PSI Report on the Review of the Operation of the Pharmacy Assessment System

August 2018

1. Introduction

About the Pharmaceutical Society of Ireland - The Pharmacy Regulator

Commitment to the Public

The Pharmaceutical Society of Ireland (PSI) is a public body established in law to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. Having regard to the landscape of pharmacy in Ireland in 2018, we currently regulate the operation of 1,935 registered retail pharmacy businesses: approximately 1857 community based retail pharmacy businesses and 78 hospital based retail pharmacy businesses. In addition we regulate the professional practice of 6,056 pharmacists, and we also register 335 pharmaceutical assistants.[1]

We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007 (the "Act"), as amended, established the statutory role and responsibilities of the PSI as the pharmacy regulator, which include:

- **Registration** of pharmacists, pharmaceutical assistants and pharmacies;
- **Setting standards for pharmacy education and training** at undergraduate and postgraduate level;
- Ensuring all registered pharmacists are undertaking appropriate **continuing professional development** (CPD);
- **Promoting good professional practice** by pharmacists through raising standards and sharing information for the benefit of patients and the wider health system;
- **Assessing compliance and taking actions to address poor performance, practices and behaviours** through our inspection and enforcement functions, by **considering complaints** made against a pharmacist or a pharmacy, and through the imposition of sanctions;
- **Providing advice, support and guidance** to the public, pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.

Governance

The PSI is governed by a 21 member Council and each member is appointed by the Minister for Health in accordance with the provisions of the Act. The Council of the PSI (the "Council") is responsible for overseeing the delivery of the functions of the PSI, in the public interest. The Registrar (Chief Officer) of the PSI is responsible for leading the day-to-day work and operation of the PSI, and reports to Council at each of its meetings on the PSI's activities and performance.

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[1] The registration data contained herein is correct at 07 August 2018.

PSI Corporate Strategy 2018-2020

The PSI Corporate Strategy for 2018-2020, which was developed in consultation with our stakeholders, represents our integrated three year developmental agenda for the organisation. It consists of five key elements, with our central organisational goal to assure trust in pharmacy through effective regulation. There are four strategic results areas under which we will deliver specific results and, when taken together, will see us make significant progress towards our central goal.
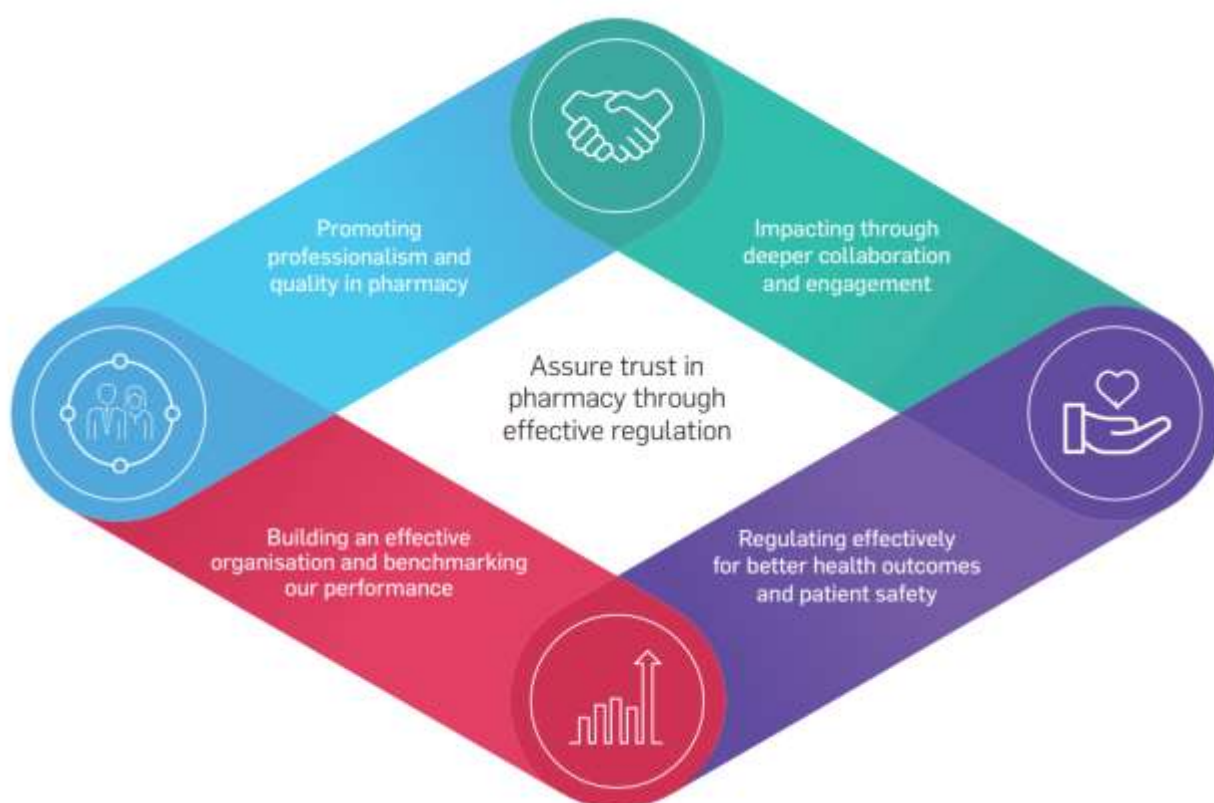
Our intention, as an organisation, is that by the time we are entering 2021, the PSI will be more developed, more effective, more capable and will be able to demonstrate that our work has impacted positively on assuring trust in pharmacists, in pharmacy services and has resulted in better health outcomes for the public.

Overview of the PSI Inspection Function

Patient safety is central to the ethos of the legislative framework for medicines and pharmacy in Ireland. As part of our function we are empowered under Section 7 of the Act to conduct inspections of registered pharmacies (community/retail and hospital) for the purposes of assessing compliance with the Act and with other pharmacy and medicines legislation and PSI Guidance.

Background of the Inspection Policy

The first full cycle of community pharmacy inspections was completed in December 2014. In anticipation of the completion of this, the Council set up an independent Project Expert Group to carry out a strategic review of the existing inspection policy. The Expert Group prepared a report based on its findings and included a number of recommendations for a new inspection policy: Report of the Project Expert Group. Additional information on the Inspection Policy Project can be accessed on the PSI website.

One of the recommendations made by the Expert Group was for the PSI Executive to develop and incorporate a mandatory self-audit system into their regulatory approach. In recognition of the clinical and corporate structure of the pharmacy as provided for by the Act, the Expert Group recommended that the supervising pharmacist, as the person in whole-time charge of the pharmacy, would be the most appropriate person to complete the self-audit. In furtherance to that, the Expert Group suggested that the superintendent pharmacist and pharmacy owner, if different from the supervising pharmacist, should also be involved in the self-audit process by reviewing and signing off on the completed self-audit.

In May 2015 the Council endorsed the view of the Expert Group and agreed to update the inspection policy approach for routine pharmacy inspections, to include a self-audit for pharmacies (now referred to as the Pharmacy Assessment System).

The Pharmacy Assessment System

Prior to the introduction of the pharmacy assessment system pharmacies were not obliged to maintain documentary evidence of their ongoing assessment of compliance with

statutory requirements. It was observed, however, by PSI inspectors that the existing inspection checklist for routine pharmacy inspections appeared to be regularly used by the profession on a voluntary basis in preparation for an inspection, and that compliance rates were higher in those pharmacies where there was evidence that it had been used.

The pharmacy assessment system was developed, in collaboration with our stakeholders, based on legislation, PSI Guidance and best practice. Its introduction, as a self-audit tool, was intended to facilitate a continuous cycle of on-going compliance and to ensure that the pharmacy is operating to the highest standards of patient safety at all times.

Completion of the Pharmacy Assessment System is one way of providing documentary evidence of the commitment of all the pharmacy team to ensuring patient safety and quality of care on a consistent basis.

In May 2016, Council agreed that the pharmacy assessment system should be conducted every six months. In addition to this, Council requested that in the context of the ongoing development and evolution of the inspection policy project that a report on the review of the operation of the pharmacy assessment system be presented to Council once three cycles had been completed.

Development, Roll-Out and Use of the Pharmacy Assessment System

Development

The pharmacy assessment system together with a guide to completing the pharmacy assessment system were developed by the PSI following a collaborative approach involving the PSI and our stakeholders. This engagement was crucial for its successful development. It provided the PSI with an opportunity to seek the views of our stakeholders, and to learn from their experience on the use of self-audits generally.

Various methods of engagement were used. For example, individual meetings were held with members from other organisations, focus group meetings were held with pharmacists and pharmacy owners in July and August 2015, and a public consultation was also carried out. In addition, supervising pharmacists were invited to pilot a draft version of the pharmacy assessment system for two months in early 2016, and provide feedback through an online survey. Over 250 supervising pharmacists, from pharmacies all around the country, participated in this pilot. The PSI Report on the Pilot of the Pharmacy Assessment System and Guide can be accessed here .

The contributions and submissions received proved invaluable and were considered in finalising the format and content of the pharmacy assessment system. In its current presentation, it contains five core sections, each relating to the following areas of pharmacy practice:

- Section 1: Management and Supervision
- Section 2: Sale and Supply of Non-Prescription Medicines
- Section 3: Sale and Supply of Prescription Medicines
- Section 4: Documentation and Record Keeping
- Section 5: Premises, Equipment and Storage

There is also Section 6: Supply of Medicines to Patients in Residential Care Settings which only needs to be completed if the pharmacy provides medicines to patients in residential care settings.

A separate Action Plan booklet is also available. This is used to set out the actions that a pharmacy plans on taking in order to achieve pharmacy practice improvements or compliance.

An accompanying guide to completing the pharmacy assessment system was also developed. It provides an overview of each of the sections, a question and answers section together with completed sample sections and action plans.

Roll-Out

The final version of the pharmacy assessment system, together with the accompanying guide, was launched in October 2016 with the first cycle commencing in all pharmacies, community and hospital pharmacies which are registered as a retail pharmacy business, in January 2017. The cycles were to be completed by pharmacies in the order outlined below:

- Cycle 1- commenced in January 2017 and ended in June 2017
- Cycle 2- commenced in July 2017 and ended in December 2017.
- Cycle 3- commenced in January 2018 and ended in June 2018.

Prior to the commencement of the first cycle all registered pharmacies received a folder which contained the pharmacy assessment system, including action plan booklets to facilitate completion of cycle 1 and cycle 2 together with the guide to completing the pharmacy assessment system. Additional hard copies were also sent by the PSI for cycle 3 and cycle 4. An editable PDF version was also developed which can be downloaded from the PSI website and completed.

In order to provide information and support to pharmacies on the roll-out of the pharmacy assessment system, the PSI held 12 information events in various locations around the country in October and November 2016 and in March 2017. In addition between February and June 2017, PSI

inspectors visited 1,826 of 1,911[2] pharmacies, which was 95.5% of the PSI Register, to conduct advisory visits to answer questions in support of its introduction.

Use of the Pharmacy Assessment System

To help pharmacies keep on track, and facilitate completion, a completion schedule outlining the recommended section to be completed each month is available on the PSI

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[2] 7 new community pharmacies did not receive an advisory visit, but were advised on the PAS during their pre-registration inspection. 78 hospital pharmacies were not visited as part of this exercise.

website. In addition, monthly email reminders are sent to the supervising pharmacist. A designated email address, inspectionproject@psi.ie is also available for the purposes of receiving questions or feedback on the pharmacy assessment system.

By June 2018, all pharmacies were expected to have completed three cycles of the pharmacy assessment system, and are expected to continue completing it every six months until such time as Council has considered the findings from this review together with the recommendations contained herein.

2. Review of the Operation of the Pharmacy Assessment System

As outlined above, Council directed that a review of the pharmacy assessment system be conducted after three six-month cycles. The main purpose of the review was to evaluate the pharmacy assessment system's implementation to date up until mid-2018.

Since the implementation of the pharmacy assessment system, the PSI has given renewed consideration to its strategic direction with the development of the Corporate Strategy 2018-2020, which recognises that our regulatory approaches must evolve. Reflecting on our current and evolving approaches to regulation, it afforded us the opportunity to review the pharmacy assessment system to ensure that it aligns with our strategic objectives whereby we aim to make a clear and demonstrable contribution to the availability and quality of pharmacy services to assure public trust in pharmacy.

The review sought the perspective of relevant stakeholders engaged in the use of the pharmacy assessment system and so we arranged to meet and hear from, pharmacists and their pharmacy team. This informed us of the attitudes and any challenges faced by the profession in this regard.

In order to gather this information, the following two methods were used:

1. A Survey: Review of the Pharmacy Assessment System 2018.
2. Pharmacy Assessment System Review Visits.

In addition to the stakeholder engagement exercise, members of the PSI Executive took the opportunity to conduct a detailed review of the content of the pharmacy assessment system in consideration of regulatory, legislative or other changes since its development and roll-out.

Steering Group from PSI Executive

A Steering Group comprising PSI Executive was set up to oversee the development and management of the project which was requested to undertake the review of the operation of the pharmacy assessment system. The steering group provided advice and assistance to the project team, and also assisted in developing the recommendations contained herein.

About this Report

The aim of this report is to provide an overview of the operation of the pharmacy assessment system based on its use in pharmacies after three cycles and its contribution to promoting professionalism and quality in pharmacy, and the delivery of safe, reliable and trusted pharmacy services.

The report is structured as follows:

- **2.1 Survey: Review of the Pharmacy Assessment System 2018**
- **2.2 Pharmacy Assessment System Review Visits**
- **2.3 Review of the Content of the Pharmacy Assessment System**
- **3. PSI Executive Findings and Recommendations**
- **4. Next Steps**

2.1 Survey: Review of the Pharmacy Assessment System 2018

Purpose of the Survey

An online survey was designed to obtain feedback from pharmacists and members of the pharmacy team who had been involved in the completion of the pharmacy assessment system, and aimed to gather their feedback on how it has worked in their pharmacy since its roll-out.

The survey was sent to all registrants, but welcomed submissions from all members of the pharmacy team. Feedback from the survey was anonymous in that participants were not required to provide their name or details of the pharmacy they worked in.   As several members of the pharmacy team may have participated in the completion of the pharmacy assessment system, the survey was not limited to one response per pharmacy and could be completed by all those who were involved.

The survey opened on 27 April 2018 and closed on 18 May 2018. A copy of the survey is included at Appendix 1.

About the Survey

In total 46 questions were included in the survey with a skip logic setting used to direct participants to questions relevant to their roles (for example for the supervising pharmacist) while other questions were only to be completed by those who were involved in completing the action plan. It was estimated to take less than 15 minutes to complete.   Certain questions included an option for participants to provide additional comments. In order to analyse the qualitative data, each comment was analysed individually and categorised, and in certain cases categorised according to a respondent's position in the pharmacy, for example, pharmacy staff, supervising pharmacist, superintendent pharmacist and pharmacy owner.

Response to the Survey

A total of 627 responses were received to the online survey. However, for the overall analysis, there were 529 completed responses used because certain participants indicated that they did not confirm consent to providing their answers to the questions to the survey (=3), others indicated that they were not involved in the completion of the pharmacy assessment system (=68) or did not indicate their role or position at the pharmacy (=27). A summary of the results from the online survey is included at Appendix 2.

Key Findings from the Online Survey

- Overall there was positive engagement with the pharmacy assessment system whereby we see that a majority of pharmacies are continuing to complete the pharmacy assessment system.

- The completion of the pharmacy assessment system helps review pharmacy practice and identify areas for improvement(s) in the pharmacy.

- Other members of the pharmacy team helped the supervising pharmacist with the completion of the pharmacy assessment system.

- Biannual completion became repetitive. It would be sufficient to complete the pharmacy assessment system annually. Amongst other things, this would afford pharmacies the opportunity to implement the action(s) that they have decided to take to make the required improvements.

- In a majority of cases, the completion time indicated for subsequent cycles were either similar time or less time.

- Participants highlighted the benefits of developing an online version of the pharmacy assessment system.

- Although a mixed response was received when participants were asked if completing the pharmacy assessment system improved communication between their pharmacy team, it was noted that it can serve as a communication tool within the clinical and corporate structure of the pharmacy. For example, in cases where the supervising pharmacist is not the superintendent pharmacist or the pharmacy owner, it can serve as a tool to raise issues.

- The pharmacy assessment system helped those that held key governance positions with governance and quality management in the pharmacy.

2.2 Pharmacy Assessment Review Visits

Purpose of the Review Visits

PSI inspectors visited 100 community pharmacies between April and May 2018, which equated to 5% of the PSI Register. The purpose of these visits was to discuss the use of the pharmacy assessment system to date. In circumstances where the supervising pharmacist was not present, the pharmacist(s) on duty were invited to provide the visiting inspector with any feedback they might have on the pharmacy assessment system. A summary of results from the review visits is included at Appendix 3.

Key Findings from the Review Visits

- **Overall there was positive engagement with the pharmacy assessment system whereby we see that a majority of pharmacies are continuing to complete the pharmacy assessment system.**

- **Having regard to the approval of the action plans, it was noted that there was a higher rate of approval by the supervising pharmacists as opposed to the superintendent pharmacist and pharmacy owners where rates of approval were considerably lower.**

- **The completion of the pharmacy assessment system helps review pharmacy practice and identify areas for improvement(s)**

- **Having regard to completion times, subsequent cycles took similar or less time to complete.**

- **Having regard to the frequency of completion, it was felt that annual completion of the pharmacy assessment system would be sufficient.**

2.3 Review of the Content of the Pharmacy Assessment System

Purpose of the Content Review

The main purpose of the pharmacy assessment system is to enable the demonstration of a pharmacy's quality management system whereby it could be used to provide evidence of the commitment of all the pharmacy team to ensuring patient safety and quality of care in providing services and treatments in compliance with statutory requirements.

