

Report on PSI's Public Consultation on revised draft Guidelines on Record- Keeping in a Retail Pharmacy Business

About PSI – the pharmacy regulator

The Pharmaceutical Society of Ireland (PSI) – The Pharmacy Regulator, is the statutory body responsible for regulating pharmacists and pharmacies in the public interest. The PSI regulates 7,961 pharmacists, 130 pharmaceutical assistants and 1,991 pharmacies (May 2026 stats).



Our Mission

We assure patient safety and public trust in pharmacy through effective regulation



Our Vision

Safe and effective pharmacy care supporting the health of our communities



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1. Introduction

1.1 Purpose of this report

This report summarises feedback received during our public consultation on revised draft Guidelines to support pharmacists with record-keeping in retail pharmacy businesses. The public consultation ran from 21 April to 19 May 2026.

The Guidelines have been prepared with a view to publication in compliance with Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended), which provides that the PSI Council may publish Guidelines for the purpose of facilitating compliance with these Regulations.

Further information on the consultation, including analysis and findings of feedback received, is outlined in this report.

1.2 About the public consultation

The revised draft Guidelines incorporate recent legislative amendments that allow certain pharmacy records to be kept electronically from 30 June 2026, along with additional new record-keeping requirements for pharmacists. The revised draft Guidelines were considered and approved for public consultation by the PSI Council at its meeting of 26 March 2026.

1.2.1 Background to this consultation

In November 2025, the Department of Health established a multi-stakeholder Electronic Record-Keeping Implementation Group to deliver on its commitments made under the [Community Pharmacy Agreement 2025](#) and the [PSI Workforce Intelligence Report 2023](#), to progress legislative change aimed at modernising prescription management, supporting the adoption of electronic record-keeping practices to reduce administrative burden in pharmacies and enabling a more streamlined and digitally supported pharmacy workflow.

The Group is chaired by the Department of Health and includes the following key stakeholders:

- PSI
- Irish Pharmacy Union (IPU)
- Health Service Executive Primary Care Reimbursement Service (HSE-PCRS)
- Health Service Executive National Quality and Patient Safety Directorate (HSE-QPS)
- HSE Access and Integration Drug Management Programme (HSE -AIDMP)

- HSE ePharmacy Programme
- Hospital Pharmacists Association of Ireland (HPAI)
- Irish Platform for Patient Organisations, Science and Industry (IPPOSI)

In April 2026, new legislation was enacted to enable retail pharmacy businesses to keep pharmacy records electronically and to introduce new record-keeping requirements for pharmacists. Under the new legislation, the following pharmacy records can be maintained electronically, provided the pharmacy computer software system in use meets certain specified minimum requirements set out in the legislation:

- Duty Register
- Prescription Register/Daily Audit
- Controlled Drugs Register
- Prescriptions transferred through Healthmail and the High-Tech Hub

Changes to the legislation to allow electronic record-keeping, thereby reducing the administrative burden for pharmacists, are a very positive step towards modernising record-keeping requirements in community pharmacies. These changes are also an important interim step towards the development of the national ePrescribing solution and wider digitisation in pharmacies and our health system.

The option to continue to keep these records in a paper-based format is retained in the legislation. In circumstances where the pharmacy computer software system does not meet the minimum required standard, pharmacies must continue to keep these records in paper-based format.

In addition, the following new record-keeping requirements were also introduced:

- Pharmacists will be required to include their registration number on paper-based prescriptions as part of endorsing requirements
- All pharmacists (including superintendents and pharmacy owners) working in a pharmacy will be required to record their details in the duty register

Including these changes now provides for greater transparency and visibility of the pharmacist involved in the dispensing of a prescription and prepares for the rollout in the near future of national digital health systems.

The following statutory instruments were signed into law by the Minister for Health in April 2026 to enable electronic record-keeping and the additional new record-keeping requirements:

- [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) Regulations 2026 \(S.I. No. 138/2026\)](#)
- [Misuse of Drugs \(Amendment\) \(No.2\) Regulations 2026 \(S.I. No. 139/2026\)](#)
- [Regulation of Retail Pharmacy Businesses \(Amendment\) Regulations 2026 \(S.I. No. 140/2026\)](#)

These amendments come into operation on 30 June 2026.

Revised Draft PSI Guidelines on Record-Keeping in a Retail Pharmacy Business

The PSI has updated the existing record-keeping guidelines to reflect the changes to the legislation. In line with recent Guidelines and Guidance issued by the PSI, the Guidelines have undergone significant review and update and have been reformatted as principles-based Guidelines that are intended to be supportive, enabling, explanatory and facilitate compliance with the legislative requirements for record-keeping. The Guidelines comprise five guiding principles (*see Figure 1*) designed to support consistent, safe, compliant and high-quality record-keeping in pharmacies. The Guidelines will be issued under Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. 488 of 2008) (as amended), subject to the approval of the Minister for Health.



Figure 1. Guiding Principles to Support the Keeping of Records in a Retail Pharmacy Business.

Further information on record-keeping, including FAQs, is available on the [PSI website](#).

1.2.2 How we gathered feedback during the consultation period

The public consultation was open from 21 April to 19 May, and we gathered feedback in two ways:

- We sought feedback from a wide range of stakeholders who could respond through an online survey or by email.
- We also held an online workshop with members of our PSI Pharmacist Panel.

The initial consultation email was sent to registrants on 21 April 2026; registered pharmacists (n=7924), pharmaceutical assistants (n=130) and pharmacies (n=1719¹).

In addition:

- A targeted email was also sent on 28 April to just over 100 stakeholder organisations and individual recipients – those involved in advocating for and supporting patients, organisations responsible for the education and training of pharmacists, representative organisations, regulatory bodies, and health service providers – to highlight the legislative changes and to invite input in relation to the Guidelines.
- Reminder emails to raise further awareness and encourage feedback were sent to all registered pharmacists (n=7924), pharmaceutical assistants (n=130) and pharmacies (n=1719) on 5 May and 14 May.
- A targeted email was also sent to all superintendent pharmacists on 12 May.
- The consultation was highlighted to the Pharmacy eHealth Group (PeHG) at its meeting of 7 May.
- The Irish Pharmacy Union also shared information about the public consultation with their members in their newsletters on 23, 30 April and 7 and 14 May.
- Additional information was made available on the PSI website, and information was shared on PSI's social media channels throughout the consultation period. During the consultation period, the PSI consultation webpage had 560 views and 383 active users. The new webpage about record-keeping in retail pharmacy businesses, containing FAQs to support the changes, had 250 active users.
- A follow-up email was also issued to all Pharmacist Panel attendees on 14 May as a reminder that the public consultation remained open until 19 May if they wished to

¹ The number of emails issued to retail pharmacy businesses is lower than the number of pharmacies on the RPB Register as some chain/group pharmacies use the same email address for a number of their pharmacies. Therefore, 1,991 pharmacies were contacted through 1719 emails

provide any additional feedback on the draft Guidelines. Attendees were also asked to share the survey with their colleagues who may be interested in providing feedback on the draft Guidelines.

