Developing Governance and Accountability Standards for Retail Pharmacy Businesses

Standards Advisory Group

Meeting 2

Presentation 1

26 March 2019

PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Agenda – Meeting Overview

- Presentations on:
  - Where we are in the Process for the development of standards
  - Literature Review Results
  - Scoping Consultation
    - Patient engagement at the HSE National Patient Forum
    - Pharmacist Focus Group
    - Scoping consultation survey results
- Group discussion
  - Scoping Consultation Key themes emerging
  - What is inside the scope, and outside the scope, of the standards?
  - What areas should the standards address?
- Next Steps
- Confirmation of next meeting date and time
- **Lunch**

Terms of Reference for the Group

Terms of Reference for the Standards Advisory Group

- Experts in the field, service users and service providers

- The Role of Advisory Group:
  - ➤ 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

PSI Corporate Strategy 2018 -2020

Our Vision

That the public has access to trusted pharmacy services and that the PSI makes a clear and demonstrable contribution to the availability and quality of those services

Our Mission

We protect and promote the health, safety and wellbeing of patients and the public by taking timely and effective action to ensure that pharmacists in Ireland are competent and that pharmacies are operating to high standards of safety and reliability.

Our Values

Serve the public
The safety of the public is at the heart of everything we do, and we act to ensure that safety.

Everyone Counts
We value, appreciate and respect everyone we engage with.

Work Together
We work in partnership with our colleagues and all our stakeholders.

Lead by example
We behave with integrity and objectivity. Our actions are evidence-based and timely.

Embrace Change
We are innovative and we adapt to achieve results and continuously improve.

Four Strategic Results Areas

We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.

We will deepen our engagement and communication with stakeholders to ensure our work is making an impact and that we are focused on the key outcome areas .

Promoting professionalism and quality in pharmacy

Impacting through deeper collaboration and engagement

Assure trust in pharmacy through effective regulation

Building an effective organisation and benchmarking our performance

Regulating effectively for better health outcomes and patient safety

We will build an agile and high-performing organisation, capable of delivering on our mission and have our performance independently assessed.

We will regulate in ways that are proportionate, effective and risk-based, with a focus on the key areas relevant to patient health and safety.

- **Four strategic results areas** under which we will deliver specific results.

- Together, these will see us make significant progress towards our central goal.

Why Standards in Retail Pharmacies matter

Medicines

- most frequent intervention in the health system-across all disciplines

- critical element for many people living with illness

- often key to helping people live more healthy and stable lives

- making sure people use these medicines appropriately is a matter of significant public importance
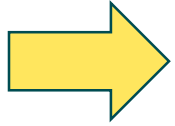
Pharmacists in Retail Pharmacies

- most frequently accessed healthcare professionals in our communities

- contribute to positive health initiatives for the public

- provide medicines counselling to patients in the community setting

- tackle medicines risk issues such as polypharmacy, non-adherence, errors and wastage