As part of its development, it was acknowledged that the pharmacy assessment system was designed to be to be a dynamic, evolving and relevant document which should be updated in line with developments in pharmacy practice or indeed legislation. Now that three cycles have been completed by pharmacies, it was felt that it was an appropriate time to review the overall content to determine if any aspect of the pharmacy assessment system could be modified, needed further clarification, and above all to ensure that it focused on the key areas relevant to patient health and safety.

How the Content Review was Conducted

Prior to commencing the review, review criteria were established and included the following:
- Impact on patient outcome/patient safety
- Overall alignment with purpose of the pharmacy assessment system
- Overall impact on the pharmacy which included:
    o What is involved in completing each review activity?
    o Estimated time burden to pharmacy to complete the review activity?
    o Ability to delegate tasks?
- Requirements of legislation, PSI Guidance, Code of Conduct
- Potential to change frequency (from 6-monthly)
- Suggested updates from the PSI Executive

Having regard to the established criteria outlined above, each of the six sections of the pharmacy assessment system together with the action plan booklet were reviewed in detail. A summary of the content review is included at Appendix 4.

In addition, each section of the pharmacy assessment system was reviewed by the Inspection and Enforcement unit and the Pharmacy Practice Development Department and the comments or suggestions received also forms part of the content review.

Key Findings from the Content Review

- **Each section of the pharmacy assessment system is aligned to the overall purpose of self-assessment which is to facilitate a continuous cycle of on-going compliance and to ensure that the pharmacy is operating to the highest standards of patient safety at all times.**

- **The content review is aligned to the legal, professional and governance arrangements in place in pharmacy.**

- **The content of the pharmacy assessment system can be linked to patient safety and quality services provided by a pharmacy.**

- **There is potential to review the frequency of completion.**

- **Update and amend the content of the pharmacy assessment system in line with developments in pharmacy practice, and consider including additional sections.**

3. PSI Executive Findings and Recommendations

Recommendations of the PSI Executive to Council

Recommendation 1

- **Require all registered retail pharmacy businesses to continue completing the pharmacy assessment system and for this requirement to be underpinned by legislation.**

Recommendation 2

- **Reduce the frequency of completion of the pharmacy assessment system to once annually.**

Recommendation 3

- **Require all pharmacies to provide the PSI with an annual declaration at continued registration to confirm that the pharmacy assessment system has been completed.**

Recommendation 4

- **Explore the development of an online version of the pharmacy assessment system.**

The following paragraphs set out a summary of our findings together with the associated recommendations. The set of recommendations were developed having regard to the key findings from each part of the review of the operation of the pharmacy assessment system that was conducted, which included the findings from the online survey, review visits and the content review.

In addition, the view of the PSI Executive together with other aspects of PSI policy were taken into consideration to ensure, amongst other things, that the pharmacy assessment system accords with the strategic direction set out in the current Corporate Strategy which is intended to further enhance public trust in pharmacy by ensuring that the PSI's regulatory

approaches protect the public and encourage improvement and ongoing quality development within pharmacy practice in Ireland.

1. Completion

In 2015, Council agreed to update its policy approach for routine pharmacy inspections, to include the development and implementation of a self-assessment for pharmacies. The purpose of Council's policy change was to facilitate self-evaluation and effective governance in pharmacies.

The PSI Executive can see from the findings from the survey and review visits, in particular, that there is positive engagement with the pharmacy assessment system as demonstrated by the high percentage of pharmacies that are using and continuing to use it. Furthermore, there is agreement amongst the profession that the completion of the pharmacy assessment system helps review pharmacy practice and identify areas for improvement(s). The content review also highlights that completion of the pharmacy assessment system is aligned to its overall purpose whereby it provides assurances to the PSI that the pharmacy is regularly reviewing areas of the pharmacy's practice that impact on patient safety.

During the course of the advisory visits in 2017, 1,826 community pharmacies were visited and 90.4% had started the pharmacy assessment system. Further positive engagement was observed during the review visits in 2018. One hundred community pharmacies were visited and 94% indicated that they were completing the system. This ongoing engagement with the pharmacy assessment system demonstrates pharmacies commitment to ensuring patient safety and quality of care in providing services in compliance with statutory requirements, PSI Guidance and good pharmacy practice. It also highlights a positive return of the PSI's investment in terms of the high quality communication and engagement that was invested during the development and roll-out stages of Council's agreed policy.

To ensure that the pharmacy is operating to the highest standards of patient safety at all times and to ensure public trust in pharmacy through effective regulation, it is the view of the PSI Executive that it is important that the pharmacy assessment system is a live tool and all pharmacies continue to complete it. This is further supported by the evidence received to date as to the positive impact that the pharmacy assessment system has had on pharmacy practice to date in terms of helping pharmacies to review their practice and identify areas for improvement(s). This will ultimately impact positively on patients and supports the PSI's goal of assuring trust in pharmacy services. While there is a clear expectation that pharmacies complete the pharmacy assessment system, and a high level of voluntary engagement by the majority of pharmacies, its completion is not currently underpinned by legislation.

Recommendation 1

Require all registered retail pharmacy businesses to continue completing the pharmacy assessment system and for this requirement to be underpinned by legislation.

2. Frequency

The pharmacy assessment system is a self-assessment tool which is intended to help pharmacies review and improve their own standards and practices on an ongoing basis in order to ensure that the pharmacy is operating to the highest standards of patient safety at all times.

In May 2016, Council agreed with the Expert Group's recommendations that the pharmacy assessment system should be conducted twice yearly, and more frequently in response to a significant change in the operation of the pharmacy, for example in circumstances where the supervising pharmacist changes, in order to facilitate a culture of ongoing improvements in pharmacies and to promote and assure public confidence.

As part of the review the PSI sought feedback from those using the pharmacy assessment system on the frequency of completing the pharmacy assessment system.   On average, for all sections 72% of participants indicated that it may be sufficient to complete less frequently. In the additional comments provided by respondents, time constraints were raised as the main issue in completing the pharmacy assessment system. Participants indicated that they felt it was repetitive completing it every six months, and in some cases they indicated that they did not have time to implement the actions prior to commencing the next cycle. As part of the content review, it was also recognised that there was potential to review the frequency of completion.

Separately to the review, during March and April 2018, the PSI held regional seminars for superintendent pharmacists to introduce the Corporate Strategy and to discuss areas of mutual interest, with PSI staff facilitating a wide range of discussions. While participants felt that the first cycle of the pharmacy assessment system was very useful to help assess practice and prepare for an inspection, they queried the relevance of repeating it at six monthly intervals.[3]

The PSI Executive acknowledge the benefits of ensuring that the pharmacy assessment system is a live tool which pharmacies should be required to complete in order to promote and encourage a culture of continuous review and improvement, and also to sustain the improvements that pharmacies have already made to their practice. In light of the feedback received together with the positive engagement demonstrated during the three cycles, the PSI Executive considers it an appropriate juncture to reconsider the biannual (every six months) frequency of completion, and recommend reducing this to once annually. However, in saying that it is also the view of the PSI Executive that the pharmacy assessment system should be recompleted in circumstances where there has been a significant change to the operation of the pharmacy. For example, where a pharmacy has been renovated or re-fitted, where there has been a change in the pharmacy's activity, such as the introduction of a new service, or where there has been a change in the key governance positions in the pharmacy, i.e. the superintendent or supervising pharmacist.

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[3] The Report on the Seminars for Superintendent Pharmacists can be accessed here

The PSI Executive is of the view that such changes would be considered significant and should trigger the recompletion of the pharmacy assessment system.

Recommendation 2

Reduce the frequency of completion of the pharmacy assessment system to once annually.

3.   Declaration of Completion of the Pharmacy Assessment System

The PSI's principal function is to ensure patient safety and public protection and assure the public of the quality and safety of the care and services they receive in pharmacies. One of the ways we do this is by looking for assurances of quality practices and behaviours.

It is recognised by the PSI, and has been suggested by participants during the focus group meetings held in 2017 on the quality services that pharmacies provide, that the completion of the pharmacy assessment system plays an important role in providing evidence of a pharmacy team's commitment to continuous quality improvement directed towards ensuring patient safety and quality care.

As part of the PSI's updated regulatory approach, at inspections PSI inspectors seek assurances that a pharmacy is completing the pharmacy assessment system on a continued basis. The PSI Executive acknowledge, however, that there is no formal declaration provided by pharmacies to the PSI to confirm that pharmacies have completed the pharmacy assessment system. Therefore, having regard to Recommendation 1 above, the PSI Executive gave some consideration as to how pharmacies could formally declare its completion. Given that pharmacy owners must apply on an annual basis for continued registration of their pharmacy, it was on this basis that the PSI Executive recommend that each registered pharmacy should be required to provide a declaration of completion at continued registration, to the PSI that the pharmacy assessment system has been completed.

This declaration would provide an assurance that the pharmacy is engaged with the process of self-assessment and continuous improvement, and above all is committed to providing a safe and effective pharmacy service to patients and the public. In circumstances where this declaration is not provided, this information could be used to identify those minority of pharmacies that are not actively engaged in the process of self-assessment and continuous improvement, and would be used as part of the PSI's responsive regulatory approach.

In summary, this would mean that on one hand credit is given to the majority of pharmacies for their active engagement and commitment to continuous quality improvement, while on the other hand it could be used to identify the minority of pharmacies who have not engaged in self-assessment.

> **Recommendation 3**
>
> **Require all pharmacies to provide the PSI with an annual declaration at continued registration to confirm that the pharmacy assessment system has been completed.**

4.   Explore the Development of an Online Version of the Pharmacy Assessment System

Technology is a key enabler of pharmacy practice. The development of a convenient and secure online version of the pharmacy assessment system would, amongst other things, allow for operational efficiencies for pharmacies in engaging with the system. This development would be aligned with Government policy which aims to promote efficiencies and use technology to streamline the delivery of services.

Through our stakeholder engagement, feedback suggests that the development of an online version would be welcomed by pharmacies. As part of the survey, it was indicated that in its current presentation, it increased paper based administration. Therefore, an online version would undoubtedly be more accessible and user friendly for pharmacies. This would assist and help sustain completion overall. While we saw from both the survey and the review visits that a majority of the profession are completing the paper based version of the pharmacy assessment system, feedback suggests that this could be attributable to the fact that the editable PDF was not in a user friendly format.

In addition to an online version being more user friendly, participant feedback through the online survey suggested that a live system would be able to identify those pharmacies that are completing it and those that are not. Participants also indicated that it would be a cost saving measure for the PSI in terms of printing costs. They also gave feedback that it would allow for the creation of in the moment management information to enable greater oversight in a pharmacy group structure, and that there were opportunities for the integration of data which could be utilised as a communication tool to exchange information.

In addition to the above, it must be acknowledged that the pharmacy assessment system was designed to be a relevant tool, which should be dynamic and evolving, and would be updated in line with developments in pharmacy practice or legislation. As part of the online survey, a small percentage of participants provided comments and agreed that additional sections could be added, which has been a useful part of the engagement process with registrants and their pharmacy teams.

The PSI Executive also acknowledge the importance of the pharmacy assessment system being up to date and is reflective of current regulatory requirements. The PSI Executive acknowledge that an online version would also make it easier to update and amend the pharmacy assessment system in line with developments in pharmacy practice.

As part of the exploration of the development of an online version of the pharmacy assessment system, a number of matters would need to be considered and a business case developed for such a project, to include costs, benefits and impacts.   This would also include consideration of issues around data collection and sharing to ensure that, amongst other things, the collection and processing of data meets the requirements of data protection legislation, and the General Data Protection Regulation.

> **Recommendation 4**
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> **Explore the development of an online version of the pharmacy assessment system.**

4. Next Steps

The PSI Executive's four recommendations contained in this report will be considered by the Council of the PSI at its meeting in September 2018. Council are asked to consider the recommendations and make a decision to approve or reject the recommendations.

Should the Council approve the recommendations, the PSI Executive will proceed with the implementation of the recommendations. The agreed policy will also be included in updates to the PSI's Inspection Policy which would, amongst other things, take into account the completion of the pharmacy assessment system by individual pharmacies.

Information about any proposals or changes that will arise following the review of the operation of the pharmacy assessment system will be communicated to registrants. Separately, but in addition to the implementation of the recommendations, the pharmacy assessment system will continue to be amended and updated in line with developments in pharmacy practice or legislation.

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Review of the Pharmacy Assessment System 2018

Welcome to our Survey

Thank you for taking the time to complete this survey. The survey is open to any members of the pharmacy team who have been involved in the completion of the Pharmacy Assessment System, and aims to gather their feedback on how it has worked to date.

The closing date for responses is XX May 2018. If you do not have time to complete all questions in one sitting you may exit and return at a later stage, providing you are using the same device or browser.

Data Protection and Freedom of Information:

The survey is anonymous and voluntary. By completing it you are agreeing to allow your responses to be processed and analysed by the PSI for the purpose of gathering feedback on the Pharmacy Assessment System. This feedback will form part of a review of the current system, a report on which will be complied for the Council of the PSI. The report or a summary of findings will be published on the PSI website at a later stage.

The information you provide will be stored in a secure and confidential manner by the PSI, it will only be utilised for the purposes outlined above and it will be deleted in line with the PSI's record retention policy. The PSI uses SurveyMonkey to gather feedback to our public consultations. Full details of how your information is processed via SurveyMonkey is documented in the privacy policy available here.

Submissions made to the PSI during consultations are subject to the provisions of the Freedom of Information Act 2014.

* 1. Do you agree to the terms above? By selecting Yes you are confirming you consent to providing your answers to the questions in this survey.

◯ Yes, I agree

◯ No, I do not agree

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How you completed the Pharmacy Assessment System

* 2. Were you involved in the completion of the Pharmacy Assessment System at your pharmacy?

○ Yes

○ No

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How you completed the Pharmacy Assessment System

* 3. Please indicate your role / position at the pharmacy (you may select more than one)

☐ Supervising Pharmacist

☐ Superintendent Pharmacist

☐ Pharmacy Owner

☐ Support Pharmacist

☐ Other Pharmacist (eg Locum, Relief)

☐ Pharmaceutical Assistant

☐ Other pharmacy employee (please indicate role)

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How you completed the Pharmacy Assessment System

* 4. Did you complete the Pharmacy Assessment System:

○ By yourself

○ With assistance from other pharmacy team members

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How you completed the Pharmacy Assessment System

5. Which other members of the pharmacy team assisted you? (you may select more than one)

☐ Superintendent Pharmacist

☐ Pharmacy Owner

☐ Support Pharmacist

☐ Other Pharmacist (eg Locum, Relief)

☐ Pharmaceutical Assistant

☐ Other pharmacy employee (please state role)

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How you completed the Pharmacy Assessment System

6. What format of the Pharmacy Assessment System did you use?

◯ Paper Version

◯ Editable PDF (available on PSI website)

◯ Mix of both

7. Did you refer to the Guide to Completing the Pharmacy Assessment System (included in the folder)?

◯ Yes

◯ No

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The Pharmacy Assessment System Cycles

8. Did your pharmacy fully complete the Pharmacy Assessment System for:

	Yes	No
Cycle 1 (January to June 2017)	○	○
Cycle 2 (July to December 2017)	○	○

If no, please tell us why

[   ]

9. After completing the first cycle of the Pharmacy Assessment System, did you find that completing the subsequent cycle(s) required:

○ Less time ○ Similar time ○ More time

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The Pharmacy Assessment System Sections

10. Please use the drop down menus to provide feedback on statements A, B and C for each of the sections your pharmacy completed.

	A: This section was useful in reviewing the pharmacy's practice and compliance with legislation	**B:** Completing this section helped identify areas for improvement	**C:** It may be sufficient to complete this section:
Management and Supervision	[⬍]	[⬍]	[⬍]
Sale and Supply of Non-Prescription Medicines	[⬍]	[⬍]	[⬍]
Sale and Supply of Prescription Medicines	[⬍]	[⬍]	[⬍]
Documentation and Record Keeping	[⬍]	[⬍]	[⬍]
Premises, Equipment and Storage	[⬍]	[⬍]	[⬍]
Supply of Medicines to Patients in Residential Care Settings	[⬍]	[⬍]	[⬍]

11. Would you like to see sections related to the following added to the Pharmacy Assessment System? (You may select more than one)

- ☐ Vaccination Services
- ☐ Veterinary Medicine
- ☐ Opioid Substitution
- ☐ None of the above
- ☐ Other (please specify)

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The Compliance Assessment

12. I found The Compliance Assessment at the end of each review section to be useful

○ Strongly Disagree ○ Disagree ○ Neutral ○ Agree ○ Strongly Agree

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The Action Plan

* 13. Regarding the development of your pharmacy's Action Plans, which of the following describes you best:

○ I understand the process involved in developing Action Plans, and feel confident in doing so

○ I am not fully confident in developing Action Plans and would like further support

○ I am not involved in developing Action Plans for the pharmacy

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The Action Plan

14. Did you encounter any difficulties when completing your Action Plan?

○ Yes

○ No

If yes, please tell us about the difficulties encountered

[   ]

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The Action Plan

15. The Action Plan was useful

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

16. The Action Plan helped plan the improvements required in the pharmacy

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

17. The Action Plan helped highlight the improvements required to all members of the pharmacy team

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

18. Were all of the areas identified for improvement during completion of the review sections, addressed in the Action Plans?