2. Consultation feedback received

2.1 Who we heard from

We received 106 responses to our online survey and an additional nine consultation responses via email, including from the following organisations:

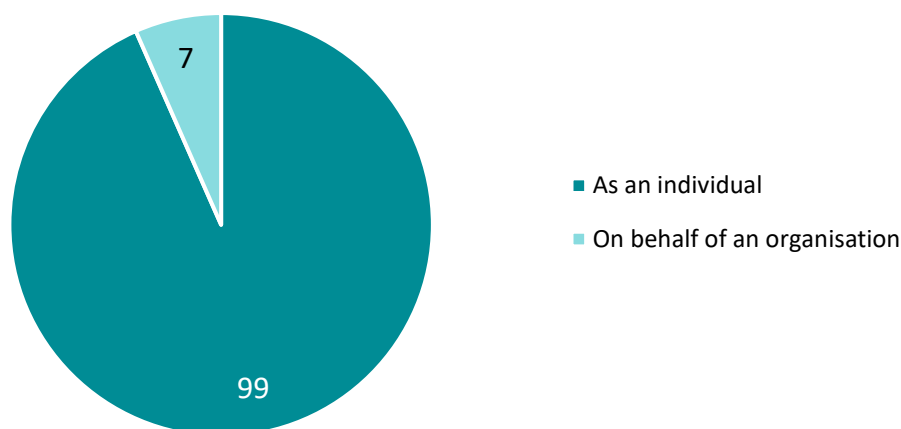
- Irish Pharmacy Union (IPU)
- Irish Medicines Verification Organisation (IMVO)
- Pharmaceutical Assistants Association (PAA)
- Refill Assistant

Email responses have been included in the Feedback Themes and Discussion section. The term 'respondents', which is used below, includes both individuals and organisations.

Questions 1-4

We asked respondents to indicate whether they were responding as an individual or on behalf of an organisation. 93.40% of respondents told us they were responding as individuals (n=99), 6.60% were on behalf of an organisation (n=7).

Are you responding as an individual or on behalf of an organisation? (n=106)



Question 2: Are you responding as an individual or on behalf of an organisation?	Number of respondents	%
As an individual	99	93.40%
On behalf of an organisation	7	6.60%

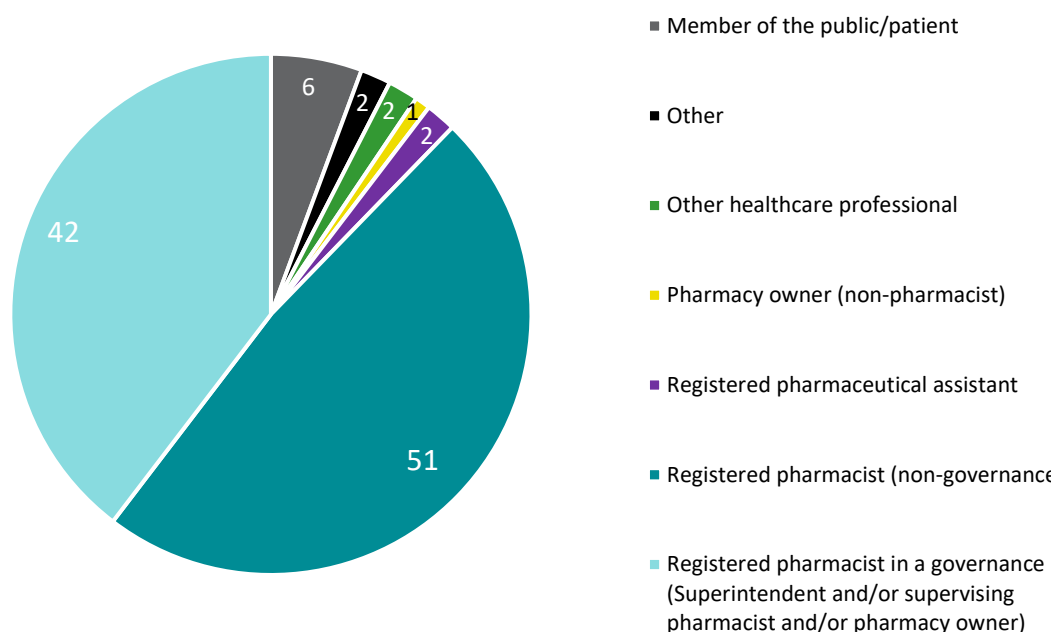
We then asked respondents in circumstances where they were responding on behalf of an organisation, which organisations they were responding from. Of these, five of the seven respondents provided details of the organisations they were responding on behalf of. These included two pharmacy chains and a non-dispensary software supplier to Irish community pharmacies.

Respondents were provided with a number of categories to best describe themselves. The breakdown of responses from the 106 respondents is as follows:

- Registered pharmacist in governance role (Superintendent and/or supervising pharmacist and/or pharmacy owner) = 42/106 respondents (39.62%)
- Registered pharmacist (non-governance role) = 51/106 respondents (48.11%)
- Registered pharmaceutical assistant = 2/106 respondents (1.89%)
- Pharmacy owner (non-pharmacist) = 1/106 respondents (0.94%)
- Member of the public/patient = 6/106 respondents (5.66%)
- Other healthcare professional = 2/106 respondents (1.89%)

- Other = 2/106, Dispensary Area Manager and non-dispensing software supplier to Irish community pharmacies (1.89%)

Which of the following best describes you? (n=106)



Which of the following best describes you? (n=106)	Number of respondents	%
Member of the public or a patient	6	5.66%
Registered pharmacist (non-governance role)	51	48.11%
Registered pharmacist in a governance role (<i>Superintendent and/or supervising pharmacist and/or pharmacy owner</i>)	42	39.62%
Registered pharmaceutical assistant	2	1.89%
Pharmacy owner (non-pharmacist)	1	0.94%
Other healthcare professional	2	1.89%
Other	2	1.89%

2.1.1 Email responses

As previously outlined, nine in-scope responses to the public consultation were received via email, as follows:

Respondents via email	Number of respondents
Named individual pharmacist	4
Named large pharmacy chain	1
Irish Pharmacy Union (IPU)	1
Irish Medicines Verification Organisation (IMVO)	1
Pharmaceutical Assistants Association (PAA)	1
Refill Assistant	1
Total number of responses via email	9

A number of themes were identified within the email responses and are included in the Feedback Themes and Discussion section of this report below.