Standards for good governance & clear accountability underpin and support quality and safety in retail pharmacies
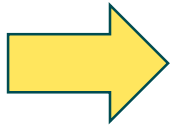
How are Standards different?
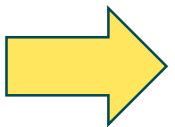
Standards-based approach to guideline development
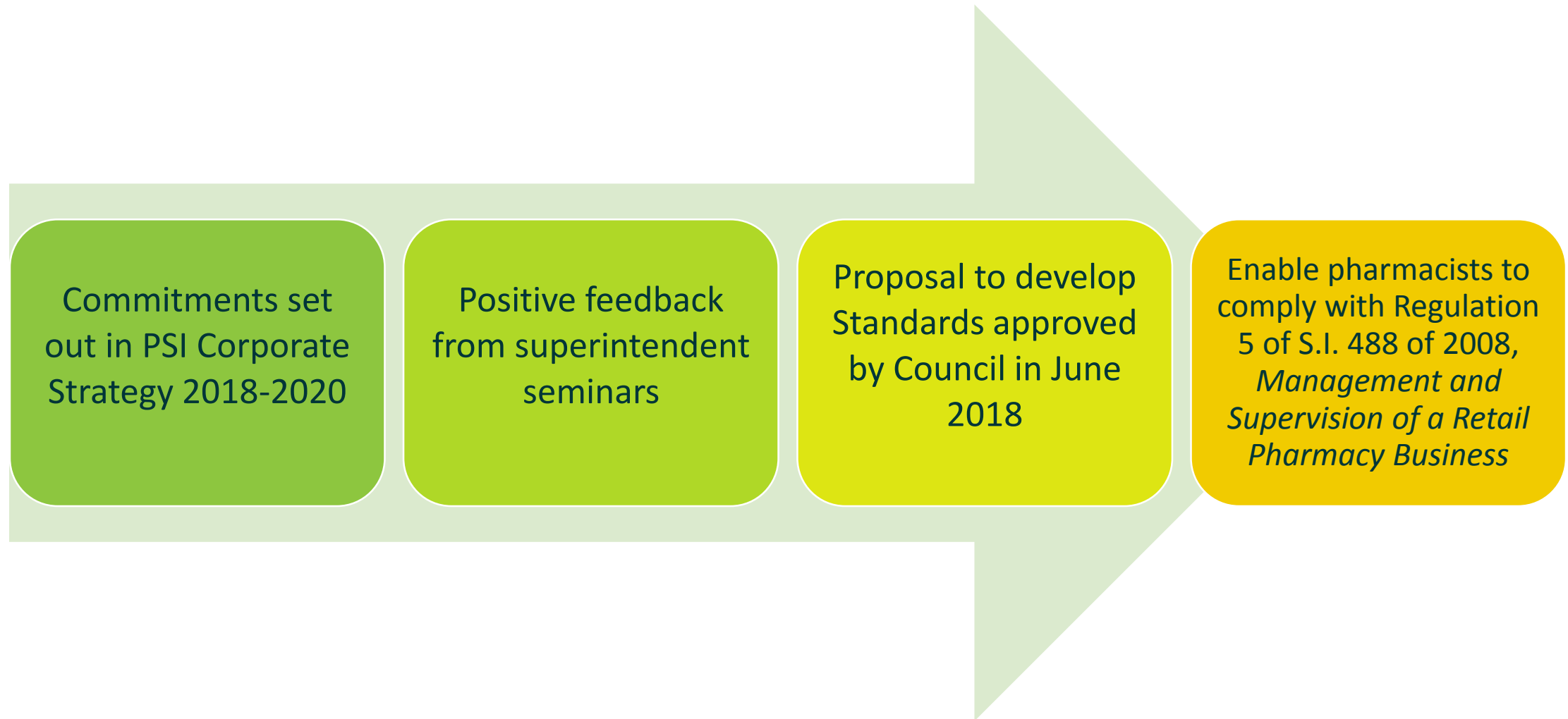
| Commitments set out in PSI Corporate Strategy 2018-2020 | Positive feedback from superintendent seminars | Proposal to develop Standards approved by Council in June 2018 | Enable pharmacists to comply with Regulation 5 of S.I. 488 of 2008, *Management and Supervision of a Retail Pharmacy Business* |

Role of PSI Guidelines and how Standards are different

PSI Guidelines to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008

- Keeping of Records in Respect of Medicinal Products

- Counselling and Medicine Therapy Review

- Sourcing, Storage and Disposal of Medicinal Products

- Equipment

- Premises

- Patient Consultation Area
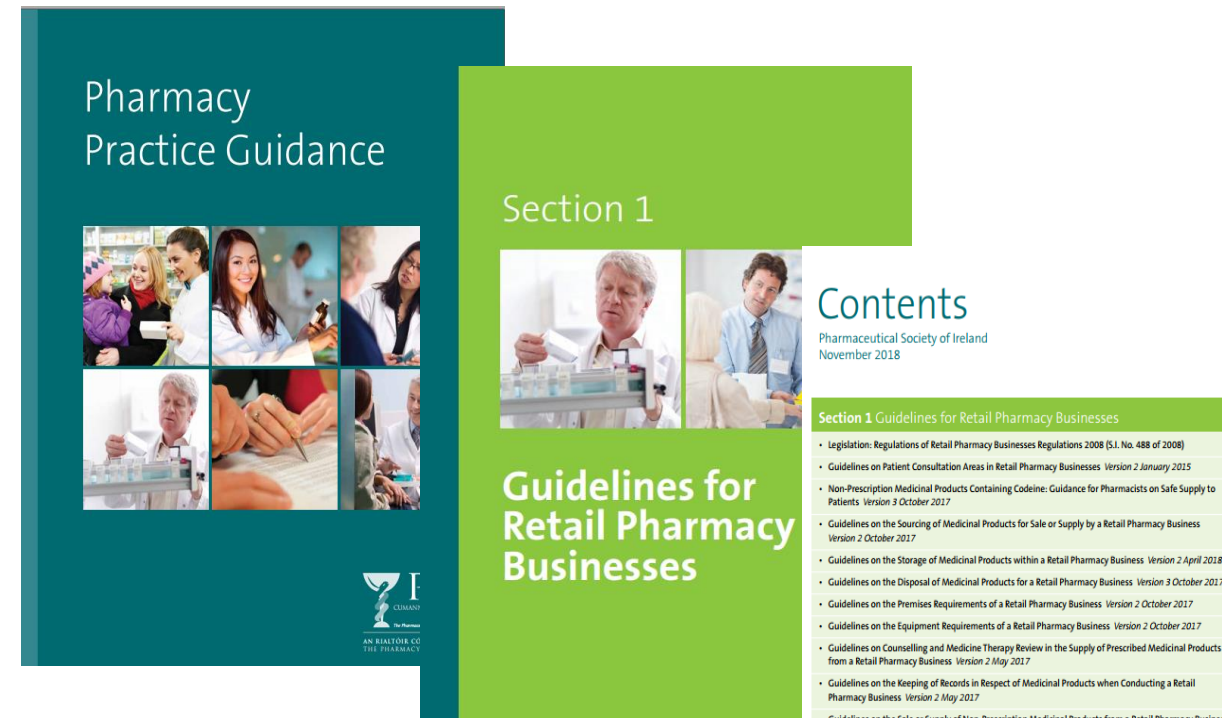
Where are we now in the Standards Development Process?