○ Yes

○ No

If no, please tell us why

[   ]

19. Were all of the actions fully completed?

○ Yes

○ No

If no, please tell us why

20. Did all required individuals (Supervising Pharmacist, Superintendent Pharmacist and Pharmacy Owner) approve and sign-off on the Action Plans for:

	Yes	No	Unsure
Cycle One (January to June 2017)	☐	☐	☐
Cycle Two (July to December 2017)	☐	☐	☐

If no, please tell us why

21. Did your Action Plan for Cycle Two include:

○ More actions than in Cycle One

○ Similar number of actions as Cycle One

○ Less actions than in Cycle One

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Communication, Training and Governance

22. Completing the Pharmacy Assessment System improved communication between the pharmacy team

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

23. Completing the Pharmacy Assessment System helped with staff training

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

24. Completing the Pharmacy Assessment System helped the pharmacy be more prepared for a PSI inspection

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
○	○	○	○	○

* 25. The following section contains questions for Supervising Pharmacists. Please select to continue:

☐ I am not a Supervising Pharmacist - Skip this section

☐ I am a Supervising Pharmacist - Continue to questions

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Questions for Supervising Pharmacists

* 26. Did completing the Pharmacy Assessment System facilitate your communication with your Superintendent Pharmacist?

○ Yes

○ No

○ I am also the Superintendent Pharmacist

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Questions for Supervising Pharmacists

27. Did completing the Pharmacy Assessment System and the Action Plans help you to raise issues with your Superintendent Pharmacist?

○ Yes

○ No

○ No issues were identified

28. Did your Superintendent Pharmacist support you and provide any assistance you required?

◯ Yes

◯ No

◯ Support was not required

29. If you have additional comments on how you and your Superintendent Pharmacist worked together in completing the Pharmacy Assessment System, please provide these here:

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Questions for Supervising Pharmacists

* 30. Did completing the Pharmacy Assessment System facilitate your communication with your Pharmacy Owner(s)?

◯ Yes

◯ No

◯ I am also the Pharmacy Owner

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Questions for Supervising Pharmacists

31. Did completing the Pharmacy Assessment System and the Action Plans help you to raise issues with the Pharmacy Owner(s)?

◯ Yes

◯ No

◯ No issues were identified

32. Did your Pharmacy Owner(s) support you and provide any assistance you required?

◯ Yes

◯ No

◯ Support was not required

33. If you have additional comments on how you and your Pharmacy Owner(s) worked together in completing the Pharmacy Assessment System, please provide these here:

[ ]

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Questions for Supervising Pharmacists - Email Reminders

* 34. Did you find the monthly reminder emails about completing the Pharmacy Assessment System useful?

◯ Yes

◯ No

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Questions for Supervising Pharmacists - Email Reminders

* 35. Would you prefer to receive these email reminders:

◯ Every month

◯ Only when a new Cycle is due to commence

◯ Not at all

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Email Reminders

* 36. Would you like to receive email reminders from the PSI about the completion of the Pharmacy Assessment System?

◯ Yes

◯ No

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Email Reminders

* 37. Would you prefer to receive email reminders:

◯ Every month

◯ Only when a new Cycle is due to commence

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Questions for Superintendent Pharmacists and Pharmacy Owners

* 38. The following section contains questions for Superintendent Pharmacists and Pharmacy Owners. Please select to continue:

☐ I am not a Superintendent Pharmacist or a Pharmacy Owner - Skip this section

☐ I am a Superintendent Pharmacist **and / or** a Pharmacy Owner - Continue to questions

Review of the Pharmacy Assessment System 2018

Questions for Superintendent Pharmacists and Pharmacy Owners

* 39. The following section contains questions for Superintendent Pharmacists and Pharmacy Owners. Please select to continue:

☐ I am not a Superintendent Pharmacist or a Pharmacy Owner - Skip this section

☐ I am a Superintendent Pharmacist **and / or** a Pharmacy Owner - Continue to questions

Review of the Pharmacy Assessment System 2018

Questions for Superintendent Pharmacists and Pharmacy Owners

* 40. Did completing the Pharmacy Assessment System facilitate your communication with the Supervising Pharmacist?

○ Yes

○ No

○ I am also the Supervising Pharmacist

Review of the Pharmacy Assessment System 2018

Questions for the Superintendent Pharmacist and Pharmacy Owner

41. Did you provide support to your Supervising Pharmacist in order to address any issues identified by the Pharmacy Assessment System?

○ Yes

○ No

○ No issues were identified

42. If you have additional comments on how you worked together with the Supervising Pharmacist in completing the Pharmacy Assessment System please provide these here:

[   ]

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Questions for the Superintendent Pharmacist and Pharmacy Owner

43. Did you review the Pharmacy Assessment System and sign off on the Action Plans for:

	Yes	No
Cycle one (January to June 2017)	○	○
Cycle two (July to December 2017)	○	○

If no, please tell us why

[   ]

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Questions for Supervising Pharmacists, Superintendent Pharmacists and Pharmacy Owners

44. Completing the Pharmacy Assessment System helped me to demonstrate my governance and quality management in the pharmacy

○ Strongly disagree ○ Disagree ○ Neutral ○ Agree ○ Strongly agree

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Review of the Pharmacy Assessment System 2018

Final Questions

45. Based on your knowledge, please give the Pharmacy Assessment System an overall rating. (With 1 being very poor and 10 being excellent)

1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○

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Final Questions

46. If you have any further feedback in relation to the Pharmacy Assessment System please provide it here:

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Thank You

Thank you again for taking the time to participate in our survey,

The PSI Inspection Policy Project Team

inspectionproject@psi.ie

Summary of Results from the Online Survey

Who are the Participants?

As the survey could be completed by pharmacists and other pharmacy team members, participants were asked to indicate their role or position in the pharmacy, which sought to elicit the profile of the participants.

Role or Position at the Pharmacy

Role	Number of Participants
Supervising Pharmacist	378
Superintendent Pharmacist	212
Pharmacy Owner	136
Support Pharmacist	62
Other Pharmacist (e.g. Locum, Relief)	20
Pharmaceutical Assistant	7
Other Pharmacy Employee	7
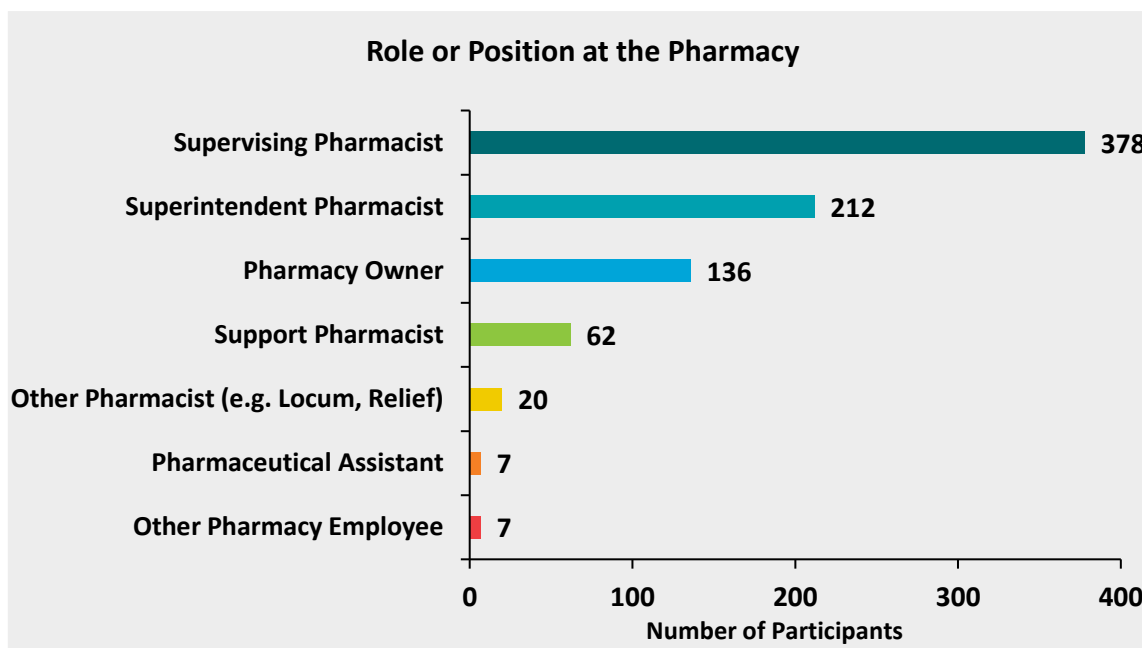
Figure 1: (Answered: 529, Skipped: 0). It can be seen from the the figures in the chart that the number of participants add up to more than 529, . This is due to the fact that in this question, participants were able to tick more than one role or position.

Most participants, as indicated above, were supervising pharmacists, with superintendent pharmacists and pharmacy owners being the next biggest groups, followed by support pharmacists.

In cases where participants selected 'other pharmacy employee', it was noted that the following personnel were listed: 1) pharmaceutical technician, 2) other pharmacists that occupy a clinical governance/head office or store manager role and 3) Pharmacy Intern

Summary of Submissions

The analysis of the survey data identifies key points about the operation of the pharmacy assessment system, and for the purposes of the report have been summarised under each of the sections outlined below:

1. General Comments
2. Action Planning
3. Communication
4. Comments from the Supervising Pharmacists
5. Comments from Superintendent Pharmacists and Pharmacy Owners
6. Governance and Quality Management
7. Additional Comments

Appendix 2

1. General Comments

Overview

This section examines some of the general comments on the pharmacy assessment system received through the online survey, which sought to elicit information to give a general overview of the operation of the pharmacy assessment system from all participants.

How did Participants Rate the Pharmacy Assessment System?

Participants were invited to give their overall rating for the pharmacy assessment system on a scale of 1 to 10, with 1 being very poor and 10 being excellent. The average overall rating attributed to the pharmacy assessment system was **5.5.** The graph below illustrates the distribution.
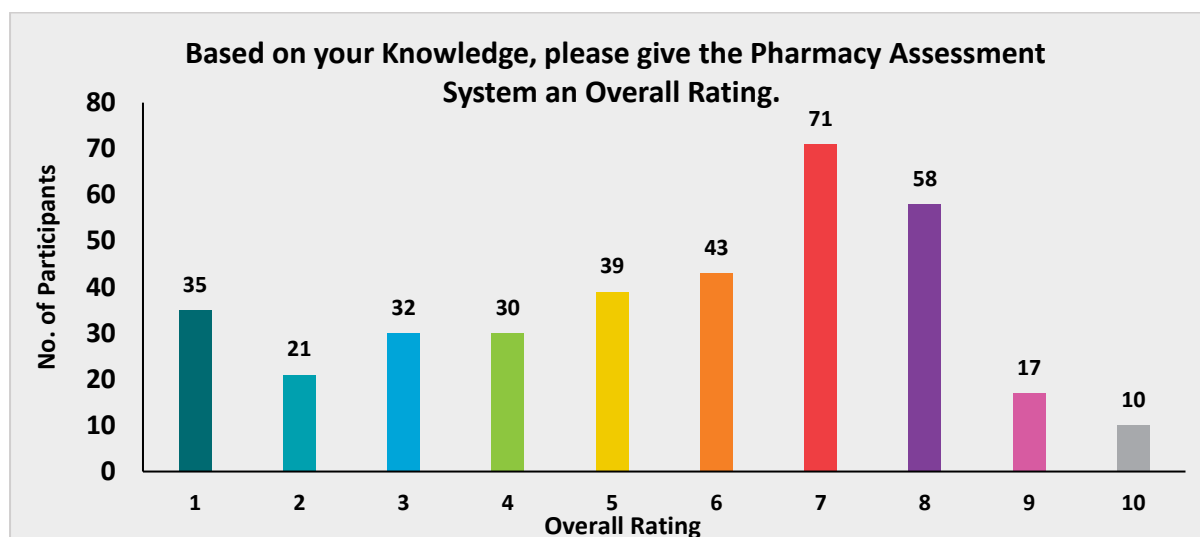
Figure 2: (Answered 356, Skipped 173)

It can be seen that the majority of participants attributed an overall rating of between 5 and 10.

What did Participants say about Completion in General?

In terms of the overall completion of the pharmacy assessment system, when we looked at the results, we found that:

- While two versions of the pharmacy assessment system are available, a paper version or an editable PDF, **83%** of participants indicated that they used the paper version of the pharmacy assessment system as opposed to **7%** who indicated they used the editable PDF while **10%** indicated they used a mix of both.
- **66%** strongly agreed or agreed that completing the pharmacy assessment system helped the pharmacy be more prepared for a PSI inspection.
- **91%** of participants indicated that they referred to the guide to completing the pharmacy assessment system
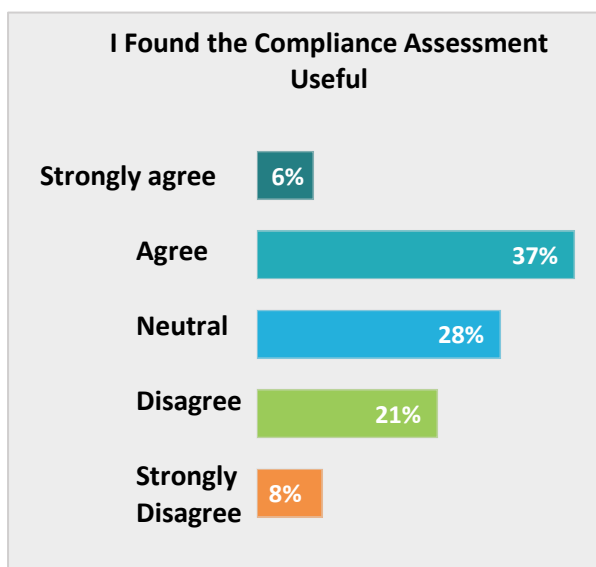
Figure 3: (Answered: 397, Skipped: 132)

Figure 4: (Answered: 365, Skipped: 164)

- **93%** fully completed the pharmacy assessment system for Cycle 1
- **83%** fully completed the pharmacy assessment system for Cycle 2

In cases, however, where it was indicated that the cycles were not fully completed, participants were asked to tell us why. It was expressed by many that time constraints were a dominant factor. Others indicated that there were issues with staff such as staff shortages, changes to staff, waiting for support from the superintendent pharmacist and personal reasons were another factor. Others felt that the process was repetitive and imposed an administrative burden on pharmacies, and that annual completion would be sufficient. In other cases, they indicated that the nursing home section was not applicable to their practice.

Having regard to the corporate structures of pharmacy, in order to determine if responses varied between individuals who occupied different governance roles or positions, the responses were analysed on this basis. It was interesting to note that the **supervising pharmacist** who is responsible for the overall completion of the pharmacy assessment system indicated in a majority of cases that time constraints was the dominant factor. They felt that it was time consuming, they had insufficient time to complete it or found it time consuming in terms of implementing the changes.

Similarly, comments received from **superintendent pharmacists** and **pharmacy owners** related to time management whereby they indicated that they had a lack of staff and time to complete the pharmacy assessment system and felt that annual completion would be sufficient.

How Long Did it Take to Complete Subsequent Cycles?

After completing Cycle 1, we were interested in finding out how long it took participants to complete further cycles of the pharmacy assessment system. The results of which are illustrated below:
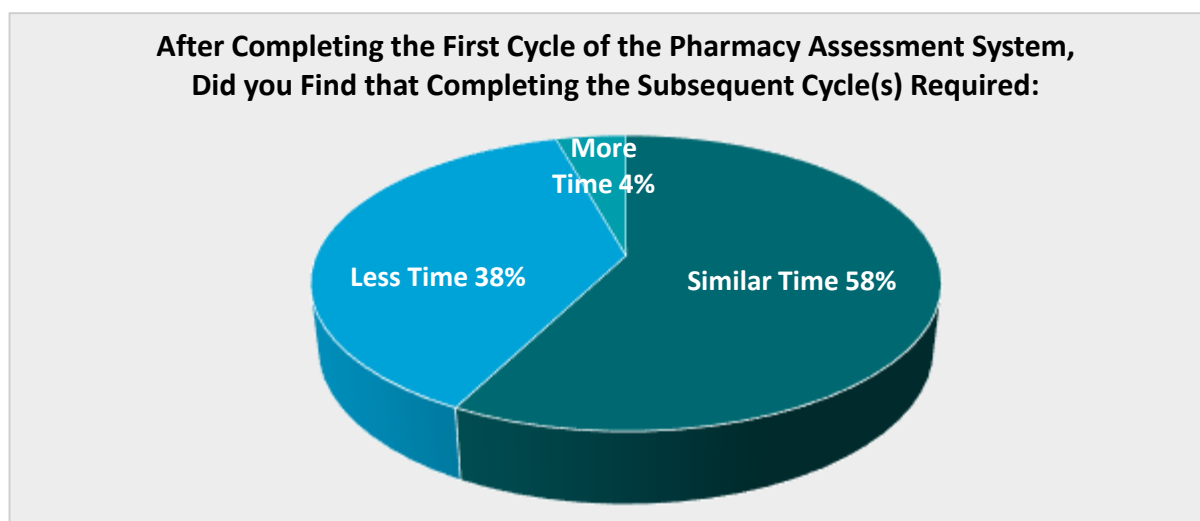

Figure 5: (Answered: 488, Skipped: 41)

What did Participants say about the Individual Sections?

In its current presentation, there are six sections. Five sections relate to the core aspects of pharmacy practice, and the sixth section relates to the supply of medicines to patients in nursing homes. The latter would not be applicable to all pharmacy practices. Participants were asked to provide feedback on each of the six sections under the statements outlined at (A)-(C) below:

- **A-** This section was useful in reviewing the pharmacy's practice and compliance with legislation
- **B-** Completing this section helped identify areas for improvement
- **C-** It may be sufficient to complete this section more frequently, same frequency or less frequently

The following graphs illustrate that 68% strongly agreed or agreed that the five core sections were useful in reviewing the pharmacy's practice and compliance with legislation, and 59% strongly agreed or agreed that the completion of these sections helped identify areas for improvement. For section 6, however, for Statement A: 57% and for Statement B: 59% of participants were undecided as to whether or not it was useful.

