PSI

CUMANN CÓGAISEOIRÍ NA hÉIREANN

The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

PSI Report on the Scoping Consultation for Governance and Accountability Standards for Retail Pharmacy Businesses

Version 1   **March 2019**

1. Introduction

The central goal of the Pharmaceutical Society of Ireland's (PSI) Corporate Strategy 2018-2020 is to assure trust in pharmacy through effective regulation. In line with commitments set out in the Corporate Strategy[1] the PSI is seeking to develop Governance and Accountability Standards for Retail Pharmacy Businesses (RPB). The development of Standards will be a new approach for the PSI. Standards differ from the guidelines issued to date, in that Standards provide concise, outcome focussed statements against which a service provider establishes and delivers their service, and which the regulator can use to assess performance. Standards empower the service provider, in this case the healthcare setting of a RPB, to meet the requirements of the standards in a range of different ways, i.e., it is not a prescriptive approach.

This report details the activities carried out as part of the scoping consultation and provides a summary of the information/feedback gathered on the development of the standards.

1.1. About the Scoping Consultation

There were four main elements to the engagement aspect of the scoping consultation;

- **Patient Focus Group**

  The PSI had extensive engagement with the Health Service Executive (HSE) Quality Improvement Division in order to gain patient and public insight in the standards scoping process. As a result of this collaborative work, the PSI were invited to present at the National Patient Forum meeting in February 2019. As part of this presentation a substantial interactive session was carried out and invaluable information was gained from a large number of advocacy groups and individual patients/carers on what the standards should address to meet the public's needs from pharmacists and pharmacy services.

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[1] Strategic Results Area 1 - Action 7 of the PSI's Corporate Strategy 2018-2020 sets out the PSI's intention on reviewing whether governance and management structures within retail pharmacy businesses are working to protect the public, and defining, with stakeholders, the high standards of leadership and accountability that must be practised by those holding key governance positions. This accountability framework will apply to supervising and superintendent pharmacists as well as those responsible for the overall governance of pharmacy businesses, for example, the senior management and the boards of corporate entities.

- **Pharmacist Focus Group**

  In February 2019, a focus group was held with pharmacists from a number of different backgrounds and roles. Formation of the focus group was considered with a view to gaining insight on the standards from pharmacists employed in independent pharmacies and chains, and also those in superintendent, supervising and employee pharmacist roles. This facilitated the gathering of information and deepening our understanding of the potential use of the standards from a number of perspectives.

- **Online Consultation Survey for Pharmacists**

A link to an online survey was sent to all pharmacists in March 2019, the questions sought information on what the standards should address and examples of good pharmacy practice. Submissions were also accepted by email. The consultation survey was also sent to all registered Pharmaceutical Assistants.

- **Online Consultation survey for Other Stakeholders**

Also in March 2019, a separate online survey was sent to a broad range of other stakeholders, including other regulators, relevant state bodies and patient/advocacy groups. The survey invited comments on developing Governance and Accountability Standards for retail pharmacy businesses and examples of good pharmacy and healthcare practices. Submissions were also accepted by email and the consultation was highlighted on various social media accounts.

2. Results

2.1 Results of the Patient Focus Group Discussion (National Patient Forum)

The PSI had extensive engagement with the SE Quality Improvement Division in order to gain patient and public insight in the standards scoping process. As a result of this collaborative work, the PSI were invited to present at the National Patient Forum meeting in February 2019. As part of this presentation a substantial interactive session was carried out and invaluable information was gained from a large number of advocacy groups and individual patients/carers on what the standards should address to meet the public's needs from pharmacists and pharmacy services.

This discussion was opened with a presentation outlining what the public can expect from pharmacists and pharmacy services, using the PSI Patient Charter, briefly detailing the role of the PSI and describing the Standards development process. This led into a number of prompt questions around what 'good' and 'bad' pharmacy services look like, in order to stimulate discussion.

There was substantial and energetic engagement from attendees on the topic and a broad range of valuable insights were received;

➢ The importance of compassion and understanding in the provision of pharmacy services was emphasised by a number of participants, this extended to both the patient and also family members/carers.