Standards - Process Summary and Timelines

SCOPING
Nov-Mar 2019

DEVELOPMENT
Mar-Sept 2019

APPROVAL
Sept 2019

Publication and Implementation

Literature
Review
+
Scoping
Consultation

Draft Standards,
Focus Groups
↓
Public
Consultation

Internal
+
Council
↓
Minister for
Health

Project Scoping Phase

- Literature Review
- Focus Groups
- Scoping Consultation Survey

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Presentation 2 – Literature Review

26 March 2019

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What literature was searched?

Pharmacy setting	Non pharmacy setting
• International Chapter 2	• International Chapter 3 • Ireland Chapter 4

Chapter 2: Pharmacy specific international standards, guidelines and guidance documents

Australia
- Pharmacy Board of Australia

Canada
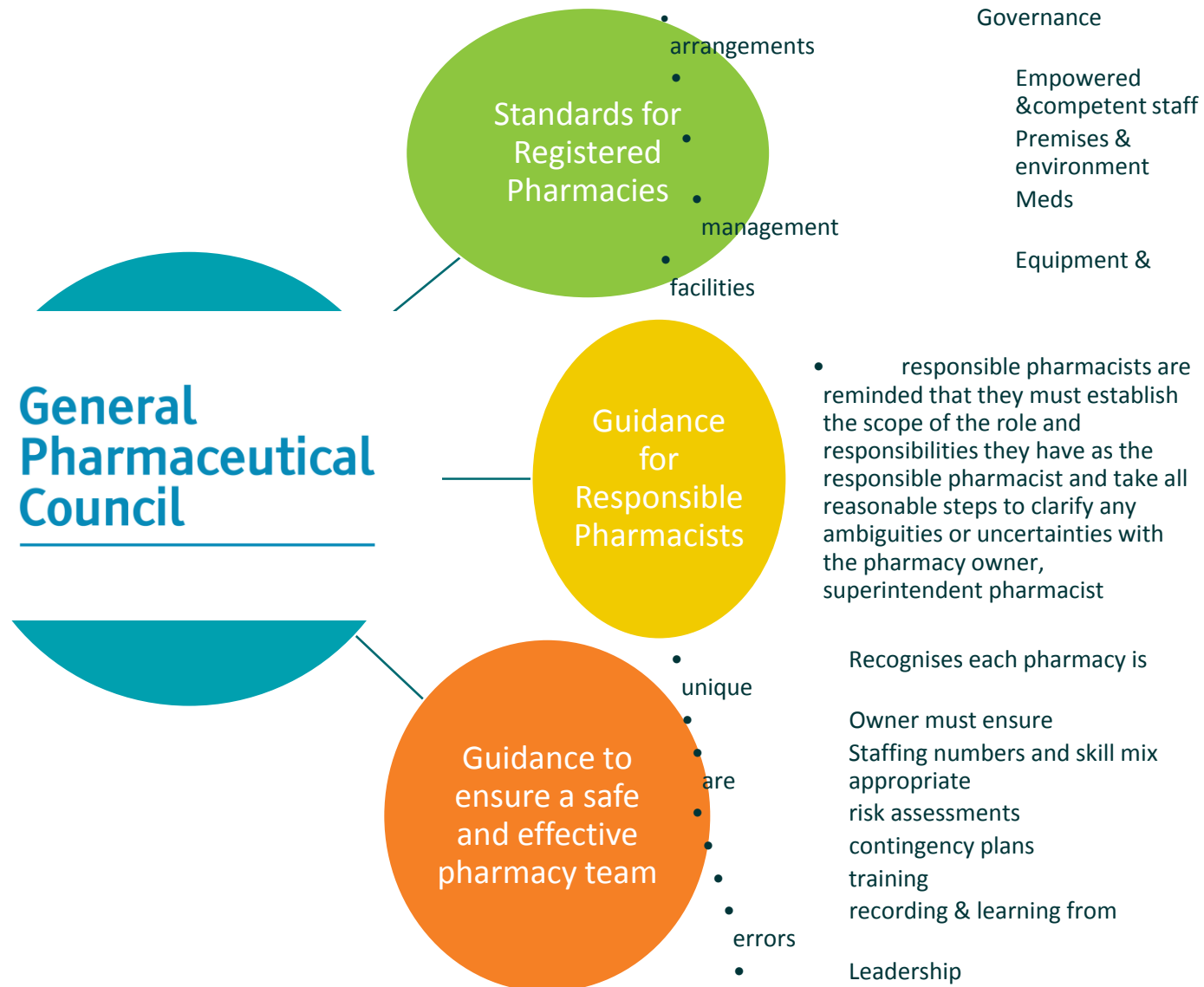- Ontario College of Pharmacists (OCP)

