

Seminars for Superintendent Pharmacists

Governing for Safety in Pharmacy

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Spring 2018

Welcome & Seminar Overview

- Welcome to everyone
- We very much appreciate people taking the time to attend
- Overview of tonight's Seminar:
 - Part 1: PSI Corporate Strategy 2018 -2020
 - Part 2: Interactive Workshop on Governance & Accountability in Pharmacy
- Questions/comments and aiming to finish by 9.30pm

Part 1: PSI Corporate Strategy 2018 -2020

- Quick overview:
 - Some quotations from the Strategy
 - Updated Vision, Mission & Values
 - One overarching strategic goal
 - Four Strategic Results Areas
 - The outcomes we will achieve by 2021
 - Three thoughts to leave you with
 - Handover to my colleagues



Some quotations....

“...a strongly collaborative approach...create new opportunities and develop new relationships with PSI registrants...”

“...make sure that our regulatory approaches...impact on health outcomes and patient safety,... minimising unnecessary compliance costs...”

“...examining our own internal processes...engaging independent assessors to provide objective evidence that we are...delivering value-for-money.”

“...we will enhance public trust in pharmacy...ensuring that our regulatory approaches protect the public...encourage ongoing quality development within pharmacy practice in Ireland.”

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.

One overarching strategic goal

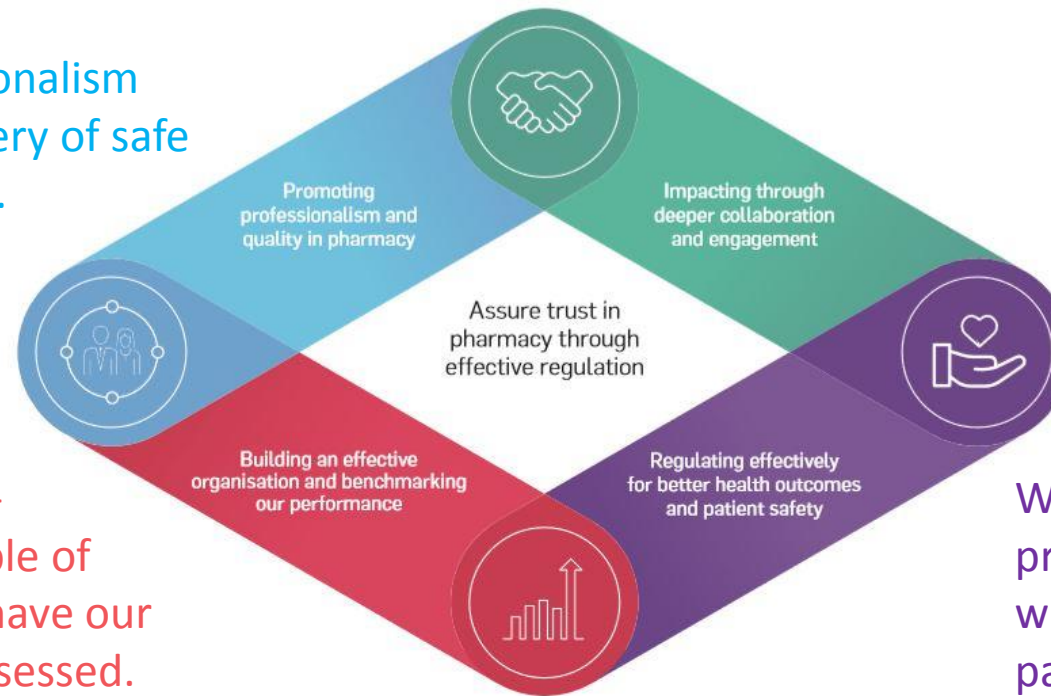


- **One central strategic goal.**
- Makes a clear commitment for the coming three years.
- The key measure against which we will assess how we perform.
- The measure against which the public and our stakeholders can hold us accountable.

Four Strategic Results Areas

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

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



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 .

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.
- By 2021, PSI will be more developed, more effective and more capable.
- We will demonstrate that our work has impacted positively on assuring trust in pharmacists, in pharmacy services and has resulted in better health outcomes for the public.