➢ Ensuring consistency of service was another key area discussed. It was noted that engaging with pharmacist(s) that are familiar with their medication and their condition adds value to the service provided.

➢ The issue of maintaining confidentiality and privacy was also raised by an attendee, and the better use of the consultation area in pharmacies to this end.

➢ A number of participants highlighted the importance of medication reviews by pharmacists, especially at transitions of care where medication errors potentially can occur e.g. discharge from a hospital.

➢ Related to this medication review discussion, the need for pharmacists not to become complacent was noted and the value of pharmacists proactively offering counselling to patients even if they had received the medicine previously was highlighted.

➢ The importance of using plain English and being aware of different levels of adult literacy, in providing pharmacy services, was also discussed, along with the provision of training for staff to assist patients with additional needs.

➢ Better use of resources, including staffing resources was considered during the discussion. Participants commented that having sufficient staffing resources would help improve the quality of care received and accuracy of the dispensing process, enabling the pharmacist to spend more time counselling and advising the patient/public.

➢ It was suggested that an advertising campaign to inform the public of what pharmacists can do for them would improve understanding of pharmacy services and the role of the pharmacist.

> ➢ The roles and responsibilities of pharmacists in other settings, specifically in hospitals, was also briefly discussed.

These areas raised will be considered in the context of the other information received in the course of the scoping consultation and this information will be essential in enabling the drafting of standards which support pharmacy services which meet patient and public needs.

2.2 Results of the Pharmacist Focus Group Discussion

A short introductory presentation was provided to give context on the project in light of the PSI Corporate Strategy and the Governance and Accountability Standards development process. The open discussion section of the focus group was structured using four prompts;

- o Top priorities in providing good quality pharmacy services,
- o Obstacles to providing good quality pharmacy services
- o How do you ensure consistency of care?
- o What areas should the standards address?

Firstly the group focused on the top priorities the pharmacists had when providing safe and quality care to the public. All participants believed that a retail pharmacy business focused on patient safety was the top priority for them. Ensuring that all staff are educated and trained to carry out their roles was emphasised by participants as being very important to achieve this. The need to have a high standard of patient counselling was also highlighted as playing a vital role in making sure a safe and quality service is provided by pharmacists at all times. In addition the participants also discussed the importance of accuracy during the dispensing process, a high level of competence and being open and transparent.

The second part of the focus group discussion explored obstacles to providing a safe and quality pharmacy services. Insufficient staffing resources emerged as a challenge to all participants present, relating to both pharmacists and over the counter (OTC) and dispensary staff. Many associated issues to this matter were discussed, such as a lack of work breaks and long working hours. It was noted during this discussion that problems with staffing resources can have a negative impact on

patient safety, can result in reduced time for pharmacists to complete day to day administrative tasks and potentially a decrease in the accuracy of the dispensing process. Another theme that emerged during the discussion was the lack of integrated care in the Irish health care system, and it was commented that the introduction of electronic prescribing would improve safety considerably, for example, by reducing errors of mistaken identity, incorrect dosage, incorrect medication and adverse drug interactions.

The next part of the focus group examined the leadership role that all pharmacists have in the provision of quality services and asked participants to discuss how they ensure consistency of care in their different roles. All participants agreed that having knowledgeable staff is key to ensuring consistency of care. Ways in which they have achieved this include a programme of staff training and using locums who have a knowledge of the pharmacy and how it works. Delegation of jobs to trained staff was also discussed, thus by reducing the administrative burden, freeing up the pharmacist to spend more time counselling and engaging with patients and the public. The importance of good communication with both patients and staff was discussed, including appropriate handover structures particularly between pharmacists to ensure consistency and fluidity of quality care. It was noted that all of the elements discussed contribute to enhanced patient safety, professionalism and consistency in the service provided by the retail pharmacy business.

The final part of the focus group investigated what areas the participants felt the standards should address to support safe, quality and consistent care. Some of the topics discussed may be outside the scope of the standards, including pharmacist welfare, isolation and excessive working hours. However, it was indicated that the standards should address appropriate staffing resources, pharmacist and support staff education and training systems (including re-training and upskilling), communication skills/systems and quality assurance.