United Kingdom
- General Pharmaceutical Society (GPhC)
- Royal Pharmaceutical Society (RPS)
- Pharmaceutical Society of Northern Ireland (PSNI)

Australia and Canada

- Australia: *The Guidelines for Proprietor Pharmacists*
  - Professional responsibilities of proprietor pharmacists (PP)
  - PP must ensure
    - practice of pharmacy is conducted in accordance with laws, standards and guidance
    - Risk management procedures in place
    - Confidential data is secure
    - Suitable staff resourcing and staff training
    - SOPs up to date

- Canada: *Professional Supervision of Pharmacy Personnel Policy*
  - Defines responsibilities of 'designated manager' pharmacist (DM), appointed by pharmacy owner
    - Performance measurement and staff improvement systems
    - Staff – competence and adequate resourcing levels
    - Support employee pharmacists in collaborating with other HCPs

United Kingdom

General Pharmaceutical Council

Standards for Registered Pharmacies

- Governance
- Empowered &competent staff
- Premises & environment
- Meds management
- Equipment & facilities

Guidance for Responsible Pharmacists

- responsible pharmacists are reminded that they must establish the scope of the role and responsibilities they have as the responsible pharmacist and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacy owner, superintendent pharmacist

Guidance to ensure a safe and effective pharmacy team

- Recognises each pharmacy is unique
- Owner must ensure
- Staffing numbers and skill mix are appropriate
- risk assessments
- contingency plans
- training
- recording & learning from errors
- Leadership

Royal Pharmaceutical Society and Pharm. Society of Northern Ireland

- *RPS Standards for Hospital Pharmacy Services*
  - Leadership (strategic, meds management, operational, clinical management)
  - systems governance
  - financial management
  - workforce
- *PSNI Standards and Guidance on the Responsible Pharmacist Regulations*
  - three areas for responsible pharmacists:
    1. their legal obligations,
    2. Mandatory Professional Standards and
    3. their Good Practice Guidance

Establishing, maintaining and reviewing procedures in the pharmacy

Quality Framework

UK Research and Projects

- *Supervision in Community pharmacy final report to Pharmacy Research UK*
  - Aim?
    - investigate arrangements for supervision, role delegation and skill-mix in community pharmacy
    - Investigate potential future arrangements and perceived requirements for pharmacy team composition and role delegation with varying levels of supervision
    - Identification of clear roles and responsibility would ultimately allow a governance structure to enable pharmacists to provide more clinical and patient-centred services.

- *Rebalancing Medicines Legislation and Pharmacy Regulation Project*
  - Examined roles of superintendent pharmacists and responsible pharmacists
  - Why?
    - to provide clarity *re* scope and purpose of each role
    - Need to define relationship in place between pharmacy owners, responsible pharmacists and superintendent pharmacists and the associated accountability framework in place

Chapter 3: Summary of non- pharmacy specific international standards, guidelines and guidance documents

- Australia
  - *National Model Clinical Governance Framework*
    - development and implementation of governance systems, considering local needs, values and the context in which services are provided
    - strong and strategic leadership of clinical services
    - clear responsibilities for managing the safety and quality of care
    - Delegation, effective use of data/intelligence to monitor performance of h/care setting
    - Outlines the essential partnership between patients, clinicians, managers and governing board in implementing effective clinical governance systems
  - *Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service (NSQHS) Standards* (i.e. for hospitals)
    - Clinical governance
    - Safety and quality systems
    - Reliability/consistency of high quality care
    - HCPs are accountable to patients

UK

- *NHS Code of Governance*
  - Guidance on how to implement an effective governance structure
    - Accountability
    - Decision making
    - Risk management
    - Performance assurance
  - Leadership section:
    - Details functions of board of directors, chairperson, non-executive directors

Canada

- *Qmentum Programme Governance Standards*
  - Defined roles and responsibilities for those in management positions
  - Formal decision making process
  - Manage risks
  - Drive quality improvement
- *Raising the Bar for Healthcare Governance and Leadership in Canada*
  - Define and clarify role and remit of governing boards vs senior management
  - Culture of safety
  - Decisions based on research, evidence and ongoing quality improvement

Chapter 4 - Summary of non- pharmacy specific Irish standards, guidelines and guidance documents

- holistic view of best practice in the area of good governance and accountability