2.1.2 Pharmacist Panel feedback

In addition to our online survey, we also held an online evening workshop on 12 May with members of the PSI Pharmacist Panel, to capture further feedback on the revised draft Guidelines.

The PSI's Pharmacist Panel was established in late 2023 through an expression-of-interest process to provide an additional forum for PSI to engage with practising pharmacists across a diversity of roles and practice settings on our regulatory work. During December 2025/January 2026, the panel was opened to new members.

In advance of the workshop, we sent an expression-of-interest email and form to all current pharmacist panel members (n=101). We received responses from 40 panel members, 28 of whom attended the workshop. The panel members were asked to read and consider the revised draft Guidelines and additional supports on the PSI website to support the public consultation process, in advance of the workshop.

Following the workshop, an evaluation survey was sent to all attendees, providing a further opportunity to ask questions. Questions raised by the pharmacist panel have been collated with all other questions from the consultation and will be used to update existing frequently asked questions (FAQs) and to inform the development of further regulatory supports, as required. These will also be shared with other key stakeholders involved in implementing electronic record-keeping, where appropriate.

Feedback from the panel has been included in the Feedback Themes and Discussion section of this report. We would like to thank the members of the panel for their time and valuable input on this process.

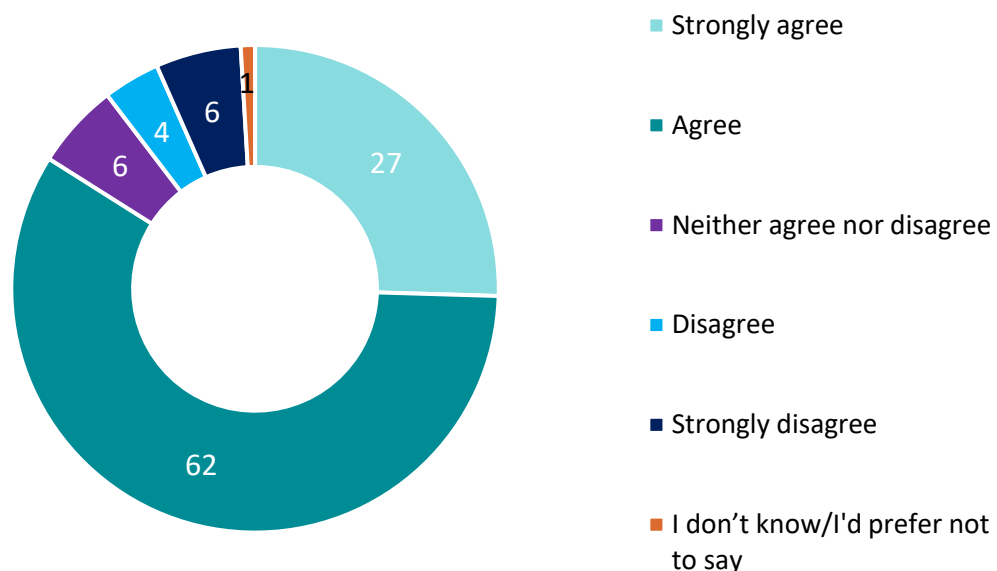
2.1.3 Survey feedback on the draft Guidelines

Question 5: Please indicate your agreement with the following statements.

Respondents were asked to indicate their agreement with seven statements relating to the draft Guidelines. None of the questions were mandatory. A high level of agreement is evident across all seven statements, with the majority of responses indicating agreement or strong agreement.

Statement 1: Overall, the Guidelines are clear and easy to understand.

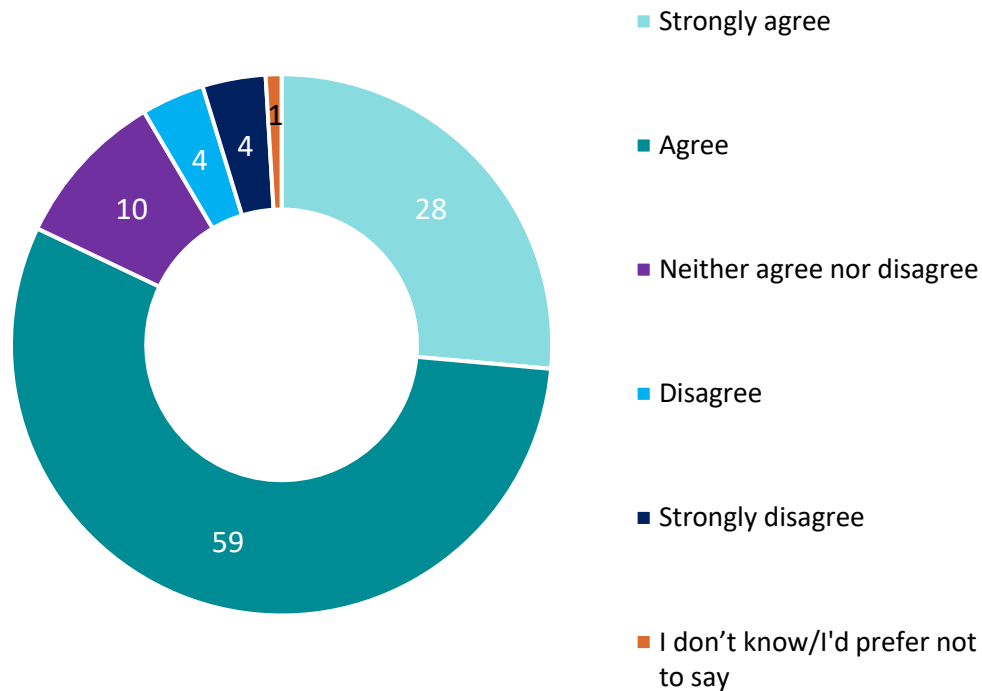
A combined total of 83.96% of respondents agreed or strongly agreed that the guidelines are clear and easy to understand.



Overall, the Guidelines are clear and easy to understand (n=106)	Number of respondents	%
Strongly agree	27	25.47%
Agree	62	58.50%
Neither agree nor disagree	6	5.66%
Disagree	4	3.77%
Strongly disagree	6	5.66%
I'd prefer not to say/I don't know	1	0.94%

Statement 2: The Guidelines clearly set out the expectations of those in statutory governance roles in pharmacies (pharmacy owner, superintendent pharmacist, supervising pharmacist) in relation to record-keeping.

