PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Process for Development of PSI Standards

Version 0.1

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About the Pharmaceutical Society of Ireland

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.

As the pharmacy regulator, we set the standard for pharmacists' education and training in Ireland and create the standards and supports to promote good professional practice in pharmacy. We register pharmacists, pharmaceutical assistants and pharmacies, carry out inspections of pharmacies and take action when there is a concern about a pharmacist or a pharmacy, including when we receive a complaint from a member of the public.

The PSI is an independent body and an agency of the Department of Health. We are governed by a 21-member Council, with each of the members appointed by the Minister for Health.

Our role

Our principal function is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically and transparently.

The Pharmacy Act 2007 (as amended) established the role and responsibilities of the PSI, 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.

Introduction

One of the roles of the PSI is to promote good professional practice by pharmacists through raising standards. One of the ways the PSI fulfils this role is by producing guidelines[1] to support pharmacists and pharmacy owners in complying with pharmacy and medicines legislation and to provide a safe and effective service to patients. All guidelines produced by the PSI are available on the PSI's website.

At the June 2018 Council meeting, PSI Council approved a proposal to develop a standards-based approach to guideline development for retail pharmacy businesses. This is in line with commitments set out in the PSI Corporate Strategy 2018-2020[2] and follows positive discussions about this approach to regulation with superintendent pharmacists at 11 regional seminars held during springtime 2018[3]. In particular, the proposed standards-based guidelines will enable pharmacists to comply with Regulation 5 of S.I. 488 of 2008; *Management and Supervision of a Retail Pharmacy Business*.

A standards-based approach to guideline development will differ from the format of PSI guidelines issued to date, in that they will provide concise, outcome-focused statements against which a service provider will establish and deliver their service. This new approach can be used to monitor and improve practice and will provide a framework to enable the provision of safe, effective and consistent services and high-quality care to patients and members of the public.

As standards are focused on the outcomes achieved, they enable the service provider, in this case the healthcare setting of a Retail Pharmacy Business, to meet the requirements of the standards in a range of different ways.

Outcome focused standards are particularly suited to the setting of Retail Pharmacy Businesses which vary in size, have differing management structures (e.g. independent or chain), as well as providing differing types of services depending on their location and patient/customer needs. Standards also provide assurance for patients and members of the public about what they can expect when they engage with the healthcare setting of a retail pharmacy business. It is expected that this new approach to guideline development will avoid a prescriptive, one-size-fits-all approach and ensures that the standards do not stifle innovation.

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[1] Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) (SI 488/2008) provides that the PSI Council may publish detailed guidelines for the purpose of facilitating compliance with these Regulations.

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

[3] A Report on the Seminars for Superintendent Pharmacists is available on the PSI website.

Process for the Development of Standards

This section sets out the process to be followed when developing PSI standards. It was created following engagement with the Health Information and Quality Authority (HIQA) and closely aligns with their established process to develop national standards for health and social care[4].

Best practice would indicate that standards are most successful if they are created through a collaborative approach involving different stakeholders, including:

(i) The regulating body developing the standards,
(ii) The service providers,
(iii) Users of the service and
(iv) Relevant independent experts.

To enable the stakeholders to feed into the development process from an early stage, a Standards Advisory Group comprising key stakeholders, including those from the pharmacy sector and patient groups, together with independent experts, will be convened. The Standards Advisory Group will use their expertise to guide and inform the work of the PSI project team in the development of standards to ensure that they are useful, practical and meet their objective.

A scoping consultation is also carried out at an early stage of the process to provide an opportunity for stakeholders to:

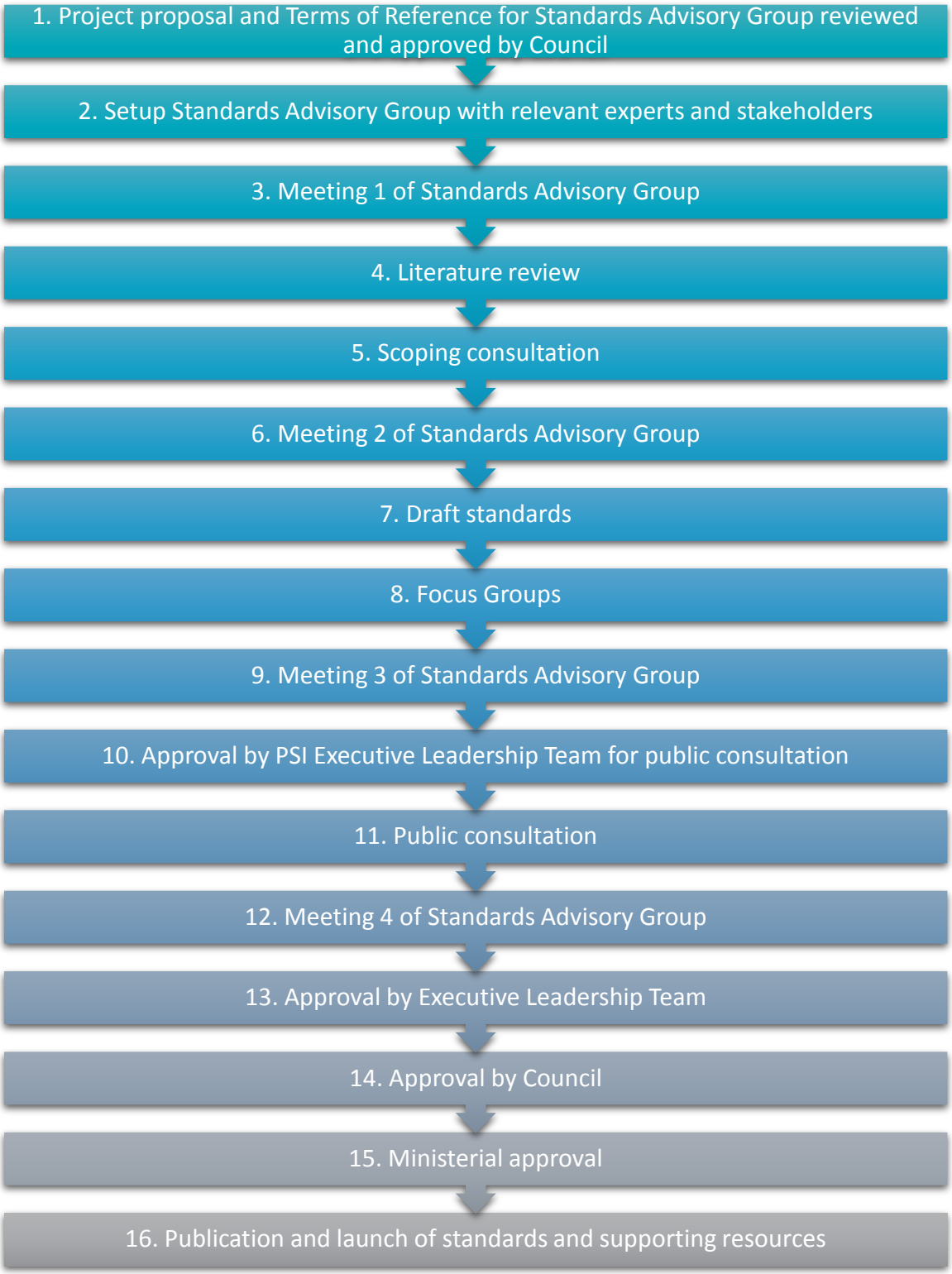
(i) Identify the key issues that should be addressed by the standards,
(ii) Provide experiences of using related services and examples of best practice, and
(iii) Raise awareness of the development of standards in this area.

Focus groups, 1:1 interviews and public consultations are used at relevant points throughout the process to gather insight and comments from a wide audience and test the standards before publication.

The development of PSI standards is also informed by an in-depth review of the available literature[5] and grey literature[6] on the topic. This will include analysis of relevant standards, guidance, reports, audits, reviews, relevant studies, government guidance and regulatory and professional body publications, from both national and international sources. This ensures that the standards are evidence-based, developed in line with national and international best practice and will help to future proof the standards.

[4] HIQA's process for development of national standards was developed following a review of national and international evidence, engagement with national and international experts and applying HIQA's knowledge and experience of the health and social care context.
[5] Literature in this context refers to peer reviewed and published research and articles.
[6] Grey literature in this context refers to information and research that is not commercially published, for example newsletters, government reports and policy statements.

Overview of the process for the development of PSI standards



1. Project proposal and Terms of Reference for Standards Advisory Group reviewed and approved by Council

An overview of the proposed project, including background information on the need for standards on the proposed topic, the proposed approach and estimated timelines is sent to Council for review and approval. The terms of reference for the Standards Advisory Group is also provided to Council for review and approval. The terms of reference for the group outlines the role of the Standards Advisory Group, governance and membership as well as frequency and format of meetings.

2. Setup Standards Advisory Group with relevant experts and stakeholders

Key stakeholders relevant to the scope of the standards and experts in the field are identified for membership of the Standards Advisory Group, in line with the membership set out in the terms of reference approved by Council. The role of the Standards Advisory Group is to advise the PSI project team at relevant points in the development of the standards, rather than to own the process of creating the standards.

The role of the Standards Advisory Group is to:

- Provide practical guidance and expertise to the PSI project team drafting the standards
- Advise on the draft standards for public consultation and on the revised standards post consultation
- Advise on implementation of the standards

All comments received from members of the Standards Advisory Group are carefully considered and used to inform the final standards. The PSI Council are responsible for approving the final standards for submission to the Minister for Health.

