification and decommissioning of Safety Features? *Regulation 2016/161/EU art. 25(3)*	**3**
15.2	Is the verification and decommissioning of the unique identifier performed for the supply to the public of medicinal product affected by the Regulation 2016/161/EU? *Regulation 2016/161/EU art. 25(1)*	**3**

Section H: Extension of the Pharmacy Inspection for Pharmacies carrying out Domiciliary Services (fill in only if service is being carried out)

1	**Policies and Standard Operating Procedures**	
1.1	Is the pharmacy equipped with procedures for all processes carried out for delivery of medicines?	
	At a minimum, the following procedures should be in place:	
	National Domiciliary Service 70+ Scheme (as provided by the Chamber of Pharmacists)	
	Extension of the Delivery of Medicine Service (To include cold chain items and Narcotics and Psychotropic)	
	Training of staff involved in this service	
	Handling of errors and/or complaints	

2	**Services**	
2.1	National Domiciliary 70+ Service	
2.2	Extension of the Delivery of Medicine Service *Please specify: _____*	
2.3	Others *Please specify: _____*	
3	**Records**	
3.1	Are prescriptions being kept? *If soft copies are kept, back-up system required*	**2**
3.2	Are temperature records being kept, during transportation of medicinal products? *Temperature logs with Min/ Max records of vehicle and delivery container for cold chain medicinal products during transport should be available*	**3**
3.3	Is an order preparation log being kept? *Order preparation log should consist of 'prepared by' and 'checked by'(pharmacist)*	**2**
3.4	Is a delivery log being kept? *Delivery log should consist of name and address of patient, delivery location, patient and pharmacist signature*	**2**

4	**Process**	
4.1.2	Is there a specific software being used to receive orders and deliver this service? *Please specify and describe role of software:* _____	**1**
4.1.3	Is there a specific area designated for the preparation of medicinal products? *This must be temperature monitored and recorded*	**1**
4.1.4	Are prepared medications labelled appropriately? *At minimum, name and surname, ID card number, **contact number** and address*	**2**
4.2	**Delivery Procedure**	
4.2.1	Are the cold storage medicines being kept in a validated cool box? *Specify brand:*_____	**3**
4.2.2	Is the vehicle of adequate capacity and of acceptable condition to carry out this service? *Vehicle needs to have a functioning air conditioner system*	**2**
4.2.3	Are boxes and/or bags used to deliver medicine of acceptable condition?	**3**
4.2.4	Are temperature loggers available, for the duration of the delivery?	**3**
4.2.5	Are calibration records available for the temperature loggers used during the delivery process? **Certificate number:_____**	**3**
4.2.6	Are distances and areas covered being recorded on the delivery sheets?	**2**
4.2.7	Are deliveries being carried out by a pharmacist? *Only pharmacists are allowed to deliver medicines to patients*	**3**

Section I: Inspector Officers signatures and date:

_____

Appendix 6

Dissemination of results

Abstract accepted for poster presentation at the International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences, Abu Dhabi, United Arab Emirates, September 2019

AN INNOVATIVE REGULATORY FRAMEWORK IN COMMUNITY PHARMACY

Marina Langaro[1], Annalise Attard[2], Anthony Serracino- Inglott[1, 2]

[1]Department of Pharmacy, Faculty of Medicines and Surgery, University of Malta, Msida, Malta

[2]Malta Medicines Authority, Life Sciences Park, San Gwann, Malta

Background

The regulatory framework for community pharmacies consists of assessment through regulatory audits. Implementing innovative regulatory frameworks may improve pharmacist's performance and patient care.

Purpose

To integrate the assessment of pharmacist competencies with the assessment of regulatory requirements.

Methodology

An analysis of the present regulatory assessment tool identifying risk factors, strengths and weaknesses in moving towards a patient-centred audit through a focus group consisting of 9 participants is performed. The analysis results and the Good Pharmacy Practice guidelines are used to develop a new regulatory assessment tool. Self-assessment of the regulatory tool is implemented, and audits are performed by the researcher. The results of the self-assessment and the audit are correlated, and gaps in the audit identified. Actions such as educational seminars are carried out.

Results

The analysis identified 4 risk factors, 2 weaknesses and 5 strengths in moving towards a patient-centred audit. The risk factors comprised of oversight of legal requirements, demand in preparation by the pharmacist, unacceptability of clinical interventions and lack of harmonisation of pharmacy practice. The weaknesses included a resistance to change and lack of robustness in self-assessment. The strengths were offering a clinical service to the patients, recognising the pharmacist's competence, meeting patient needs, reduction in redundant bureaucracy and improvement in personalised healthcare.

Discussion

The analysis results will be used to develop the regulatory assessment tool. Implementing self-assessment as an innovative regulatory framework may improve pharmacist's performance and patient care.

Abstract accepted for the International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences, Seville, Spain, September 2020

INNOVATIVE REGULATORY FRAMEWORK IN COMMUNITY PHARMACY

Marina Langaro[1,2], Anthony Serracino-Inglott[1,2]

[1]Department of Pharmacy, Faculty of Medicines and Surgery, University of Malta, Msida, Malta

[2]Malta Medicines Authority, Life Sciences Park, San Gwann, Malta

Background

The evolution of the regulatory sciences introduced the need for a patient-centred regulatory framework.

Purpose

To establish a regulatory self-audit (RSA) model in community pharmacy aiming at satisfying regulatory requirements while meeting patient needs.

Method

The methodology included 1. Design of a Pharmacist Competencies Self-Audit (PCSA), 2. Regulatory risk-based assessment, 3. RSA, regulatory audit (RA), PCSA implementation in 61 community pharmacies.

Results

The PCSA was designed to evaluate professional strengths, interests, goals and opportunities for improvement (OFI). RSA and RA compliance were measured as percentage of criteria accomplished (N=76). The number of minor (n=19), major (n=34) and critical (n=23) findings defined pharmacies high (1 minor or above 5 major), medium (1-5 major) and low-risk (only minor) categories. In the RSA, pharmacies declared higher compliance (94.7% ± 4.65) and were classified in lower risk-category (high-risk pharmacies=16) than in RAs (82.7% ± 8.14; high-risk pharmacies=46). The pharmacists managing the 61 pharmacies (56 female, age between 25-73 years, mean age 43 years) showed a difference between age groups. Pharmacists below-30 and over-60 years-old gave a lower RSA-pharmacy-risk compared to intermediate age-categories (p-value=0.041). In the PCSA, pharmacists reported understanding patient needs (57.4%) and patient-orientation (49.2%)) as the two highest strengths, personalised healthcare (44.3%) as the major area of interest, service optimisation (49.5%) as the main goal and continuous education (63.9%) as an OFI.

Conclusion

A regulatory self-audit showed significant differences from the established inspection audit.