Mental Health Commission	TUSLA
Government departments	HIQA

Governance and Accountability
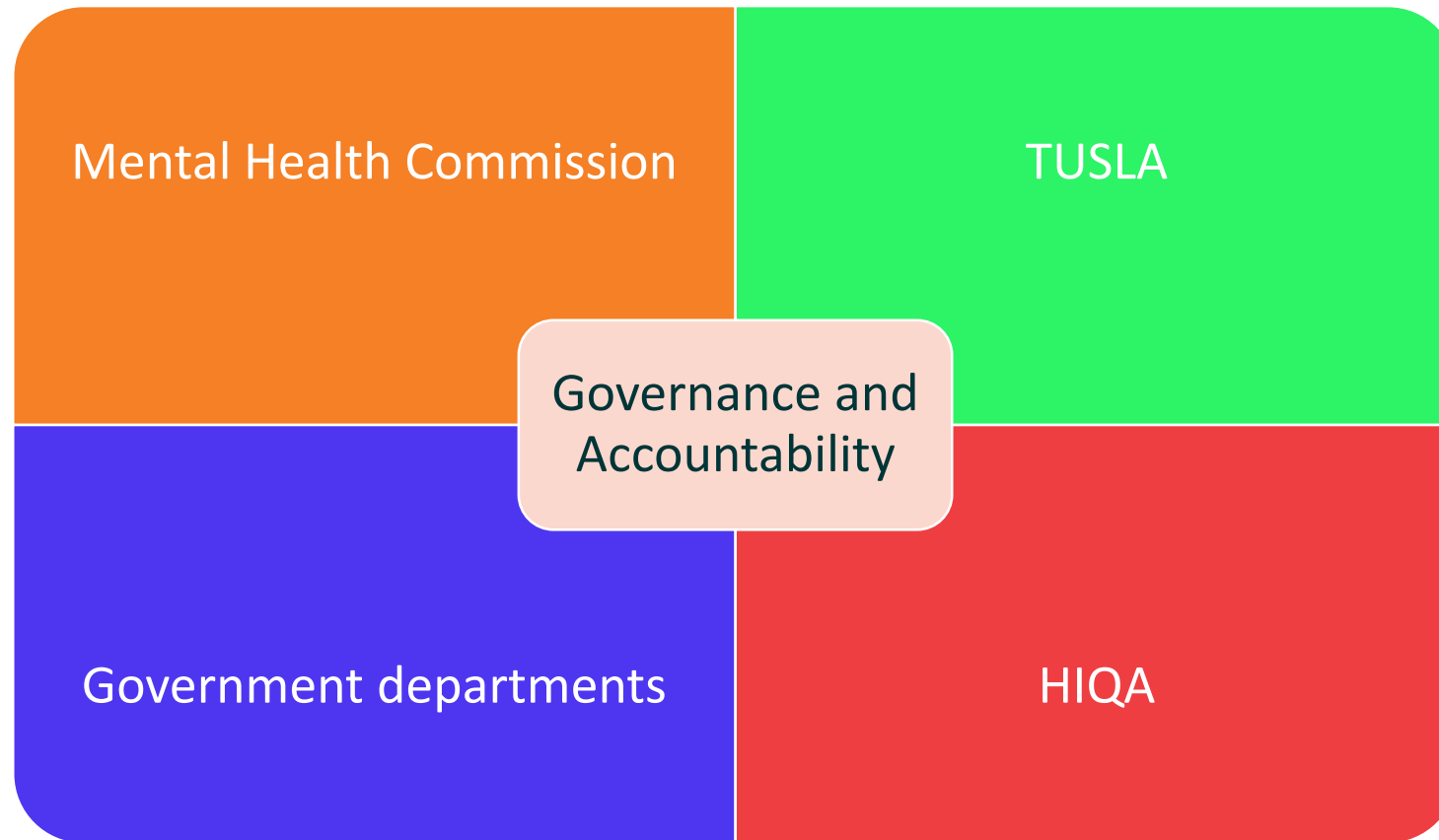
DPER's Corporate Governance Standard for the Civil Service

- Adaptable
- Develop capabilities of leadership, management and staff
- Implement good practices in transparency, reporting, communications, audit & scrutiny
- Maintain high standard of behaviour amongst staff

TUSLA's Good Governance Framework

- Consistency of service provision
- Improve awareness of benefits of good governance
- Helps services comply with requirements & regulations

Mental Health Commission's Quality Framework

- Flexible framework for service providers
  - Accommodates diverse needs of service users & inherent differences in service providers
  - Allows service providers to continuously assess, measure & improve quality of their services

Main findings

standards to protect the health safety and well-being of people using pharmacy services

effective leadership, governance and management arrangements in place with clear lines of accountability

safe delegation of tasks to appropriately trained staff

encourage communication between all those in leadership positions in the pharmacy

clinical governance frameworks in pharmacies at a local level so that local needs, local values and the local context are considered

partnership between, patients, clinicians and pharmacists

culture of safety

decisions are based on research, evidence and ongoing quality improvement

formal and transparent arrangements are in place in pharmacies for reporting errors and managing risk

high standards of behaviour are demonstrated in pharmacies towards patients

transparency, reporting, communications, audit and scrutiny so that effective accountability is delivered.