3. Meeting 1 of Standards Advisory Group

At this meeting, the Chair will explain what is expected of members of the group, including the appropriate structure to provide feedback on the draft standards, their role in providing suggestions for stakeholders and contacts for focus groups, as well as publicising the public consultation and standards once approved. The Standards Advisory Group also discuss and confirm the proposed process for the development of standards.

4. Literature review

The PSI project team carry out a review of available literature and evidence relevant to the topic. This will include analysis of relevant standards, guidance, reports, audits, reviews, relevant studies, government guidance and regulatory and professional body publications, from both national and international sources.

5. Scoping consultation

Before work begins on drafting the standards, a scoping consultation is carried out. Focus groups[7] and/or 1:1 interviews, and a 2 week public consultation is held to engage and consult with key stakeholders. Stakeholders will generally include subject matter experts, pharmacists and pharmacy owners, people using pharmacy services and members of the public.

The purpose of the scoping consultation is to ascertain who will be affected by the introduction of standards in this area, what issues are important to stakeholders, the key issues that should be addressed by the standards and to gather the experiences of those providing or using related services, including examples of best practice. At the first meeting, members of the Standards Advisory Group will be asked to suggest possible stakeholders that the PSI project team could contact to take part in the focus groups.

6. Meeting 2 of Standards Advisory Group

The Standards Advisory Group meet to discuss the findings from the literature review and scoping consultation. The group is asked to agree on the scope, purpose and audience of the standards.

7. Draft standards

In line with the agreed scope and purpose for the standards, the PSI project team prepare an initial draft of the standards, considering information gathered from the literature review, scoping consultation and feedback received from the Standards Advisory Group.

8. Focus groups

Several focus groups are held with key stakeholders including patients and members of the public, pharmacists working at both managerial/ownership and practice level, and other healthcare professionals affected by the introduction of the standards to test the viability and applicability of the draft standards and provide feedback. The draft standards are revised in light of comments received.

9. Meeting 3 of Standards Advisory Group

The Standards Advisory Group meet to discuss the draft standards in detail. Each member of the group is provided with a number of standards to review in advance of the meeting. At the meeting, the group is divided into a few smaller groups to discuss their comments and then feedback to the larger group. All comments from the group are considered by the PSI project team when refining the standards.

[7] Focus groups are a form of qualitative research in which small groups of participants explore predetermined topics in an open or guided discussion (HIQA).

10. Approval by Executive Leadership Team for public consultation

The Executive Leadership Team (ELT)[8] of the PSI is provided with the draft standards which include comments from the Standards Advisory Group. The ELT is asked to provide any further comments relevant to their department's role within the PSI. The draft standards are revised in light of comments received and, when agreement is reached, the ELT provides approval of the draft standards for public consultation.

11. Public Consultation

A public consultation on the standards is held for at least 6 weeks. The draft standards are published on the PSI website along with a survey to elicit views and comments from any interested individual or party on the draft standards. Respondents are also given the option to provide comments by email.

The consultation is communicated through the PSI newsletter and via email to all registrants and key stakeholders. It is also publicised through our social media channels (Twitter and LinkedIn). All submissions to the public consultation are reviewed and the draft standards are revised in light of comments received.

12. Meeting 4 of Standards Advisory Group

The Standards Advisory Group meet to discuss comments received from the public consultation along with changes to the draft standards made in light of these comments. The Standards Advisory Group are asked to discuss and provide comment on any key issues or areas of conflicting feedback and provide any further comments as they see fit. All comments are considered by the PSI project team and the draft standards are revised in light of comments received. The group is also invited to provide suggestions on how best to launch and implement the standards once approved.

13. Approval by the Executive Leadership Team

The ELT is provided with the draft standards which include changes following the public consultation and comments from the Standards Advisory Group. The ELT is asked to provide any further comment relevant to their department's role within the PSI. The draft Standards are revised in light of comments received and when agreement is reached, the ELT provides approval of the draft standards for referral to Council.

14. Approval by Council

All documents relevant to the development of the standards are presented to Council, including the process used to develop the draft standards, the literature review, summary of the feedback from focus groups and public consultation along with the draft standards, for review. Council are asked to provide any further comment. The draft standards are revised

[8] The Executive Leadership Team comprises the Head of each department of the PSI, with the Registrar as Chair.

in light of any comments received and, when agreement is reached, Council approve the standards for referral to the Minister for Health for approval and publication.

15. Ministerial approval

The Standards are sent to the Minister for Health for approval as required under Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended).