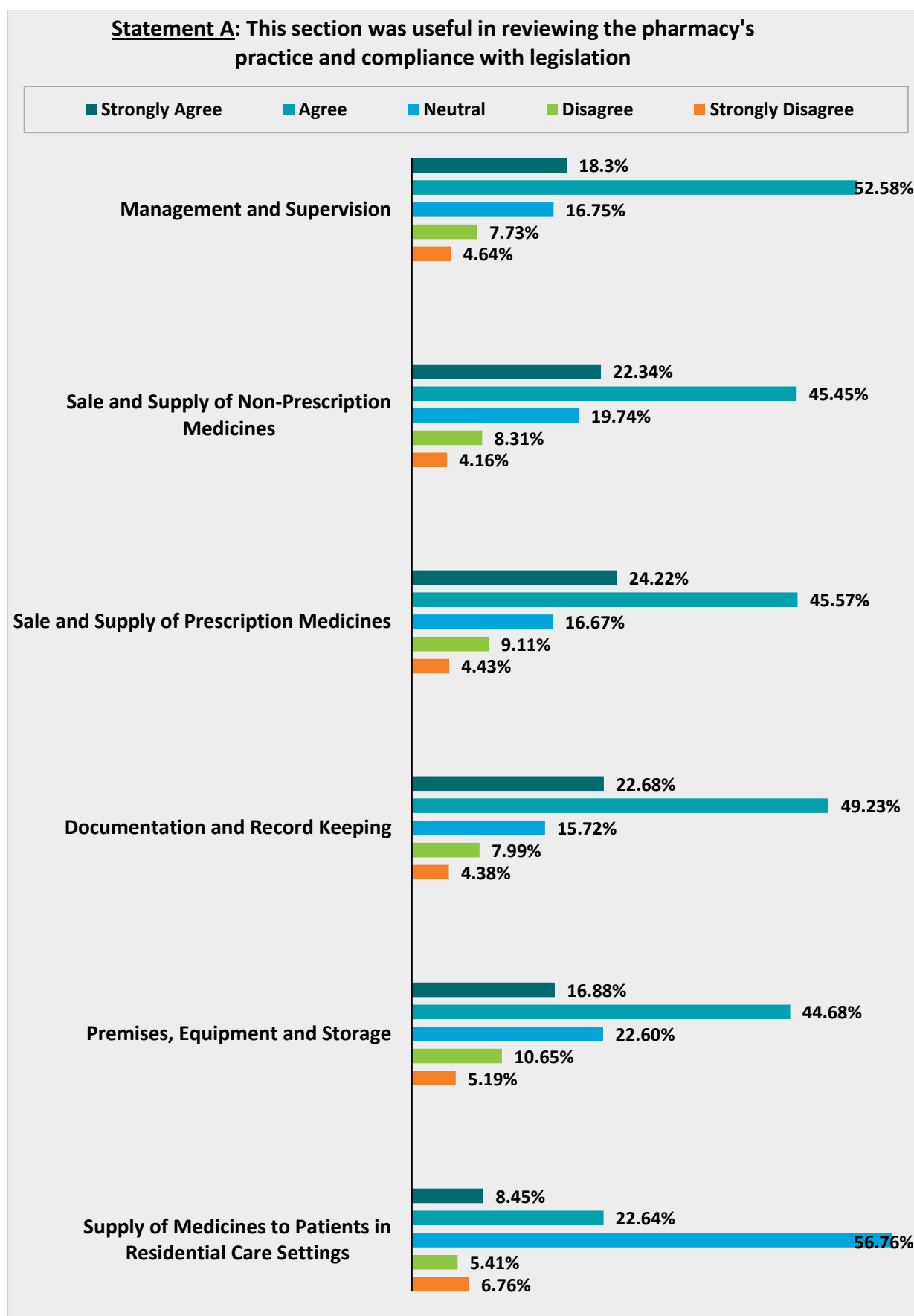**Statement A:** This section was useful in reviewing the pharmacy's practice and compliance with legislation

Legend: ■ Strongly Agree ■ Agree ■ Neutral ■ Disagree ■ Strongly Disagree

Management and Supervision
- 18.3%
- 52.58%
- 16.75%
- 7.73%
- 4.64%

Sale and Supply of Non-Prescription Medicines
- 22.34%
- 45.45%
- 19.74%
- 8.31%
- 4.16%

Sale and Supply of Prescription Medicines
- 24.22%
- 45.57%
- 16.67%
- 9.11%
- 4.43%

Documentation and Record Keeping
- 22.68%
- 49.23%
- 15.72%
- 7.99%
- 4.38%

Premises, Equipment and Storage
- 16.88%
- 44.68%
- 22.60%
- 10.65%
- 5.19%

Supply of Medicines to Patients in Residential Care Settings
- 8.45%
- 22.64%
- 56.76%
- 5.41%
- 6.76%

Figure 6: (The overall response rate for Statements A-C was as follows Answered: 394, Skipped: 135). However, the response rate for each section varied.

Statement B: Completing this Section Helped Identify Areas for Improvement

Legend: ■ Strongly Agree ■ Agree ■ Neutral ■ Disagree ■ Strongly Disagree

Management and Supervision
- Strongly Agree: 16.34%
- Agree: 49.03%
- Neutral: 20.22%
- Disagree: 9.14%
- Strongly Disagree: 5.26%

Sale and Supply of Non-Prescription Medicines
- Strongly Agree: 16.01%
- Agree: 43.26%
- Neutral: 25.00%
- Disagree: 11.52%
- Strongly Disagree: 4.21%

Sale and Supply of Prescription Medicines
- Strongly Agree: 13.57%
- Agree: 44.32%
- Neutral: 26.04%
- Disagree: 11.91%
- Strongly Disagree: 4.16%

Documentation and Record Keeping
- Strongly Agree: 12.22%
- Agree: 46.39%
- Neutral: 24.72%
- Disagree: 11.39%
- Strongly Disagree: 5.28%

Premises, Equipment and Storage
- Strongly Agree: 9.80%
- Agree: 44.26%
- Neutral: 24.65%
- Disagree: 15.97%
- Strongly Disagree: 5.32%

Supply of Medicines to Patients in Residential Care Settings
- Strongly Agree: 6.37%
- Agree: 20.60%
- Neutral: 59.18%
- Disagree: 7.49%
- Strongly Disagree: 6.37%

Figure 7: (The overall response rate for Statements A-C was as follows Answered: 394, Skipped: 135). However, the response rate for each section varied.

Statement C: It may be sufficient to complete this section:

- ■ Less Frequently
- ■ Same Frequency
- ■ More Frequently

Management and Supervision
- 74.79%
- 23.53%
- 1.68%

Sale and Supply of Non-Prescription Medicines
- 66.57%
- 29.46%
- 3.97%

Sale and Supply of Prescription Medicines
- 65.54%
- 31.07%
- 3.39%

Documentation and Record Keeping
- 71.07%
- 26.69%
- 2.25%

Premises, Equipment and Storage
- 85.88%
- 12.99%
- 1.13%

Supply of Medicines to Patients in Residential Care Settings
- 67.19%
- 31.25%
- 1.56%
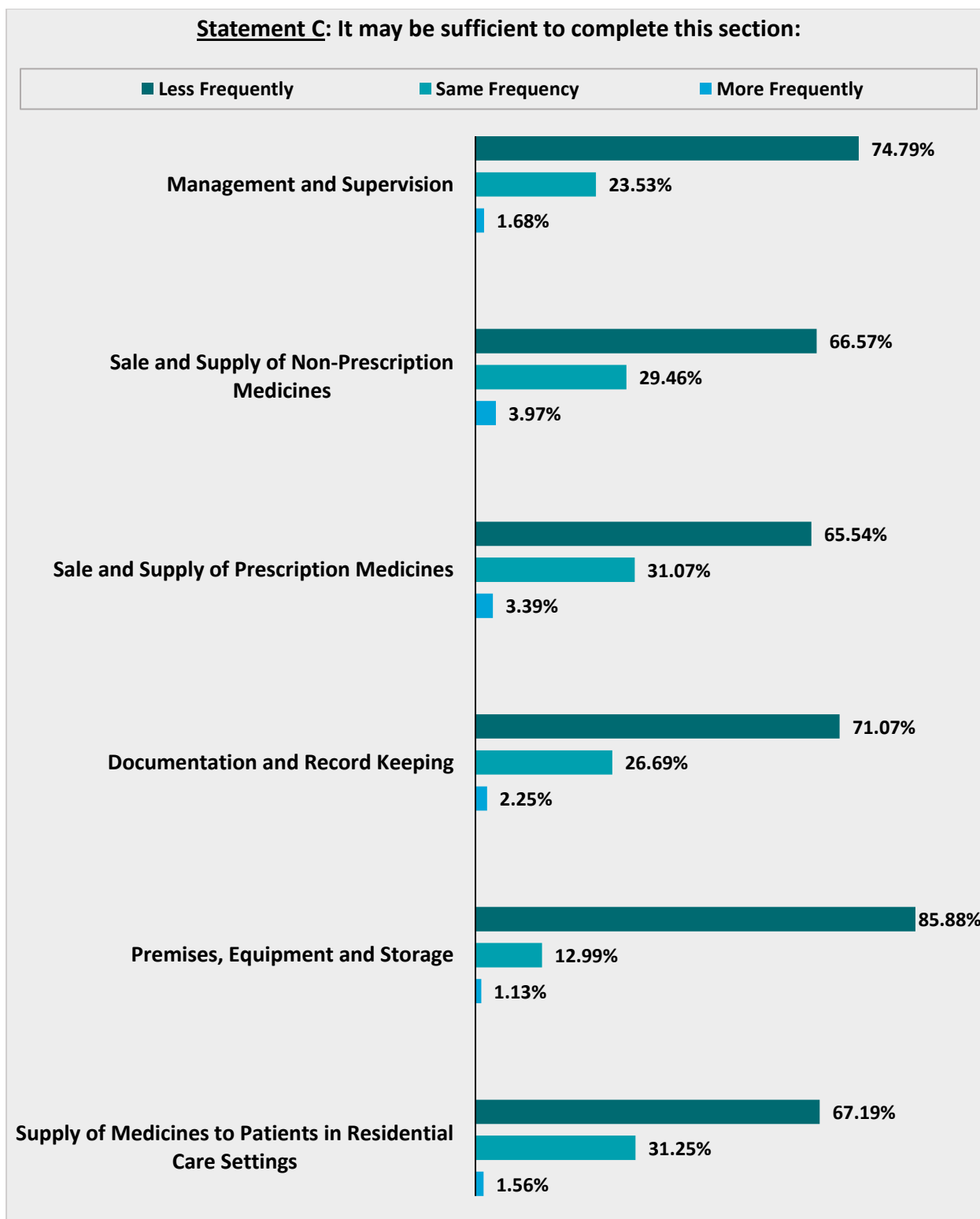
Figure 8: (The overall response rate for Statements A-C was as follows Answered: 394, Skipped: 135). However, the response rate for each section varied.

Having regard to the frequency of completion for each section, participants were asked if it may be sufficient to complete the particular sections: more frequently, same frequency or less frequently. On average, for all sections 72% felt it may be sufficient to complete the sections less frequently.

Could Additional Sections be added?

When asked if additional sections such as vaccination services, veterinary medicines and opioid substitution should be added, 53% of participants said no. Others felt that no additional sections should be added primarily due to time constraints. One participant felt that the current version of the pharmacy assessment system should be shortened, and if additional sections were added they should be shorter. Another participant indicated that the pharmacy assessment system was repetitive, and annual completion would be sufficient.

Would you like to see Sections Related to the Following; Vaccination, Opioid Substitution and Veterinary Medicines added to the Pharmacy Assessment System

None of these	53.39%
Vaccination services	35.16%
Opioid substitution	21.09%
Veterinary medicine	16.41%
Other	6.51%
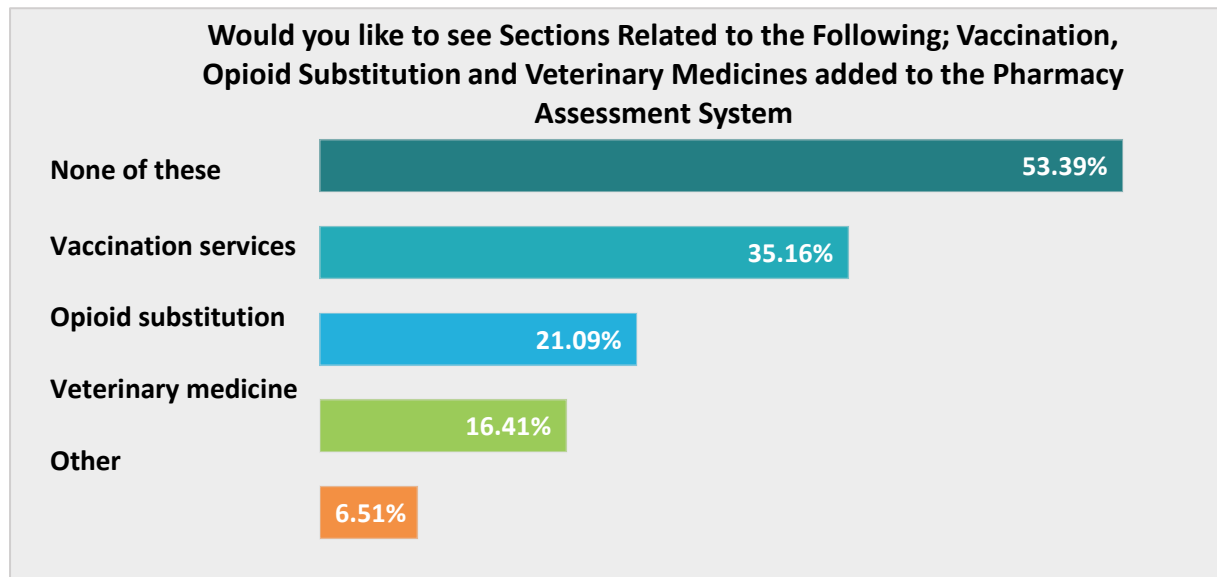
Figure 9: (Answered: 384, Skipped: 145)

Some did however suggest that other sections could be added, for example emergency medicines, high tech medicines, not a section, but a piece with premises, storage and equipment on health promotion aids, continuous education, pharmacy services generally (incorporating vaccination, health screening), emergency contraception, new medication for sale, for example "Pharmacy Only" in the last 12 months, blood pressure monitoring, over the counter training.

Would Non-Supervising Pharmacists Like to Receive the Monthly Reminder Emails?

In order to help pharmacies keep on track and facilitate completion, the PSI send monthly email reminders to supervising pharmacists only.

As part of the survey, non-supervising pharmacists were asked whether or not they too would like to receive these email reminders: **51%** said 'No', while **49%** said 'Yes'. In cases where participants indicated yes to this question, **35%** said they would like to receive them every month, and **65%** said only when a new cycle is due to commence.

2. Action Planning

What did Participants say about Action Planning?

The action plans set out the action(s) that will be undertaken to correct the areas for improvement identified, the person responsible for each action(s) and the target date for completing the action(s). The supervising pharmacist must sign off on the action plans. However, if the superintendent pharmacist and the pharmacy owner(s) are different individuals, they are expected to support the supervising pharmacist with reviewing the pharmacy assessment system and signing-off on the action plans that identify areas for improvement or review within the pharmacy.

During the development stage, it was established that action planning was a new concept for certain individuals. Therefore we were interested to hear from people who were involved in action planning to determine how they were getting on and if they encountered any difficulties.

