

PSI Consultation Report on the Draft Guidelines to Support Medicines Therapy Review, Counselling, and Prescription Extension

Introduction

Purpose of the Report

PSI carried out a public consultation on the revised PSI draft Guidelines to Support Medicines Therapy Review, Counselling, and Prescription Extension. This report presents an overview of feedback received during the consultation and a summary of amendments to the draft Guidelines in response to the consultation.

We would like to thank all respondents and stakeholders for their invaluable input to the guidelines. We greatly appreciate their contributions and time. The feedback received was carefully considered and incorporated into the finalised version where appropriate.

Background

[An Expert Taskforce to support the expansion of the role of pharmacists in Ireland](#) was established in July 2023 by the Minister for Health, Stephen Donnelly. The Taskforce is charged with considering and examining ways in which pharmacists can expand upon their present scope of practice for the benefit of patients, the public and the wider health system.

The first recommendation of the Expert Taskforce, published in November 2023, was that pharmacists should be enabled to extend and dispense certain prescriptions from six months up to a maximum of 12 months where appropriate.

Amendments were made to the [Regulation of Retail Pharmacy Businesses \(Amendment\) Regulations 2024 \(S.I. No. 74/2024\)](#) and Medicinal Products (Prescription and Control of Supply) Regulations 2003 ([S.I. No. 73/2024 - Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) \(No. 2\) Regulations 2024 \(irishstatutebook.ie\)](#)) to give effect to this recommendation which was introduced on 1 March 2024. As part of the changes, from 1 September 2024, pharmacists can decide to extend certain prescriptions that have been written for six months.

Revisions to PSI Guidelines on the Counselling and Medicines Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business

To support pharmacists with the implementation of the first recommendation and pharmacies to prepare for prescription extension from 1 September on, PSI has revised the Guidelines on the Counselling and Medicines Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business.

Regulation 9 of the [Regulation of Retail Pharmacy Businesses Regulations 2008 \(S.I. No. 488/2008\)](#) provides a legislative basis for the review of medicines therapy and counselling of patients in the supply of medicinal products on foot of a prescription, while 9A of the [Regulation of Retail Pharmacy Businesses \(Amendment\) Regulations 2024 \(S.I. No. 74/2024\)](#) provides a legislative basis for extending the validity of certain prescriptions up to 12 months.

It was therefore considered that revising and amending the Guidelines on the Counselling and Medicines Therapy Review would be the most appropriate approach to support pharmacists.

These Guidelines have undergone significant internal review and update. The key changes are as follows:

- (a) Adopting a principles-based framework which is intended to be supportive and enabling, rather than prescriptive.
- (b) Removal of information that does not relate to supporting compliance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations (as amended).
- (c) Addition of guidance to support prescription extension.

In April the updated guidelines were approved for public consultation by the Regulatory and Professional Policy Committee.

About the Public Consultation

In April the updated guidelines were approved for public consultation by PSI's Regulatory and Professional Policy Committee.

The public consultation on the revised draft Guidelines to Support Medicines Therapy Review, Counselling and Prescription Extension took place from 24 April 2024 to 15 May 2024. Participants could provide feedback via an online survey, by email, or by post.

Information about the public consultation and the draft guidelines was made available on our website. An email, which included information on the public consultation and inviting feedback, was sent to all registrants and relevant stakeholders. At the time of the public consultation, there were 7565 pharmacists registered with the PSI. In addition, the public consultation was highlighted through social media and was included in the PSI newsletter.

In late 2023, we established a PSI Pharmacist Panel to collaborate with us and provide input on our regulatory work. Working with our panel allows us to hear feedback from a diverse range of pharmacists. During the public consultation period, we held a focus group with the PSI Pharmacist Panel to further explore pharmacist views on the revised Guidelines.

Response Rate

170 responses were received via the online survey. One response was deemed unusable, as the respondent did not consent to their response being processed and analysed by the PSI, leaving 169 usable responses. Three additional responses were received via email.

Findings from the online survey are provided below. Feedback received from the three email responses has been included in the thematic analysis to question 18.

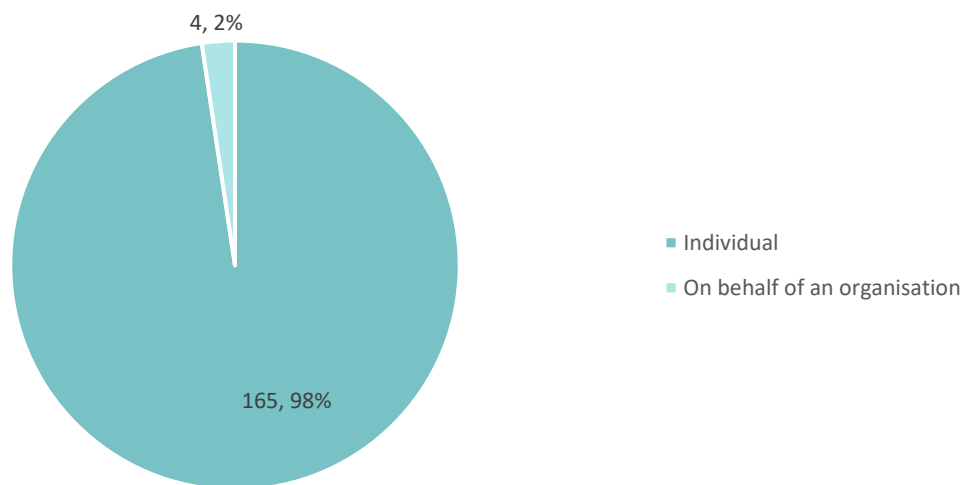
Findings from the online survey

Question 1: Data Protection question

169 out of the 170 respondents confirmed that they consented to providing their answers to the questions in the survey. One respondent did not and, therefore, could not progress to the rest of the questions.