Our Objectives and Outcomes for 2018-2020

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.

We regulate the professional practice of approximately 6,000 pharmacists and the operation of over 1,900 pharmacies. We also register 360 pharmaceutical assistants.

Key Outcomes for 2021

How will we know we have succeeded?

Four examples of key outcomes for 2021



Promoting professionalism and quality in pharmacy

- Pharmacies are demonstrating good governance and are delivering care and services that are reliable, safe and effective.



Impacting through collaboration and engagement

- Effective partnerships are in place with our stakeholders, including patient representatives and the pharmacy sector, and are resulting in more informed pharmacy practice policy development and regulation.



Regulating effectively for better health outcomes and patient safety

- Our regulatory model is recognised as being effective, proportionate, streamlined and one which assesses key outcome areas which underpin trust in pharmacy.



Building an effective organisation and benchmarking our performance

- Our internal processes, performance and delivery of results have been assessed independently against external standards and accreditation has been achieved.

Three thoughts to leave you with this evening

1. Positive collaboration between Superintendent Pharmacists and the regulator is essential to both parties and is no threat to the position or role of either party
2. There are many areas of mutual concern which bring PSI and Superintendent Pharmacists together rather than separating us – delivering quality healthcare, promoting professionalism, ensuring trust in pharmacy, championing high standards, keeping people safe.
3. This Strategy gives PSI and Superintendent Pharmacists an opportunity and a rationale to create a new dynamic based on mutual engagement and trust

Part 2: Workshop Session

Part 2: What might an Accountability & Governance Framework look like?

- This is one of our strategic actions
- Provides an opportunity to explore possible use of Standards in Pharmacy regulation
- Standards are much-used in health and social care regulation
- Standards create a vision as to what health services can be like for patients/users
- Standards are more enabling for providers than are regulations
- Standards can be successfully co-created by regulators and those being regulated

Strategic Results Area 2 - Action 7

Reviewing 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.

Producing Standards is about asking two key questions about the healthcare service:

1. What does “good” look like?
2. How would I know this is a “good” service?

These are straightforward questions but answering them is not necessarily simple.

Promotion of Best Practice Standards and the Improvement of Pharmacy Practice

- Develop Pharmacy Guidelines and Guidance
- Learning from Fitness to Practise Inquiries
- Practice Updates in our newsletter
- Future Pharmacy Practice Report
- Collaboration with others - Joint Guidance with Medical Council on Safe Prescribing and Dispensing of Controlled Drugs

Guidelines on the Keeping of Records in Respect of Medicinal Products when Conducting a Retail Pharmacy Business

to facilitate compliance with R₁ Pharmacy Businesses Regulatory
Pharmaceutical Society of Ireland

Version 2 May 2017

Updates made following the enactment
(which replaced the Misuse of Drugs Reg

Contents

1. Introduction
2. Legislative Basis
3. Guidance
3.1 Records Related to Supply of a Prescription
3.1.1 Supply of a Prescription-Only
3.1.2 Supply of a Prescription-Only
3.1.3 Retention of Prescriptions
3.1.4 Emergency Supply of a Prescription
3.2 Records for Supply to a Person for A and other Circumstances
3.3 Requirements for the Register/Dial
3.4 Records Relating to Supply and Administration of Vaccines and
3.5 Patient Medication Record
3.6 Controlled Drugs
3.6.1 Records for Receipt and Supply
3.6.2 Retention of Other Controlled
3.7 Supply of Exempt Medicinal Product
3.8 Other Important Records to be Kept
3.9 Ensuring Accuracy of Pharmacy Records
3.10 Access to Records