The graphics below illustrate the feedback received for the action plan part of the pharmacy assessment system.

a) General Comments on Action Planning

Regarding the Development of your Pharmacy's Action Plans, which of the following describes you best:

73.67%
I understand the process involved in developing Action Plans, and feel confident in doing so

21.27%
I am not fully confident in developing Action Plans and would like further support

5.06%
I am not involved in developing Action Plans for the pharmacy

Figure 11: (Answered 395, Skipped 134)

The Action Plan was Useful

Strongly agree **4.84%**
Agree **49.86%**
Neutral **26.5%**
Disagree **12.82%**
Strongly disagree **5.98%**
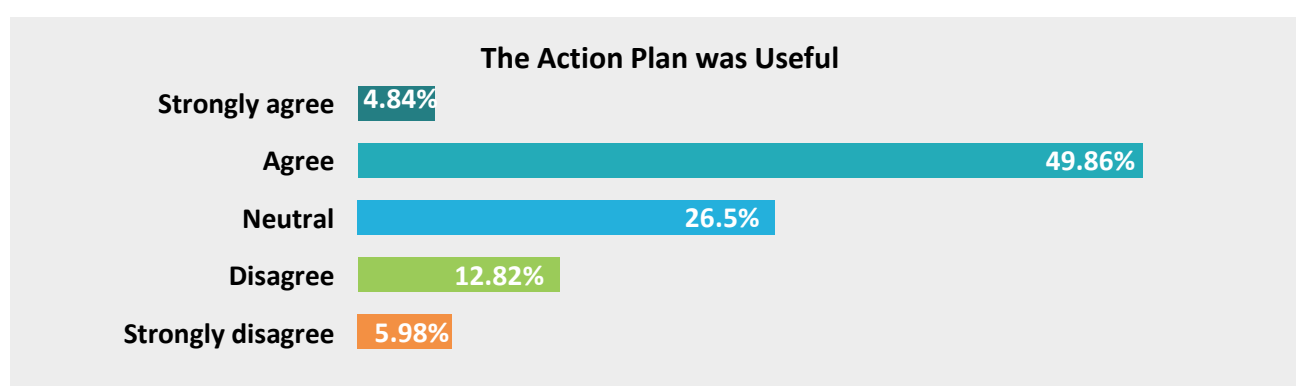
Figure 12: (Answered: 351 Skipped: 178)

The Action Plan helped Plan the Improvements Required in the Pharmacy

Strongly agree **5.43%**
Agree **50.57%**
Neutral **25.43%**
Disagree **13.14%**
Strongly disagree **5.43%**
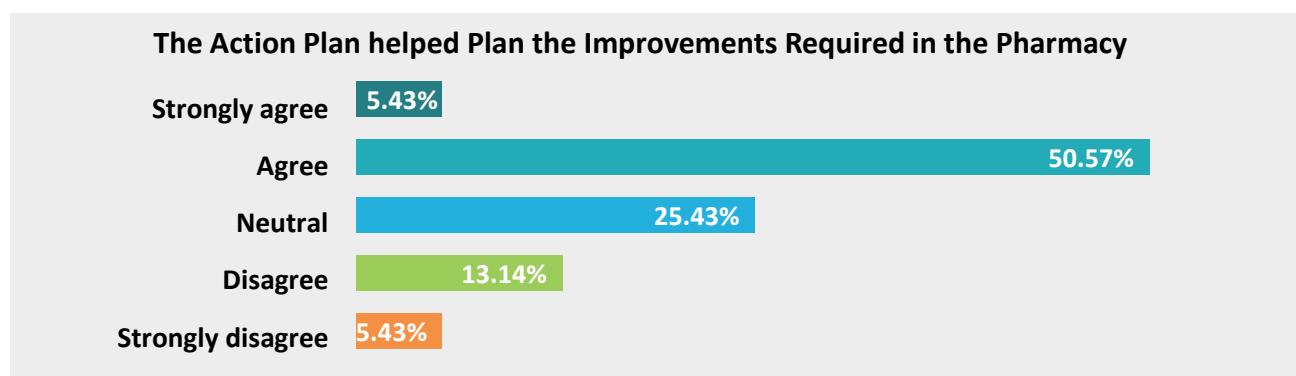
Figure 13: (Answered: 350, Skipped: 179)

The Action Plan helped Highlight the Improvements Required to all Members of the Pharmacy Team

Strongly agree **6.02%**
Agree **45.85%**
Neutral **23.78%**
Disagree **19.48%**
Strongly disagree **4.87%**
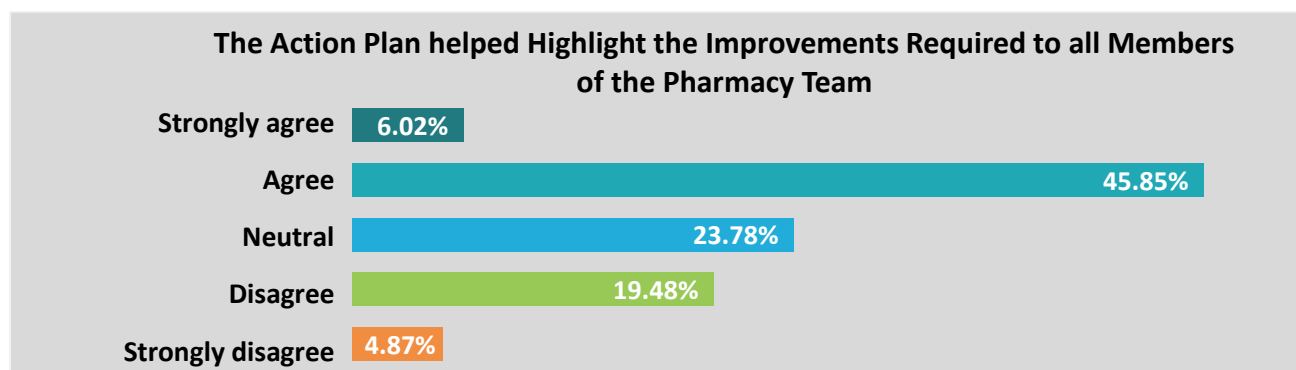
Figure 10: (Answered: 349, Skipped: 180)

b) Difficulties Encountered

Did you Encounter any Difficulties when Completing your Action Plan?

Yes 29%

No 71%
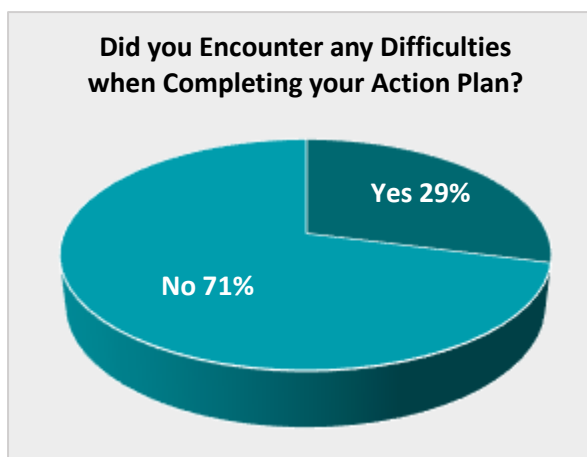
Figure 14: (Answered 365, Skipped 164)

Participants indicated that the main difficulties encountered related to:

- Time Constraints –didn't have specific time to complete the actions, attempted too many tasks to start with or didn't delegate enough tasks. Not enough time to implement the actions
- Staff - changes in staff disrupted the process or lack of support
- Repetitive nature of cycles- felt it was too frequent. One respondent indicated that it was too soon to reassess the sections on equipment (Section 5) and management (Section 1).
- Administrative Burdens, increased paper based administration.
- Terminology and Format were not clear. One participant indicated that they use their own action plan as the PSI version is "too unwieldly", another indicated that there was no space to record that tasks, from previous cycles, were completed.
- Difficult to Set Target Dates as some actions will be ongoing.

In addition to the comments outlined above, supervising pharmacists indicated that they encountered the following difficulties:

- Some areas where they wanted to improve were outside their control. For example they didn't have the resources to make the changes on time without getting approval
- Lack of support received from the pharmacy owner and superintendent pharmacist in terms implementing the action plan and getting the action plans signed off.
- Colleague's resistance to change
- Felt pressurised into coming up with an action plan when one was not needed.
- Concerned if they were inspected and it wasn't completely finished

c) Were Actions Addressed and Completed?

In cases where participants indicated 'no' to the question in *Figure 15* below, they were asked to tell us why. The comments were summarised and are outlined hereunder:

Were all of the Areas Identified for Improvement during Completion of the Review Sections, Addressed in the Action Plans?

No 15%

Yes 85%
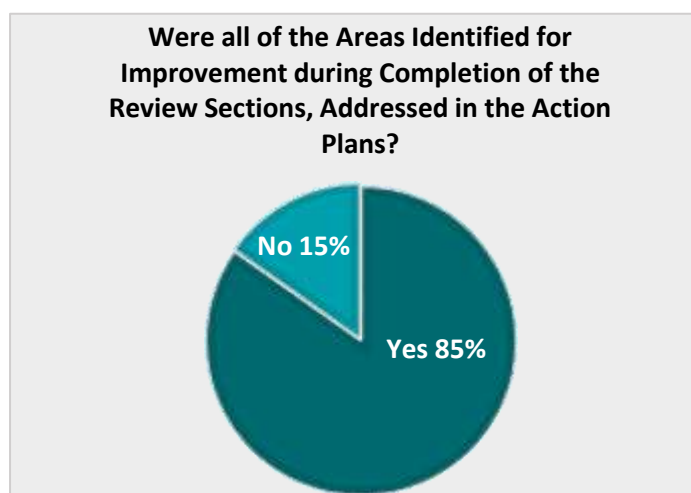
Figure 15: (Answered: 348, Skipped: 181)

- Time Constraints in that there is not enough time and it takes time to implement actions, and difficult to follow up with new cycles starting
- Staff- new staff or lack of support
- No Areas for Improvements Identified therefore action plan was not relevant.
- It seemed Unnecessary

In addition to the comments outlined above, **supervising pharmacists** indicated that there was a lack of support from superintendent pharmacist and pharmacy owner in terms of being provided with the resources needed, as finances were outside their control.

Superintendent pharmacists felt that most pharmacists tended to use the action plans as a call for more resources due to the overburden of administration work placed on them. And due to financial constraints this isn't possible. Therefore, it has only proved to become a point of disagreement and frustration.

In cases where participants indicated 'no' to the question in *Figure 16* below, they were asked to tell us why. The comments were summarised and are outlined hereunder:

- Time Constraints, spare time was filled by completing multiple assessments, rather than implementing changes.
- Staff - lack of support or did not always have the suitable staff to delegate some of the workload to. In one case it was indicated that there was a high staff turnover.
- Some Actions were Ongoing.
- Repetition- the cycles are happening too frequently so difficult to keep up. Some sections would be more appropriate to complete annually as opposed to biannually. This would provide time to implement the actions.
- Queried the value of this.

Were All of the Actions Fully Completed?

No 41%

Yes 59%
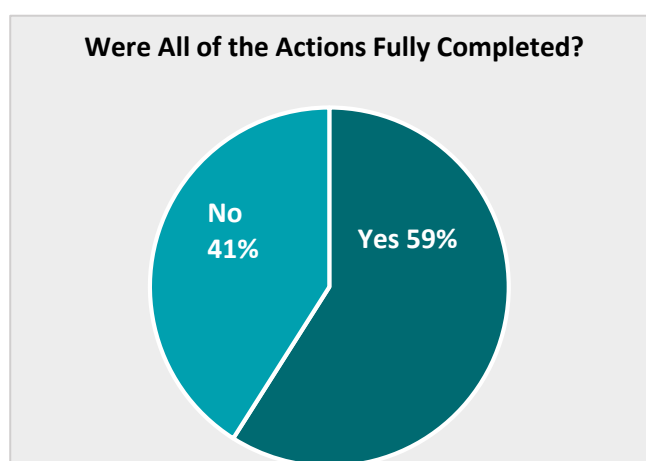
Figure 16: (Answered: 347, Skipped: 182)

The comments were analysed according to the respondent's roles, particularly the supervising and superintendent pharmacists, and the details of this are outlined below:

In addition to the comments outlined above, **supervising pharmacists** indicated that:
- There was a lack of support from the superintendent pharmacist and pharmacy owner. In one case, it was indicated that there was disagreement with the superintendent pharmacist.
- In the hospital setting there is a dependency on the hospital CEO or management to respond to the required actions.
- They weren't allocated extra hours.
- They didn't receive support from others such as the pharmacist or manager.

Comments provided by **superintendent pharmacists** related mainly to time constraints and that actions were ongoing.

d) Approval and Sign-Off
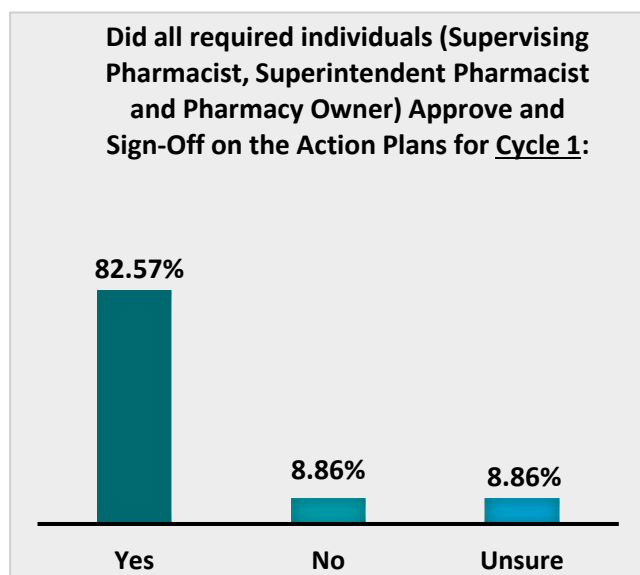
Figure 17: (Answered: 350, Skipped: 179)
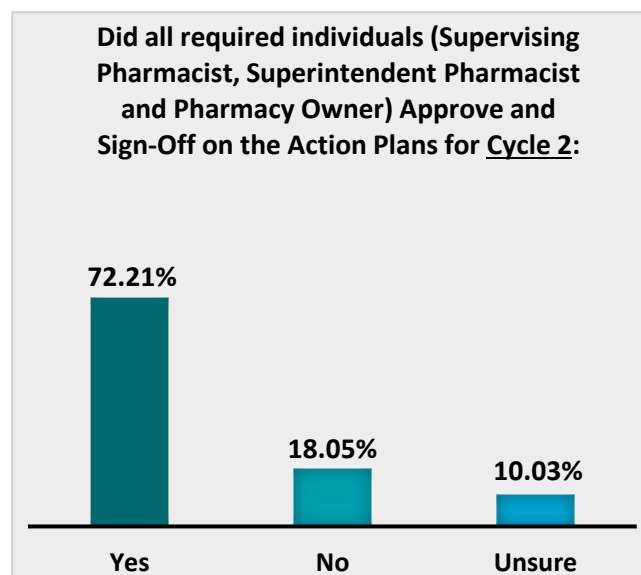
Figure 18: (Answered: 349, Skipped: 180)

In cases where participants indicated 'no' to the questions in *Figure 17* and 18 above, they were asked to tell us why. The comments were summarised and are outlined hereunder:
- Time Constraints was raised as a factor.
- Staff- new staff. Superintendent rarely on site.
- Repetition- felt annual completion was sufficient.
- Cycle 2 was not completed.
- Didn't know they had to.

In addition to the comments outlined above, **supervising pharmacists** indicated that the actions were not signed because the superintendent pharmacist was not always available or on site or there was a change in the superintendent or supervising pharmacist. However,

they did indicate that they had read them. Other supervising pharmacist participants indicated that they fax copies to clinical governance pharmacist to review each month but that the in store copies are not signed routinely - area manager asked to sign once but not a pharmacist and not sure if they are technically considered owner. It was also indicated that pharmacy forms part of a large chain and that the supervising pharmacist did approve and sign off on actions and always emailed them to superintendent, but were unsure if the pharmacy owner did approve and sign-off on the action plans.

Comments from **superintendent pharmacists** related to: time constraints, the pharmacy owner was not interested in box ticking and it was an oversight.

e)   Actions and Subsequent Cycles

During the course of the development and implementation stages, it was anticipated that if the pharmacy assessment system was conscientiously completed during cycle 1, and where actions were identified, less actions would be identified during subsequent cycles. This would demonstrate that the actions taken during earlier cycles were successful and resulted in sustained improvements in the pharmacy. The graph below illustrates the findings in respect to this:
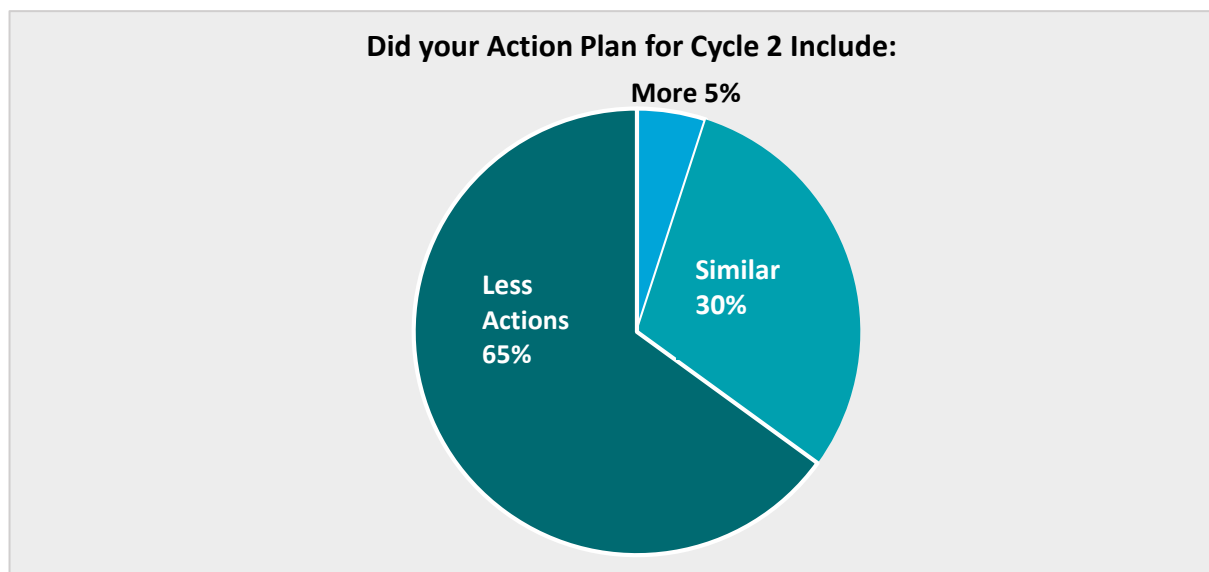
Figure 19: (Answered: 340, Skipped: 189)

3. Communication

Did the Pharmacy Assessment System Improve or Facilitate Communication?

As illustrated in the graph below, a mixed response was received when participants were asked if completing the pharmacy assessment system improved communication between their pharmacy team. *Figure 20* below represents the comments from all participants.