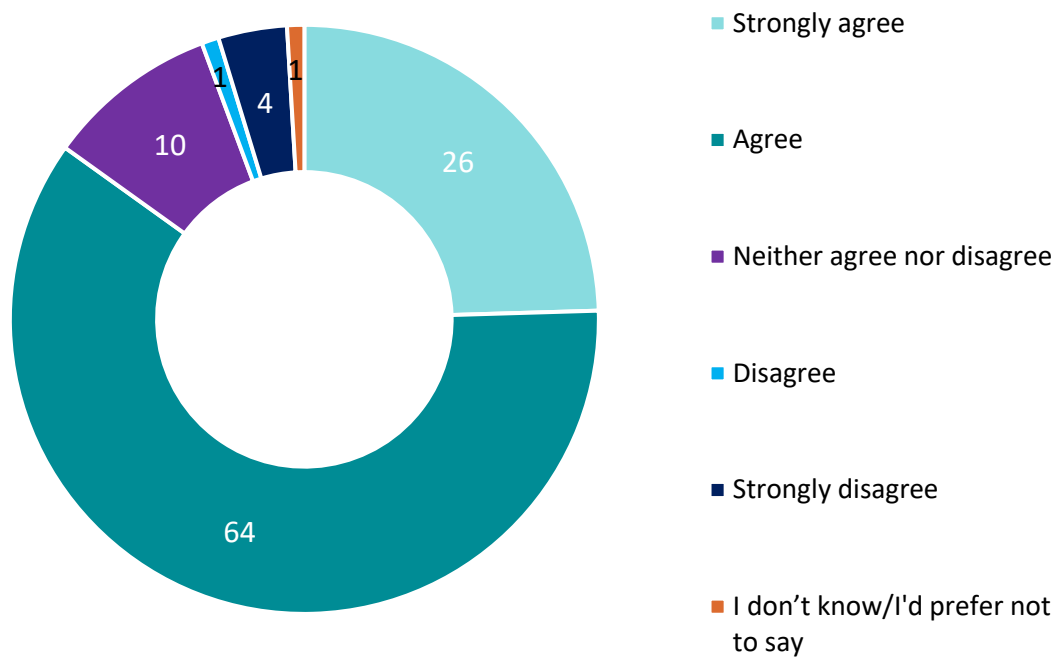
A combined total of 82.08% of respondents agreed or strongly agreed that the guidelines clearly set out the expectations of those in statutory governance roles in pharmacies.



The Guidelines clearly set out the expectations of those in statutory governance roles in pharmacies (pharmacy owner, superintendent pharmacist, supervising pharmacist) in relation to record-keeping (n=106)	Number of respondents	%
Strongly agree	28	26.42%
Agree	59	56.67%
Neither agree nor disagree	10	9.43%
Disagree	4	3.77%
Strongly disagree	4	3.77%
I'd prefer not to say/I don't know	1	0.94%

Statement 3: Principle 1 – Good Governance: The principles and indicators of Good Governance clearly set out the expectations for oversight and accountability in record management.

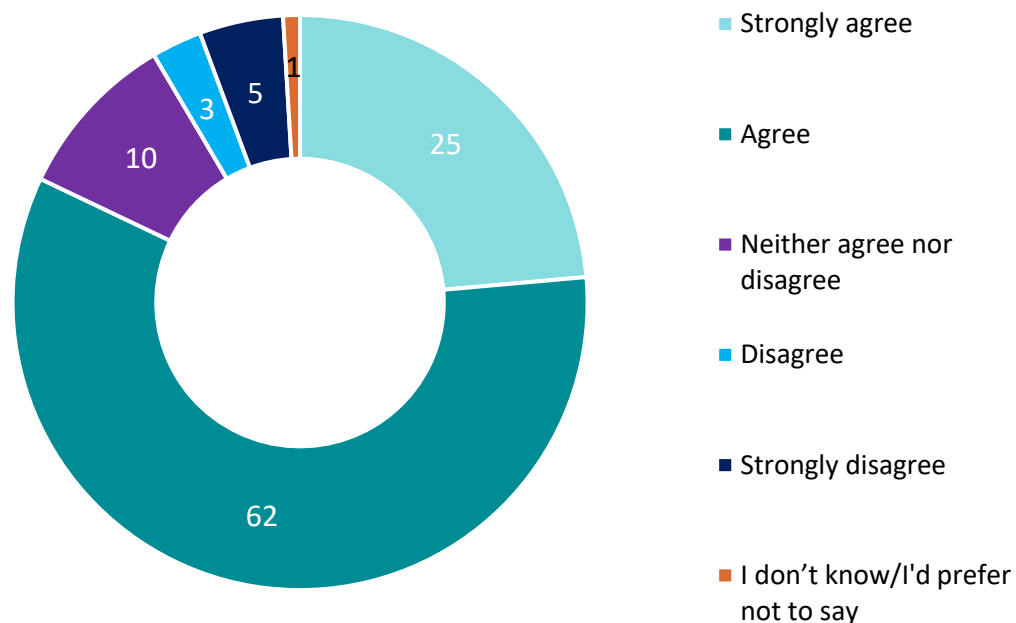
A combined total of 84.91% of respondents agreed or strongly agreed that the principles and indicators of Good Governance clearly set out the expectations for oversight and accountability in record management.



Principle 1 – Good Governance: The principle and indicators of Good Governance clearly set out the expectations for oversight and accountability in record management (n=106)	Number of respondents	%
Strongly agree	26	24.53%
Agree	64	60.39%
Neither agree nor disagree	10	9.43%
Disagree	1	0.94%
Strongly disagree	4	3.77%
I'd prefer not to say/I don't know	1	0.94%

Statement 4: Principle 2 – Premises: The principle and indicators relating to Premises appropriately set out the role of the pharmacy environment in supporting workflow and good record-keeping.