Guidance on the Provision of Testing Services in Pharmacies

Pharmaceutical Society of Ireland

Version 1 February 2014

Contents

1. Introduction
2. Regulatory Requirements
3. Implementation of Testing Services Within a Retail Pharmacy Business
3.1 Clinical Governance
3.1.1 Professional Management
3.1.2 Policies and Procedures
3.1.3 Clinical Appropriateness
3.1.4 Patient Consultations
3.1.5 Information and Consent
3.1.6 Interpretation of Results, Follow up and Referral
3.1.7 Recordkeeping
3.2 Pharmacy Staff
3.2.1 Training, Competence and Continuing Professional Development
3.3 Pharmacy Facilities and Equipment
3.3.1 Testing Service Delivery Area
3.3.2 Equipment and Consumables
3.3.3 Incident Management
3.3.4 Waste Management
3.3.5 Health and Safety
3.4 Quality Assurance
3.4.1 Internal Quality Control
3.4.2 External Quality Assurance
3.5 Public Information and Awareness
3.6 Samples for Analysis outside the Retail Pharmacy Business
3.7 Tests Carried Out by Pharmacists outside a Retail Pharmacy Business
3.8 Tests Carried Out by an Independent Practitioner
4. Home Use Tests Sold or Supplied in a Retail Pharmacy Business
5. Self-assessment Checklist



Comhairle na nDochtúirí Leighis
Medical Council



Safe Prescribing and Dispensing of Controlled Drugs

Joint Guidance
Medical Council and Pharmaceutical Society of Ireland



Some of our current projects

Revised Code of Conduct

Guidelines on the Sale or Supply of Non-Prescription Medicines from a Retail Pharmacy Business - Reg 10

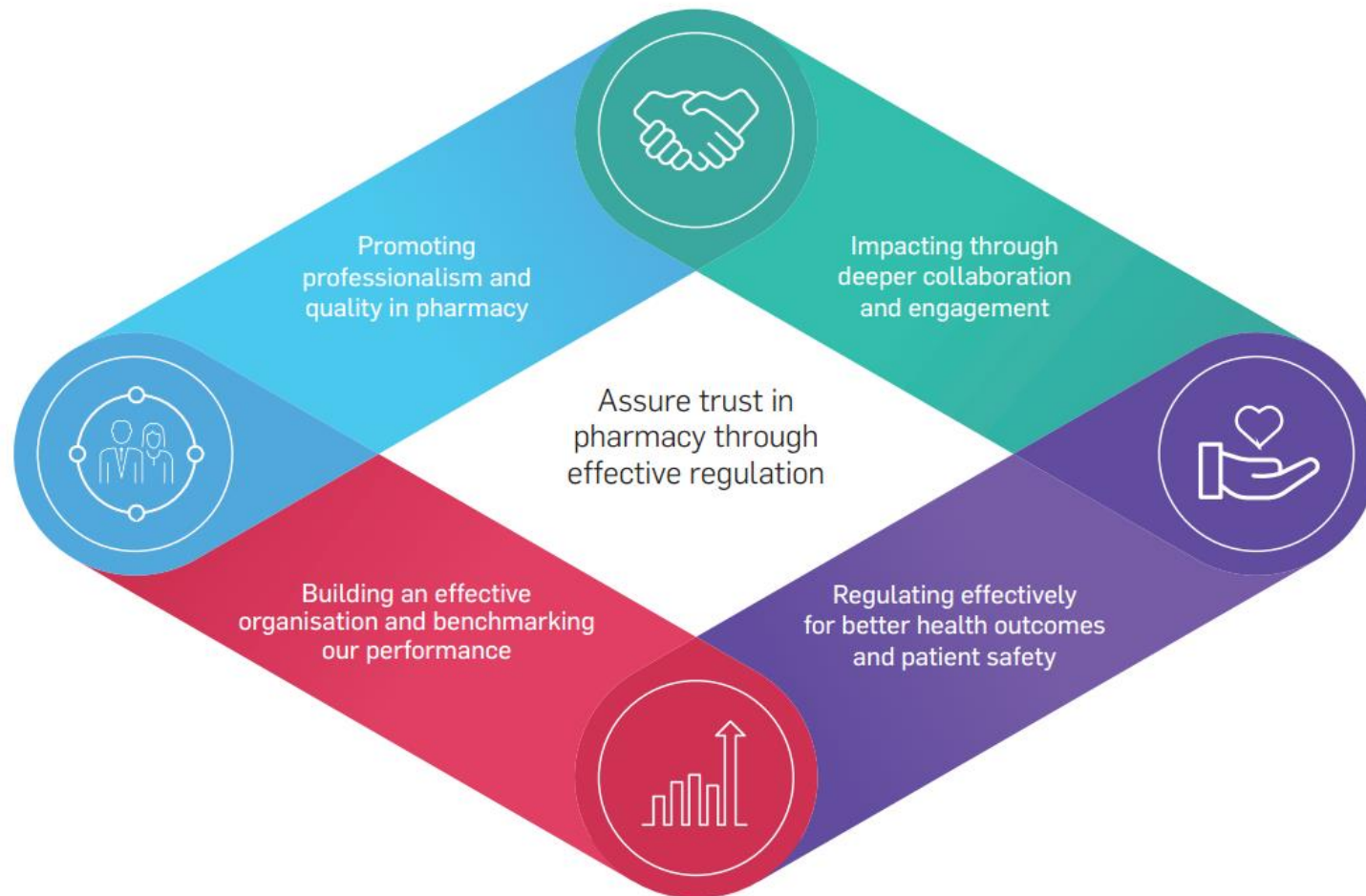
Guidelines on the Storage of Medicinal Products
- Reg 5(1)(ea)