Completing the Pharmacy Assessment System Improved Comunication between the Pharmacy Team

- Strongly agree: 4.37%
- Agree: 31.97%
- Neutral: 30.05%
- Disagree: 24.04%
- Strongly disagree: 9.56%
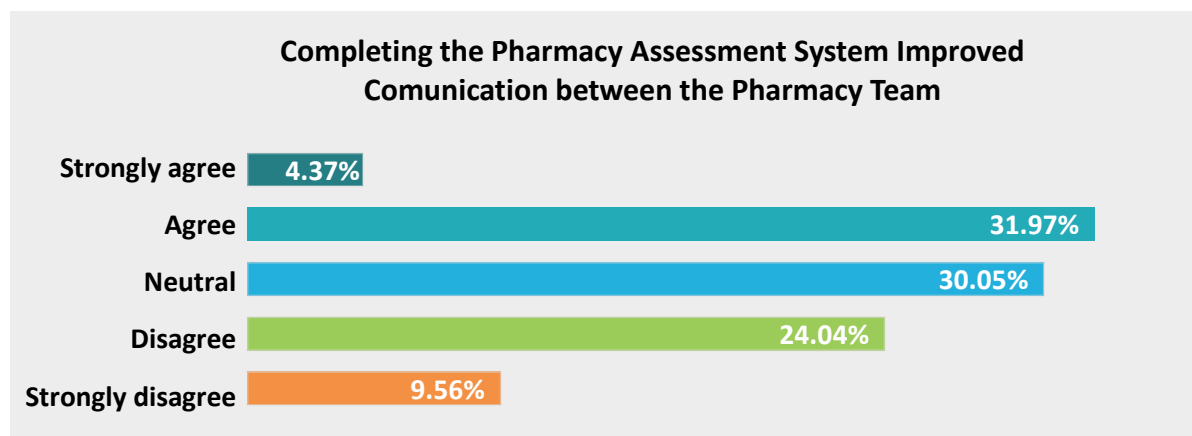
*Figure 20: (**Answered: 366, Skipped 163**)*

Due to the ownership and governance structure in certain pharmacies, the supervising pharmacist is not always the superintendent pharmacist and or the pharmacy owner. Therefore, the survey sought to elicit if by completing the pharmacy assessment system it facilitated communication between these individuals.

Did Completing the Pharmacy Assessment System Facilitate Communication with your Superintendent Pharmacist?

- I am also the Superintendent Pharmacist 49.32%
- Yes 22.3%
- No 28.38%

Figure 21: (Answered 296, Skipped 233)

Did Completing the Pharmacy Assessment System Facilitate Communication with your Pharmacy Owner?

- I am also the Pharmacy Owner 40.75%
- Yes 20.21%
- No 39.04%
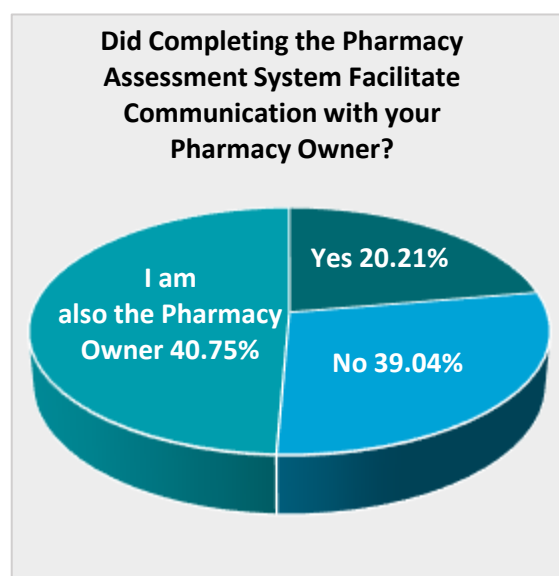
Figure 22: (Answered 292, Skipped 237)

4. Comments from the Supervising Pharmacist

Who helped the Supervising Pharmacist Complete the Pharmacy Assessment System?

As supervising pharmacists are responsible for completing each section of the pharmacy assessment system, we wanted to establish if they completed the pharmacy assessment system on their own or with assistance from other pharmacy team members. **53%** of supervising pharmacists had done so on their own. The remaining **47%** indicated that other members of the pharmacy team assisted them, and the graph below illustrates these individuals.
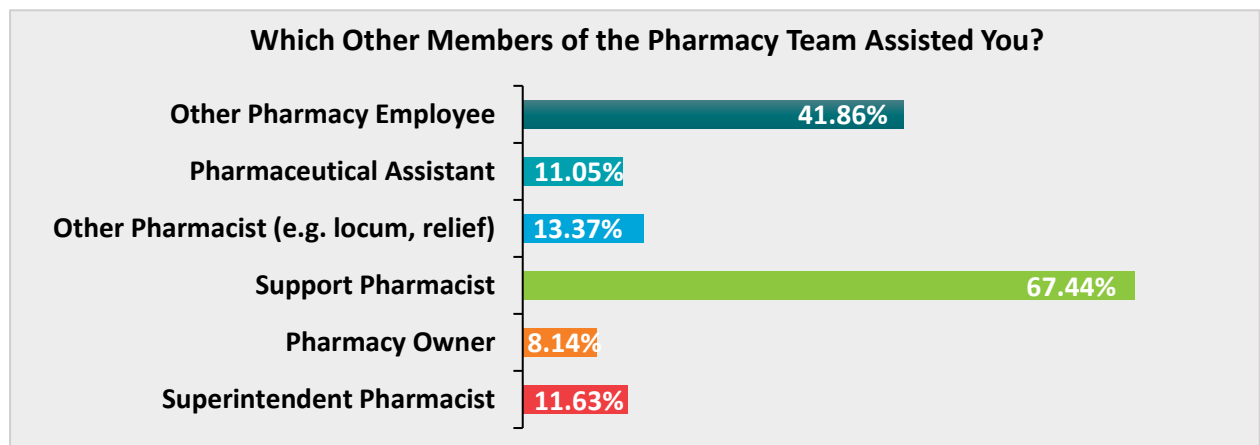
Figure 23: (Answered: 172, Skipped: 357) It can be seen from the figures in the chart that they add up to more than 100%. This is due to the fact that in this question, the supervising pharmacist was able to tick more than one member of the pharmacy team that assisted them.

Under pharmacy employee, the majority indicated that this related to pharmaceutical technicians.

How did the Pharmacy Assessment System help the Supervising Pharmacist?

Although the supervising pharmacist is responsible for completing the pharmacy assessment system, the superintendent pharmacist and the pharmacy owner(s), if different, are expected to support the supervising pharmacist in its completion.

a) Supervising Pharmacist and Superintendent Pharmacist

Having regard to the superintendent pharmacists, the graphs below illustrate that (1) the pharmacy assessment system was used to raise issues and (2) support, where required, was provided to the supervising pharmacist.
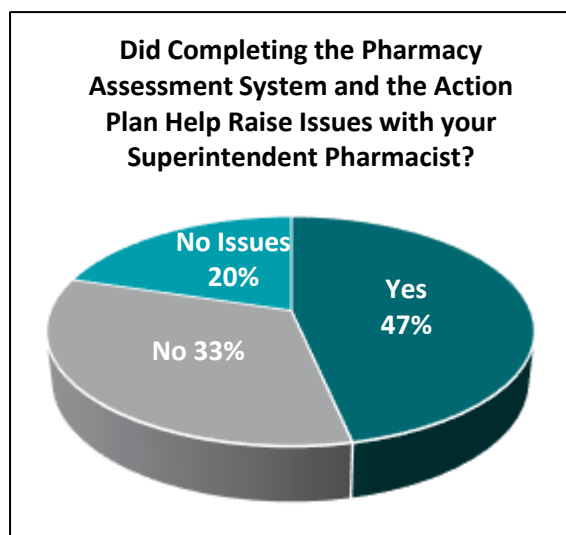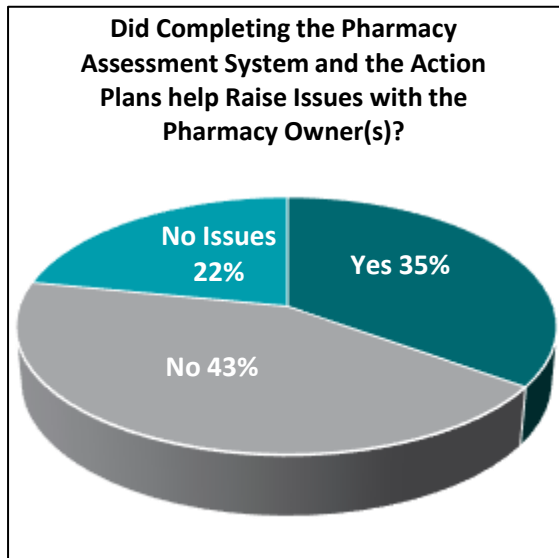

Figure 24: (Answered 148, Skipped 381)
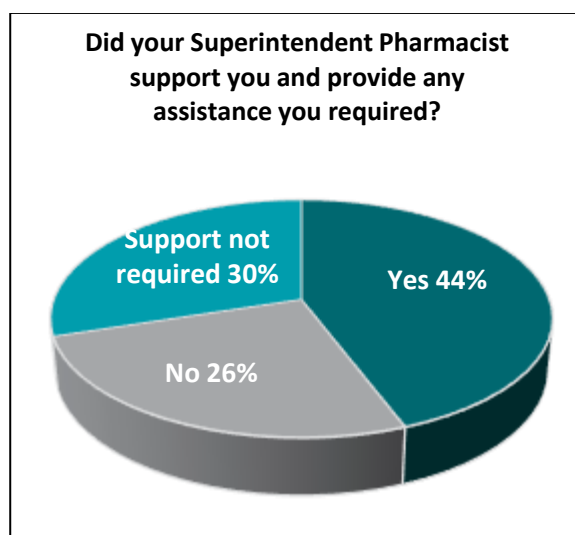
Figure 25: (Answered 147, Skipped 382)

Supervising pharmacists were also invited to provide additional comments on how they and the superintendent pharmacist worked together in completing the pharmacy assessment system. The comments were summarised and outlined below:

- Responses varied in respect of the support provided. On one hand it was indicated that there was no support while others indicated that the support, when required, was excellent.
- They didn't work together on completing it. Either the superintendent pharmacist was not interested in it or they were too busy.
- The pharmacy assessment system was not rated as a priority.
- No involvement by the superintendent pharmacist. Responsibility of superintendent pharmacist appeared to be delegated to the clinical governance manager or pharmacist.

b) Supervising Pharmacist and Pharmacy Owners

Having regard to the pharmacy owner(s), the graphs below illustrate that (1) the pharmacy assessment system was used to raise issues and (2) support, where required, was provided to the supervising pharmacist.

Did Completing the Pharmacy Assessment System and the Action Plans help Raise Issues with the Pharmacy Owner(s)?

No Issues 22%
Yes 35%
No 43%

Figure 26: (Answered 169, Skipped 360)

Did your Pharmacy Owner(s) Support you and Provide any Assistance you Required?

Support was not required 37%
Yes 32%
No 31%

Figure 27: (Answered 168, Skipped 361)

Supervising pharmacists were also invited to provide additional comments on how they and their pharmacy owner(s) worked together in completing the pharmacy assessment system. The comments were summarised and outlined below:

- The completion did not have an impact as they always worked well together
- In one case it was indicated that it was the superintendent pharmacist who raised issues with the pharmacy owner.
- Input from pharmacy owner was not required as issues identified were minimal.
- Indicated that there was a need to inform superintendent pharmacists and pharmacy owners of the importance of signing off on the pharmacy assessment system.
- Provided an opportunity to raise awareness.
- Unsure who the pharmacy owner was.
- The pharmacy owner is not interested in the pharmacy assessment system and relies solely on the views of the superintendent pharmacist.

What did the Supervising Pharmacist say about the Monthly Reminder Emails?

Monthly reminder emails are sent to supervising pharmacists only. Therefore, they were asked to indicate if they found them useful or not, the results of which are illustrated in the graphs below.
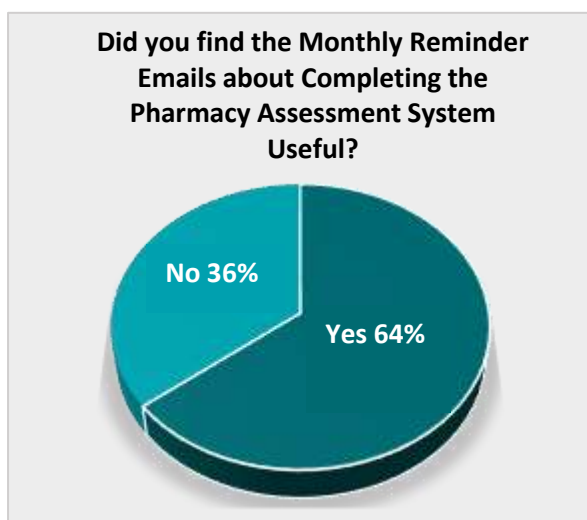
Figure 28: (Answered 289, Skipped 240)
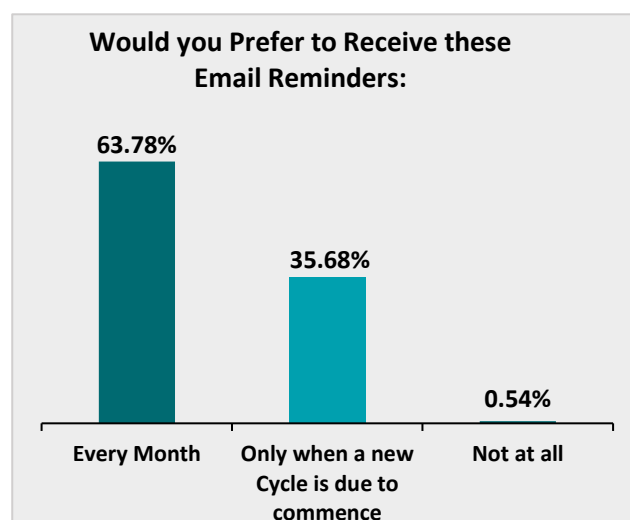
Figure 29: (Answered 185, Skipped 344)

5. Comments from the Superintendent Pharmacist and Pharmacy Owner(s)

Superintendent pharmacist and the pharmacy owner(s) are individuals who hold key governance positions within the overall pharmacy business, and are therefore expected to support the supervising pharmacist in the completion of the pharmacy assessment system.

a) Support and Communication

Figure 30: (Answered 185, Skipped 344)
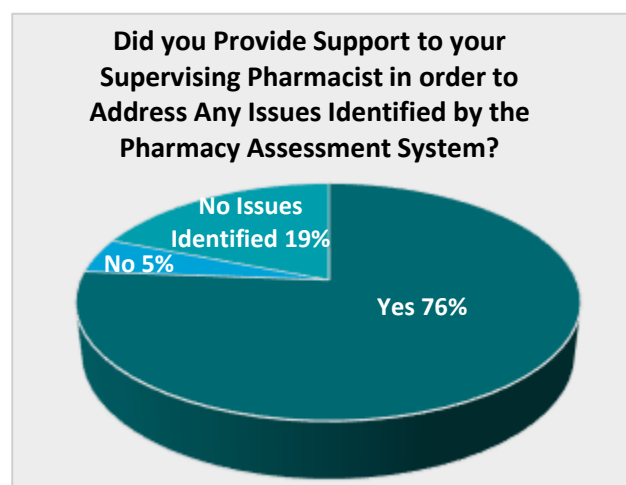
Figure 31: (Answered 42, Skipped 487)

Superintendent pharmacists and **pharmacy owners** were also invited to provide additional comments on how they worked together with the supervising pharmacist in completing the pharmacy assessment system. The comments were summarised and are outlined below:

- They reminded the supervising pharmacist to complete the pharmacy assessment system and reviewed it with them.
- Biannual completion was repetitive and felt that annual completion may be sufficient.

- The need to complete the pharmacy assessment system together with other paperwork is huge drain on resources, and felt that pharmacies should be able to focus on patient care.
- Highlighted the benefits of developing an online version of the pharmacy assessment system. One participant indicated that the lack of readily accessible dashboard type information from the pharmacy assessment system is a significant limitation to the current system.
- Took time away from the pharmacy so that they could complete the pharmacy assessment together
- Had a specific meeting for Cycle 1, but this wasn't required for Cycle 2.

b) Review and Sign Off

The supervising pharmacist must sign off on the action plans. If the superintendent pharmacist and or the pharmacy owner (s) are different from the supervising pharmacist, they should review the completed assessment and also approve the action plans. The graph below illustrates the findings in relation to review and sign off for Cycle 1 and Cycle 2 only. Information on Cycle 3 was not requested as it ongoing at the time of the survey.
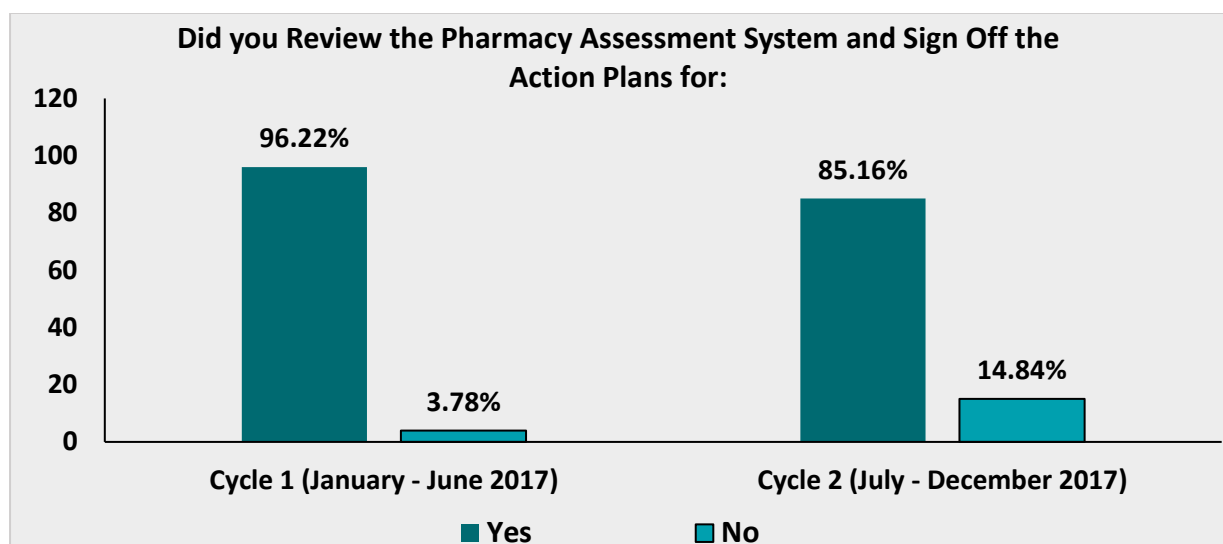
Figure 32: (Answered 185, Skipped 344)

In cases, however, where it was indicated that they did not review the pharmacy assessment system and sign off on the action plans, participants were asked to tell us why. The comments were summarised and are outlined below:

- Time constraints was an issue.
- It was repetitive in that there was a lot of duplication in too short a timeframe.
- Annual completion would be sufficient.
- Cycle 2 was not completed.
- Thought it best to focus on the action plan which wasn't complete from the previous cycle.
- Not confident in the system in that it felt like 'homework'.

6. Governance and Quality Management

Did the Pharmacy Assessment System help with Governance and Quality Management in the Pharmacy?

Governance and management structures within retail pharmacy businesses must work to protect the public. Therefore, it is important that high standards of leadership and accountability are practised by those holding key governance positions. Accordingly, by having a robust quality management system in place it will help ensure that patients are consistently provided with a high quality service, which meets patients' needs and expectations. The graph below illustrates how the superintendent pharmacist, supervising pharmacist and pharmacy owners answered this.
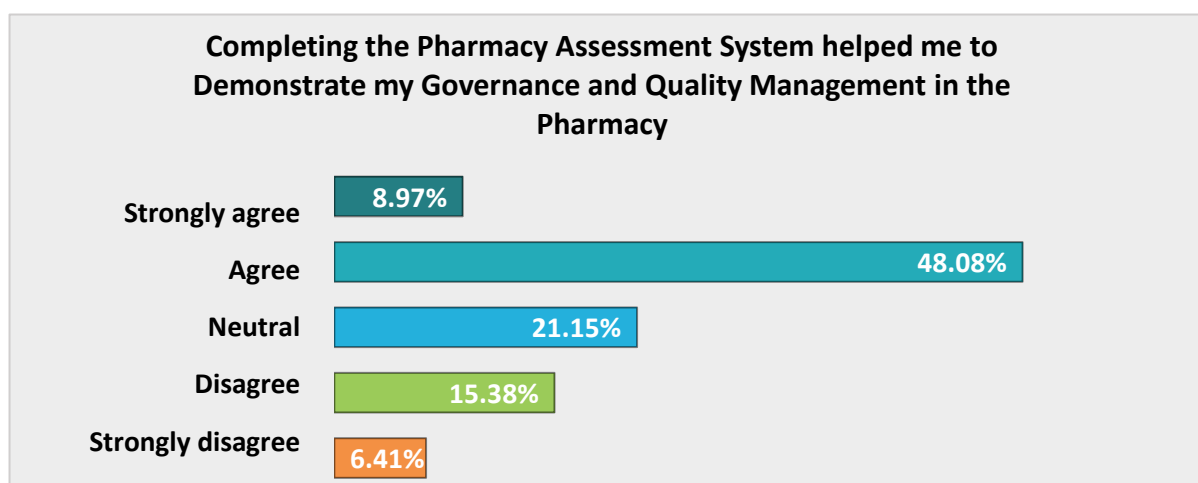
Figure 33: (Answered 312, Skipped 217)

7. Additional Comments

What Additional Comments were provided by the Participants?

Participants were invited to provide any further feedback in relation to the pharmacy assessment system. The comments were summarised and are outlined below:

- The biggest barrier to completion is time constraints. While participants indicated that the first cycle was useful and beneficial from the perspective that it helped pharmacists identify the expected standards, the survey data, however, points the way toward reducing the frequency of the completion with participants indicating that annual completion was sufficient. The main reason for this was that people felt that biannual completion was a burden and became repetitive, and it was felt that it was too frequent to remain meaningful. It was also suggested that parts of Section 5 which related to premises, equipment and storage should only be completed once every 2-3 year. One respondent felt that there was no need to complete it after 3 cycles, and that it should only be returned to when required by the supervising pharmacist. In addition, it was felt that annual completion would allow time to implement action plans.

- It was a useful practical tool, and helped improve delivery of service from the pharmacy and help support pharmacies improve standards.
- However, it was indicated that cooperation should be mandatory from the superintendent pharmacist. Some did however indicate that it was unhelpful. It was also indicated that there was no value to the patient and it was a distraction for the Superintendent and Supervising Pharmacists. Others felt it was more of a box ticking exercise which has no beneficial effect on the quality of the services provided to patients.
- While it was indicated that initially they were sceptical with the process, but see the benefits of the pharmacy assessment system now.
- The content could be refined, and the current version could be shortened.
- An online version of the pharmacy assessment is welcomed. An online system would be more user friendly, and crucial to future adherence.
- Found certain sections such as Section 2: Sale and Supply of Non-Prescription Medicines and Section 3: Sale and Supply of Prescription Medicines difficult to implement and objectively evaluate, and many were noted retrospectively.
- Suggested that the pharmacy assessment system could be integrated as part of the inspection process in that the assessments can be reviewed by the inspector to ensure compliance within the program.
- It was suggested that it could be amended and updated- new sections would be welcomed and it should be shorter and simpler.
- It was indicated that current form was belittling and demeaning to the profession. It is so similar to a workbook exercise.
- It was a waste of money by the PSI in that money could have been spent elsewhere.
- It was indicated that at this stage the assessment process has lost credibility, relevance and causes resentment.
- It is an effective tool to demonstrate compliance.
- It was felt that the pharmacy assessment system was a positive move by the PSI. It was indicated that the assessment system from a governance perspective is an excellent tool in demonstrating the accountability supervising pharmacists have in terms of the management and supervision of their pharmacy. Furthermore, it was indicated that the active recording of actions highlighted and made both pharmacy owners, superintendent and supervising pharmacists aware of their pharmacy's level of compliance and standards of practice.
- It was indicated that the system needs to be amended. It should not be necessary to go into the same level of detail every subsequent six months.

Summary of Results from the Review Visits

Who was Present During the Course of the Review Visits?

As the supervising pharmacist is the person responsible for completing the pharmacy assessment system, the review visits sought to elicit who was providing professional cover in the pharmacy during the course of the visits. In a majority of cases 66% the supervising pharmacist was present during the visit.

In cases where the supervising pharmacist was not present, and for example a locum pharmacist was on duty, general comments were provided which were based on their experience of using the pharmacy assessment system in other pharmacies. However, in some cases where either a pharmaceutical assistant and a newly appointed superintendent/supervising pharmacist were providing cover, they indicated that they were unable to provide feedback as they had no involvement in completing it at the pharmacy or they had only recently commenced working in the pharmacy respectively.

General Completion

Information was sought to elicit whether or not pharmacies were continuing to engage with the pharmacy assessment system. The graph below illustrates the positive engagement thus far with 94% of pharmacies completing it.

Is the Pharmacy Completing the Pharmacy Asssesment System?

No 6%

Yes 94%
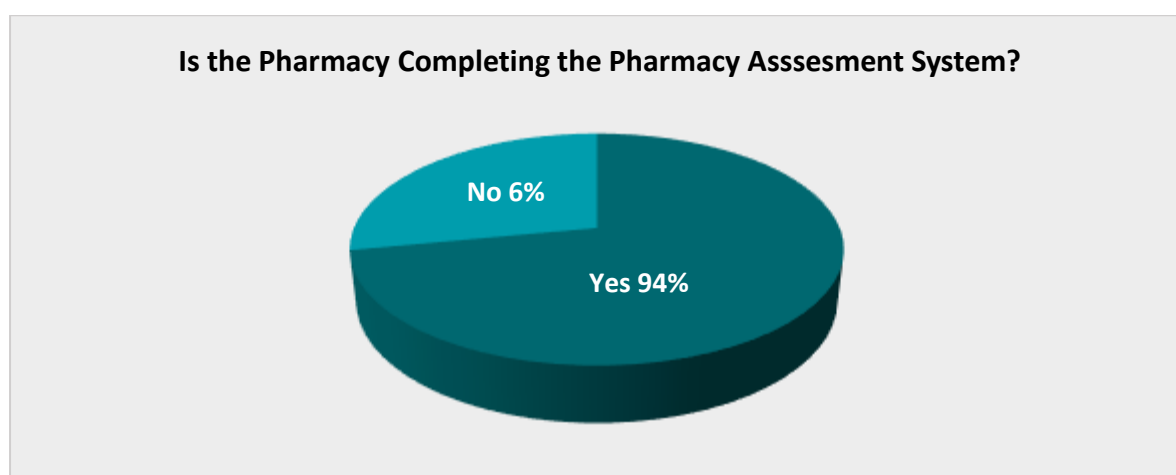
Figure 34

Completion over the Various Cycles

Pharmacies were asked if they had completed the pharmacy assessment system for the various cycles. The following chart illustrates the breakdown. As can be seen, high percentages (88% and 80%) of the pharmacies had completed the pharmacy assessment system for Cycle 1 and Cycle 2 respectively.

Appendix 3

Pharmacises had Completed Cycle 1 and Cycle 2 of the Pharmacy Assessment System as indicated below:
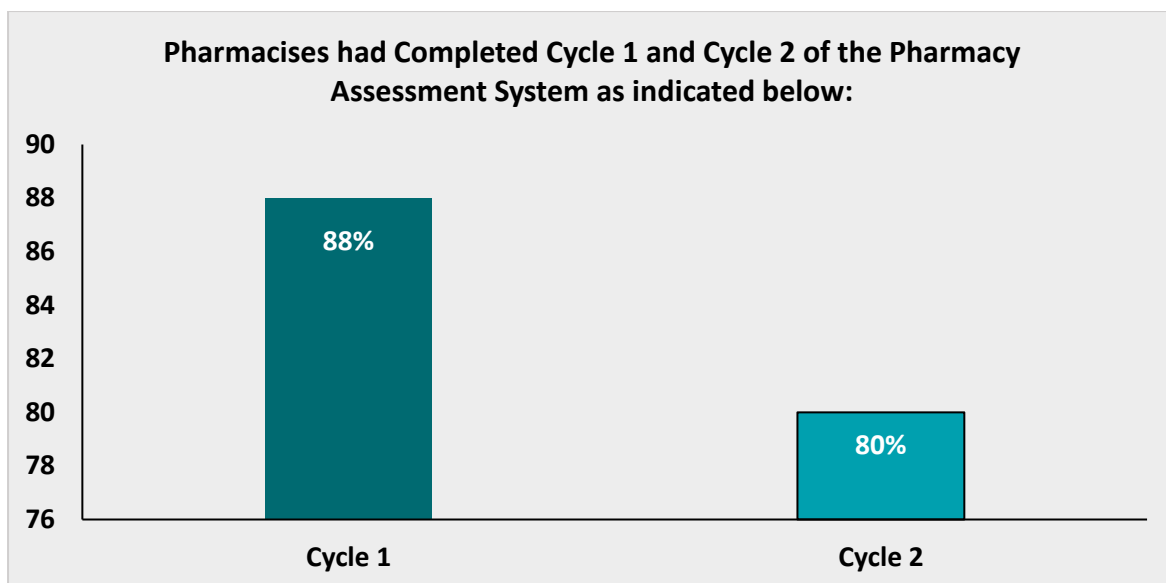

Figure 35: The figures for Cycle 3 are not included due to the fact that Cycle 3 was ongoing during the course of the review visits and was not due to be completed until June 2018.

Did Completing the Pharmacy Assessment System help the Pharmacy Review Pharmacy Practice/Identify Areas for Improvement?

The following chart illustrates that a majority of pharmacies (75%) felt that by completing the pharmacy assessment system it helped review pharmacy practice/identify areas for improvement. Non-applicable (N/A) represented those pharmacies whereby the pharmacist on duty did not provide a comment on the basis that they had no involvement in completing the pharmacy assessment system.
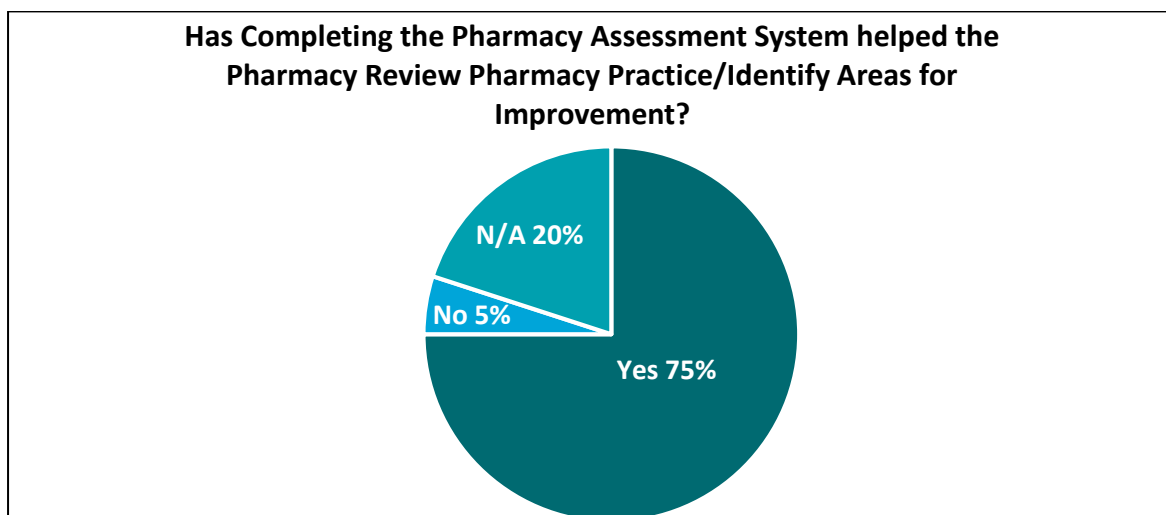
Figure 36: Non-Applicable (N/A) - this represents cases where the authorised officer could not establish this information for reasons such as the pharmacist on duty was not in a position to answer the question.

57

How long did it take to Complete Subsequent Cycles?

After completing Cycle 1, we were interested in finding out how long it took pharmacies to complete further cycles of the pharmacy assessment system. The results of which are illustrated below:
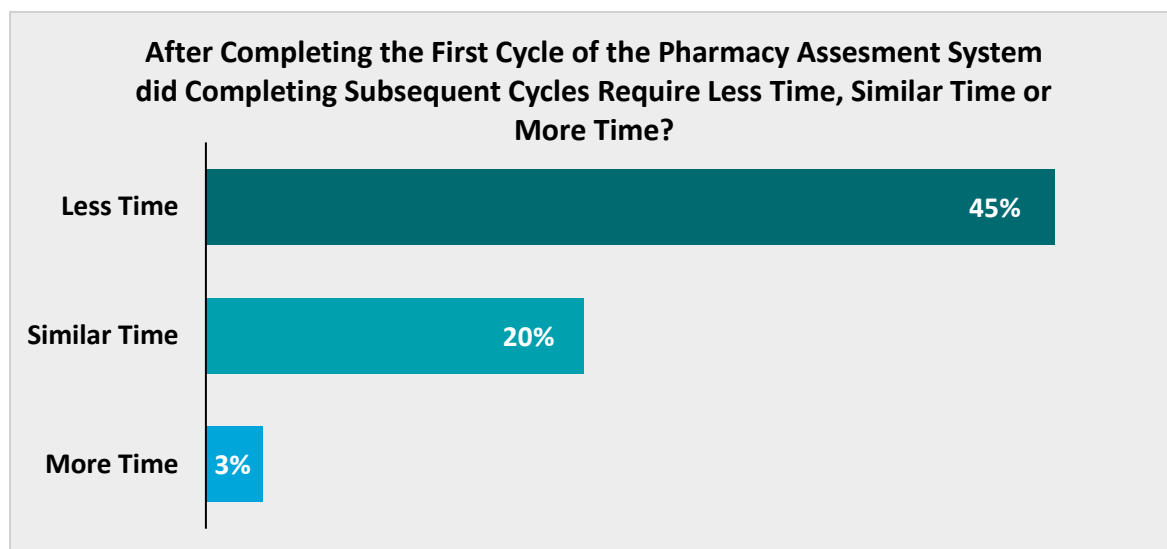

Figure 37: Please note that for the remaining 32%, the authorised officer could not establish this information for reasons such as the pharmacist on duty was not in a position to answer the question, only one cycle of the pharmacy assessment system had been completed or in one case no cycle had been completed at all.

Which Version of the Pharmacy Assessment System are Pharmacies Using?

Information was sought to determine which version of the pharmacy assessment system pharmacies were using. The following chart illustrates that a majority (86%) use the hard copy paper version.
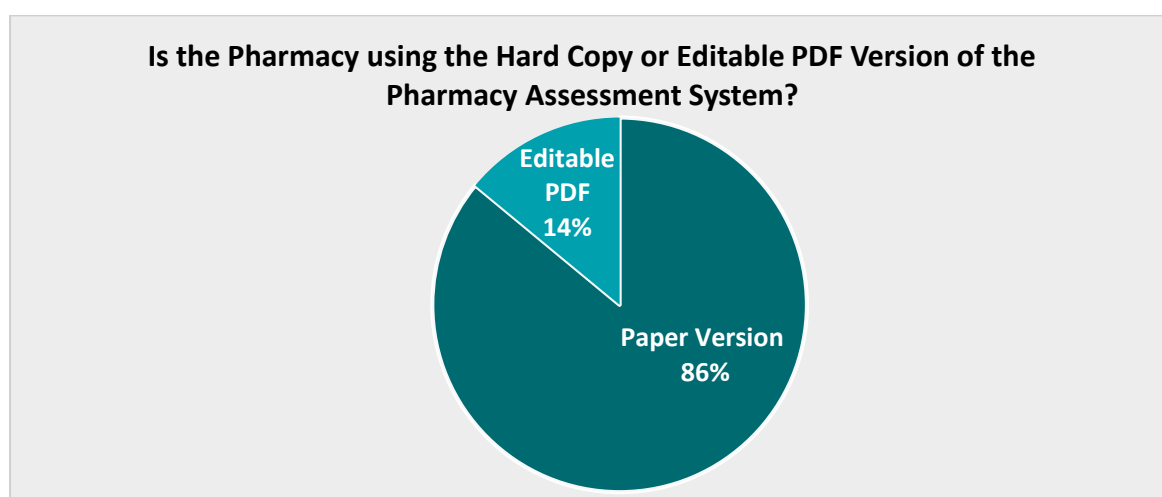
Figure 38

Are there any Additional Sections which the Pharmacist Thinks Should be Included in the Pharmacy Assessment System?

A majority of pharmacies (54%) said no additional sections should be included, while 31% of pharmacies indicated yes. In these cases, pharmacists provided the following information on additional sections which they thought should be included: vaccination Services 20%, veterinary Services 11%, opioid Substitution 12%.[1] Where 'other' was selected, suggestions included data Protection/GDPR/Social Media, Sale of new OTC products, Internet Supply and Additional Services

In 15% of cases it was indicated that this question was non-applicable due to the fact that the pharmacist on duty was not in a position to answer this on behalf of the pharmacy.

Action Planning

Information was sought to elicit whether or not the individuals holding key governance positions, which include the supervising pharmacist, superintendent pharmacist and pharmacy owner(s) had approved the action plans for the various cycles. The following chart illustrates the findings.
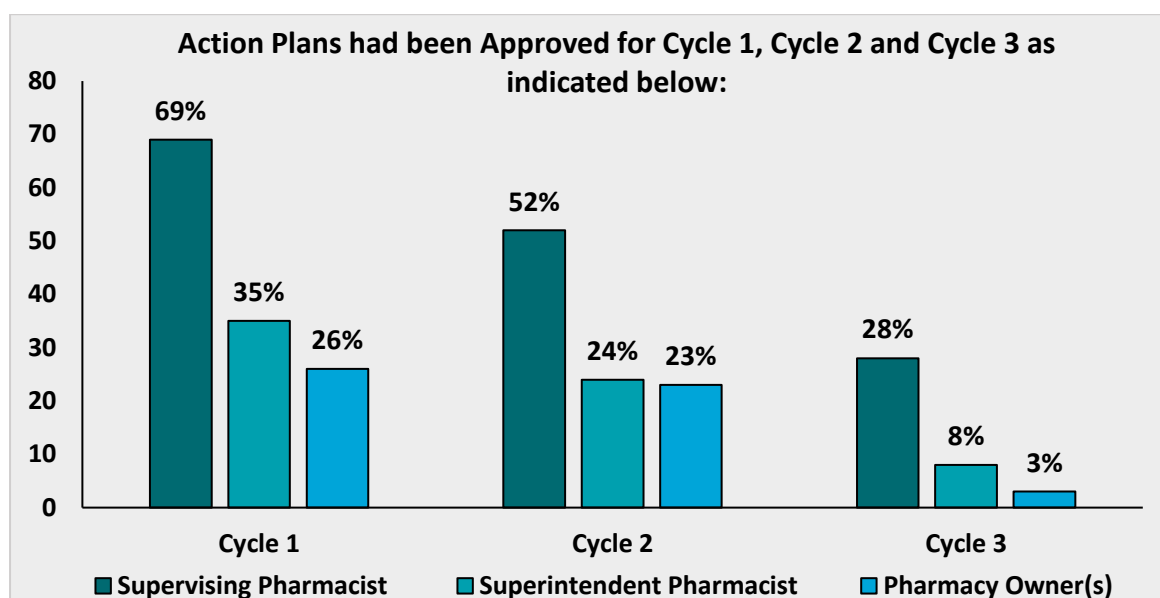

Figure 39

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[1] Please note that pharmacists were able to tick more than one option.

Communication

When asked if completing the pharmacy assessment system improved communication between the pharmacy team, 63% of pharmacies said yes.
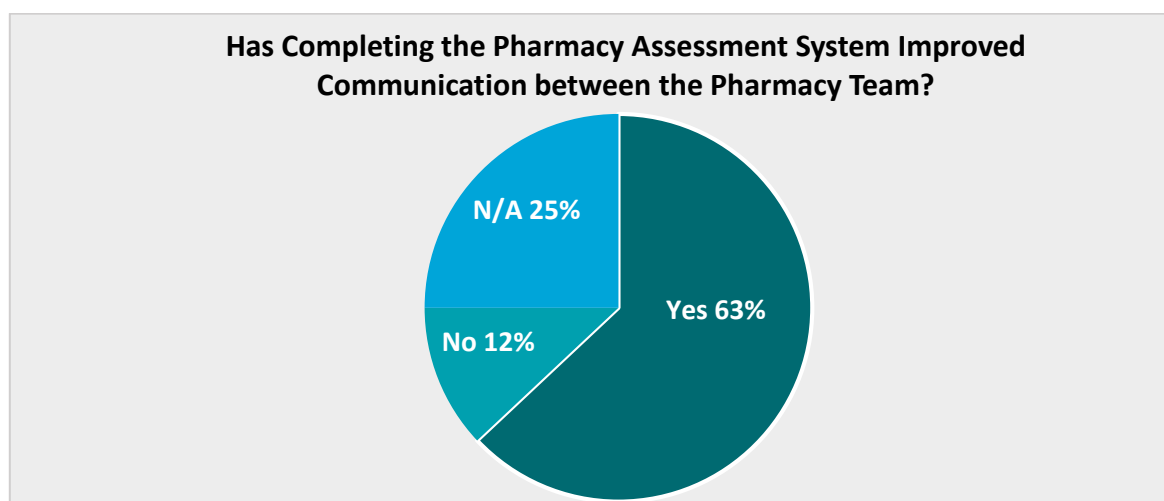

Figure 40: (N/A) - this represents cases where the authorised officer could not establish this information for reasons such as the pharmacist on duty was not in a position to answer the question.

Questions for the Supervising Pharmacist only.

During the visits, in 66 pharmacies the supervising pharmacist was on duty, and it was established that they were different from the superintendent pharmacist and pharmacy owner. Therefore, specific questions were asked, and the findings are outlined below:

- **36%** of supervising pharmacists indicated that the pharmacy assessment system helped facilitate their communication with the superintendent pharmacist.
- **21%** of supervising pharmacists indicated that the pharmacy assessment system helped facilitate their communication with the pharmacy owner.
- **44%** of supervising pharmacists indicated that the pharmacy assessment system and the action plans helped them raise issues with the superintendent pharmacist or pharmacy owners.
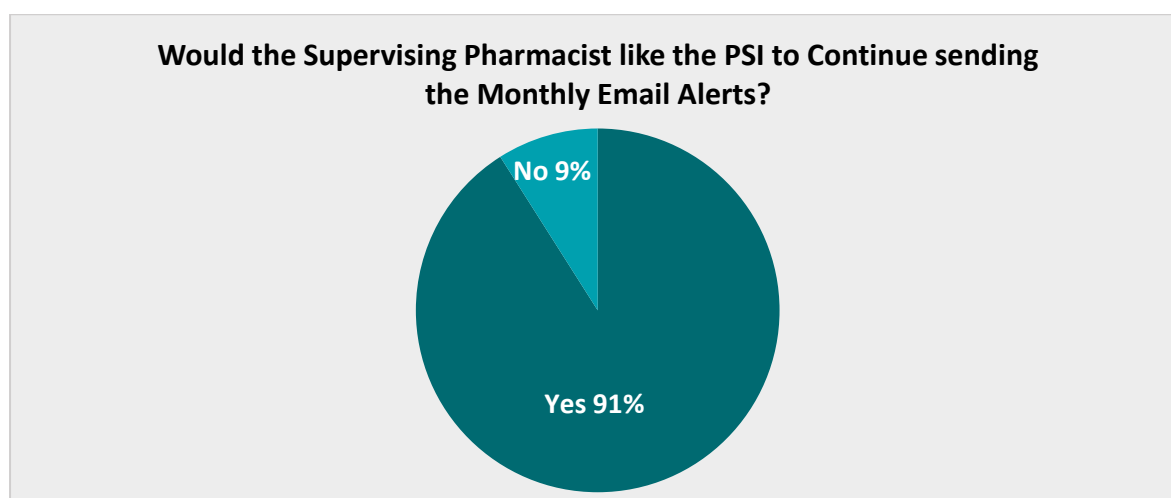

Figure 41

What Additional Comments were Provided by Pharmacies?

Pharmacies were invited to provide any further feedback in relation to the pharmacy assessment system. The comments received were summarised and are outlined below:

Having regard to the **frequency** of completion, some indicated that biannual completion was fine, while a majority indicated that annual completion would be sufficient for reasons such as it being repetitive and difficult to complete due to time constraints.

- It was a useful practical tool, and helped improve delivery of service from the pharmacy.
- It was an additional administrative burden.
- It was felt that it took the pharmacist away from spending time with patients.

An **online system would be more user friendly**.

- It was a useful tool to facilitate communication with the pharmacy team.
- Useful to identify staff training needs.
- Useful tool for staff training
- Useful to prepare for a PSI inspection.
- Helping to sustain the pharmacy's ongoing compliance with pharmacy and medicines legislation, PSI Guidance and good pharmacy practice
- The content could be refined.
- Integration of the pharmacy assessment system and inspections in that it could lead to a notified inspection.

Summary of Observations from the Content Review of the Pharmacy Assessment System

For ease of reference a summary of the observations made as part of the content review for each section, together with the action plan booklet are outlined below.

Section 1: Management and Supervision

Impact on Patient Outcome / Patient Safety
Assurance to the public that the pharmacy is regularly reviewing issues that impact on patient safety and patient outcomes in the areas of staffing, staff training, policies and procedures and staff communication.

Aligned with Purpose of Pharmacy Assessment System
Review of staffing and documented procedures, which form part of a pharmacy's Quality Management System and help ensure patient safety and the quality of care in providing services from the pharmacy.

Overall Impact on Pharmacy:

a) What is Involved in Completing the Review Activity?
Mix of review activities, yes/no questions and reflective questions.

b) Estimated Time Burden to Pharmacy to Complete Review Activity
Time taken to complete section will be dependent on who is completing the section, their familiarity with pharmacy staff and procedures, and the availability of relevant records / information.

c) Ability to Delegate Tasks?
Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct
Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?
Yes - could be less frequent, particularly if no staffing changes or changes to procedures.

Suggested Updates from the Content Review
- Expand to review the maintenance of staff qualifications / competence and training
- Include further clarification where needed
- May need to be updated in line with proposed Rules on Temporary Absence
- Suggest reviewing the format of the questions on reviewing SOPs.

Section 2: Sale and Supply of Non-Prescription Medicines

Impact on Patient Outcome / Patient Safety
Review / Verification by the supervising pharmacist that the medicine supplied was safe and appropriate for the patient and their needs, and that the patient was provided with sufficient information to allow them to use their medicine safely and effectively.

Aligned with Purpose of Pharmacy Assessment System
Review of the safe and appropriate supply of a non-prescription medicine from the pharmacy.

Overall Impact on Pharmacy:

a) **What is Involved in Completing the Review Activity?**
Review and record the details of the supply of 5 non-prescription medicines from the pharmacy.

b) **Estimated Time Burden to Pharmacy to Complete Review Activity**
Dependent on number of medicines requested / supplied / patient symptoms, the questions asked and advice given, and the level of detail recorded by the reviewer.

c) **Ability to Delegate Tasks?**
Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct
Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?
Yes - could look at numbers of supplies to be reviewed over a period of time.

Suggested Updates from the Content Review
- Suggest adding a note on the availability / use of patient consultation area as part of patient counselling.

Section 2: Sale and Supply of Prescription-only Medicines

Impact on Patient Outcome / Patient Safety
Review / Verification by the supervising pharmacist that the medicine supplied was safe and appropriate for the patient and their needs, that the supply was made in accordance with relevant legal requirements, and that the patient was provided with sufficient information to allow them to use their medicine safely and effectively.
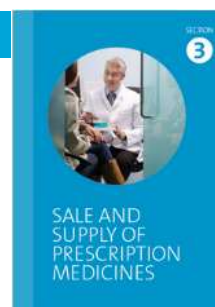
Aligned with Purpose of Pharmacy Assessment System
Part of review of how prescription medicines have been supplied from the pharmacy under the personal supervision of a pharmacist. The supply of prescription medicines is one of the core services a pharmacist provides. Completing this section verifies the provision of a consistently safe, quality service to patients.

Overall Impact on Pharmacy:

a) What is Involved in Completing the Review Activity?
Review and record the details of the supply of 5 prescription medicines from the pharmacy.

b) Estimated Time Burden to Pharmacy to Complete Review Activity
Time required dependent on how easily prescriptions and prescription registers can be retrieved. Time taken may also be affected if need to consult with staff involved in supply.

c) Ability to Delegate Tasks?
Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct
Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?
Yes - could look at numbers of supplies to be reviewed over a period of time.

Suggested Updates from the Content Review
- Suggest adding a question on retention of copies of schedule 4 part 1 controlled drug prescriptions.
- Update question on recording of emergency supplies to reflect that this is only required where at the request of a patient.

Section 4: Documentation and Record Keeping

Impact on Patient Outcome / Patient Safety

Assurance to the public that appropriate records are in place in the pharmacy, including records of supplies and errors, and these are accurately maintained and regularly reviewed, as part of the accountability and traceability of medicines and the pharmacy's quality management system.

Aligned with Purpose of Pharmacy Assessment System

Verification that the required records for the pharmacy are completed and retained in accordance with legal requirements, and to ensure records for the traceability of medicines are available in the pharmacy.

Overall Impact on Pharmacy:

a) What is Involved in Completing the Review Activity?

Mix of review activities, yes/no questions and reflective questions.

b) Estimated Time Burden to Pharmacy to Complete Review Activity

Time required dependent on the availability of relevant records, and whether issues are identified as part of the review.

c) Ability to Delegate Tasks?

Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct

Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?

Could be completed less frequently where records are maintained.

Suggested Updates from the Content Review

- Update to reflect updated Data Protection requirements, and suggest adding additional question on the maintenance of patient confidentiality.

Section 5: Premises, Equipment and Storage

Impact on Patient Outcome / Patient Safety

Assurance that the pharmacy has appropriate premises, equipment and storage arrangements to ensure the safety of patients attending the pharmacy, and receiving pharmacy services from the pharmacy premises.

Aligned with Purpose of Pharmacy Assessment System

Verification that medicines are stored safely, securely and appropriately within the registered pharmacy premises, and that the pharmacy's premises and equipment facilitate the provision of a safe service to patients.

Overall Impact on Pharmacy:

a) What is Involved in Completing the Review Activity?

Mix of review activities and yes/no questions / lists.

b) Estimated Time Burden to Pharmacy to Complete Review Activity

Depends on the size and condition of the premises and availability of required equipment.

c) Ability to Delegate Tasks?

Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct

Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?

Yes - particularly if no change to premises, equipment or storage arrangements.

Suggested Updates from the Content Review

- Suggest reviewing questions relating to the use of the patient consultation area to include further reflection on how this area is used within the pharmacy, and how it is made available to patients to facilitate counselling by the pharmacist in a private and confidential setting.

Section 6: Supply of Medicines to Patients in Residential Care

Impact on Patient Outcome / Patient Safety

Assurance that patients in residential care settings are provided with the same level of professional care and attention as patients who come to the pharmacy in person, and that supplies of medicines are made in accordance with relevant legal requirements, and that the patients are provided with sufficient information to allow them to use their medicine safely and effectively.

Aligned with Purpose of Pharmacy Assessment System

Verification that where medicines are supplied to patients in residential care settings from a pharmacy, that this is being done in a safe manner, in accordance with legal requirements.

Overall Impact on Pharmacy:

a) What is Involved in Completing the Review Activity?

Mix of review activities, yes/no questions and reflective questions.

b) Estimated Time Burden to Pharmacy to Complete Review Activity

Only required to complete if pharmacy provide services to patients in residential care settings. Staff member completing this review should be familiar with this service.

c) Ability to Delegate Tasks?

Yes - certain questions / activities can be delegated to other staff, and reviewed by the supervising pharmacist.

Requirement of Legislation, Guidance, Code of Conduct

Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?

Yes.

Suggested Updates from the Content Review

- Update question on recording of emergency supplies to reflect that this is only required where at the request of a patient.

Action Plan Booklet

Impact on Patient Outcome / Patient Safety
Assurance to the public that where areas for improvement have been identified in the pharmacy, that actions are planned and undertaken.

Aligned with Purpose of Pharmacy Assessment System
Part of a system of continuous improvement, where areas for improvement are identified and actions undertaken to ensure patient safety and quality of care provided by the pharmacy.

Overall Impact on Pharmacy:

a) **What is Involved in Completing the Review Activity?**
Recording of actions planned and undertaken, and approval of action plans by supervising pharmacist, superintendent pharmacist and pharmacy owner.

b) **Estimated Time Burden to Pharmacy to Complete Review Activity**
Dependent on the number of areas for improvement and the number / type of actions identified.

c) **Ability to Delegate Tasks?**
Yes - certain actions can be delegated to other members of the pharmacy team, where appropriate to their role. However, the approval of action plans cannot be delegated.

Requirement of Legislation, Guidance, Code of Conduct
Yes - questions based on legislation, guidance and principles of good pharmacy practice.

Potential to Change Frequency (from 6-monthly)?
The completion of the action plan is dependent on area(s) for improvement and actions identified and is ultimately linked to the overall frequency of completion of the pharmacy assessment system. If, however, the frequency of completion was reduced to annually it would mean that pharmacies wold have more time to implement or complete the actions that were identified.

Suggested Updates from the Content Review
- Review of format of the templates and the wording provide further clarification to terms/headings which in their current presentation may cause confusion.