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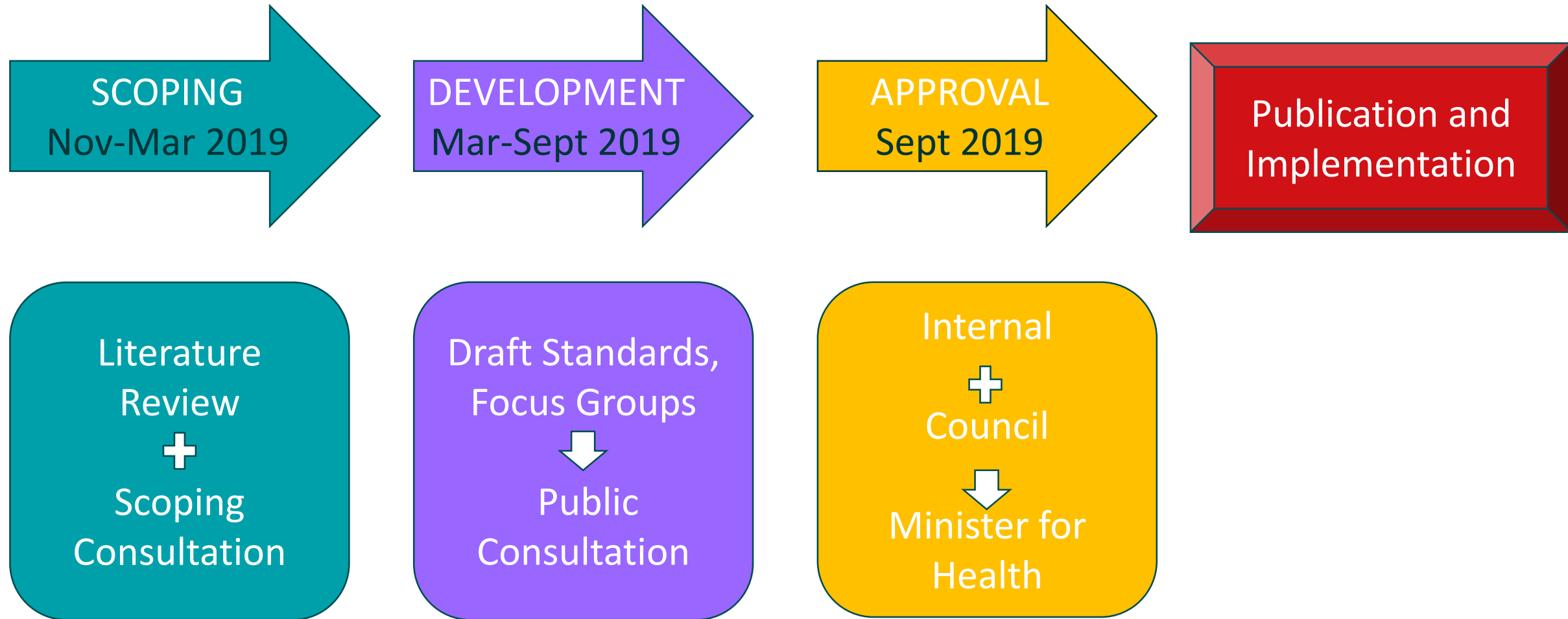## Presentation 3 – Scoping Consultation

26 March 2019

Standards - Process Summary and Timelines

SCOPING Nov-Mar 2019 →	DEVELOPMENT Mar-Sept 2019 →	APPROVAL Sept 2019 →	Publication and Implementation

| Literature Review + Scoping Consultation | Draft Standards, Focus Groups ↓ Public Consultation | Internal + Council ↓ Minister for Health | |

Scoping Consultation Process

- Patient Engagement – National Patient Forum

- Pharmacist Focus Group

- Online Consultation Survey for Pharmacists

- Online Consultation survey for Other Stakeholders

Patient Engagement – National Patient Forum

- HSE Quality Improvement Division collaboration
- Broad range of advocacy Groups
- Patient Engagements Panel
- Focus Group considered
- Opportunity to present at the National Patient Forum
- Meeting 21 February
- PSI invited to present on the Standards
 project

Discussion Structure

- Opening presentation outlining;
  - What the public can expect from pharmacists and pharmacy services (PSI Patient Charter)
  - Role of the PSI
  - Standards development process.