Updating Methadone Guidance

Sodium Valproate Guidance

Standards for Governing and Management in
Community Pharmacy

PPD role in the Corporate Strategy



Safer practice and quality services

We will assure the safe practice of pharmacists and the quality of pharmacy services, while enabling future developments in pharmacy.

Superintendent Pharmacist

Pharmacy Owner

Safe and effective
care for the public

Supervising Pharmacist

Pharmacist

Why is governance important?

By having effective governance in place in pharmacies, superintendents can assure safe practice of pharmacists and the quality of the pharmacy services provided to the public.

We asked 1,000 members of the public...

MOST IMPORTANT TO THE PUBLIC: SURVEY



Draft Standards for a Governance and Accountability Framework



Example of a Draft Standard

Quality Assurance



Retail pharmacy businesses have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of pharmacy services

Features of quality assurance include:

- Retail pharmacy businesses must have **appropriate risk assessment systems** in place to **identify, prevent or minimise** unnecessary or **potential harm** associated with the provision of care, support and services to patients. They should actively promote and demonstrate a clear **commitment to promote and strengthen a culture of quality and safety**.
- **Systematic monitoring arrangements** and clear documented policies must be in place in pharmacies to manage risk which should include **continuous review and recording of incidents** such as medication errors and near misses.
- **Analysis and review** of such quality assurance systems will **help identify learning needs**, the consequent re-training of staff, and contribute to the continuous review of the policies and procedures in place in the pharmacy.
- To enable quality assurance systems to be truly effective, superintendent pharmacist should foster a **non-blame culture** and encourage transparency within the pharmacy.
- A robust **complaints system** should be in place in every pharmacy in the interest of patients and the public.

Structure of Group Work

- Each group is assigned a standard
- Explore as a group what you believe this standard should encompass
- Examine what best practice should look like for each standard
- Discuss how a pharmacy can demonstrate that it is operating to a good standard
- Feedback to group

Draft Standard - Accountability

Accountability is the acknowledgement and assumption of a set of responsibilities.

Pharmacies should have clear **accountability frameworks** in place to ensure the delivery of **high quality, safe, reliable professional pharmacy services**.



Draft Standard – Governance and Management

Having formalised governance and effective management arrangements in pharmacies is a key element in **improving efficiency** and **accountability** as well as enhancing **openness** and **transparency**.

Good governance and management serves to **support** and **promote** the delivery of **safe, reliable** and **high quality** services to the public.