2.3 Results of the Online Consultations

The pharmacist online consultation survey was comprised of eight specific feedback questions on the standards and how pharmacists ensure their pharmacy provides a safe and effective service to the public. The stakeholder consultation survey was comprised of five general questions regarding what areas the pharmacy standards should address to assure safe and quality care. The aim of these

general and specific feedback questions was to elicit opinion on what the draft standards should contain. The PSI would like to thank all those who took part and gave their time to provide submissions.

2.3.1 Results of the Online Consultation Survey for Pharmacists

A total of 304 respondents accessed the online survey and one email response was received. Of those who accessed the survey between 22 and 36 respondents went on to complete each of the preceding eight questions. The number of responses received to each question is indicated in the results for each individual question below.

Question one: What areas should these standards address?

Answered	36

In particular feedback was received that staff training must be addressed as part of the retail pharmacy business standards. The importance of having well trained staff, with a good skill mix and adequate staff numbers was indicated as essential to ensure a pharmacy provides a safe and quality service to the public. In addition, it was suggested that clarity on who has overall responsibility for activities in a pharmacy should be addressed in the standards through emphasis on leadership, providing clarity to all staff on their roles and responsibilities. Some respondents highlighted the importance of effective delegation in these standards, thus empowering other qualified staff to undertake appropriate administrative activities. It was indicated that this could allow pharmacists increased capacity to deal with patient queries, provide advice and more effectively supervise medicine sales. A number of respondents suggested that the standards should support pharmacists in exercising their professional judgement, in particular in response to any conflicting commercial pressures. Some respondents highlighted that the standards should address the different pharmacy services that are offered such as vaccination, health screening and medicines management. It was also noted that the standards should examine the risk aspect of managing a retail pharmacy, by having systems in place to continuously analyse errors and near misses and adapt the dispensing and supply process to minimise these. In addition, some feedback was received that minimum standards for management training for staff in managerial roles to cover all aspects of the business

model, including HR and Health and Safety, should be covered, although this may be outside the direct scope of the standards.

Question two: What are the issues that are important to you in this area?

Answered	36

The second question asked respondents to describe the issues they felt are important to them in the area of the standards. In particular feedback was received on staff wellbeing, in particular having adequate staffing levels to ensure the dispensary can operate safely and with appropriate staff breaks. Some respondents highlighted the need for minimum training standards for all staff including medicines education, hygiene and health and safety training. A number of respondents stated that providing a safe and quality service to the public in an environment that is friendly and one that they trust is very important. One respondent stated that the value of the time a pharmacist has with patients should be emphasised as a key resource. Respondents raised the importance of professionalism, communication and recognition of pharmacies who invest in people and systems to provide a safe and effective pharmacy service to the public. One respondent addressed the importance of liaising with other healthcare professionals to address polypharmacy and providing more services to ensure timely access to care to the public.

Question three: What management structures do you currently have in place in your pharmacy, to ensure safe and effective care for patients?

Answered	34

This question specifically asked respondents to explain any management structures they currently have in place to ensure their pharmacy offers safe and effective care for patients. Respondents indicated that they had systems in place to ensure all staff employed are trained, supported and listened to. It was noted that having experienced, well trained, competent staff ensures; patients are appropriately cared for and given correct advice, communication does not break down and safe supply of medicines is facilitated. It was also commented that to enable safe care all pharmacists and other staff must have a clear definition of their specific roles and understand their professional and legal responsibilities. Some feedback was received that related to having systems in place to

double check all steps in the dispensing/supply process. The importance of effective communication and discussing any issues relating to patient care on a regular (daily) basis in a structured manner was also raised, in order to allow meaningful sharing of relevant information. Finally, comments were received on the importance of having Standard Operating Procedures (SOPs) in place that reflect the everyday running of the pharmacy, which are periodically reviewed, and against which compliance is assured through the use of self-audits.

Question four: How do you ensure consistency in the care given to patients in your pharmacy?