Question 2: Are you responding to this consultation as an individual or on behalf of an organisation?

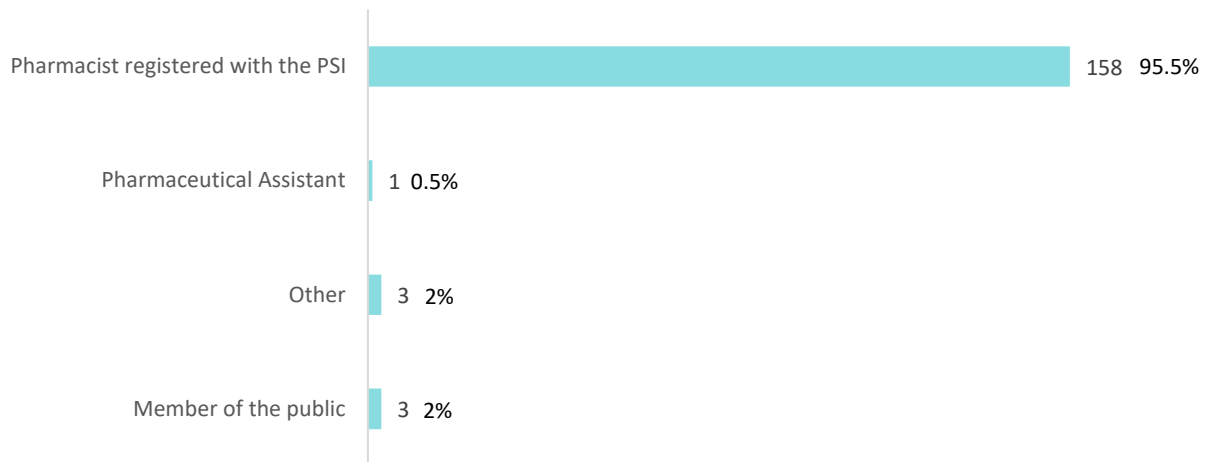
Answered	169
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98% of respondents indicated that they were responding on their own behalf, and 2% of respondents indicated that they were responding on behalf of an organisation.

Question 3: If responding to this consultation as an individual, how would you identify yourself?

Answered	165
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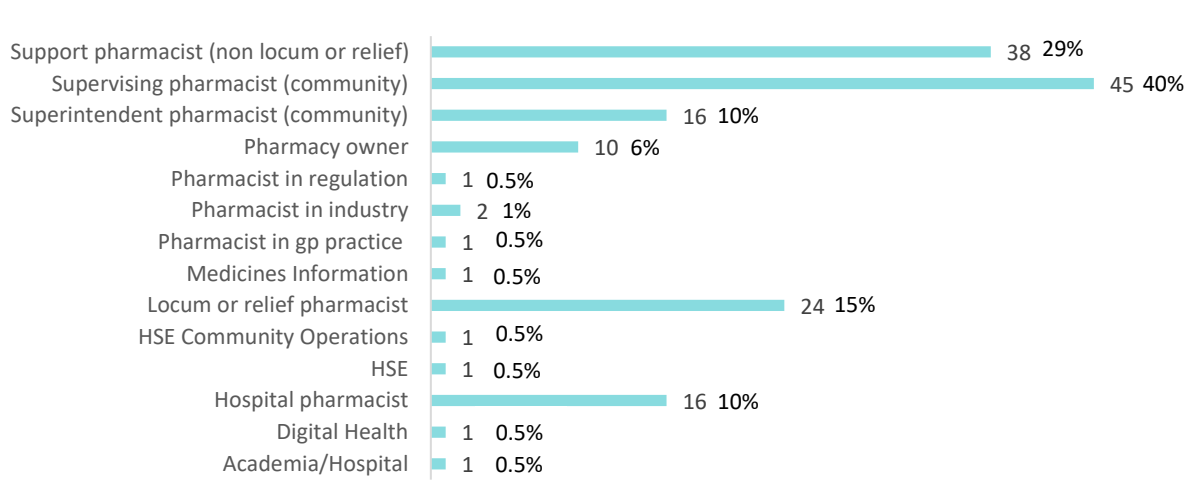


95.5% of respondents indicated they were registered pharmacists. One respondent declared themselves as a pharmaceutical assistant, three respondents indicated that they were members of the public, and a further three people indicated that they were 'Other'. Of those who declared themselves as other, one said they were a Pharmacy Dispenser, one said they were a professor, and the other said they were a TCQR Pharmacist.