- This led into a number of Prompt Questions to stimulate discussion;
  - What do 'good' pharmacy services look like
  - What do 'bad' pharmacy services look like

Summary of Patient Feedback

- Importance of Compassion and Understanding
- Consistency of Care/Service (Staffing consistency)
- Maintaining Confidentiality and Privacy
- Importance of Medication Reviews (transitions of care/ongoing care)
- Using Plain English and Adult Literacy awareness and training
- Better use of resources, including staffing resources
- Suggestion around an 'advertising campaign' on the role of the pharmacist
- Roles/Responsibilities of pharmacists in other settings (hospitals)

Pharmacist Focus Group

- Focus group with pharmacists from a number of different backgrounds and roles.

- Insight from independent pharmacies and chains,

- Insight from those in superintendent, supervising and employee roles

- Short introductory presentation to give context on the project
  - o PSI Corporate Strategy
  - o Governance and Accountability Standards development process

- Open discussion section structured using four prompts;
  - o Top priorities in providing good quality pharmacy services
  - o Obstacles to providing good quality pharmacy services
  - o How do you ensure consistency of care?
  - o What areas should the standards address?

Summary Pharmacist Focus Group Feedback

- Staffing
  - Appropriate staffing levels (pharmacist and support)
  - Training and Education (including appropriate upskilling)
  - High level of competence
  - Delegation
  - Insufficient staffing resources (Lack of work breaks and long working hours), negative impact)

- Communication
  - Patients/carers and the public
  - Other pharmacists
  - Support Staff
  - Handover structures and supports
  - High Standard of Patient Counselling

- Quality Assurance

- Being Open and Transparent

- Lack of integrated care

- Insufficient use of IT (e.g. electronic prescribing)

Summary Pharmacist Focus Group Feedback

Results and Outcome areas identified;
- ✓ Improved Focus on Patients
- ✓ Enhanced Patient Safety
- ✓ Consistency of Care
- ✓ Improved Quality of service
- ✓ Increased Professionalism
- ✓ Good Clinical Governance

- Topics discussed outside the scope of the standards, including administrative burden.

Consultation survey - Pharmacists

- First time PSI used a scoping survey of this kind

- Responses received;
  - 304 respondents accessed the online survey
  - One email response was received.
  - Between 22 and 36 respondents went on to complete each of the eight questions

- Some Themes from pharmacist focus group echoed in survey responses

- Other issues raised

- Some comments outside project scope

Consultation survey – Pharmacists; Results

Staffing

- o Staffing levels (work breaks and wellbeing)
- o Education and Training (minimum standards) and appropriate skill mix
- o Effective delegation
- o Managerial training
- o Enabler for Consistent care

Governance

- o Clear Patient Focus
- o Clarity on Roles and Accountability
- o Leadership
- o Support of professional role and judgement (Commercial tension)
- o Appropriate availability of Supervising and Superintendent Pharmacist
- o SOPs and Self Audits
- o Culture which enables and supports change/review

Consultation survey – Pharmacists; Results (2)

Communication
- o Staff and Patients
- o Collaboration with other HCPs
- o Standardised structures
- o Inadequate use of IT (Barrier to quality)

Quality Assurance
- o Formal/Informal
- o Risk assessment
- o Analysis of Complaints processes
- o Incident/near miss logs (no blame culture)
- o Patient feedback
- o Peer evaluation

Administrative, regulatory and financial burdens

Consultation Survey- Other Stakeholders

- First time PSI used a scoping survey of this kind

- Separate online survey sent to a broad range of other stakeholders

(including other regulators, relevant state bodies and patient/advocacy groups)

- Comments on developing Governance and Accountability Standards for RPBs and examples of good pharmacy and healthcare practices.

- Consultation was highlighted on various social media accour

- Responses received;
    - o 24 other stakeholders accessed the online survey
    - o Between 7 and 9 respondents went on
      to complete the preceding five
      questions.

Consultation survey – Stakeholders; Results

Governance

- o Management and Leadership
- o SOPs
- o Accountability
- o Privacy and Confidentiality
- o Compliance with legislation and Guidelines
- o Clinical Governance
- o Clear separation of Commercial vs Professional service
- o Risk management

Consultation survey – Stakeholders; Results (2)

Staff
- o   Well trained and Sufficient staff numbers
- o   Approachable and engaging
- o   Appropriate Referral
- o   Communication Skills
- o   Professionalism