Answered	36

This question asked respondents to explain how they ensure consistency in the care provided in their pharmacy. Again feedback was received on how respondents valued the importance of staff in providing consistency to patients. It was stated that training and empowering staff to take on responsibility and good management of the staff welfare will help ensure a consistent and safe service is offered to patients. One respondent described how they regularly assess staff performance in all roles from handling non-prescription medicines queries to counselling patients on their medication. Involvement and availability of the superintendent and supervising pharmacist was also noted by some respondents, particularly where there is a locum pharmacist working who may require extra support and advice. Respondents acknowledged consistency can at times be difficult to maintain and check, many currently use standardised procedures and good practise to help staff ensure outcomes are of the same standard for all patients. It was also noted that some respondents have tested their consistency by seeking feedback from patients and/or patient groups and through peer evaluation and group discussion.

Question five: How do you assess the quality of the service provided to the public in your pharmacy?

Answered	32

This question asked respondents how they go about assessing the quality of the service offered. Some stated that they have a formal system for assessing quality such as by engaging with a market research company, using mystery shoppers to provide an external report on the quality of service

provided and participating in external quality assurance schemes. Other feedback indicated that respondents do not have any formal method in place for assessing quality. Respondents also stated that they have informal methods of assessing quality such as managing complaints, examining their error and near miss logs and incident reviews. Others highlighted that they encourage open communication and feedback from customers and patients and examine returning customer numbers in attempt to assess the quality of the service they offer.

Question six: What does a well-managed pharmacy service look like?

Answered	33

This question asked respondents to tell us what they thought a well-managed pharmacy service looks like. Respondents emphasised that a well-managed pharmacy is customer orientated and focused on providing the best possible outcomes for the patient. They expanded stating that the provision of personalised care, with up-to-date, relevant and evidence based advise relevant to the patient is key to ensuring this happens. Under this theme, a number of respondents suggested that having adequate, professional and efficient staff facilitates this effective care. Some highlighted the importance of demonstrating professionalism and integrity at all times by pharmacists. A number of responses raised the importance of good communication in a well-managed pharmacy, not just communication amongst staff but also with other health care professionals. Others stated that having a well-maintained premises may be indicative of a well-managed pharmacy. Having systems in place to learn from errors and near misses without fear of recriminations was also noted. A number of respondents emphasised the positive presence, in a well-managed pharmacy, of a culture that welcomes opportunities to review, improve or develop services as a result of learnings or regulatory change. This along with efficient procedures, clear lines of responsibility and accountability was cited as leading to an appropriately managed pharmacy service. Many respondents also noted that by ensuring the pharmacy is well manged and providing a good service patients will continue to return to the pharmacy because they are treated with respect, courtesy and access products, advice and services in a timely and trustworthy manner.

Question seven: What are the barriers to providing a good pharmacy service?

Answered	35

Question seven asked respondents to explain what barriers they felt were inhibitors to providing a good pharmacy service. Similar to feedback provided in previous questions it was stated that staff shortages, inability to retain staff due to working conditions and inadequate staff knowledge are all barriers to a pharmacy providing a good service. In particular feedback was received on the shortage of pharmacists available. Some feedback was received on time being a barrier to a good pharmacy service, indicating that time restraints were due to many reasons, including increased dispensing volume, prescription complexity, extra dispensing steps, excessive regulatory demands and other administrative duties. Financial barriers such as poor remuneration and business management costs were also cited as barriers by some. Other barriers highlighted were inadequate use of Information Technology (IT) and current legal restraints such as the lack of electronic prescribing and shared access to patient discharge records from hospital.

Question eight: Do you have any examples of information we should review to inform the development of these standards? (Key sources of information could include national and international peer-reviewed literature, policy, legislation, standards, tool-kits, guidelines and guidance)

Answered	22

In response to this question respondents gave examples of information the PSI can use to inform the development of the standards. Both the National Health Service (NHS) and the Pharmacist Defence Association (PDA) were cited as having information available on good governance guidelines and also templates to assist pharmacists. It was also highlighted that the Society of Hospital Pharmacists in Australia have developed standards of practice for clinical pharmacy services which could also be used to inform the development of these standards.

2.3.2 Results of the Online Consultation Survey for Other Stakeholders

A total of 24 other stakeholders accessed the online survey. Of those who accessed the survey between 7 and 9 respondents went on to complete each of the preceding five questions. The number of responses received for each question is indicated in the results for each individual question below.

Question one: What does a well-managed pharmacy service look like to you?