Four respondents responded on behalf of the National Cancer Control Program (NCCP), Boots Ireland, the IPU and a government department or organisation.

Question 6: What is your primary role?

Answered	158
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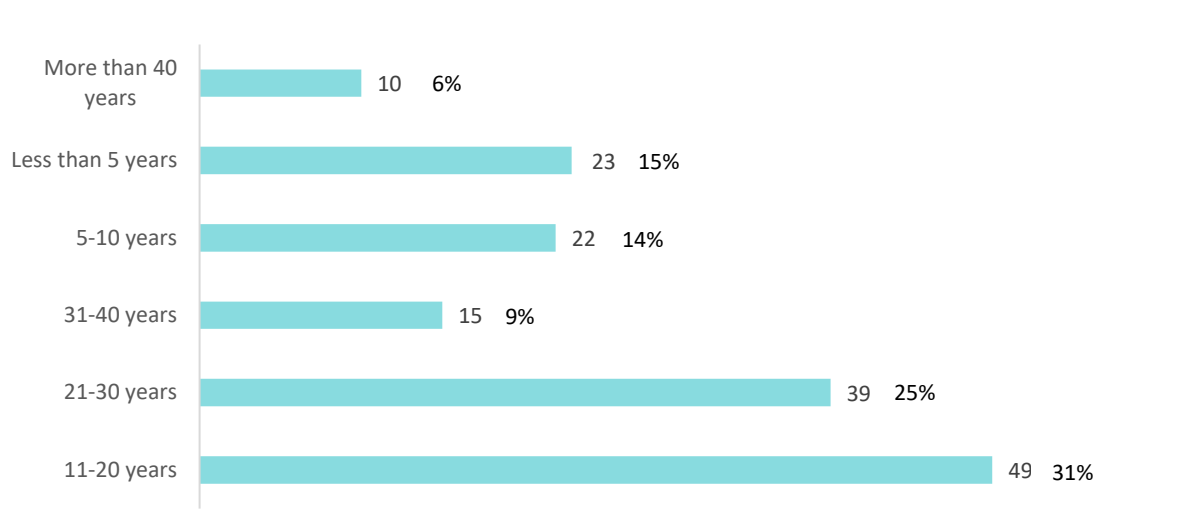
A breakdown of the responses to Question 6 was as follows:

- 40% of respondents indicated that they currently work in community pharmacy as a Support Pharmacist.
- 29% of respondents indicated that they currently work in community pharmacy as a Supervising Pharmacist.
- 10% of respondents indicated that they currently work in community pharmacy as a Superintendent Pharmacist.
- 6% of respondents indicated that they currently work in community pharmacy as a pharmacy owner.
- 0.5% of respondents indicated that they currently work in regulation.
- 1% of respondents indicated that they currently work in pharmaceutical industry.

- 0.5% of respondents indicated that they currently work in a GP Practice.
- 0.5% of respondents indicated that they currently work in Medicines information.
- 1% of respondents indicated they currently work in HSE or HSE Community Operations.
- 15% of respondents indicated that they currently work in community pharmacy as a Locum or Relief Pharmacist
- 10% of respondents indicated that they currently work in a hospital setting.
- 0.5% of respondents indicated that they currently work in Academia/Hospital.
- 0.5% of respondents indicated they currently work in digital health.

Question 7: I have been a registered pharmacist for

Answered	158
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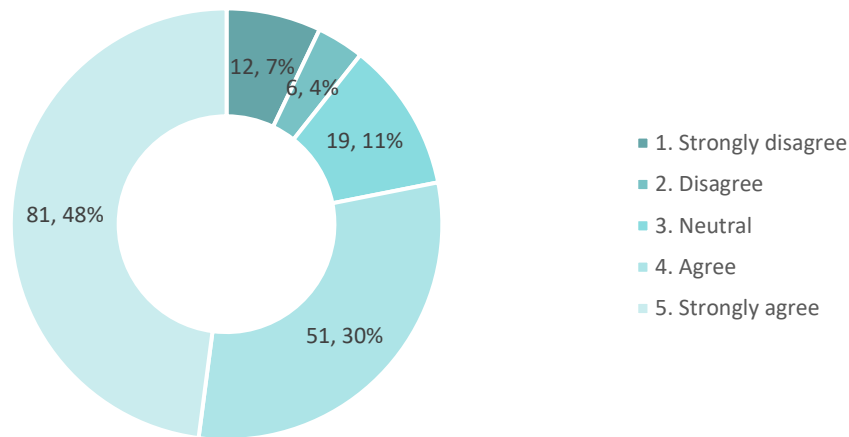
A breakdown of the responses to Question 7 was as follows:

- 15% of respondents indicated that they have been registered as a pharmacist for less than 5 years.
- 14% of respondents indicated that they have been registered as a pharmacist for 5-10 years.
- 31% of respondents indicated that they have been registered as a pharmacist for 11-20 years.
- 25% of respondents indicated that they have been registered as a pharmacist for 21-30 years.
- 9% of respondents indicated that they have been registered as a pharmacist for 31-40 years.
- 6% of respondents indicated that they have been registered as a pharmacist for more than 40 years.