Quality assurance
- o   Consistency
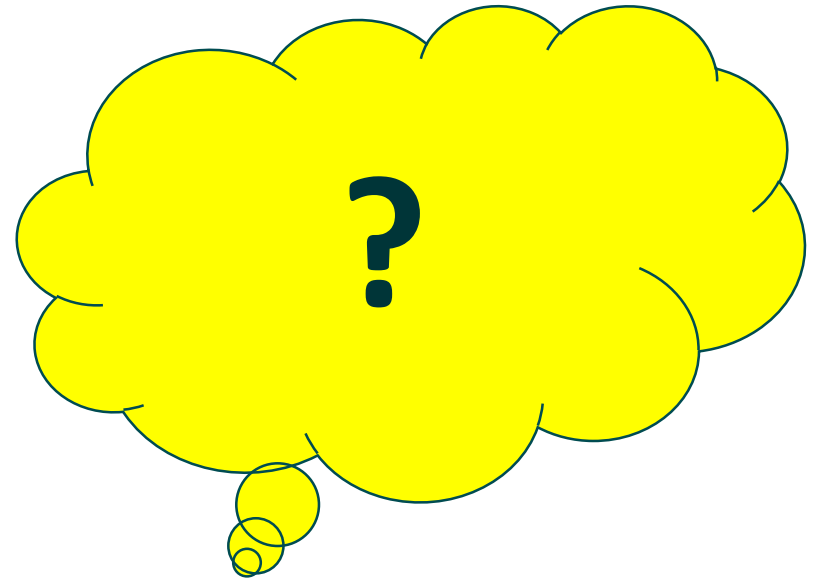- o   Patient feedback
- o   Audit

Other
- o   Evidence based goods and services
- o   Premises and Equipment
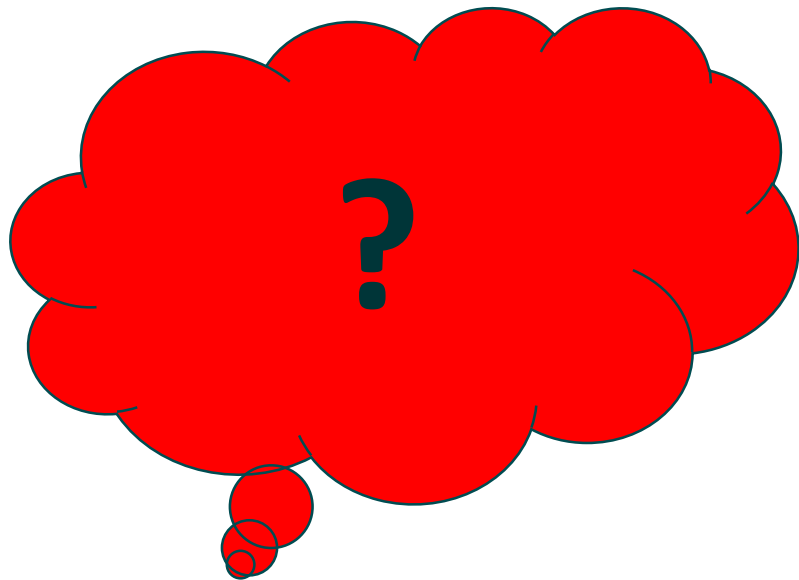- o   Agility of pharmacy services

Any questions?

Group Discussion

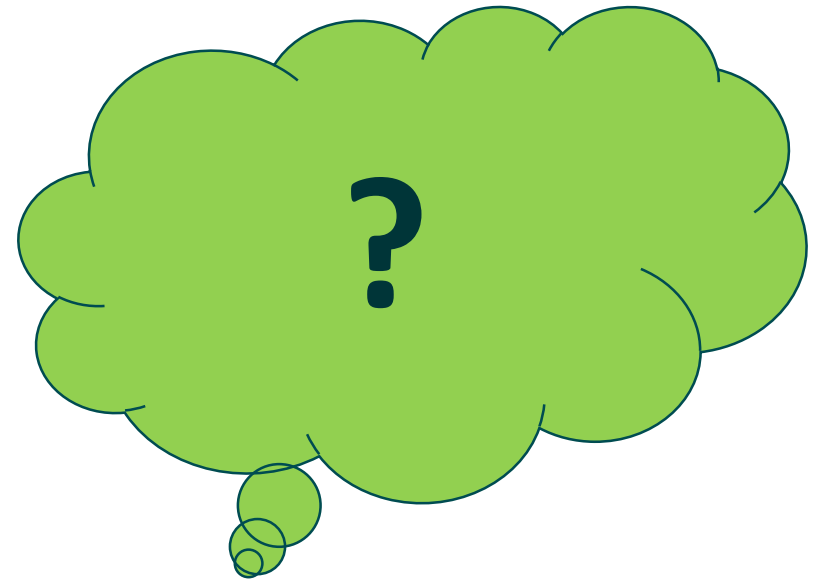# Scoping Consultation – Identify Key themes Emerging?

?

What is inside the scope, and outside the scope, of the standards?

?

What areas should the standards address?

Emerging Themes from Scoping Consultation

Thoughts-

- ➢ Staffing
- ➢ Accountability
- ➢ Communication
- ➢ Governance
- ➢ Quality Assurance
- ➢ Consistency
- ➢ Privacy and Confidentiality

Next Meeting Date

- Date Change

- Tuesday 4th June 11am

Thank You!

Further feedback welcome