Answered	9

A number of respondents suggested that a well-managed pharmacy has staff that are approachable, well trained and engaged with patients, indicating that knowledgeable staff will ensure that any referrals to pharmacists or other healthcare professionals for further advice are made appropriately and consistently. Some respondents also looked at a pharmacy's ability to ensure the privacy of patients is maintained through the use of the consultation area. The importance of presenting a professional image to both stakeholders and patients, good counselling skills by pharmacists across all aspects of medicines and services was also highlighted. One respondent noted that pharmacies should be able to adapt and evolve to meet the ever changing needs of patients while continuously looking to improve the quality and safety of all services offered. Respondents emphasised that well managed pharmacies manage any potential risks, dispense accurately and in a timely manner and aim to provide knowledge to patients to enable a shared decision making process. It was indicated that encouraging feedback and adhering to all guidelines and polices support these processes. It was also noted a well-managed pharmacy will have a clear separation of commercial activities and health service provision.

Question two: What does a poorly-managed pharmacy service look like to you?

Answered	8

In this area some respondents suggested that a poorly managed pharmacy service happens in a poor pharmacy environment, one that is cluttered, not well stocked, unhygienic and disorganised. They stated that this results in poor patient care. Other respondents emphasised how the lack of trained staff, not enough staff, and no clear lines of accountability will lead to a poor service. It was

also indicated that there may be a risk of non-pharmacist staff either giving poor advice or giving advice when the patient should be referred to the pharmacist. Lack of communication skills and unprofessional behaviour was also highlighted as leading to a poorly managed pharmacy. Examples of bad service provided included reluctance to follow regulations and guidelines, a lack of respect for patient privacy and the supplying of over the counter products that are unregulated.

Question three: What areas should these standards address? For example, 'governance, staffing, accountability'

Answered	8

Question three asked stakeholders to examine what areas they felt the Governance and Accountability Standards for Retail Pharmacy Businesses should address. In particular feedback was received on the importance of including governance in the standards. It was stated that good governance results in the use of an evidence based practice approach to provide a good service to patients and continuously works to improve on it. A number of respondents felt accountability must be included and staff must be trustworthy, reliable and knowledgeable to help ensure continued public trust. One respondent highlighted the need to ensure the use of professional judgement and to speak up if there are any concerns. The management and leadership of the pharmacy team was also emphasised, stating that good leadership will ensure systems are in place for appropriate monitoring and evaluation. It was also indicated that good leadership will ensure all staff promote patient safety and wellbeing not only in their medication management but also their lifestyle. It was stated that well documented policies and procedures in place will support good management and supervision. Other respondents suggested the standards should also address the premises, equipment used, training and additional services offered.

Question four: Have you examples of how best to measure quality and patient safety in a healthcare setting?

Answered	7

All respondents recognised the importance of measuring quality and patient safety. One respondent suggested implementing an audit system against expected standards in pharmacies and

the use of performance indicators. Some respondents suggested obtaining feedback from patients on a regular basis, this would have the added benefit of ensuring patients are aware of the importance of management of their medication. One respondent highlighted that whatever measure is used it needs to be practical and deliver robust, accurate and timely information to inform learning and improvement.

Question five: Do you have any examples of information we should review to inform the development of these standards? (Key sources of information could include national and international peer-reviewed literature, policy, legislation, standards, tool-kits, guidelines and guidance)

Answered	7

In response to this question respondents gave examples of different policies and procedures that have been developed. One respondent suggested the Department of Health's (DoH) Patient Safety Complaints and Advocacy Policy, the primary aim of which is to provide a framework for Ireland's healthcare services to support the development and improvement of healthcare complaint handling. Other examples from the DOH highlighted include their policy on open disclosure and the integration of best evidence in service provision, through clinical effectiveness processes. It was also noted that the pharmaceutical society of Australia have worked on this as have the NHS and European Patient Forum and Medicines Agency.

3. Conclusion

A wealth of information was received in the course of the scoping consultation activities, both through face to face engagements and the online surveys. This information will be carefully analysed and considered by the PSI, with the support of the Standards Advisory Group, to inform the drafting and development of the standards. PSI would like to acknowledge the valuable contributions of all those who engaged in this important process.