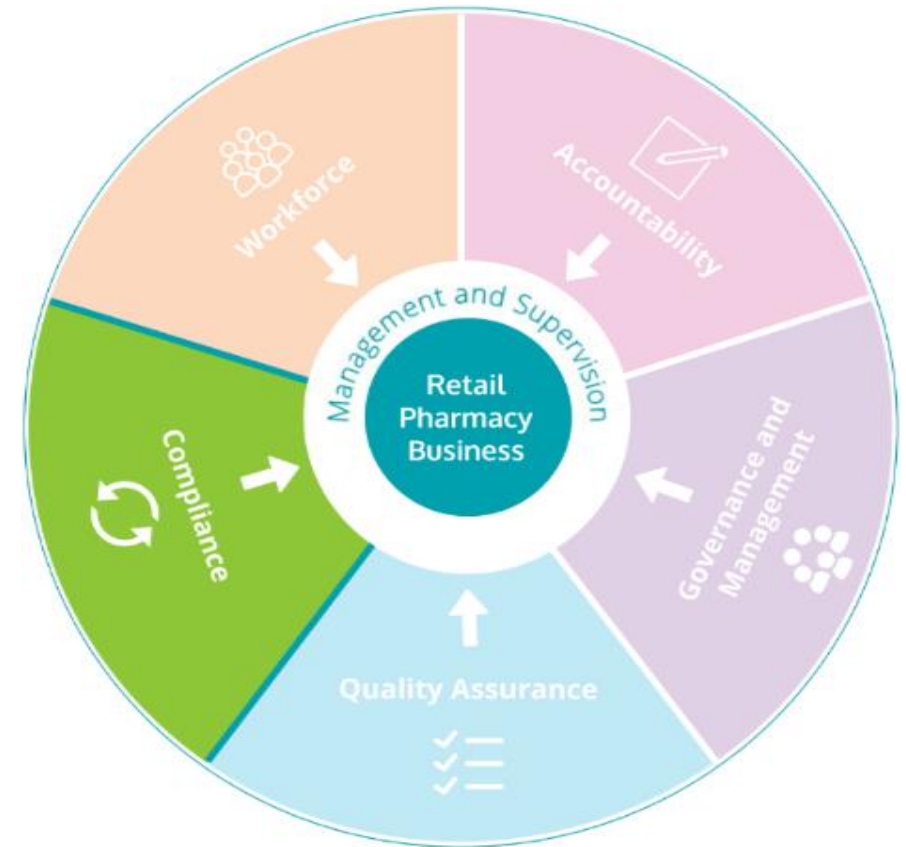
Draft Standard – Quality Assurance

Pharmacies should have **systematic monitoring arrangements** in place to **identify** and **act on** opportunities to **continually improve** the **quality, safety** and **reliability** of pharmacy services.



Draft Standard – Compliance

Pharmacies should be **compliant** with relevant **legislation** and take into account **recommendations** and **guidance** as formally issued by relevant regulatory bodies, government agencies etc., as they apply to them.



Draft Standard – Workforce

Recruiting, planning, organising, managing and supporting the workforce to ensure that colleagues are enabled to exercise their **personal and professional responsibilities** and that they have the required **competencies** to deliver **high quality, safe and reliable** pharmacy services.



Topics for discussion

Are you happy with the definition provided for your standard – is it clear?

How is best practice exhibited for this standard?

What would bad practice look like for this standard?

What does excellence look like for this standard?

What further initiatives can I take to achieve this standard?

What does good practice look like?