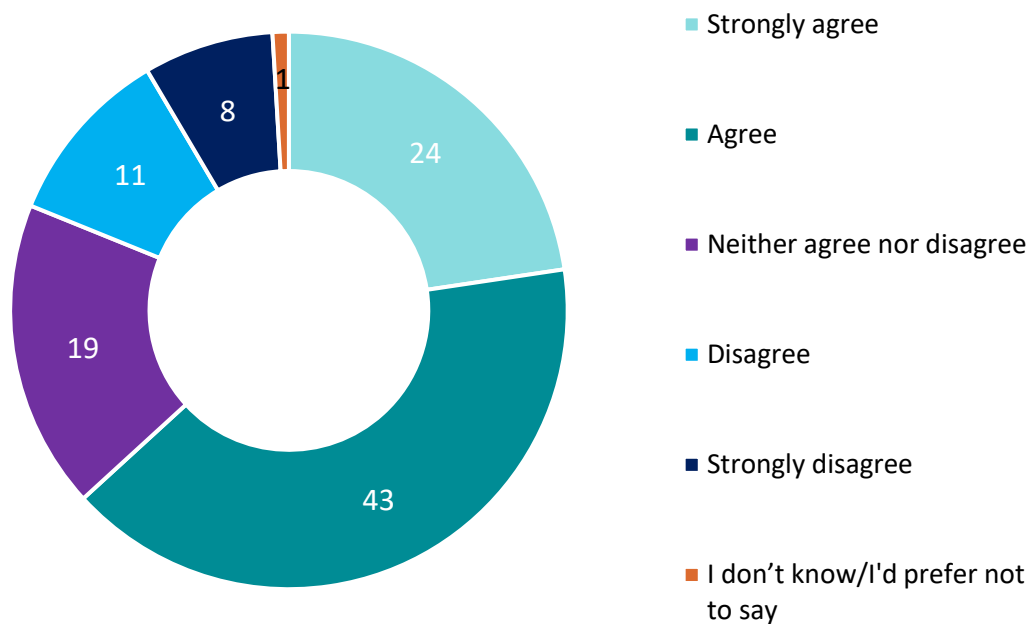
A combined total of 82.08% of respondents agreed or strongly agreed that the principles and indicators of Premises appropriately set out the role of the pharmacy environment in supporting workflow and good record-keeping.



Principle 2 – Premises: The principle and indicators relating to Premises appropriately set out the role of the pharmacy environment in supporting workflow and good record-keeping (n=106)	Number of respondents	%
Strongly agree	25	23.58%
Agree	62	58.50%
Neither agree nor disagree	10	9.43%
Disagree	3	2.83%
Strongly disagree	5	4.72%
I'd prefer not to say/I don't know	1	0.94%

Statement 5: Principle 3 – Equipment and IT: The principle and indicators relating to Equipment and IT clearly explain what the equipment and IT software requirements are to ensure records are secure, accessible and compliant.

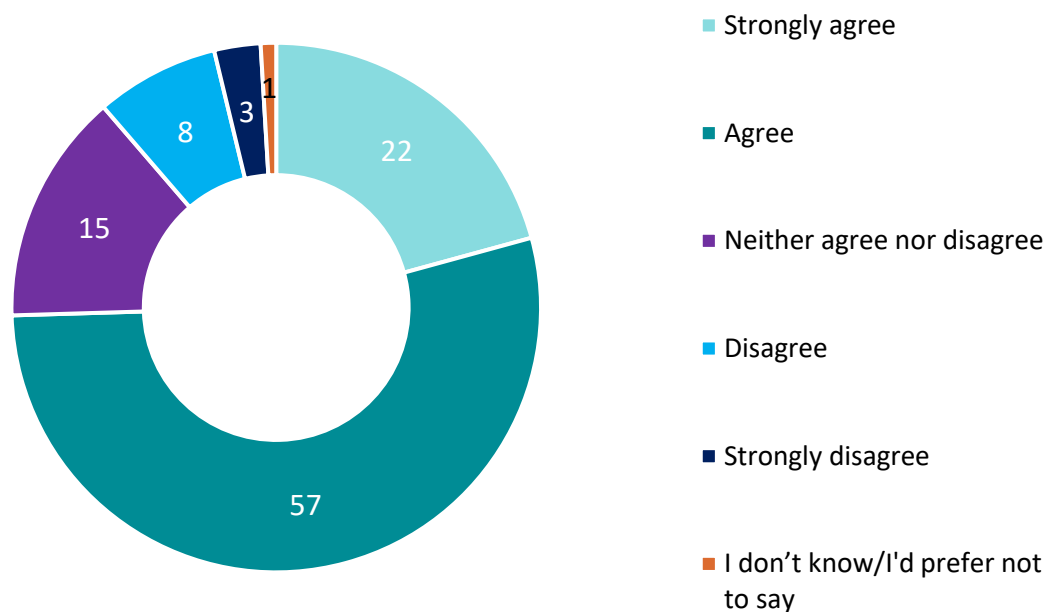
A combined total of 63.21% of respondents agreed or strongly agreed that the principle and indicators relating to Equipment and IT clearly explain what the equipment and IT software requirements are to ensure records are secure, accessible and compliant.



Principle 3 – Equipment and IT: The principle and indicators relating to Equipment and IT clearly explain what the equipment and IT software requirements are to ensure records are secure, accessible and compliant (n=106)	Number of respondents	%
Strongly agree	24	22.64%
Agree	43	40.57%
Neither agree nor disagree	19	17.92%
Disagree	11	10.38%
Strongly disagree	8	7.55%
I'd prefer not to say/I don't know	1	0.94%

Statement 6: Principle 4 – Staffing and Training: The Staffing and Training principle and indicators clearly set out the expectations for staff training and competence in relation to record-keeping in retail pharmacy businesses.

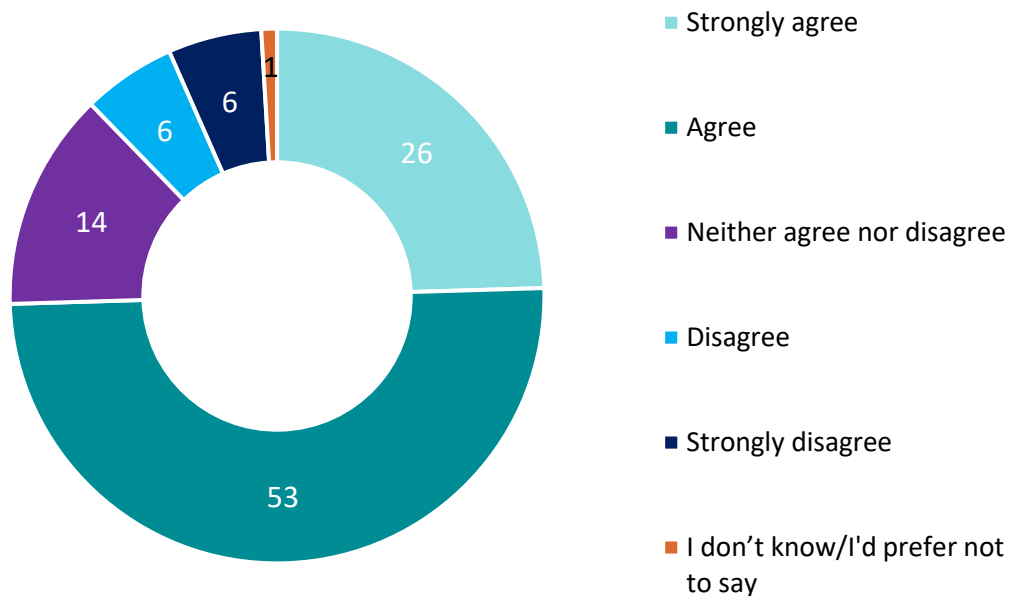
A combined total of 74.53% of respondents agreed or strongly agreed that Staffing and Training principle and indicators clearly set out the expectations for staff training and competence in relation to record-keeping in retail pharmacy businesses.