For Questions 8-13, respondents were asked to give a rating on a scale from 1 to 5, on how strongly they agree that the overarching principle, principle statement, and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.

Question 8: Principle 1: Robust Governance Arrangements

Answered	169
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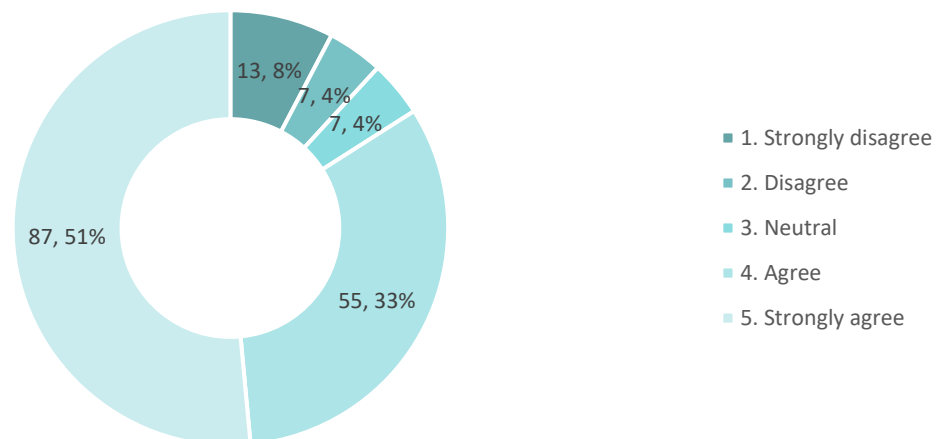


A breakdown of the responses to Question 8 was as follows:

- 7% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 3% of respondents indicated that they disagreed.
- 11% of respondents indicated that they were neutral.
- 30% of respondents indicated that they agreed.
- 48% of respondents indicated that they strongly agreed.

Question 9: Principle 2: Reviewing prescribed medicines for safety and appropriateness.

Answered	169
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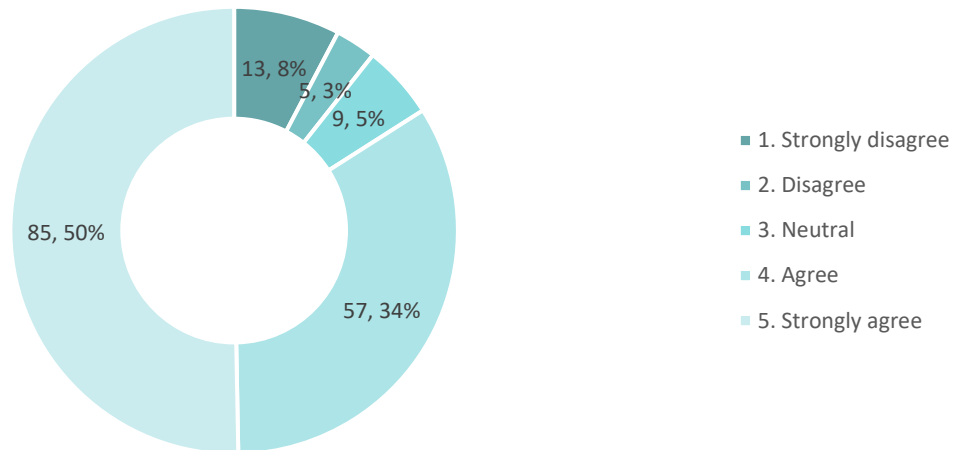
A breakdown of the responses to Question 9 was as follows:

- 8% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 4% of respondents indicated that they disagreed.
- 4% of respondents indicated that they were neutral.

- 33% of respondents indicated that they agreed.
- 51% of respondents indicated that they strongly agreed.

Question 10: Principle 3: Effective patient counselling

Answered	169
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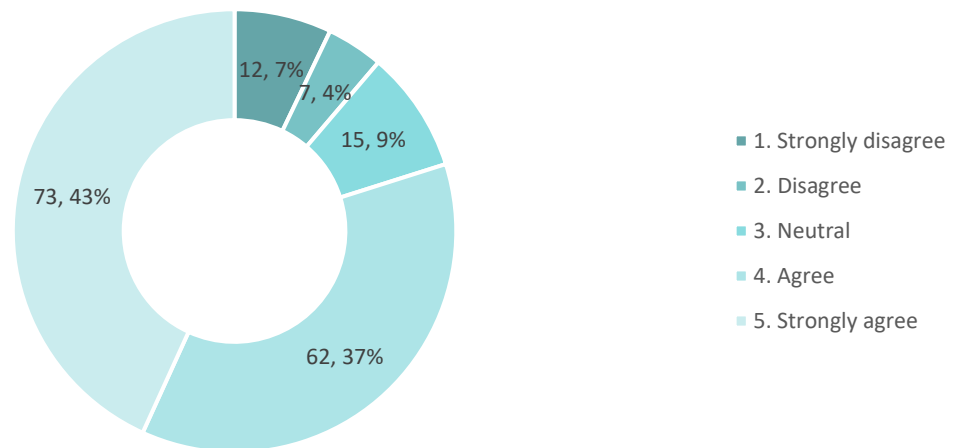


A breakdown of the responses to Question 10 was as follows:

- 8% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 3% of respondents indicated that they disagreed.
- 5% of respondents indicated that they were neutral.
- 34% of respondents indicated that they agreed.
- 50% of respondents indicated that they strongly agreed.