16. Publication and launch of standards and supporting resources

Once written approval has been received from the Minister for Health, the standards are published and launched via the PSI website. The PSI proceeds with a 'Knowledge Sharing and Impact Strategy'. This includes a suite of resources/digital packages which provides the public and pharmacists with information on the standards presented in different ways to facilitate understanding and implementation of the standards. This mirrors the strategy employed in HIQA upon the publication of their standards. An example of how HIQA manages the sharing of standards upon publication is available here.

Figure 1 below outlines possible resources to be used and approaches to be adopted, upon the publication of standards, in order to disseminate our message:

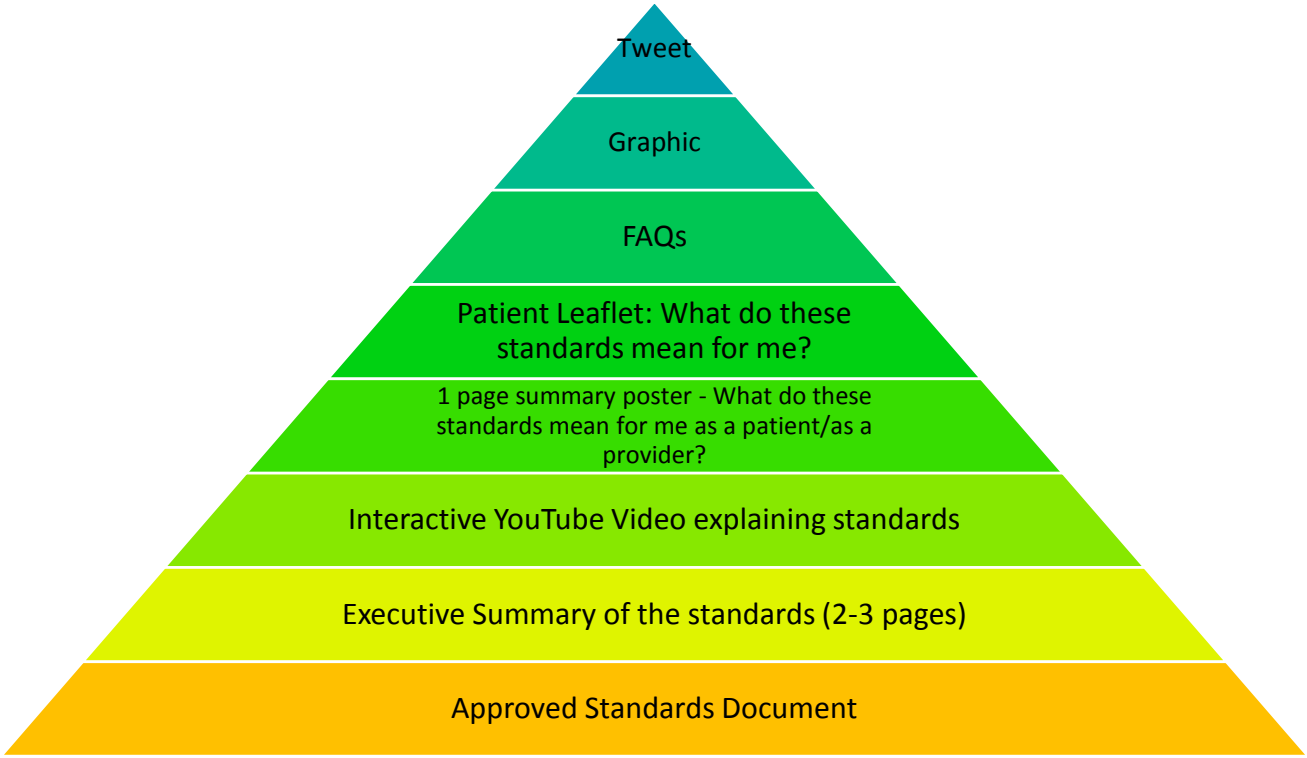


Figure.1 Suggested Knowledge Sharing and Impact Strategy in descending order of complexity (adapted with permission from HIQA's communication strategy)

It is suggested that the standards be linked to an interactive resource e.g. an animation published on YouTube, LinkedIn etc. It is also recommended that the standards are retweeted at key points throughout the year (e.g. to coincide with a national

campaign/global initiative) to keep the standards ‘alive’ and reinforce the PSI’s message. Animations are a very useful way to present key points/learnings from the standards so that a wide audience can easily grasp what the purpose and requirements of the standards are.

References

Conducting focus groups, Methods in the development of National Standards, Guidance and Recommendations for the Irish health and social care sector; Health Information and Quality Authority, September 2018

Evidence synthesis process, Methods in the development of National Standards, Guidance and Recommendations for the Irish health and social care sector; Health Information and Quality Authority, September 2018

Professional standards, guidance and frameworks process development manual; Royal Pharmaceutical Society, July 2016

Version Control

Version	Date	Description	Drafted by	Approved by
0.1	October 2018	First draft	Irene Patterson	Conor O'Leary