Principle 4 – Staffing and Training: The Staffing and Training principle and indicators clearly set out the expectations for staff training and competence in relation to record-keeping in retail pharmacy businesses (n=106)	Number of respondents	%
Strongly agree	22	20.75%
Agree	57	53.78%
Neither agree nor disagree	15	14.15%
Disagree	8	7.55%
Strongly disagree	3	2.83%
I'd prefer not to say/I don't know	1	0.94%

Statement 7: Principle 5 – Compliance with Legislative Requirements: The Compliance with Legislative Requirements principle and indicators help clarify the legislative record-keeping requirements for each pharmacy record.

A combined total 74.53% of respondents agreed or strongly agree that the Compliance with Legislative Requirements principle and indicators help clarify the legislative record-keeping requirements for each pharmacy record.



Principle 5 – Compliance with Legislative Requirements: The Compliance with Legislative Requirements principle and indicators help clarify the legislative record-keeping requirements for each pharmacy record (n=106)	Number of respondents	%
Strongly agree	26	24.53%
Agree	53	50.00%
Neither agree nor disagree	14	13.21%
Disagree	6	5.66%
Strongly disagree	6	5.66%
I'd prefer not to say/I don't know	1	0.94%

Question 12: If you have any specific feedback on the Guidelines, please provide this in the box below.

Respondents were next asked if they had any specific feedback on the Guidelines. **44.34% (n=47)** of respondents answered this question. Two of the 47 respondents stated they had no specific feedback.

The most common themes from the comments provided were:

Theme	No. of responses
Concerns on increased administrative burden	14
Comments supporting the draft Guidelines and electronic record-keeping	9
Insufficient (or lack of) clarity on IT systems/technology requirements/accreditation of pharmacy software systems	8
Implications for pharmacy dispensing workflow	6
Implementation challenges and readiness	5

Similar themes were identified across the email responses and the pharmacist panel workshop and are discussed in the Feedback Themes and Discussion section below.

3. Feedback Themes and Discussion

The PSI appreciates the feedback provided during the consultation process on the revised draft PSI Guidelines on Record-Keeping in a Retail Pharmacy Business and gratefully acknowledges the consideration and time taken by all who have contributed to this consultation.

The feedback received through the consultation process was both quantitative and qualitative in nature. The quantitative data demonstrated strong overall support for the revised draft Guidelines. The qualitative feedback provided deeper insights into specific areas where respondents sought further clarity or raised concerns. Some of the issues raised were outside the scope of the Guidelines but are relevant to the next steps for implementation of electronic record-keeping in pharmacies, the supports that are needed to assist pharmacists with changing workflows and the verification required for IT systems

The key themes identified are outlined below, along with the PSI's response to each.

Quantitative Data

Overall, feedback on the revised draft Guidelines was positive, showing strong agreement among respondents on both the clarity and usefulness of the draft Guidelines:

83.96% agreed or strongly agreed that the Guidelines are clear and easy to understand

82.08% agreed or strongly agreed that the Guidelines clearly set out the expectations of those in statutory governance roles in relation to record-keeping

Feedback on the five principles was also positive:

84.91% agreed or strongly agreed that the Good Governance principle clearly outlines expectations around accountability and oversight

82.08% agreed or strongly agreed that the principle relating to Premises supports effective record-keeping

63.21% agreed or strongly agreed that the Equipment and IT principle clearly explains the relevant requirements

74.53% agreed or strongly agreed that the Staffing and Training principle clearly sets out expectations for staff competence and training

74.53% agreed or strongly agreed that the Compliance with Legislative Requirements principle and indicators help clarify the legislative record-keeping obligations

Overall, the quantitative results show broad support for the structure, clarity and purpose of the Guidelines in supporting pharmacists with record-keeping in retail pharmacy businesses.

Qualitative Data

Qualitative data was also gathered from the consultation survey comments, email responses, and the Pharmacist Panel. This data has been analysed and synthesised, with six key themes identified. Some of the issues raised were outside the scope of the Guidelines but are relevant to the next steps for implementation of electronic record-keeping in pharmacies, the supports that are needed to assist pharmacists with changing workflows and the verification required for IT systems. Where possible PSI have sought to provide further information on the proposed next steps for implementation.

The six key themes are:

- Comments supporting the draft Guidelines and electronic record-keeping in pharmacies
- Concerns raised on increasing administrative burden
- Requests for further information on the IT systems/technology requirements and accreditation of pharmacy software systems
- Implications for pharmacy dispensing workflow
- Challenges and readiness for implementing electronic record-keeping in pharmacies
- Clarification on the requirement for pharmaceutical assistants to record their PSI registration number with new record-keeping requirements

1. Comments Supporting the Draft Guidelines and Electronic Record-Keeping in Pharmacies

Overall, respondents were positive about the revised draft Guidelines, describing them as clear, easy to understand, and not overly prescriptive, and welcoming PSI's principles-based approach. They considered the Guidelines helpful in setting out the expectations and responsibilities of those in pharmacy governance roles. Several respondents supported the move towards electronic record-keeping, particularly in relation to the electronic Duty Registers, Prescription Registers/Daily Audits and Controlled Drugs Registers, with some noting the benefit of reducing paper in the dispensary. Respondents also welcomed the flexibility for pharmacies to retain paper-based systems or transition to electronic records, while acknowledging the broader policy direction towards ePrescribing.

PSI Response:

PSI notes the positive feedback on the revised draft Guidelines and the support for the move to electronic record-keeping.

2. Concerns Raised on Increasing Administrative Burden

Respondents raised concerns that some of the new legislative requirements, particularly the requirement for pharmacists to record their PSI registration number when endorsing prescriptions, may increase administrative workload. This was viewed by some as unnecessary, inefficient and duplicative, given other existing records such as the Duty Register and Patient Medication Record (PMR) systems, and was also seen as potentially undermining the anticipated efficiencies of a move to electronic record-keeping. Views were more mixed in relation to the new requirement for all registered pharmacists on duty to record their details in the duty register, which was seen as supporting accountability but also adding to the administrative workload.