Question 11: Principle 4: Individual competence to inform decisions.

Answered	169
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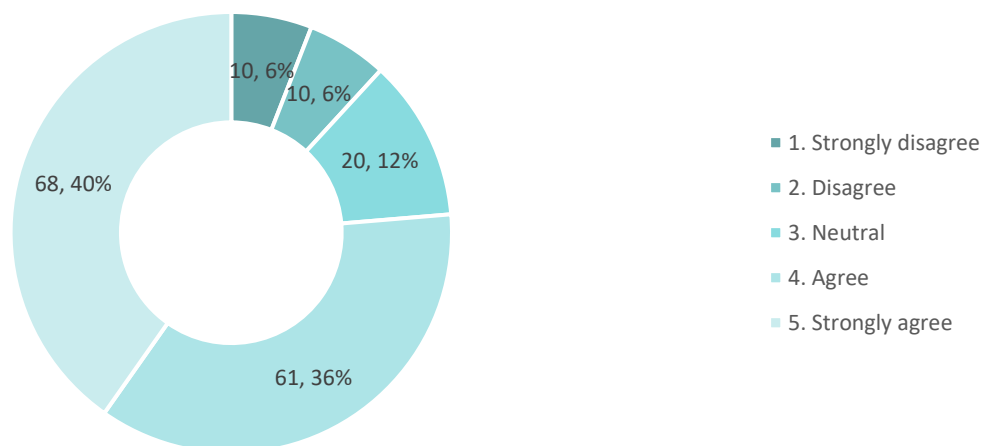


A breakdown of the responses to Question 11 was as follows:

- 7% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 4% of respondents indicated that they disagreed.
- 9% of respondents indicated that they were neutral.
- 37% of respondents indicated that they agreed.
- 43% of respondents indicated that they strongly agreed.

Question 12: Principle 5: Appropriate record-keeping and documentation

Answered	169
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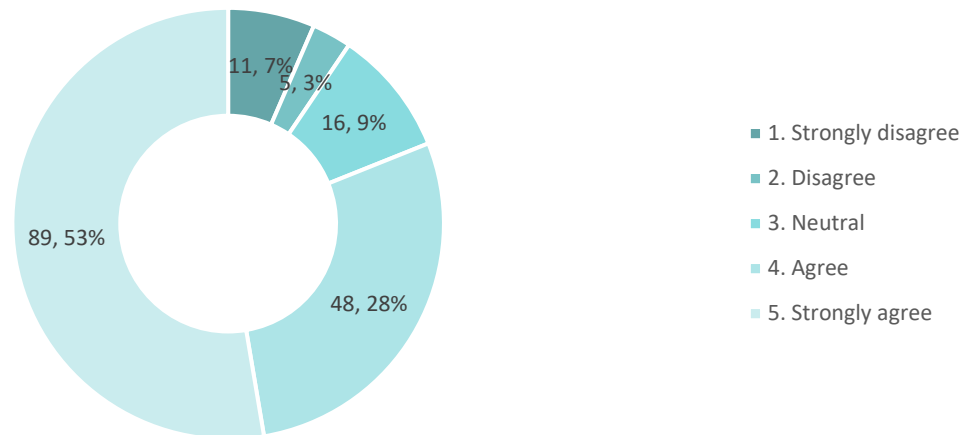
A breakdown of the responses to Question 12 was as follows:

- 6% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 6% of respondents indicated that they disagreed.
- 12% of respondents indicated that they were neutral.

- 36% of respondents indicated that they agreed.
- 40% of respondents indicated that they strongly agreed.

Question 13: Principle 6: Communication between healthcare professionals

Answered	169
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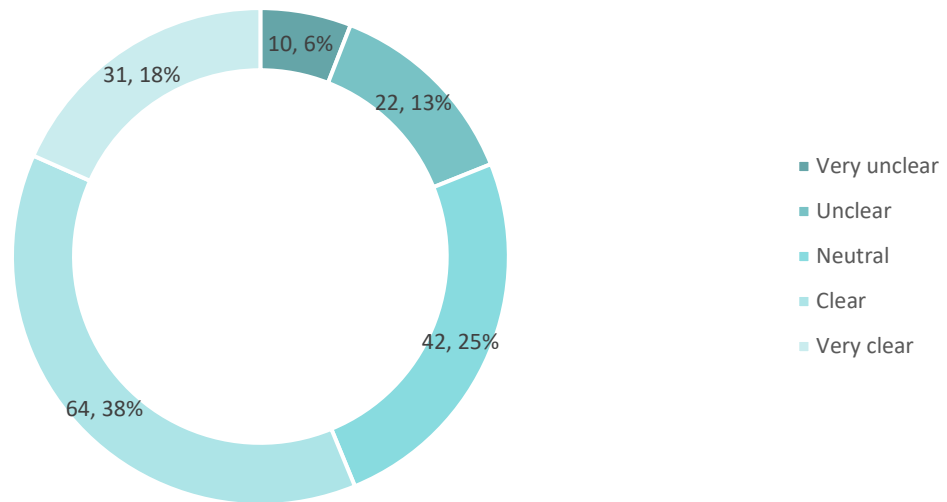
A breakdown of the responses to Question 13 was as follows:

- 7% of respondents indicated that they strongly disagreed that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.
- 3% of respondents indicated that they disagreed.
- 9% of respondents indicated that they were neutral.
- 28% of respondents indicated that they agreed.
- 53% of respondents indicated that they strongly agreed.

In summary, survey feedback was positive across all of the principles with the majority of respondents either answering strongly agree or agree that the overarching principle, principle statement and principle indicators will effectively guide decision-making to ensure compliance with the overarching principle.

Question 14: How clear and easy to understand is the language used in the draft guidelines?

Answered	169
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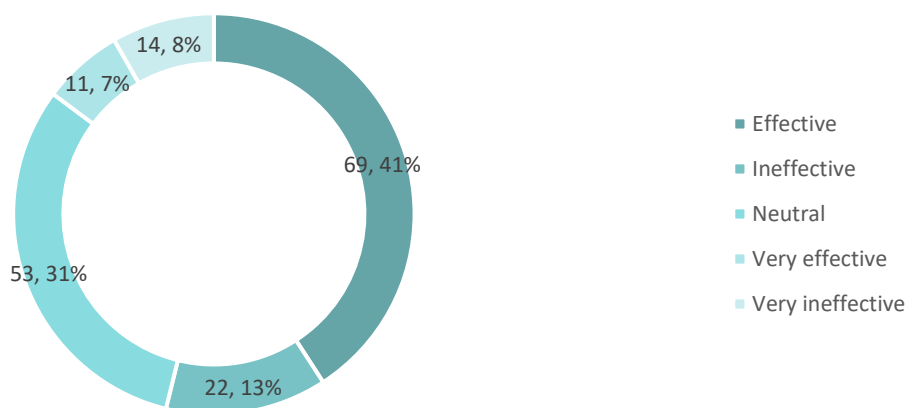
A breakdown of the responses to Question 14 was as follows:

- 6% of respondents indicated that they feel the language used in the draft guidelines is very unclear.
- 13% of respondents indicated that they feel the language is unclear.
- 25% of respondents indicated that they were neutral.
- 38% of respondents indicated that they feel the language is clear.
- 18% of respondents indicated that they feel the language is very clear.

The majority (56%) of respondents said that the language of the Guidelines was very clear or clear, 25% indicated that they were neutral and 19% indicated that the guidelines were unclear or very unclear.

Question 15: To what extent do you believe the draft guidelines will be effective overall in achieving their intended objective of supporting the consistent delivery of safe and high-quality person-centred care regarding medicines therapy review, counselling, and prescription extension?

Answered	169
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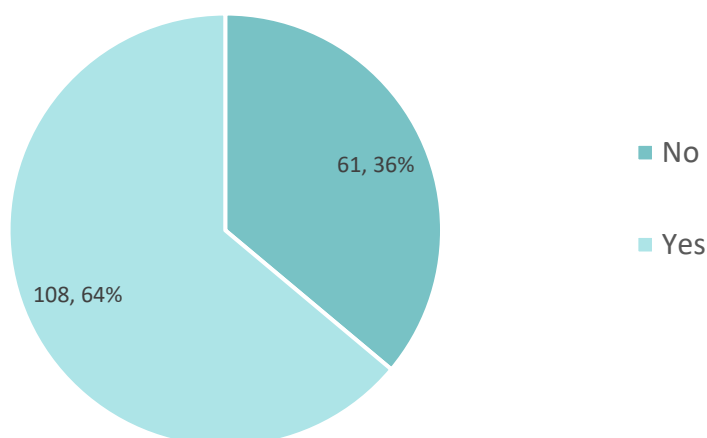
A breakdown of the responses to Question 15 was as follows:

- 8% of respondents indicated that they feel the draft guidelines will be very ineffective.
- 13% of respondents indicated that they feel the draft guidelines will be ineffective.
- 31% of respondents indicated that they were neutral.
- 41% of respondents indicated that they feel the draft guidelines will be effective.
- 7% of respondents indicated that they feel the draft guidelines will be very effective.

The majority here (48%) said the guidelines will be effective or very effective, 31% of the respondents indicated that they were neutral and 21% indicated they thought the guidelines will be ineffective or very ineffective.

Question 16: Do you believe that any additional support tools or information are needed in addition to the draft guidelines to support medicines therapy review, counselling, and prescription extension?

Answered	169
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Breaking this down 64% of respondents believed that additional supports would be needed on top of these guidelines.

Question 17: Please specify the type of support or information you believe would be beneficial.

Answered	108
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In this question respondents were invited to comment, and some comments did not pertain directly to additional support tools, therefore these comments were included in question 18 for analysis. The consultation generated a variety of suggested tools to provide additional information and support.

Videos (4 comments)

Some respondents suggested creating short videos or recorded presentations demonstrating best practices. These resources should be accessible at any time, allowing pharmacists to refer to them as needed.

Online training/ Workshop (5 comments)

In addition to videos, there were recommendations for online training sessions or workshops. These would provide pharmacists with opportunities to ask questions, engage in discussions with peers, and share experiences. It was also suggested that one of these sessions could involve the HSE PCRS to address some of the queries that are within their remit.

Flowcharts/Procedures/ Algorithms for Medicines therapy review (14 comments)

There were requests for a standardized flowchart to guide pharmacists through the process of conducting a medicines therapy review when considering prescription extensions. Respondents stated that this would help ensure uniformity across all pharmacies and outline responsibilities, prescriber notifications, and record-keeping protocols.

Case study examples (9 comments)

Respondents also suggested that case studies and practical examples be provided. These could be incorporated into online training sessions, allowing pharmacists to discuss and ask questions about real-world scenarios.

Access to online resources (14 comments)

Several respondents expressed the need for additional online resources to support prescription extension. This included access to information on monitoring patients' blood results and guidelines for specific patient subsets. Respondents suggested such resources could be highlighted in training events or videos, directing pharmacists to the necessary information.

Lists of exemptions/ approved classes or situations (9 comments)

Respondents also requested information on medicines that can and cannot be extended. This information would help pharmacists explain to patients why certain prescriptions cannot be extended. There were some comments requesting a list of situations where extensions would not be appropriate be included.

General/ broad request for more information (4 comments)

There were general comments suggesting that PSI could offer more comprehensive support and documentation to pharmacists.

PSI Response

PSI appreciates the feedback and suggestions for additional support tools. We are actively collaborating with our stakeholders, including IIO, to implement some of these recommendations.

Question 18: Do you have any additional comments or feedback on any aspect of the draft revised guidelines?

Answered	71
Email responses included in this thematic analysis	3
Answers from question 17 included in this thematic analysis	49

Some comments from the previous section were more relevant to this question and have been included in the analysis below. These comments have been categorised by theme, and PSI has responded accordingly.

Information for the public

Numerous comments focused on the importance of communicating effectively with the public about the legislative changes on prescription extension to increase clarity and understanding about the changes among patients.

PSI Response

A number of key actions are necessary to ensure the effective and smooth delivery of this change in a manner that enhances health and social care services and the provision of healthcare for patients and the public.

The Department of Health has implemented a schedule of engagement and consultation with internal and external stakeholders to ensure all aspects of the recommendation are considered and all relevant stakeholders are informed.

Work has commenced and is ongoing to ensure patients and the public are informed about the prescription extension process.

This includes a [dedicated webpage](#) for patients and the public created by the Department of Health that includes example scenarios for patients. The PSI has also created a dedicated webpage on the [Expert Taskforce and prescription extension](#) providing information for patients and the public on the PSI will continue to work with the Department and other key stakeholders on this matter as part of our role in supporting the Taskforce.

General Practice

Respondents also highlighted a need for awareness among GPs regarding the role of pharmacists in prescription extensions.

PSI Response

PSI is working collaboratively with a number of key stakeholders to support awareness among prescribers of these changes. A subgroup of the Expert Taskforce was established to focus on the implementation of the first recommendation of the Taskforce. The subgroup includes

representatives from the PSI, the Medical Council, Nursing and Midwifery Board of Ireland and the Dental Council.

Administration burden and digitalisation

Some respondents expressed concerns about a potential increase in administrative workload for pharmacists as a result of the changes around prescription extension. A number of respondents suggested ways of reducing a potential increase in administrative workload including implementing new Patient Medication Record (PMR) systems or other software to capture consultation details.

PSI Response

The Expert Taskforce and PSI are aware of and acknowledge this potential issue.

One of the recommendations of the Expert Taskforce is that operational supports and infrastructure should be facilitated to evolve to reduce any undue administrative burden, optimise communication, and facilitate reporting and feedback between professions.

The Department of Health and HSE are working collaboratively with their respective eHealth/ePharmacy teams to improve ICT for pharmacy in Ireland and ensure alignment with overall plans for the delivery of eHealth strategies. Pharmacists must maintain accurate records in accordance with legislative record keeping requirements.

Workforce pressures and time constraints

Another theme that emerged from consultation feedback was workforce and time pressures. Some pharmacists described a need for additional staff or support and outlined that time pressures and additional workload may prevent pharmacists from carrying out prescription extensions. Some respondents also felt that additional pharmacy services should be appropriately compensated.

PSI Response

PSI, together with the Department of Health, has established a multi-agency group to advance the recommendations of the [Workforce Intelligence Report](#) published in 2023. The recommendations outlined in the report, when implemented, seek to address workforce pressures such as those highlighted during the consultation.

In addition, PSI will ensure that consultation feedback that is not directly within our remit will be forwarded to the appropriate stakeholders for their consideration.

Request for more detailed guidelines

Some respondents requested more detail in the draft guidelines, expressing that the current draft of the revised guidelines lacked sufficient detail.

PSI response

The revised guidelines are principles-based and are intended to be supportive and enabling, rather than prescriptive, offering flexibility as to how they can be implemented. PSI considers that by focusing on principles rather than prescriptive details, pharmacists will be empowered to apply their expertise more effectively and adapt their practices to the specific needs and circumstances they encounter.

In addition to the revised guidelines, a number of other supports will be available for pharmacists including frequently asked questions (FAQs) on prescription extension that will provide further support.

Access to patient records and eHealth

Some respondents suggested that access to patient records, including recent blood tests, would aid pharmacists in making decisions around prescription extension.

PSI Response

PSI acknowledges that greater access to patient information would be beneficial for pharmacists in their practice. As outlined above, the Department of Health and HSE are working collaboratively with their respective eHealth/ePharmacy teams to improve ICT for pharmacy in Ireland and ensure alignment with overall plans for the delivery of eHealth strategies. Pharmacists should follow the guidelines, the Code of Conduct and use their professional judgment when deciding to extend a prescription.

Liability for extending prescriptions

Another theme to emerge from consultation feedback was liability for pharmacists around prescription extension, particularly in the context of a patient adverse event.

PSI Response

All pharmacies in Ireland are required to hold professional indemnity insurance cover as part of the pharmacy's registration requirements. Pharmacists are advised to clarify the status of their indemnity cover in each pharmacy where they practise, ensuring that the correct and appropriate indemnity cover is in place.

Other comments

Finally, we received feedback on several other topics which fell outside the scope of the guidelines.

PSI Response

We appreciate all feedback received from survey respondents in relation to our work. While our current focus is on feedback directly related to the guidelines, we will consider this input as part of our overall regulatory work.

Focus Group Discussion summary

PSI held an online focus group discussion on the evening of 15 May 2024 with members of our PSI Pharmacist Panel on the draft guidelines. The aim of this focus group was to further explore pharmacist views on the draft guidelines. Similar themes emerged from the focus group as those identified through consultation feedback above. In addition, the following were raised by the group:

- There was strong consensus for indicator 1.8 that prescription extension should not be used to drive targets or incentives by those in governance roles. There were some further suggestions in the focus group on where language in the guidelines could be clearer for the reader, and these were considered during redrafting.

- The panel highlighted that a pharmacist's ability to extend a prescription should be based on the information available to them, such as the medicine's indication and access to prescribing guidelines. It was also highlighted by the panel that if a pharmacist feels they need more information to extend a prescription, they should use their professional judgement and record reasons for their decision to not extend.
- Effective interdisciplinary communication was highlighted as essential for effective prescription extension by pharmacists. Discussion also raised some operational challenges to effective communication with prescribers, including that not all GPs currently use Healthmail. Another potential barrier discussed was about the capability of PMR systems in community pharmacies to record consultation notes.

PSI Response

PSI is very grateful to all members of the pharmacist panel who attended the focus group. Insights gained from the discussion have been very useful in further developing the guidelines and will be used to inform the development of other supports for pharmacists.

Summary of amendments made to the Guidelines following consideration of feedback received during the public consultation and feedback from our stakeholders.

In response to consultation feedback, several amendments were made to the draft guidelines. These are summarised below:

- **Reference to Code of Conduct**
The introduction includes a reference to the Code of Conduct, including the link, to emphasise that pharmacists are guided by it and that the health, well-being, care, and safety of patients are their primary priorities.
- **Clarification**
In response to feedback and to enhance clarity, the following amendments have been made:
 - Footnotes provide further clarification on the terminology used in the guidelines, such as a culture of person-centred care and professional autonomy.
 - An explanatory statement has been added to indicator 4.4 to enhance clarity around subsequent supplies from a prescription previously extended.
 - It is now clarified in the guidelines that the decision to extend a prescription occurs at the end of the six-month period within a prescription cycle.
- **Additional indicators for prescription extension**
As part of the 'Structure of the Guidelines' section, an explanation has been added regarding the additional indicators for prescription extension to clearly define the enhanced responsibilities for prescription extension.
- **Wording changes**
Some wording changes have been made throughout the document to make points clearer and more accessible.
- **Principle wording**

The wording in Principle 4 has been adjusted to include the word ‘pharmacist’ such that it now reads ‘Pharmacist competence to inform decisions’.

We have also added an explanation for the intention behind principles-based guidelines, emphasising greater flexibility and the fact that this approach demonstrates confidence in pharmacists to use their knowledge, skills, and expertise to make informed decisions in the interests of person-centred care.

- **Indicator**

Indicator 6.3 has been removed as it was felt that the specifications in legislation for prescriber notification were adequately addressed.

- **Layout**

One of the images has been reformatted to ensure wording is not obscured.

- **Additional information sources**

Additional information sources have been added to the ‘More Information’ section, including:

- our [Guidance on Pharmacy Governance roles](#) where we set out the responsibilities of the pharmacy owner, superintendent pharmacist, supervising pharmacist and all pharmacists involved in the operation of a retail pharmacy business and the
- the [HSE PCRS](#) where a range of information and resources are available for pharmacists and pharmacies.