Feedback from Group 1



Feedback from Group 2



Feedback from Group 3



Feedback from Group 4



Feedback from Group 5



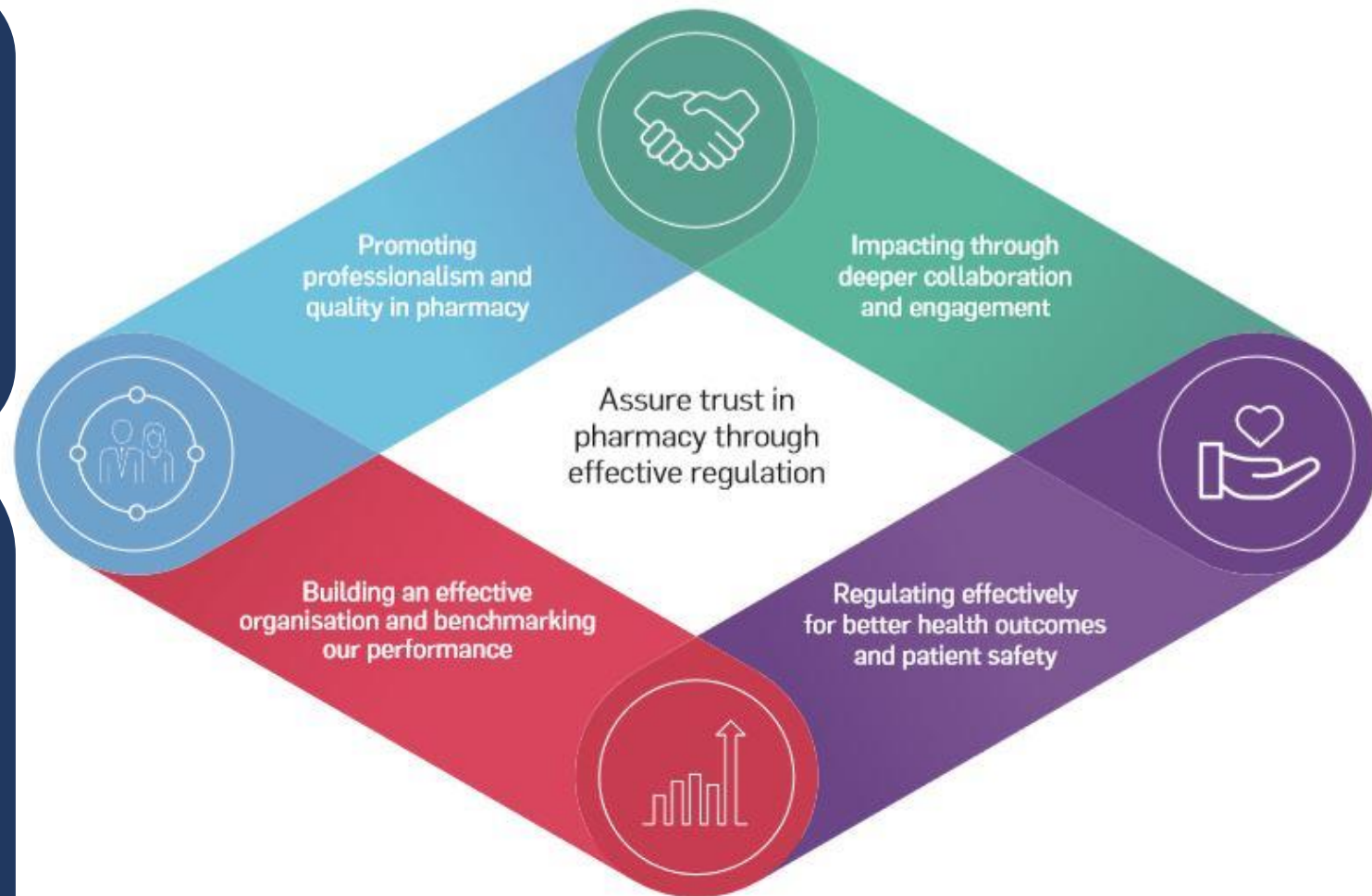
This Corporate Strategy consists of five key elements:

One central organisational goal

Assure trust in pharmacy through effective regulation – this is our commitment over the coming three years. It is the key measure against which we will assess how we perform during this period, and against which the public and our stakeholders can hold us accountable.

Four strategic results areas

The Strategy has four distinct strategic areas under which we will deliver specific results and, when taken together, will see us make significant progress towards our central goal. Our intention, as an organisation, is that by the time we are entering 2021, PSI will be more developed, more effective, more capable and will be able to demonstrate that its work has impacted positively on assuring trust in pharmacists, in pharmacy services and has resulted in better health outcomes for the public.



Thank You

ASSURING PUBLIC TRUST
IN PHARMACY THROUGH
EFFECTIVE REGULATION

Corporate Strategy **2018-2020**

Corporate Strategy **2018-2020**

PSI website: www.psi.ie

Email: info@psi.ie