PSI Response:

Changes to legislation to allow electronic record-keeping are intended to reduce the administrative burden on pharmacists and modernise record-keeping requirements in community pharmacies. PSI is very supportive of actions that can be prioritised by all relevant stakeholders to streamline and reduce regulatory and administrative burden in community pharmacies.

There are limitations to the efficiencies that can be achieved under the current legislative framework and the existing Healthmail and IT systems until a full ePrescribing solution has been developed and implemented. However, it is important to acknowledge that these changes are a positive interim step toward a fully integrated ePrescribing solution and digitisation in pharmacies.

Including the requirement for pharmacists to include their registration number when dispensing prescriptions and the requirement for all pharmacists working in a pharmacy to record their details in the Duty Register, provides for greater transparency and visibility of the pharmacist involved in the dispensing of a prescription and prepares for the rollout in the near future of national ePrescribing systems. The requirement for pharmacists to include their PSI registration number as part of dispensing and endorsing is in line with practices required of other healthcare professionals, such as doctors, who are required to include their registration number on prescriptions and all medical records maintained for patients.

In the coming years, pharmacy dispensing software systems will be required to integrate with core national digital systems under development, such as the Individual Health Identifier (IHI), National Shared Care Record (NSCR) and the National ePrescribing Service (NePS). Accordingly, pharmacies will be required to meet clear standards for functionality, traceability, security and interoperability when these national digital systems are

implemented across the health system. As part of the rollout of these national digital systems, all healthcare professionals, including pharmacists, will be required to use their PSI registration number when accessing and using these systems for prescribing or dispensing.

PSI recognises that this is a change in current practice and workflow for pharmacists and are very supportive of any processes and/or digital solutions which can be developed to automate this record-keeping and therefore minimise the impact of the requirement for pharmacists to record their registration number when dispensing prescriptions.

3. Requests For Further Information on the IT Systems/Technology Requirements and Accreditation of Pharmacy Software Systems

Some respondents sought further clarity to support implementation, particularly regarding how electronic processes will operate in practice. Questions were raised about the extent to which IT systems will support rather than complicate pharmacy workflows. A number of respondents also sought further information on how pharmacy owners can verify that their pharmacy computer software meets the requirements set out in the legislation. Respondents also highlighted a need for greater assurance regarding pharmacy software systems, with suggestions that minimum requirements be clearly defined and that such systems be subject to accreditation, validation, or certification by an appropriate body.

PSI Response:

There are currently no required standards in place currently for pharmacy software systems. Under the revised legislative framework for record-keeping in pharmacies outlined in the [Regulation of Retail Pharmacy Businesses \(Amendment\) Regulations 2026 \(S.I. No. 140 of 2026\)](#), [Medicinal Products \(Prescription and Control of Supply\)\(Amendment\) Regulations 2026 \(S.I. No. 138 of 2026\)](#) and the [Misuse of Drugs \(Amendment\)\(No.2\) Regulations 2026 \(S.I. No. 139 of 2026\)](#), the pharmacy owner is required to verify that their pharmacy computer software meets the following requirements specified in the legislation for each type of register that they intend to maintain electronically:

- The entries in the register are subject to user access controls capable of restricting the functions that may be used
- Every correction to an entry in the register is capable of being traced by identifying the original entry, the correction to the original entry, the identity of the person who made the correction and the date of the correction.

These requirements are applicable to the Controlled Drugs Register, Prescription Register/Daily Audit and the Duty Register. Additional search requirements are also

specified in the legislation for the Controlled Drugs Register and the Prescription Register/Daily Audit.

Under the current legislation, the PSI has no authority to validate or verify pharmacy computer software systems.

The next steps to enable the development of pharmacy software system updates are being advanced by various pharmacy stakeholders on the Department of Health Electronic Record-Keeping Implementation Group. The Irish Pharmacy Union (IPU) is developing an IT Requirements Specification to support pharmacy software vendors in translating the legislative requirements into practical outcomes that IT systems will need to support. The IPU is also engaging with pharmacy software vendors to support the development of the necessary changes to pharmacy software systems to facilitate pharmacies that wish to transition to electronic record-keeping.

The Department of Health Electronic Record-Keeping Implementation Group is also currently finalising a proposed process for implementing electronic record-keeping in community pharmacies and the IPU is also developing operational guidance, and workflow supports to assist pharmacies that wish to transition to electronic-record keeping. Any further information and updates will be shared through the PSI website, PSI newsletter, and direct emails to registrants when available.

4. Implications for Pharmacy Dispensing Workflow

Some respondents indicated that a move to electronic record-keeping would alter established dispensing practices, including the need for pharmacists to have direct access to digital systems and, consequently, additional hardware and system access points will be needed. Concerns were also raised about responsibility and accountability when multiple pharmacists are involved in the dispensing process, as well as potential inefficiencies stemming from limitations associated with Healthmail. Respondents also emphasised the importance of ensuring that any new or digital processes are designed to integrate smoothly into existing practice and minimise disruption.

PSI Response:

The PSI recognises that the transition to electronic record-keeping represents a significant change to established dispensing workflows and will require adjustments in pharmacy practice, including increased access to digital systems and the use of additional hardware. While the revised legislative framework is designed to enable more efficient, streamlined

processes over time and to reduce reliance on paper-based systems, PSI does acknowledge that, as reflected in the feedback, the transition phase may present challenges.

As previously outlined, the Department of Health Electronic Record-Keeping Implementation Group is actively considering a proposed process for implementing electronic record-keeping in community pharmacies. This includes the development of operational guidance and workflow supports, which are being led by The Irish Pharmacy Union (IPU) to support pharmacies that wish to transition to electronic record-keeping. Any further information and updates will be shared through the PSI website, PSI newsletter, and direct emails to registrants when available.

It is also important to recognise that there are limitations to the efficiencies that can be achieved under the current legislative framework and the existing Healthmail and IT systems until a full national ePrescribing solution is developed and implemented in the near future. However, these changes are a positive interim step toward a fully integrated ePrescribing solution and digitisation in pharmacies.

In relation to multiple team members involved in a dispensing process, it is the registered pharmacist who is at all times accountable and responsible for the personal supervision of the sale and supply of medicines in a pharmacy, notwithstanding that other members of the pharmacy team may be working under their supervision and involved in the assembly, labelling and packaging of medicines as part of the dispensing process. It is important to re-iterate that under the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended) all medicines are supplied by and under the personal supervision of a registered pharmacist.

When working as the sole pharmacist at the pharmacy, pharmacists must ensure the sale and supply of medicines, remain under their supervision. When working with other pharmacists, pharmacists must ensure there is a clear understanding as to each individual pharmacist's roles and responsibilities.

PSI acknowledges that dispensing practices and workflows differ in individual pharmacies. Those in governance roles in pharmacies, i.e., pharmacy owners, superintendent pharmacists, and supervising pharmacists, play an important role in developing and implementing robust policies and procedures for each pharmacy under their control to reflect the workflows of each pharmacy. This will ensure that all staff, including where there are a number of pharmacists employed, are clear on their individual roles and responsibilities as part of the dispensing process, and which pharmacist(s) will record their registration number when endorsing prescriptions.

It is expected that pharmacy software systems and process innovations will be facilitated to evolve to make the recording of the required information as seamless as possible. The IPU as part of the Department of Health Electronic Record-Keeping Implementation Group are actively engaging with relevant stakeholders including pharmacy software providers to support implementation of the required IT developments.

5. Challenges and Readiness for Implementing Electronic Record-Keeping in Pharmacies

While respondents were broadly supportive of the Guidelines, particularly the principles-based format, and the move towards electronic record-keeping, they emphasised that successful implementation would depend on the availability of additional, clear and comprehensive supports, including operational guidance and training. Feedback highlighted a need for further information on implementation planning and respondents also raised concerns that implementation without user-friendly software updates, adequate lead-in time and appropriate supports could lead to inefficiencies and increased workload.

PSI Response:

PSI agrees that this update to practice requires appropriate supports and guidance. As previously noted, the Department of Health Electronic Record-Keeping Implementation Group is finalising a proposed process for implementing electronic record-keeping in community pharmacies, and further information and updates will be shared through the PSI website, PSI newsletter, and direct emails to registrants when available. The Irish Pharmacy Union (IPU) is leading the development of operational guidance and has developed an IT Requirements Specification to support pharmacy software vendors in translating the legislative requirements into practical outcomes that IT systems will need to support. The IPU are also engaging with pharmacy software vendors to support the development of the necessary changes to pharmacy software systems to facilitate pharmacies that wish to transition to electronic record-keeping.

It is acknowledged that pharmacies will be at different levels of readiness; accordingly, the legislation provides flexibility for pharmacies to continue using paper-based systems until they are prepared to update their systems. The transition to electronic record-keeping is not mandatory and implementation can occur at a pace aligned with operational readiness. Pharmacies may also choose to only maintain certain records electronically, for example, the Duty Register or Controlled Drugs Register, while maintaining prescriptions in paper-based format if they wish.

The PSI will continue to communicate updates and supports as they become available to ensure that pharmacies are appropriately supported throughout implementation.

6. Clarification on the Requirement for Pharmaceutical Assistants to Record their PSI Registration Number with New Record-Keeping Requirements

Further clarification was sought regarding requirements for pharmaceutical assistants to record their PSI registration number on paper-based prescriptions and as part of the electronic retention of prescriptions.

PSI Response:

From 30 June, the [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) Regulations 2026 \(S.I. No. 138 of 2026\)](#) and the [Misuse of Drugs \(Amendment\)\(No.2\) Regulations 2026 \(S.I. No. 139 of 2026\)](#) will require pharmacists to include their registration number on paper-based prescriptions as part of endorsing requirements.

Where pharmacists retain Healthmail and High-Tech prescriptions electronically, they will also be required to record their registration number in the Patient Medication Record (PMR), along with the date of dispensing and the quantity dispensed (for partially dispensed prescriptions). They will also be required to preserve the prescription as transmitted and an electronic copy of the prescription within the PMR. Including these changes now provides for greater transparency and visibility of the pharmacist involved in the dispensing of a prescription and prepares for the rollout in the near future of national digital health systems.

In circumstances where a pharmaceutical assistant is employed at a pharmacy and acts on behalf of a registered pharmacist during the temporary absence of the registered pharmacist as provided under Section 30 of the Pharmacy Act 2007 the registration number of the registered pharmaceutical assistant who is acting on behalf of a registered pharmacist during their temporary absence must be recorded on both paper-based prescriptions and within the PMR (where Healthmail and High-Tech prescriptions are being maintained electronically).

As previously outlined, PSI is very supportive of any process and/or digital solutions which can be developed to streamline the requirement for pharmacists to record their registration number when dispensing prescriptions. This also applies to the recording of the registration number of registered pharmaceutical assistants who act on behalf of a registered

pharmacist during the temporary absence of the registered pharmacist, as provided under Section 30 of the Pharmacy Act 2007.

4. Updates to the Revised Draft PSI Guidelines on Record-Keeping in a Retail Pharmacy Business

The revised draft PSI Guidelines have been updated in response to the feedback received from the public consultation.

An overview of the changes is outlined below:

- Minor wording amendments and additions have been made throughout to improve clarity.
- Principle 5 – Compliance with Legislative Requirements:
 - An additional indicator (5.8) has been added to clarify both the legislative requirements and the best practice recommendations relating to the record of destruction of controlled drugs.
 - An additional indicator (5.9) has been added to clarify that where a pharmacy chooses to maintain a register electronically (i.e. the Controlled Drugs Register, Daily Audit/Prescription Register or Duty Register), the previous hard copy register must be retained for a period of two years from the last entry.
 - The endorsement requirements for paper-based prescriptions have been incorporated into the main body of the document at indicator 5.10.
 - The record-keeping requirements for the electronic retention of Healthmail and High-Tech Hub prescriptions have been incorporated into the main body of the document at indicator 5.11.
 - The requirement for pharmaceutical assistants, when acting in the temporary absence of the pharmacist, to record their registration number on paper-based prescriptions and within the Patient Medication Record as part of the record-keeping requirements for the electronic retention of Healthmail and High-Tech Hub prescriptions, has been clarified in indicators 5.10 and 5.11.
 - Two additional indicators (5.15 and 5.16) have been included to outline the responsibilities of registered pharmacists and pharmacy owners in relation to records for pharmacy services.

- Retention requirements for records relating to vaccination services and the Common Conditions Service have been added to Appendix 5 – Pharmacy Records Retention Requirements.
- A link to the PSI Guidelines to Support the Provision of a Common Conditions Service has been added to Appendix 6 – Additional Guidance.

5. Conclusion

PSI would like to thank all of the individuals and organisations who have taken part in this consultation. We are grateful for all feedback received, which has been carefully considered and used to inform our review of the draft Guidelines.

This consultation report and updated Guidelines were considered by the PSI Regulatory and Professional Policy Committee at its meeting of 11 June and approved by the PSI Council at its meeting of 25 June. The revised Guidelines were submitted to the Minister for Health for consideration and approval, as required under Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended).