The Pharmacy Regulator
An Rialtóir Cógaisíochta

PSI position paper on the need for reform of the Pharmacy Act 2007

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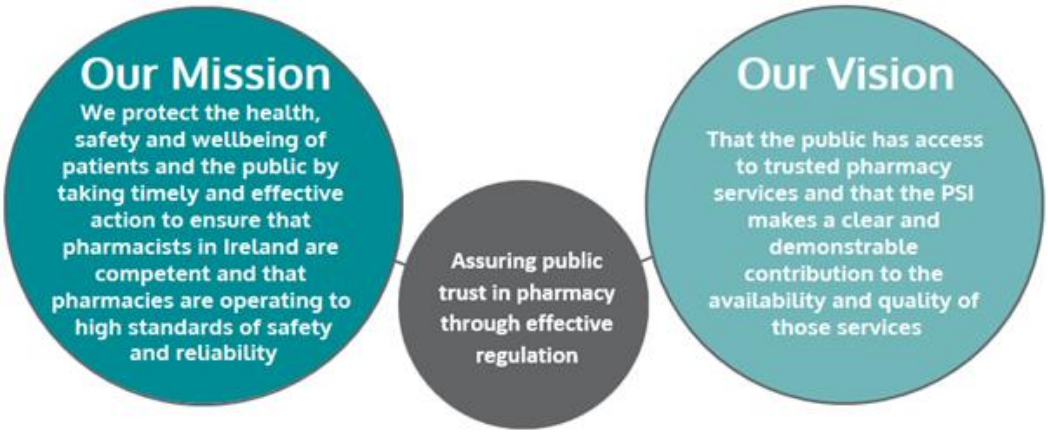
About PSI – the pharmacy regulator

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. The PSI regulates approximately 7,000 pharmacists and over 1,900 pharmacies.



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PSI – the Pharmacy regulator

PSI House, Fenian Street,
Dublin 2, D02 TD72

T +353 1 2184000
F +353 1 2837678
E info@psi.ie
W www.psi.ie

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Acronyms and abbreviations

ACP	Alberta College of Pharmacy
CHRE	Council for Healthcare Regulatory Excellence
CIPFA	Chartered Institute of Public Finance and Accountancy
CPD	Continuing Professional Development
CSO	Central Statistics Office
DOH	Department of Health
DPER	Department of Public Expenditure and Reform
FTP	Fitness to Practise
GMC	General Medical Council
GPhC	General Pharmaceutical Council
HIQA	Health Information and Quality Authority
HPAI	Hospital Pharmacists Association of Ireland
HPRA	Health Products Regulatory Authority
HSCRF	Health and Social Care Regulatory Forum
HSE	Health Service Executive
IIOP	Irish Institute of Pharmacy
IOM	Institute of Medicine
IPU	Irish Pharmacy Union
NESC	National Economic and Social Council
NHS	National Health Service
NMBI	Nursing and Midwifery Board of Ireland
OCP	Ontario College of Pharmacists
OECD	Organisation for Economic Co-Operation and Development
PCC	Professional Conduct Committee
PCRS	Primary Care Reimbursement Service
PESTLE	Political Economic Socio-Demographic Technological Legal Environmental
PPC	Preliminary Proceedings Committee

PSA	Professional Standards Authority
PSI	Pharmaceutical Society of Ireland
PSNI	Pharmaceutical Society of Northern Ireland
QP	Qualified Person
RCSI	Royal College of Surgeons in Ireland
RPB	Retail Pharmacy Business
SWOT	Strengths Weaknesses Opportunities Threats
UK	United Kingdom
WHO	World Health Organisation

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Structure of the paper

Section 1 provides an executive summary of the paper.

Section 2 introduces the purpose of the paper and the approach taken in carrying out an analysis of the Pharmacy Act 2007, including research on regulatory principles and practices.

Section 3 describes some key findings from our desk-based research.

Section 4 sets out the challenges and weaknesses in the Act, which we have identified. These fall under three main areas: the regulation of pharmacies, the regulation of pharmacy professionals, the governance structure and the role of Council.

Finally, sections 5 and 6 set out our conclusion and proposed next steps.

1. Executive Summary

Introduction

Since 2018, the PSI has been engaging with the Department of Health on advancing reform of the Pharmacy Act 2007 (the Act). The PSI has committed to developing a position paper on the need for reform to inform our discussions with the Department of Health on this important matter.

This paper sets out the PSI's position on the need for reform of the Act and the reasons why significant legislative reform is needed. We have carried out significant problem identification and analysis in order to identify the challenges and weaknesses of the Act.

As well as outlining the Act's key challenges and weaknesses, throughout this paper we provide some examples of regulatory tools and practices used by other regulators. The examples provided are not intended to propose a new definitive model of regulation for PSI but rather to illustrate potential alternative regulatory approaches.

We envisage that the next stages in advancing the reform of the Act would require the PSI to commission in-depth evidence reviews/expert reviews to inform the development of evidence-based policy proposals for reform of the Act.

It is essential that the legislation which underpins the regulation of pharmacies and pharmacy professionals in Ireland can support effective regulation now and into the future and ensure the safety of patients and the public.

The PSI is calling for fundamental reform of the Act to ensure the legislation is fit for purpose in regulating the wide range of services that are now being delivered to patients in pharmacies. Our fitness to practise system for pharmacy professionals is overly complex and lengthy and poses inherent risks to patients. The Act also presents a number of challenges for the PSI Council in carrying out its functions.

Approach

In developing this position paper, a wide range of desk-based research was carried out, including:

- a review of regulatory principles and practices,
- a national and international comparison of other regulators,
- significant analysis to capture PSI's experience of the Act.

Key research themes

As part of developing this paper, we undertook significant desk-based research on regulatory principles and practices and a review of the range of regulatory practices and tools employed across other national and international regulators. From this research, we identified four key themes which informed our analysis of the Act:

1. Regulatory systems must be reviewed to be effective and continue to meet their policy objectives. Regulators have a responsibility to be good regulatory stewards of their regulatory systems and ensure their legislation is fit for purpose.
2. Regulatory frameworks should be patient-centred and must keep pace with healthcare quality and patient safety recommendations, and pharmacy practice developments.
3. Learning from past regulatory failures is essential to mitigate the occurrence of similar failures in future.
4. International regulatory practice has evidenced the benefits of moving towards more proactive, risk-based regulation.

Challenges and weaknesses of the Act

To identify the challenges and weaknesses of the Act, we carried out a SWOT-PESTLE analysis to capture PSI's experience of the Act, both across the teams delivering the statutory functions of the PSI and with PSI Council, as well as with a number of key pharmacy stakeholders.

The most significant weaknesses that we have identified in the Act fall under three main areas:

- regulation of pharmacies
- regulation of pharmacy professionals
- governance structures and the role of PSI Council.

Regulation of Pharmacies

There is an urgent need for fundamental reform of how pharmacy services are regulated in Ireland. The Act presents significant weaknesses which limit our effectiveness in ensuring that patients receive safe, high-quality pharmacy services and limit our ability to hold pharmacies to account.

- The current Act and its regulations focus predominately on the safe management of medicines when **they should be centred on the patient and the safety and quality of the services patients receive, including the safe management of medicines**. This focus on medicines reflected pharmacy practice at the time the Act was drafted but has not kept pace with the expansion and diversification of pharmacy services, for example, vaccinations, screening services and the provision of emergency contraception. A reformed framework based around revised, broader regulations and supported by outcomes-focused healthcare regulatory standards would enable PSI to monitor broader aspects of the provision of pharmacy services.
- The Act provides the PSI with a number of enforcement powers. These, however, are limited and require the PSI to use the same fitness to practise system for pharmacies which is intended to regulate the competence and conduct of individual pharmacists. While it is typically an onerous and resource-intensive process, **findings have been made against a pharmacy only twice in the past ten years through the fitness to practise system.** It is essential for effective regulation of pharmacies that PSI can take a range of flexible enforcement actions proportionate to the risk posed to patient safety and the public.
- We believe that the governance and accountability of pharmacies need to be strengthened under a reformed Act. Firstly, there is **overlapping accountability and responsibilities across**

governance roles in the Act. In addition, the only criteria a governance pharmacist must meet under the Act is a minimum time-based level of experience. Our current legislation does not require the same level of checks and balances for an individual to take on a governance role in a pharmacy as those required by other regulators for similar governance roles.

- Currently, there is **no mandatory national system to report errors or incidents which occur in pharmacies**. This significant deficit presents patient safety risks. Moreover, the Act and the regulations place very limited statutory obligations on pharmacies to provide solicited information (information a service provider is required to provide under statutory obligations) to the PSI.

Regulation of Pharmacy professionals

From our experience operating the fitness to practise system for pharmacy professionals, as prescribed in the Act, we believe it requires substantial review and reform.

From the initial stage when a complaint is made to the end of the sanctioning process (where appropriate), the fitness to practise system can take up to 2-3 years. It is a long, inflexible process with duplication of decision-making and unnecessary complexity across a number of areas:

  - The **interim suspension process**, where PSI is concerned that a pharmacist or pharmacy presents an immediate safety risk to the public is **unsuitable when responding to urgent risks to patient safety**.
  - The Act provides a **limited set of tools to triage or investigate complaints** at the screening stage of the process. The effect of this is that the bulk of the investigation and decision-making happens much later. There are no provisions under the legislation to take an alternative action such as issuing advice or warning letters to the registrant who is the subject of a complaint.
  - We have concerns that the current process for managing health cases is overly adversarial. In turn, this could present a **risk to patient safety as it may discourage pharmacists from seeking support or an employer or colleague from raising a concern** to the regulator about the health of a registered pharmacist.

Lengthy and complex fitness to practise procedures present many risks to patient safety, including the potential to deter the public, other healthcare professionals or employers from making complaints to the regulator. There is a need for fundamental reform of our fitness to practise system to ensure it is fit for purpose.

Governance structures and role of Council

Finally, despite many strengths in the governance structure of the PSI, the Act presents a number of challenges for the PSI Council in carrying out its functions, including:

- challenges relating to the **size and structure** of the 21-member Council, and
- the role of Council in the sanctioning stage of the fitness to practise process, which creates **duplication of decision-making** and limits Council's availability to oversee policy, strategy and governance.

Conclusion

The PSI is calling for urgent and fundamental review of the Pharmacy Act 2007. The Act and regulations must be centred on the needs of the patient and adequately fit for purpose to support effective pharmacy regulation now and into the future in line with how healthcare services are usually regulated nationally and internationally.

As set out under the Act, our fitness to practise system for pharmacy professionals is overly complex and lengthy and carries a risk that employers, professionals, or members of the public will be deterred from making a complaint. The Act also presents a number of challenges for the PSI Council in carrying out its functions.

Next steps

As outlined previously, the focus to date has been on problem identification and analysis of the challenges and weaknesses of the Act. We envisage that the next stages in advancing reform of the Act would involve the PSI commissioning in-depth evidence reviews/expert reviews to inform the development of evidence-based policy proposals for reform of the Act.

2. Introduction

The PSI is calling for fundamental reform of the Act to ensure the legislation is fit for purpose in regulating the wide range of services that are now being delivered to patients in pharmacies.

The current legislative framework governing pharmacy service regulation is overly centred on the safe management of medicines when it should be centred on the patient and the safety and quality of services they receive, including the safe management of medicines. The Act requires the PSI to regulate pharmacies using the fitness to practise system, which is entirely out of line with how health services are typically regulated. Instead, what is required is a range of proportionate enforcement actions.

Furthermore, our fitness to practise system for pharmacy professionals is overly complex and lengthy and poses risks to patients. The duplication and delays inherent in the current system carry the risk that employers, professionals, or the public will be deterred from making a complaint. This does not serve the public interest or registrants.

Finally, we have seen through a number of governance reviews and wider benchmarking that PSI governance structures under the Act are not in line with best practice in corporate governance and inhibit the time that the Council has available to devote to its other functions, including developing policy, strategy and governance.

This paper draws on our analysis and research on international regulatory principles and practices and our experience of implementing the provisions of the Act for almost fifteen years to identify the challenges and weaknesses in the Act. The issues set out in this paper are issues that we believe can only be addressed through legislative reform.

Throughout this paper, we provide some examples of regulatory tools and practices used by other regulators to demonstrate alternative regulatory approaches. The examples provided are not intended to propose a new definitive model of regulation for PSI but rather to illustrate potential alternative approaches.

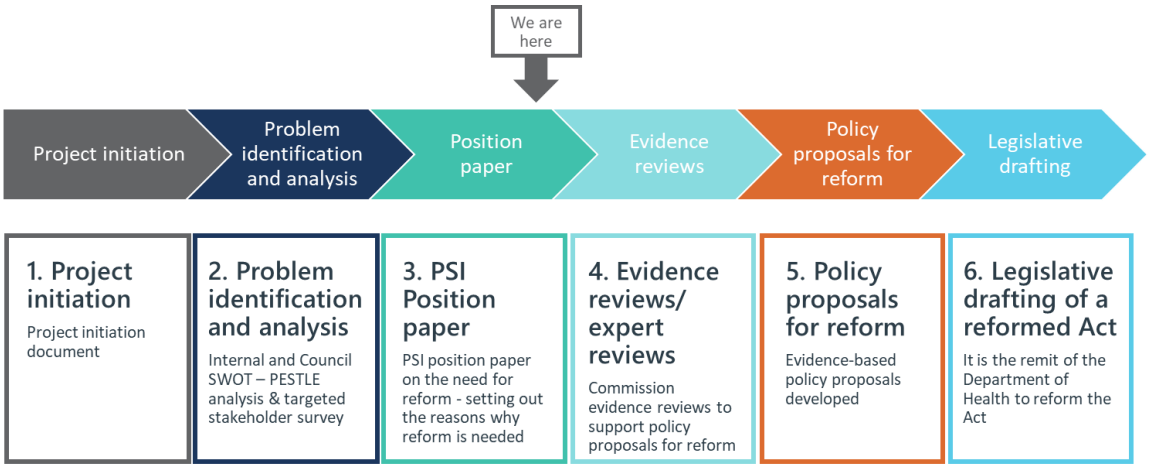

Figure 1 – Regulatory reform journey

As outlined in Figure 1, there are a number of stages involved in advancing reform of the Act. We envisage that the next stages would require the PSI to commission in-depth evidence reviews/expert reviews to inform the development of evidence-based policy proposals for reform of the Act.

2.1 Background

The Pharmacy Act 2007 (the Act) established the Pharmaceutical Society of Ireland (PSI) as the statutory regulator of pharmacy in Ireland and introduced many of the fundamentals of regulation, including mandatory registration for pharmacies and pharmacy professionals, standards for education and training, inspection and investigation powers and a new fitness to practise system.

Despite the Act's significant step forward in creating an assurance framework for patients and the public to access safe, quality pharmacy services, several significant weaknesses and gaps in the Act need urgent consideration.

The PSI has committed in our Corporate Strategy 2021-2023 to review the Act from a regulatory policy perspective and work in partnership with the Department of Health (DoH) to advance reform of the Act in the public interest.

2.2 Pharmacy in Ireland

Community pharmacies are highly accessible and frequently accessed by the public, with approximately 2 million people visiting their pharmacy per month in Ireland (PSI, 2016). Pharmacists have a higher number of potential 'contact points' with the public, both healthy and ill, than any other healthcare professional (PSI, 2016).

Since the commencement of the Act in 2007, pharmacy practice has expanded and diversified, with pharmacists providing an increasing number of pharmacy services, including vaccinations, point of care testing and health screening services.

During the COVID-19 pandemic, pharmacies have continued to play a critical role in ensuring continuity of pharmacy services and access to medicines for patients and the public, as well as being an important source of public health advice. In 2021, community pharmacies provided 606,394 COVID-19 vaccines as part of the HSE National COVID-19 Vaccination Programme.

As the pharmacy regulator, the PSI has a statutory responsibility to ensure that this vital healthcare activity is provided safely and regulated to a high and consistent standard.

Considering the evolving role of pharmacies as part of the broader healthcare system, it is essential that changes in pharmacy practice are underpinned by regulatory safeguards that are proportionate while assuring ongoing public confidence and trust in pharmacy practice.

2.3 Our approach to this paper

To identify the weaknesses and gaps in the Act that inhibit its overall effectiveness and identify where it has not kept pace with contemporary regulatory and pharmacy practice, we reviewed the Act from many perspectives (Figure 2).

Figure 2 - Overview of our approach to this paper

As part of this review, the following research and analysis was carried out:

1. **Regulatory principles and practices**

   We examined a range of international publications and landmark reports on key regulatory principles and practices, including those by the Organisation for Economic Co-operation and Development (OECD), Professional Standards Authority in the UK (PSA), the work of Harvard University's Professor Malcolm Sparrow on risk-based regulation, and the government of New Zealand's principles of regulatory stewardship.

   We reviewed learnings from inquiries and investigations into notable and relevant healthcare failures over the past two decades in both Ireland and the UK, including the Lourdes hospital inquiry (Clark, 2006), a number of HIQA investigations into patient safety incidents and poor hospital care (HIQA, 2009; HIQA, 2013; HIQA, 2015) and, from the UK, the Shipman inquiry (Smith, 2004), Francis report into Mid-Staffordshire hospital (Francis, 2013), and most recently, the Paterson report (James, 2020).

   We also examined the comprehensive report of The Commission on Patient Safety and Quality Assurance (2008) which made recommendations for significant reform across the Irish health and social care system.

2. National and international comparison of other regulators

We explored the work of other healthcare and non-healthcare regulators, both nationally and internationally, as represented in Figure 3.

The objective of this research was to carry out an initial broad scoping review on the range of regulatory practices and tools employed across other regulators whose remit is comparable, in whole or in part, to that of PSI.

Figure 3 - Desk-based research included a preliminary review of a number of legislative frameworks in other organisations including healthcare and non-healthcare regulators.

3. SWOT-PESTLE analysis

We conducted a SWOT-PESTLE analysis to capture PSI's experience of the Act, to review its strengths, weaknesses, opportunities and threats and how it supports our objective of protecting the health, safety and wellbeing of patients and the public. We evaluated it both internally across the statutory functions of the PSI, with PSI Council and with a number of key pharmacy stakeholders, namely, the Irish Pharmacy Union (IPU), Hospital Pharmacists Association of Ireland (HPAI), Irish Institute of Pharmacy (IIOP) based in the RCSI, Heads of Schools of Pharmacy, Health Service Executive Primary Care Reimbursement Service (HSE-PCRS) and practising pharmacists.

Strengths

Statutory governance structure & framework with a non-pharmacist majority Council and broad skillset.

Introduced the fundamentals of regulation including:

- a statutory registration system for pharmacy professionals and pharmacies
- standards for the education and training of pharmacists and mandatory CPD
- a formal complaints and fitness to practise system for pharmacists and pharmacies
- new powers of inspection and enforcement
- statutory Code of Conduct for Pharmacists
- clinical governance structure for pharmacies (superintendent and supervising pharmacists)

Opportunities

- An effective licensing regime for pharmacies
- To be more risk focused & patient safety focused
- Fundamental reform of the fitness to practise system
- Review of governance structures
- Regulating other members of the pharmacy team
- Update Act where technology has advanced – record-keeping, online pharmacies, remote monitoring, ePrescriptions
- Name of the PSI – better reflect our public protection duty
- Specialisation and expansion – Sláintecare

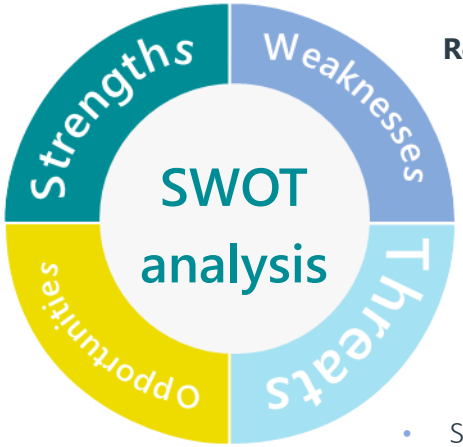

Figure 4 - SWOT analysis of the Pharmacy Act

Weaknesses

Regulation of pharmacies

- Governance & accountability of pharmacies (including ownership oversight)
- Fitness to Practise unsuitable for pharmacies
- Limited range of regulatory tools to monitor pharmacies
- Responsive and risk-based regulation
- Hospital pharmacy regulation – lacuna between PSI & HIQA
- Definition of 'retail pharmacy business'

Regulation of pharmacy professionals

- Competence assurance of pharmacy professionals
- Fitness to practise structures and processes
  - no early screening, triaging & adjudication
  - screening stage - limited investigative powers
  - interim suspensions process unsuitable for immediate safety risks (s45)
  - structure of sanctioning process – complexity & delay

Governance structure and role of Council

- Size and quorum: challenges in decision making
- Appointment process & terms of members
- Council's involvement with sanctioning

Threats

- Act & regulations focused on sale and supply of medicines
- Need for statutory patient safety notifications & to share risk data for quality and safety
- Changing pharmacy services- keeping regulatory pace
- Regulatory burden- PSI negative force versus progressive

We also carried out a PESTLE analysis to explore what impact external factors (political, economic, socio-demographic, technological, legal or environmental) may have on pharmacy practice in Ireland and how that may influence the need for regulatory reform (Figure 5).

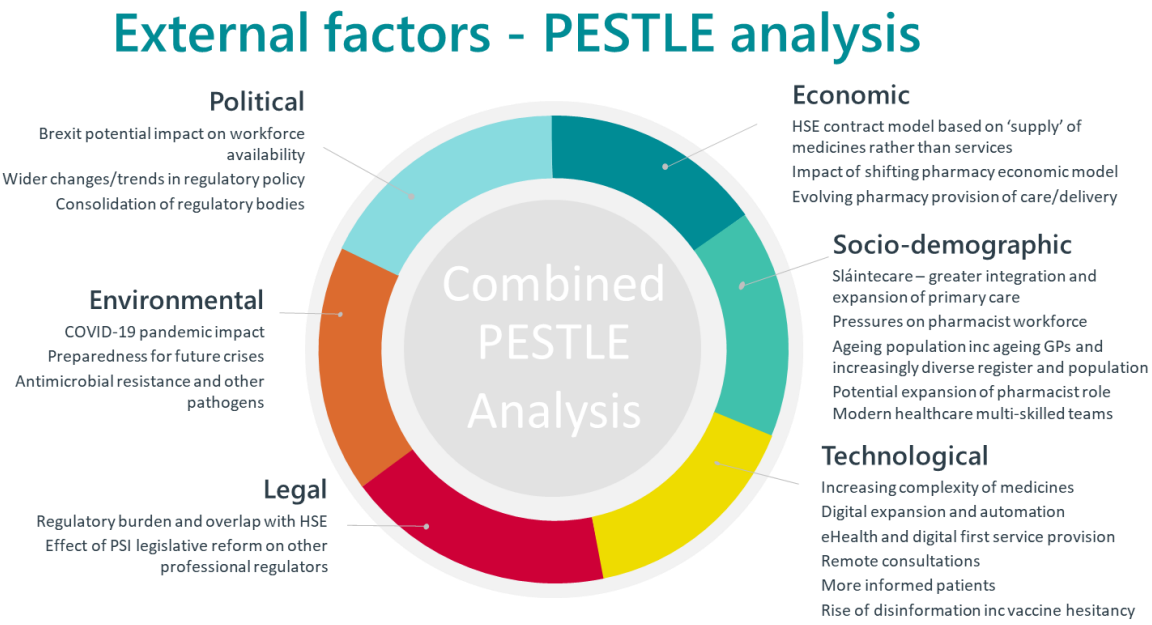

Figure 5 - Combined PESTLE analysis on the Pharmacy Act

4. Impact of the COVID-19 pandemic

Finally, we endeavoured to identify if any further strengths or weaknesses of the Act emerged during the COVID-19 pandemic, throughout which pharmacy teams have been essential providers of healthcare services and have played a key role in ensuring continuity of access to medicines for patients.

Some key lessons from the pandemic to highlight include:

- The accessibility of pharmacists in providing healthcare services in the community, particularly as part of the National COVID-19 vaccination programme.
- The potential benefits of a national electronic prescription transfer system and wider eHealth/digital health reforms.
- The benefits of close regulatory cross-collaboration between PSI and other key stakeholders.
- More broadly, the importance of regulatory stewardship and future preparedness across the health system.
- An accelerated need for a fully integrated healthcare system and healthcare reforms proposed under Sláintecare.

These lessons are further reasons for both reform of the Act and broader healthcare reforms. The importance of keeping regulatory systems fit for purpose to be prepared for changing circumstances and crises has also been emphasised in publications on the impact of COVID-19 by the Health Service Executive (HSE, 2021) and HIQA (HIQA, 2020; HIQA, 2021).

An important Professional Standards Authority (PSA) case study review highlights early learning from COVID-19 across the UK's professional health and social care regulators (PSA, 2021). The review emphasises the need to maximise the longer-term value of pandemic response actions and the importance of preparedness for future crises. The PSA (2021) also stresses that the COVID-19 pandemic accelerated the urgent need for regulatory reform to ensure greater agility balanced with appropriate oversight:

> *'The crisis has reinforced the urgent need for regulatory reform to make regulation more agile and enhances its ability to put patient protection at its centre… [the PSA] is concerned to ensure that greater flexibilities are balanced with appropriate oversight, including to minimise the risks arising from unjustifiable disparity of regulatory approaches, processes or practices; that the quality of decision-making is upheld; and that EDI impacts are fully considered'.*

The PSI also agrees that it is important to maximise learning from the pandemic response and ensure any lessons learned are considered as part of advancing reform of the Act.

3. Key research themes

When developing this paper, we undertook significant desk-based research on regulatory principles and practices and a review of the range of regulatory practices and tools employed across other national and international regulators. From this research, we have identified four key themes which have informed our analysis of the Act. These are outlined below.

1. **Regulatory systems must be reviewed to be effective and continue to meet their policy objectives**

   The first is that regulatory systems, in order to be effective, must be regularly reviewed to ensure they continue to meet their intended policy objectives.

   The OECD recommends that laws and regulations be reviewed regularly to improve their effectiveness and meet their intended policy objectives in the changing socioeconomic landscape (OECD, 2008; OECD, 2012; OECD, 2021).

   The OECD 2021 triennial policy outlook publication highlights that less than one-third of OECD member countries have a body in charge of checking the quality of reviews of existing regulations. The OECD recommends that countries move past traditional "set and forget" rule-making and improve how they assess, communicate, and manage risks, including more systematically reviewing regulations to ensure they correspond to the latest evidence and science (OECD, 2021).

   Regulatory systems are recognised as important assets of society (New Zealand Government, 2017). While it is ultimately the role of governments to reform legislation, there is also a growing recognition of the responsibility of regulators to be good regulatory stewards of their regulatory systems, to carefully manage the assets which have been entrusted to them for the future, including keeping their regulatory system and legislation fit for purpose (New Zealand Government, 2017; OECD, 2012).

   Therefore, the PSI has a responsibility as regulatory stewards to examine our legislation, ensure the Act and regulations remain fit for purpose and promote necessary reform to ensure that our grounding legislation effectively protects patients and the public. The Act has now been in operation for almost 15 years, during which time the PSI has gained significant experience in implementing its provisions. There have been significant changes in pharmacy practice, healthcare services and regulation during this period.

   HIQA also discuss the importance of ensuring that regulations continue to achieve the objectives for which they were introduced (HIQA, 2021). HIQA's The Need for Regulatory Reform report aims to 'assist policy-makers to design a regulatory system that is agile, receptive, reactive to change and proportionate in its response while ensuring the rights of people using services are upheld' (HIQA, 2021).

2. **Regulatory frameworks should be patient-centred and must keep pace with healthcare quality and patient safety recommendations, and pharmacy practice developments:**

    - **Recommendations on healthcare quality and patient safety**
      A number of important publications have been developed which set out a range of policy measures to drive the safety and quality agenda in Irish healthcare, not least the report of the Commission on Patient Safety and Quality Assurance (2008) and the principles of Right Touch Regulation developed by the Professional Standards Authority (PSA, 2015) in the UK.

      The Commission on Patient Safety and Quality Assurance (2008) made recommendations for reform across the Irish health system to provide a framework of patient safety and quality and foster a patient safety culture. The report stressed that reform of 'the regulation of healthcare professionals is central to quality improvement'. Although the report was published in 2008, it remains the driving policy basis for health and social care regulation in Ireland. Unfortunately, the report had not yet been published when the Act was being progressed through the legislature.

    - **Legislative frameworks for healthcare regulation should be patient-centred and focused on the safety and quality of healthcare services**
      Patient-centredness is one of the six domains of quality healthcare (Institute of Medicine (IOM), 2001) and should be at the heart of all healthcare services. Legislative frameworks for healthcare regulation must be patient-centred and focused on achieving the best possible outcomes for patients availing of health services.

    - **Pharmacy practice developments and healthcare reforms bring new regulatory demands and risks**
      Over the past fifteen years, pharmacy practice has expanded and diversified, with pharmacists providing an increasing number of pharmacy services that were not envisaged when the Act was drafted, including vaccinations. Medicines are also increasing in complexity, and polypharmacy is becoming more prevalent (PSI, 2016; World Health Organisation (WHO), 2017).

As the health system continues to respond to the impact of COVID-19, there are also mounting pressures on the health service from increasing chronic disease and an ageing population (Department of Health, 2016). Demographic changes alone will require an unprecedented response from everyone working in the health system, from the healthcare professional workforce to regulators (Central Statistics Office, 2016; Houses of the Oireachtas, 2017; OECD/ European Observatory on Health Systems and Policies, 2019).

With a national plan to significantly reform the Irish healthcare service under Sláintecare, moving towards greater integration, an expansion of primary care and eHealth infrastructure to support the sharing of knowledge and patient data across the system (Houses of the Oireachtas, 2017), it is envisaged that there is much change ahead in the pharmacy sector (PSI, 2016).

3. Learning from past regulatory failures is essential to mitigate the occurrence of similar failures in future

Much of the advances in healthcare regulation to date have emerged in response to a series of safety reviews of systematic failures in healthcare in Ireland and the UK (including the Shipman inquiry, the Lourdes hospital inquiry and the Francis and Paterson reports). Valuable lessons can be learned from common key findings from these crises, inquiries, investigations and failures in patient care (Smith, 2004; Clark, 2006; Commission on Patient Safety and Quality Assurance, 2008; Francis, 2013; James, 2020). We have identified some major themes common to many safety reviews applicable across all health and social care settings. These are set out in Figure 6 and include poor governance and weak accountability, regulatory failure, a lack of learning from mistakes and frontline staff not raising concerns about poor care.

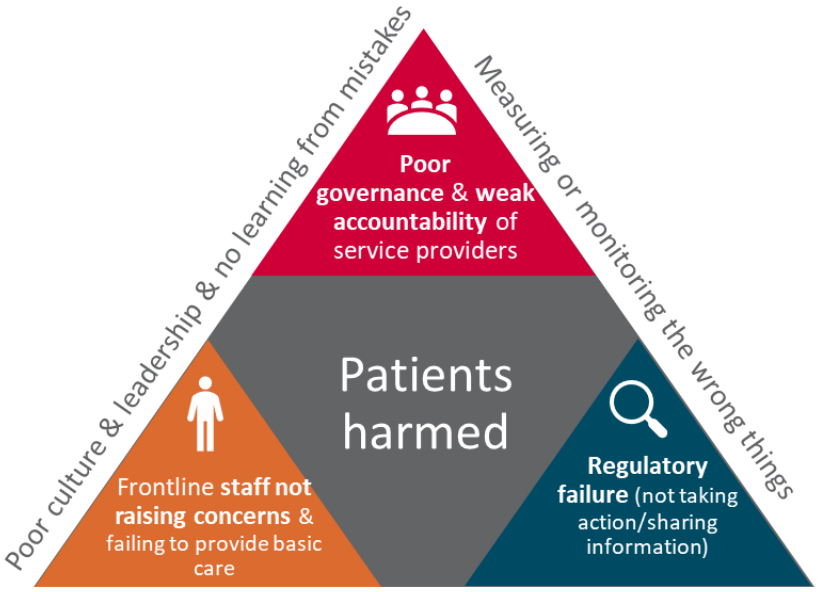

Figure 6 - Reviews into failures of patient care often show weaknesses across the three areas of frontline staff, governance and accountability of service providers and regulatory failure. We have identified some common themes here.

While it is essential to learn from inquiries and investigations to mitigate the occurrence of similar failures in future (HIQA, 2013), it has been emphasised that regulators have a responsibility to regularly review their systems and legislation and not wait for a crisis or inquiry in order to reform (New Zealand Government, 2017).

4. International regulatory practice has evidenced the benefits of moving towards more proactive, risk-based regulation

Since the Act was commenced in 2007, there has also been a greater focus on proactive, risk-focused regulation and risk-based frameworks, where regulatory activities are focused on harm reduction and delivery of effective outcomes for the public (Black, 2005; Hutter, 2005; Rothstein, 2006; Sparrow, 2008; Sparrow 2020).

Risk-based regulation involves regulators directing the majority of their resources towards the areas of greatest risk to patients, prioritising their activities to protect the public from maximum harm. Risk-based regulators focus on managing risks within their area of responsibility instead of limiting focus only to compliance with rules (OECD, 2010) and structure their regulatory decisions across a range of interventions, including education, advice and inspection and enforcement (OECD, 2010). Risk-based decision-making frameworks can 'produce resource savings, help to set outcomes and provide a framework for analysing problems or new developments' (OECD, 2010).

4. Challenges and weaknesses of the Act

In this section, we describe the most significant weaknesses that we have identified in the Act, which fall under three main areas:

- regulation of pharmacies
- regulation of pharmacy professionals
- governance structures and the role of the PSI Council.

4.1 Regulation of Pharmacies

There is an urgent need for fundamental reform of how pharmacy services are regulated in Ireland. In our experience, our current regulatory system is an unsuitable framework to regulate pharmacies and pharmacy services in line with how healthcare services are usually regulated nationally and internationally.

The legislative framework governing pharmacy service regulation is overly centred on the safe management of medicines when it should be centred on the patient and the safety and quality of the services they receive, including the safe management of medicines. The Act requires the PSI to use the fitness to practise system to regulate pharmacies, which is entirely out of line with how health services are normally regulated. Instead, what is required is a range of proportionate enforcement actions.

This section examines how fundamental weaknesses in the Act limit our effectiveness in ensuring that patients receive safe, high-quality pharmacy services and limit our ability to hold pharmacies to account.

Key issues discussed in this section include:

- **The need to strengthen governance and accountability of pharmacies under a reformed Act.** There are overlapping accountability and responsibilities across governance roles in the Act. In addition, the only criteria a governance pharmacist must meet under the Act is a baseline level of experience. Our current legislation does not require the same level of checks and balances for an individual to take on a governance role in a pharmacy as those required by other regulators. There are also weaknesses in the oversight of pharmacy ownership.
- **The need for revised, broader regulations supported by outcomes-focused standards to enable the PSI to respond to relevant and current risk areas with greater agility.** The current Act and its regulations focus predominately on the safe management of medicines when they should be centred on the patient and the safety and quality of the services patients receive, including the safe management of medicines.

- **The need for a mandatory national system to report errors or incidents which occur in pharmacies**. This significant deficit presents patient safety risks. Furthermore, the Act and the regulations place very limited statutory obligations on pharmacies to provide solicited information (information a service provider is required to provide under statutory obligations) to the PSI.
- **The need for PSI to be able to take a range of flexible enforcement actions proportionate to the risks posed to the public and patient safety.** The Act provides the PSI with a number of enforcement powers, however, these are limited and require the PSI to use the same fitness to practise system for pharmacies which is intended to regulate the competence and conduct of individual pharmacists. Due to the unsuitability of the process, findings have been made against a pharmacy only twice in the past ten years through the fitness to practise system.

4.1.1 Governance and accountability of pharmacies

The Act entrusts the PSI with the responsibility to regulate pharmacies in Ireland and requires every pharmacy to be registered with the PSI in order to operate. The Act and regulations and rules made under the Act set out the criteria required for pharmacy registration.

While the Act established mandatory registration with the PSI for all pharmacies that wish to operate, the criteria to register a pharmacy with the PSI are quite limited in comparison to the extensive criteria recommended in the report of the Commission on Patient Safety and Quality Assurance (2008) to obtain a licence to operate a healthcare service facility.

The report recommends that service providers be required to meet important patient safety and quality improvement criteria to obtain a licence: effective governance and management arrangements, risk management systems, audit and adverse event reporting, continuous quality improvement, mechanisms for patient participation and feedback, information management, and meeting health and safety standards.

Overlapping accountability and responsibilities across governance roles in the Act

Good governance of healthcare providers is a crucial component of safe patient care. Key failures identified in both the Francis report (2013) and Paterson inquiry (James, 2020) were poor governance of service providers, a failure to take responsibility among those in governance positions and providers placing financial, commercial and shareholder interests above patient safety and the delivery of appropriate standards of care for patients.

As part of the registration of the pharmacy, the pharmacy owner must inform the PSI as to who will be accountable for the overall governance of the pharmacy (superintendent pharmacist and supervising pharmacist).

The three key roles in the governance of pharmacies

Pharmacy Owner: The Act defines a pharmacy owner as a person carrying on a retail pharmacy business (pharmacy). This includes natural persons or partnerships, corporate bodies and representatives.

Superintendent pharmacist: The superintendent pharmacist is responsible for the management and administration of the sale and supply of medicines from the pharmacy. A superintendent pharmacist can occupy the role for one or more pharmacies.

Supervising pharmacist: Each pharmacy must also have a nominated supervising pharmacist responsible for the day-to-day management of the pharmacy. A supervising pharmacist can only occupy the role for one individual pharmacy.

The appointment of a superintendent pharmacist and supervising pharmacist is a key condition of a pharmacy's registration, and a pharmacy cannot legally operate without both roles being filled.

Clarity of roles and responsibilities and all individuals, including senior managers and Boards, being appropriately held accountable for their roles is one of the key components of good governance, as identified by the Commission on Patient Safety and Quality Assurance (2008) and the Francis Report (2013). Similar findings in the Paterson inquiry report (James, 2020) emphasise the important role registered managers in the independent sector have in keeping patients safe.

While the regulations made under the Act attempt to define the responsibilities of each pharmacy governance role in more detail, these are not well-delineated and often overlap. As a result, it is not always clear where accountability and responsibility rest under the Act for the safe operation of pharmacies.

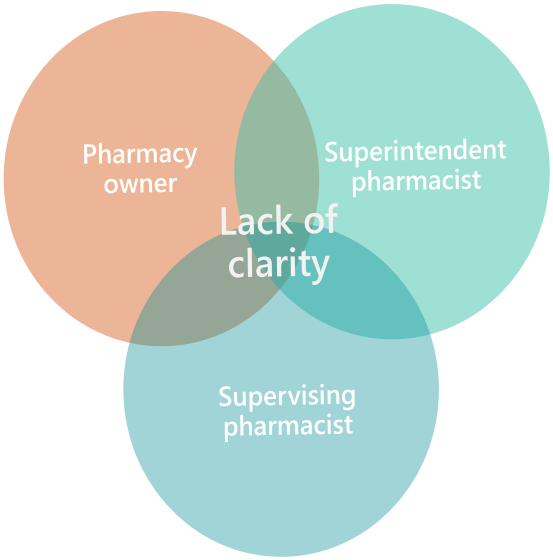

Figure 7 - Overlapping accountability and responsibilities across governance roles in the Act contribute to a lack of clarity

Furthermore, there is a predominant focus in the legislation on the sourcing, storage, supply, dispensing and disposal of medicinal products, with a distinct lack of an equivalent focus on governance responsibilities relating to patient safety and quality assurance and the delivery of safe, consistent and reliable pharmacy services to each patient. It is also worth noting that one person occupies all three governance roles in some pharmacies, contributing to a weak governance and accountability framework.

Based on our experience in regulating pharmacies, we believe that there is an urgent need to examine the framework for governance and accountability in pharmacies.

Other regulators set clearer accountability requirements for those in governance; for example, the General Pharmaceutical Council (GPhC) in Great Britain and the Alberta College of Pharmacy (ACP) in their pharmacy standards clearly specify who is responsible for ensuring that each standard is being met.

Eligibility criteria for the roles of superintendent and supervising pharmacists

In addition to overlapping accountability, the only criteria a governance pharmacist must meet under the Act is a minimum number of three years' post-registration experience. The PSI believes that this baseline level of experience required for a governance role does not provide sufficient assurance of the vital competencies required to provide safe, well-governed pharmacy services now and into the future.

In contrast, pharmacists in governance positions of pharmacies in Alberta are required to complete a specific education programme to be eligible to take on the responsibility of a governance role (Alberta College of Pharmacy, 2022). The pharmacist must also be in good standing with the regulator and submit an enhanced police information check. These relatively new requirements were introduced in 2020 to provide the regulator with greater assurances that the prospective licensee is suitably qualified and capable of fulfilling their important governance role.

The Health Act 2007 requires the Chief Inspector of Social Services (an official of the Health Information and Quality Authority (HIQA)) to assess whether an intended or registered provider and person participating in management, including the person in charge of designated centres, is a 'fit person', this includes assessing the fitness of directors in the case of a corporate body. In practice, this involves assessing governance arrangements, understanding of regulations, competence and evidence of being of good character, including by interview where necessary.

The Health Products Regulatory Authority (HPRA) have a qualified person (QP) linked to a manufacturing authorisation for a pharmaceutical manufacturer. Under the relevant medicines legislation, approval is required by the HPRA for the appointment of a QP, based on requirements for education and relevant experience to ensure the person has 'adequate knowledge and practical experience'. The person can be removed and prevented from acting as a QP if they fail to carry out their functions.

As we can see, our current legislation does not require the same level of checks and balances for an individual to take on a governance role in a pharmacy, and there is a need to examine how the governance and accountability of pharmacies could be strengthened under a reformed Act.

Oversight of pharmacy ownership

Another aspect of pharmacy registration is that pharmacy owners are required to keep PSI up-to-date on any change in the ownership of a pharmacy. This oversight of pharmacy ownership is intended to safeguard the integrity of the medicinal products supply chain and identify any conflicts of interest that may arise. However, we consider that these provisions are no longer best suited to the more complex structures of pharmacy ownership, which are becoming increasingly common.

As we can see in figure 8, corporate bodies have increased in the ownership of pharmacies since the Register of Retail Pharmacy Businesses (pharmacies) was established under the Act in early 2009, increasing from 92% in 2009 to 98% currently.

Additionally, the ownership structures of pharmacies have become more complex, with some pharmacies utilising a holding company as part of their structure.

Only certain changes of ownership require the PSI to be notified under the Act. In some instances, where ownership changes occur within a more complex company structure, such as those involving a holding company, these do not trigger any requirement under the Act for the PSI to be notified.

Consequently, we do not always have clear information about who owns or who is carrying on the business of a pharmacy and whether those persons are fit to own or operate a pharmacy. In our experience, through a recent fitness to practise case, there is a risk that these more complex ownership structures pose inherent risks, which may provide an opportunity for unfit persons to acquire pharmacies and move themselves beyond the reach of regulatory action.

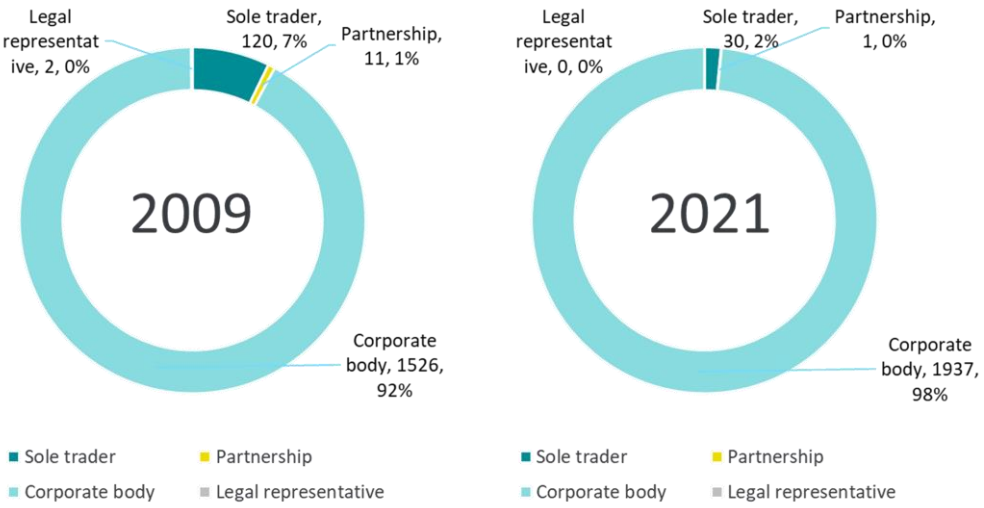

Figure 8 - Ownership of pharmacies in Ireland by type; 2009 and 2021. Source: PSI register.

4.1.2 Monitoring

As set out in the Act, one of our main statutory functions is to supervise compliance with the Act and statutory instruments, including relevant medicines and pharmacy legislation. We do this by carrying out inspections and investigations to check that pharmacies are operating safely and complying with the requirements of the Act, regulations and other relevant pharmacy and medicines legislation. Included in these monitoring tools are considerable investigative powers of entry, search and seizure.

In our experience of supervising compliance with the Act and regulations, we can see that these provisions focus almost entirely on the sale and supply of medicines as well as a minimum set of requirements around the pharmacy premises, with a corresponding lack of focus on the quality of services patients are receiving and whether the pharmacy is meeting the needs of patients and the public.

This predominant focus of the regulatory framework on the safe management of medicines reflected pharmacy practice when the Act was drafted, which was centred almost exclusively around the dispensing of medicines. Since then, however, the pharmacy landscape has expanded to include more patient services, including emergency contraception, vaccinations, point of care testing, health screening services, and dispensing services (PSI, 2016). The expansion of pharmacy services has become even more apparent during the COVID-19 pandemic, with pharmacies providing guidance on public health advice in the community and playing a key role in the National COVID-19

Vaccination Programme. It is anticipated that this diversification of pharmacy services will continue under planned wider healthcare policy reforms to expand primary care and shift treatment from the acute sector to the community under Sláintecare (Houses of the Oireachtas, 2017). It is crucial that our regulatory framework keeps pace with these changes in pharmacy service provision and continues to achieve its intended policy objectives.

The Act charges the PSI with *both* supervising compliance with the Act and its statutory instruments *and* regulating the profession of pharmacy having regard to the need to protect, maintain and promote the health and safety of the public. Our regulatory framework must remain fit for purpose in its objective of protecting, maintaining and promoting the health and safety of the public so that we as a regulator can respond to current and emerging risks to patients. We consider that a review of our existing regulations and overall regulatory framework is urgently needed to ensure that the PSI can carry out both of these functions to maximum effectiveness.

In our experience, not only has our regulatory framework not kept pace with the expansion of pharmacy services; additionally, the current regulations do not cover many important aspects of pharmacy management and governance, including many of those identified by the Commission on Patient Safety and Quality Assurance (2008) as necessary for the licensing of healthcare facilities such as risk management and adverse event reporting.

In fact, it is difficult, if not impossible, for any set of regulations to cover all aspects of healthcare delivery, including that provided in a pharmacy. A broader, more flexible framework is needed to allow PSI to be more responsive to changing patient needs and changing risks.

Many healthcare regulators, including pharmacy regulators like the GPhC in Great Britain, the Alberta College of Pharmacy in Canada, and healthcare service regulators such as the Mental Health Commission and HIQA in Ireland, use healthcare regulatory standards as part of their regulatory framework. The Health Act 2007 enables HIQA to set standards on safety and quality for health and social care services under the Minister for Health's approval and monitor performance against these standards in the areas they regulate.

Standards are typically more outcomes-focused than our current framework, which is primarily centred on pharmacy processes related to the sale, supply and supervision of medicines. Standards can be more accessible to the public and show both patients and pharmacy teams what patients should expect from their pharmacy and what good pharmacy services look like. Standards promote up-to-date, evidence-based, and consistent practice and assist service providers in identifying strengths and weaknesses in their service delivery (HIQA, 2016).

The inclusion of standards in our framework would enable PSI to focus on monitoring other broader aspects of the provision of pharmacy services. Standards can articulate what good performance and high-quality, safe patient care looks like in practice and set a vision for better and safer care by clearly communicating the regulator's expectation to those regulated (National Economic and Social Council (NESC), 2011). Standards can provide a regulator with greater flexibility and agility to respond to changing patient risks as they arise.

The development, implementation and monitoring of national health care standards are widely recognised as key mechanisms to drive improvements in the quality and safety of care provided (Schaefer & Wiig, 2017, HIQA, 2012), and the use of performance-based regulatory standards is increasing at pace in all OECD countries (Coglainese, 2016).

We have committed in our corporate strategy to developing outcome-focused standards for pharmacies, as an additional regulatory tool, as part of our approach to regulating pharmacies. It is intended that, within our current legislative framework, these standards would sit under Regulation 14 of the Retail Pharmacy Businesses regulations as guidelines. Regulation 14 enables the PSI Council, with the minister's prior approval, to publish detailed guidelines to facilitate compliance with the regulations.

In 2020, in response to the COVID-19 pandemic, we developed COVID-19 Operational Standards for Pharmacies. Through engagement with a small number of pharmacies on these Standards during exploratory visits, we saw a high degree of voluntary uptake and positive engagement.

Although PSI intends to develop standards as an additional regulatory tool insofar as the current Act can accommodate, we strongly consider that the setting and monitoring of standards should be a primary function of the PSI under the Act. This would be a more robust statutory basis to ensure compliance with the standards and, ultimately, the regulations. A reformed framework based around revised, broader regulations supported by outcomes-focused healthcare regulatory standards would strengthen our ability to deliver on our objective of ensuring that pharmacies provide safe, high-quality pharmacy services and would enable the PSI to respond to the areas of relevant and current risk with greater agility.

Regulatory Burden

An additional benefit to a review of existing regulations is the potential to remove regulatory burden in cases where practices have changed, or technological advancements have occurred in pharmacies.

Minimising unnecessary regulatory burden is an important consideration for regulators (HIQA, 2021) and part of good regulatory stewardship (New Zealand Government, 2017). The Berwick report (2013) on improving the safety of patients in the NHS recommends that system regulators simplify and remove unnecessary demands from their systems:

> *'Simplify, clarify, and align your requests and demands from the care system, to reduce waste and allow them to focus on the most important aims [and] … cooperate fully and seamlessly with each other.'*

The benefit, therefore, of reducing unnecessary regulatory burden is that it can allow healthcare professionals to spend more time with patients, providing patient care. In line with this, the PSI has taken considerable steps to provide more efficient and streamlined processes for our registrants. We have moved more of our processes online and have upgraded our registration system for registrants.

Despite the steps we have taken to reduce regulatory burden for those we regulate, some provisions of the Act create significant regulatory burden for pharmacists and the PSI, without adding any real value for the public. In particular, pharmacies must keep hard copy records of prescriptions, daily audits (prescription register), duty registers and controlled drugs registers. Legislative reform should allow for the keeping of such records in electronic format.

The pandemic accelerated the planned move towards ePrescriptions and further highlighted the need to update the Act to reflect more contemporary electronic systems and processes.

Figure 9 - PSI Eight principles of regulatory risk management (PSI, 2018)

Risk-based inspection

As previously discussed, regulation is becoming more risk-based, and nationally and internationally, regulators have developed risk-based frameworks as part of their regulatory approaches. Similarly, the PSI has developed a regulatory risk statement and eight principles of regulatory risk management to guide our decision-making in choosing the most appropriate regulatory intervention in proportion to the risks to patients and the public. These interventions include engaging, explaining, and encouraging registrants to adhere to regulatory requirements and escalating to enforcement as necessary.

We regularly receive a significant amount of unsolicited information concerning pharmacies from members of the public and others. This vital source of information is risk-assessed to inform our decision-making and regulatory actions, where necessary.

The Act and the regulations currently place very limited statutory obligations on pharmacies to provide solicited information (information a service provider must provide under statutory obligations) to the PSI. These are primarily related to situations where there is a change of supervising or superintendent pharmacist or a change of pharmacy ownership. There is no statutory requirement for pharmacies to notify the PSI of serious patient safety incidents, errors, or events that may pose risks to patients.

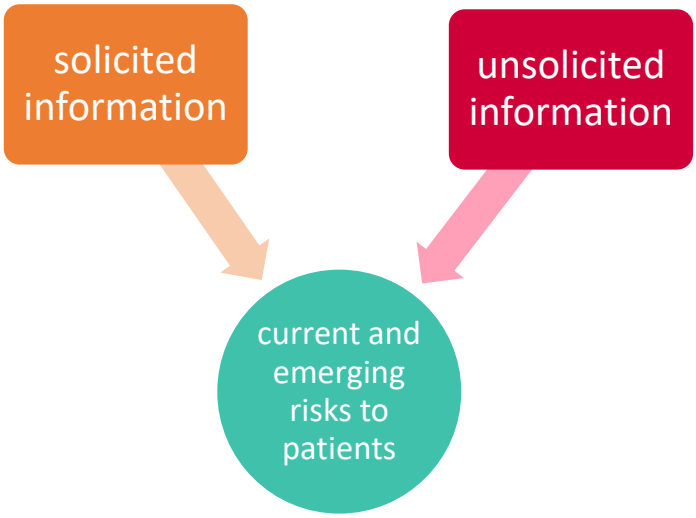

Figure 10: A greater range of solicited information from pharmacies could assist the PSI in strengthening our ability to identify current and emerging risks to patients.

Although the PSI has issued guidance to pharmacies on medication errors, pharmacies have no legal requirement to record these or to notify the PSI. Due to medication errors being one of the most common adverse events that can, in some cases, cause severe patient harm and even death (WHO, 2017), we see the lack of a national mandatory error reporting system as a significant gap in the current regulatory model for pharmacies and a key area which must be examined as part of a reformed Act.

There is an urgent need to review pharmacies' obligations to provide solicited information to the PSI. This

would assist the PSI in further developing individual pharmacies' risk profiles and identifying current and emerging risks to patients.

This information would also allow us to primarily direct our regulatory resources towards mitigating those risks that pose the most significant potential for patient harm. It would also facilitate the sharing of information and learning more widely with pharmacies, enabling them to take immediate steps to mitigate current and emerging risks.

HIQA's regulatory framework places obligations on the registered provider and person in charge of designated centres to submit regular, and other specified, solicited information to HIQA to fulfil their statutory obligations, including monitoring and registration notifications. HIQA risk assesses this information to determine the risk of harm to service users and decide which regulatory activity is most appropriate based on the overall risk profile of the centre.

In Canada, the Ontario College of Pharmacists has established a mandatory, standardised medication safety programme designed to help pharmacy teams learn from errors and near misses, reduce risk and improve the quality and safety of pharmacy care.

The Commission on Patient Safety and Quality Assurance recommend that one of the criteria for licensing should include audit and adverse event reporting. In order to maximise the regulatory actions we take, it is essential that patient safety-related information is harnessed where possible.

One of the recommendations of the Francis report is that:

> *'a coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public. Such information must be available in as near real-time as possible and should be capable of use by regulators in assessing the risk of non-compliance. It must include not only statistics about outcomes, but must take advantage of all safety-related information, including that capable of being derived from incidents, complaints and investigations. It is not the source of the information that matters, but its implications for patient safety and the quality of care.'*

As we can see, there is a need for up-to-date, reliable, dynamic risk information, including statutory patient safety notifications, to inform our approaches and prioritise our resources to the areas of most significant risk to patients. We consider that pharmacies' obligations to provide solicited information to the PSI should be urgently reviewed.

4.1.3 Enforcement

Perhaps the most significant weakness of the current Act is the area of enforcement. The Act provides the PSI with a number of enforcement powers, which can be used in cases where poor practices or breaches in legislation are identified in order to protect patients and the public. These, however, are limited and rely heavily on the use of the fitness to practise system. Where appropriate, the PSI can initiate summary proceedings against a pharmacy through the Court system for an offence under the Act.

The Act requires the PSI to use the same fitness to practise system for pharmacies which is intended to regulate the competence and conduct of individual pharmacists. This is the only mechanism the PSI has under the Act to attach conditions to, suspend or cancel the registration of a pharmacy. This approach is wholly unsuitable for regulating a health service facility and is not consistent with how healthcare facilities are usually regulated.

When a complaint is made against a pharmacy, PSI must establish, to all intents and purposes, whether or not a pharmacy is unfit to practise or has failed to reach a certain standard of conduct. The level of proof required is the criminal standard beyond a reasonable doubt. Due to the unsuitability of the process, findings have been made against a pharmacy only twice in the past ten years through the fitness to practise system.

We believe that it is essential for effective regulation of pharmacies that PSI can take a range of flexible enforcement actions proportionate to the risk posed to the public and to patient safety, including mechanisms to require a pharmacy to make improvements to protect patients and the public. This would be in line with the recommendations of the Commission on Patient Safety and Quality Assurance for licensing bodies to have a range of sanctions at their disposal to enforce compliance with stated standards and that these should range from warnings with time limits for compliance, placing specific conditions on the licence (e.g., restricting certain activities) up to the withdrawal of licence, where necessary. Matters relating to licensing should, in common with other areas of regulatory law, be brought before the District Court in the first instance, with an appeal to the Circuit Court.

Other regulators who regulate healthcare facilities, including HIQA in Ireland and the GPhC in Great Britain, have statutory powers to take a range of actions proportionate to the level of risk identified, including issuing compliance orders or improvement notices (HIQA, 2021; GPhC, 2019).

HIQA has considerable flexibility in how it uses its enforcement powers. These powers can be used at any stage of the registration cycle, as long as one or more grounds have arisen. Under HIQA's legislation, there is a clear link between the registration of service providers and monitoring those services (HIQA, 2021).

The GPhC also has a range of different enforcement options available to it in securing compliance with its pharmacy standards, from issuing improvement action plans to statutory enforcement powers, such as improvement notices or attaching conditions to a pharmacy's registration. A graduated range of powers allows a regulatory response proportionate to patient risk (GPhC, 2019).

In addition, the HPRA has powers to suspend or revoke a wholesaler's or manufacturer's authorisation under certain grounds set out in the legislation.

This flexibility in the regulatory tools of HIQA, GPhC and HPRA is consistent with responsive regulation, which enables the regulator to respond to the context, conduct and culture of those being regulated (Ayres and Braithwaite, 1992). Responsive regulation argues that regulators should begin with softer mechanisms rather than immediately opting for hard enforcement and escalate accordingly as needed (Healy, 2013).

Responsive regulation is more cost-effective and timely and allows the regulator to respond in a flexible manner to address risks to patient safety, depending on the behaviour and actions of the regulated entity (Healy, 2013). This is depicted in Figure 11.

A key recommendation of the Commission on Patient Safety and Quality Assurance (2008) is that all health services, including primary care, be regulated through mandatory licensing, linked to compliance with specified core standards and enforceable through inspection and imposition of sanctions if necessary.

As we can see, the current system of pharmacy regulation does not facilitate the PSI to impose conditions on the registration of pharmacies in a streamlined way without the need to go through the fitness to practise system, which is complex and inflexible.

It is essential that there is a firm link between a pharmacy's registration and their compliance with statutory requirements and quality and safety performance. The PSI believes that the regulatory framework for the regulation of pharmacies needs to be urgently reviewed.

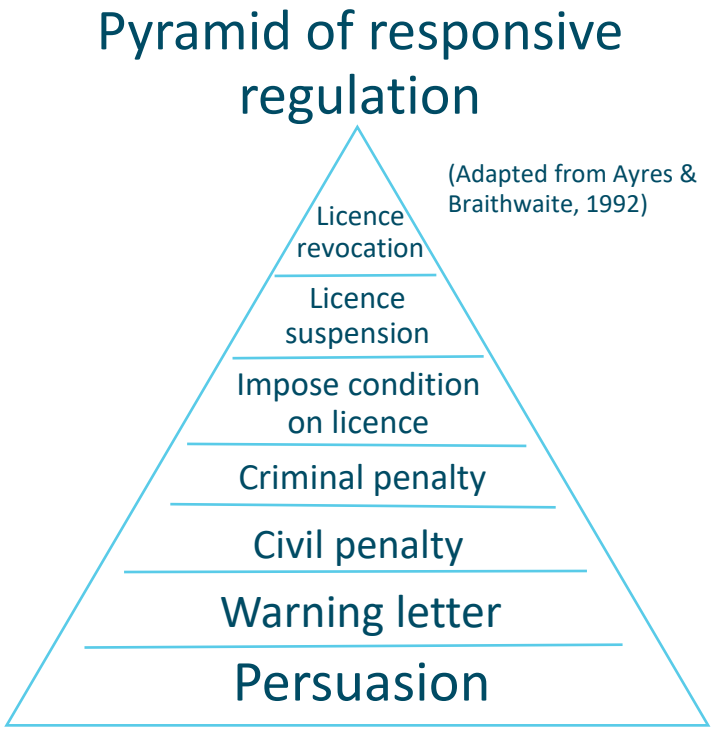

Figure 11 - The pyramid of responsive regulation is an example of how a regulator can take a regulatory action proportionate to patient risk. The actions at the bottom of the pyramid such as persuasion, are effective for the vast majority of those regulated. As we move up the triangle, regulatory actions become more serious, with the strongest powers at the top of the pyramid used only where necessary.

PSI position on the regulation of retail pharmacy businesses in hospital settings

The PSI position on the regulation of retail pharmacy businesses operating in hospital settings will be set out in a separate PSI paper, but for completeness, we outline the deficits which the Act presents in this regard.

The Act defines a pharmacy as a 'retail pharmacy business'. This definition is centred around the sale or supply of medicinal products. Any person or entity engaged in activities relating to the sale or supply of medicinal products as defined in the Act must be registered as a retail pharmacy business with the PSI, including hospital pharmacy departments engaged in such activities.

In practice, this means that only hospital pharmacy departments that supply medicines to out-patients or hospital staff on foot of a prescription or who provide retail sales of medicines must be registered with the PSI. These activities, however, are only a small subset of the overall activities provided by hospital pharmacy departments. The administration of medicines to inpatients in healthcare settings falls entirely outside the regulatory remit of the PSI. This is a considerable regulatory deficit and poses significant risks to patient safety.

The PSI considers that patients receiving medicines in any practice setting (community or hospital) are entitled to expect that the service is operating to high standards of safety and quality and is appropriately regulated by a relevant regulatory body.

There is an urgent need for a cohesive regulatory system for all hospital pharmacies. The PSI believes that this must be addressed by the Department of Health through legislative reform.

The case for Reform - Regulation of Pharmacies

There is an urgent need for fundamental reform of how pharmacy services are regulated in Ireland. The Act presents significant weaknesses that limit our effectiveness in assuring safe, high-quality pharmacy services to patients and limit our ability to hold pharmacies to account.

- We believe that the governance and accountability of pharmacies need to be strengthened under a reformed Act. Firstly, there are overlapping accountability and responsibilities across governance roles in the Act. In addition, the only criteria a governance pharmacist must meet under the Act is a baseline level of experience. Our current legislation does not require the same level of checks and balances for an individual to take on a governance role in a pharmacy as those required by other regulators. There are also weaknesses in the oversight of pharmacy ownership.
- The current Act and its regulations focus predominately on the safe management of medicines when they should be centred on the patient and the safety and quality of the services patients receive, including the safe management of medicines. Revised, broader regulations supported by outcomes-focused standards would enable the PSI to respond to relevant and current risk areas with greater agility.
- Currently, there is no mandatory national system to report errors or incidents which occur in pharmacies. This significant deficit presents patient safety risks. Furthermore, the Act and the regulations place very limited statutory obligations on pharmacies to provide solicited information (information a service provider is required to provide under statutory obligations) to the PSI.
- The Act provides the PSI with a number of enforcement powers. These, however, are limited and require the PSI to use the same fitness to practise system for pharmacies which is intended to regulate the competence and conduct of individual pharmacists. Due to the unsuitability of the process, findings have been made against a pharmacy only twice in the past ten years through the fitness to practise system. It is essential that PSI can take a range of flexible enforcement actions proportionate to the risk posed to the public and patient safety.

The PSI believes that the regulatory framework for the regulation of pharmacies needs to be urgently reviewed.

We consider that the following research question should be examined and developed further as part of commissioning an in-depth evidence review in this area:

1. **Describe the model of regulation currently used to regulate pharmacies/health and social care facilities in other jurisdictions, including:**
    a. Legislative and/or standards-based model
    b. Registration/licensing/accreditation/ownership of the facility
    c. Requirements for providers, owners and persons in charge including training, competencies, assessment of fitness and systems of governance and accountability of the facility

d. Inspection and monitoring functions of the regulator with respect to relevant legislation or standards
e. Enforcement actions the regulator can take to ensure compliance, quality improvement or mitigate harms
f. The regulation of pharmacies in hospital settings

4.2 Regulation of pharmacy professionals

4.2.1 Fitness to practise structures and processes

Fitness to practise (FTP) is the process used by professional regulators to handle complaints or deal with concerns made about healthcare professionals to 'promote and safeguard the public interest, which involves individual patient protection, the maintenance of public confidence in the profession and declaring and upholding proper standards of conduct' (Commission on Patient Safety and Quality Assurance, 2008).

While it has been described by the Shipman report as the 'teeth' behind all other monitoring and disciplinary systems (Smith, 2004), the purpose of fitness to practise is not to punish (PSA, 2017) but to protect patients and the public from harm.

The Act established the PSI's fitness to practise system. Anyone is entitled to make a complaint to the PSI on certain grounds where there is a concern about a pharmacist's behaviour, practice, conduct, or health. The PSI is unusual in that we also use the fitness to practise system to take action against pharmacies, the limitations of which, in holding a healthcare facility to account, have already been outlined above.

Our fitness to practise system is a long, inflexible process with duplication of decision-making and unnecessary complexity across a number of areas and is in need of fundamental reform from the screening to sanctioning stage to safeguard the public interest and protect patients from harm.

Key issues discussed in this section include:

- The unsuitability of the interim suspension process when responding to urgent risks to patient safety.
- The limited set of tools to triage or investigate complaints at the screening stage of the FTP process, as provided in the Act. The effect of this is that the bulk of the investigation and decision-making happens much later. There are no provisions under the legislation to take an alternative action such as issuing advice or warning letters to the registrant who is the subject of a complaint.
- The current process for managing health cases which, due to its overly adversarial nature, may present a risk to patient safety as it may discourage pharmacists from seeking support or an employer or colleague from raising a concern to the regulator about the health of a registered pharmacist.

4.2.1.1 Immediate safety risks: interim suspensions

Where PSI is concerned that a pharmacist or pharmacy presents an immediate safety risk to the public, the Act has a mechanism under Section 45 for the PSI to take action to protect the public and to request the High Court to order the suspension, in the interim, of the registration of a pharmacist or pharmacy, pending further disciplinary procedures.

The interim suspension process first involves the making of a formal complaint. PSI Council must then consider this complaint during an emergency meeting, following which they may then apply to the High Court for an interim suspension order if deemed appropriate.

The High Court must consider if there is a sufficient risk to the health and safety of the public to justify the making of the Order and determine the matter.

In our experience, this means there is duplication in the interim suspension process as both Council and the High Court consider the matter. This duplication of decision-making is unnecessarily time-consuming, and the structure of the process has proven to be highly complex and legalistic and unsuited to the purpose of urgently responding to an immediate risk to patient safety.

Reviewing the process of the Nursing and Midwifery Board of Ireland (NMBI) for obtaining an interim order, which is similar to that used by the PSI, the Professional Standards Authority (PSA) considered the interim suspension process to be 'overly complex' with 'duplication of decision making by the Board and the High Court'. The PSA recommended simplifying the process for interim orders so that risk mitigation measures could be put in place without undue delays to protect the public. The PSA believed that unnecessary complexity for interim orders could run the risk of discouraging the Board to refer cases to the High Court (PSA, 2014).

One of the Francis Inquiry recommendations was that regulators should be free to require or recommend immediate protective steps where there is reasonable cause to suspect a breach of fundamental standards. The test should be whether there are reasonable grounds in the public interest to make the interim requirements, even if it has not yet reached a concluded view or gathered all the necessary evidence (Francis, 2013).

4.2.1.2 The stages of the fitness to practise process

As can be seen in figure 12, there are a number of stages to the fitness to practise process, which are set out below.

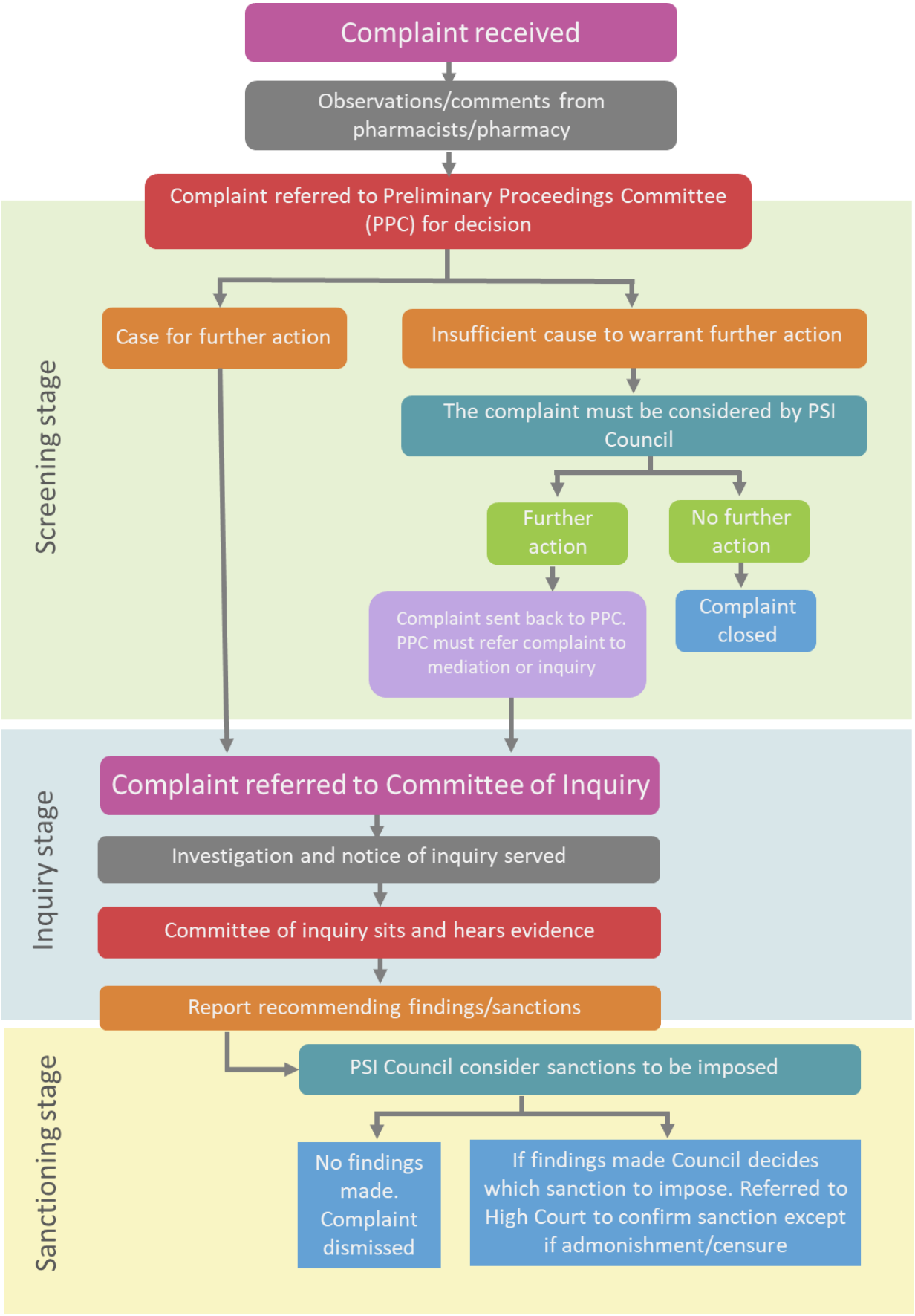

Figure 12 – Stages of the fitness to practise (FTP) process

The PSI receives, on average, 50 formal complaints per year and holds approximately 11 inquiries annually (figures averaged over the past seven years). Further information on how complaints are made can be found in the PSI's guide to making a complaint.

The fitness to practise (FTP) process

In order for the FTP process to commence, a formal complaint must be made.

Screening stage

The complaint must then be reviewed by a complaints screening committee called the Preliminary Proceedings Committee (PPC). The role of the PPC is to decide whether there is:

- a case for further action, in which case the complaint is referred for inquiry or mediation, or,
- insufficient cause to warrant further action, in which case, the complaint must be considered by the PSI Council. If the Council agrees, no further action is taken on the complaint. If the Council disagrees, it can refer the complaint back to the PPC, who must then refer it to inquiry or mediation.

It is not the function of the PPC to establish that a complaint has been proven or otherwise.

Inquiry stage

Where a complaint is referred to inquiry, it may be referred to either the Professional Conduct Committee (PCC) or, if appropriate, the Health Committee. Inquiries by the PCC are usually held in public, whereas inquiries of the Health Committee are usually held in private due to the nature of the matters under consideration. At the inquiry, the Committee will decide if the allegations against the pharmacy or pharmacist have been proven beyond a reasonable doubt. The Committee will then prepare a report setting out the complaint, the evidence presented and the findings, together with its reasons. It will also make a recommendation as to an appropriate sanction.

Sanctioning stage

The Council of the PSI considers the report of the committee and decides what sanction to impose.

Finally, the PSI must apply to the High Court to confirm the sanction, except in cases where the sanction is admonishment or censure.

Each of these stages, as set out under the Act, takes a considerable length of time to complete. From the initial stage when a complaint is made to the end of the sanctioning process (where appropriate), the entire process can take up to 2-3 years. It is a long, inflexible process with many inefficiencies.

Lengthy and complex fitness to practise procedures present many risks to patient safety. The Francis report (2013) found that there is a risk that they may deter the public, healthcare professionals and employers from making complaints to the regulator. In its NMBI fitness to practise review, the PSA states that significant delays in fitness to practise processes can undermine public confidence in the regulator and the regulatory system and, most significantly, can have a detrimental impact on patient safety (2014).

4.2.1.3 Screening stage: limited early regulatory tools

One of the most significant weaknesses of our fitness to practise system is a limited set of tools to triage or investigate complaints at the screening stage of the process. The effect of this is that the bulk of the investigation and decision-making happens much later in the process.

Firstly, as outlined above, all complaints received by the PSI must be sent to the PPC for consideration. Prior to a PPC meeting, there is no provision to screen out complaints that are clearly frivolous or vexatious or not made in good faith or triage complaints by their level of seriousness.

Secondly, although the PPC is charged with deciding if there is sufficient cause to warrant further action being taken, the Act does not provide the PSI with many statutory powers to investigate complaints at the screening stage to establish the facts of the complaint can be proven. Although the PPC can ask for more information from the complainant, the pharmacist or the pharmacy owner, it cannot compel this information to be provided. In our experience, this often results in limited information being available at the screening stage and presents difficulties for decision-making. Cases may be prematurely dismissed due to the lack of available information, which could present patient safety risks. Alternatively, cases may be sent forward unnecessarily, creating delays and substantial legal costs without any real regulatory impact.

The Act is clearly not in line with the PSA's Standards of Good Regulation (PSA, 2019). These standards provide, among other things, that 'the regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case and ensures that appropriate evidence is available to support decision-makers to reach a decision that protects the public at each stage of the process'. The Shipman Inquiry also highlighted the importance of investigating complaints at an early stage (Smith, 2004).

Separately, the Act provides the PSI with strong investigative powers to conduct pharmacy investigations under part 7 of the Act; however, these powers do not extend to the investigation of complaints made under part 6 of the Act. Under a reformed Act, there is an opportunity to harness these investigative powers.

The third aspect of the screening stage requiring reform is the lack of flexibility in the actions the regulator can take with respect to those complaints which have not met the threshold of seriousness to proceed to the inquiry stage but which still present risks to patient safety or may indicate risk or concern involving a pharmacist's practice. This inflexibility limits our ability to act in the public interest in a more proportionate, risk-based manner.

Currently, the complaints process ends for these cases (where a complaint is not referred onwards past the screening stage). There are no provisions under the legislation to take an alternative action such as issuing advice or warning letters to the registrant who is the subject of a complaint. It can, therefore, often appear to the complainant, the majority of whom are members of the public, that the PSI has not taken any meaningful action in relation to their complaint.

The Law Commission in the UK (2014) recommends that where a complaint is not referred onwards for an inquiry, a regulator should have powers to give advice on any matter related to the allegation to the registrant and any other person or body involved in the investigation and be able to give a warning to the registrant regarding their future conduct or performance.

The majority of health and social care professional regulators in the UK, including the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI), have powers to issue advice and/or warning letters to a registrant where the complaint is not referred onwards to an inquiry. Warnings are issued to demonstrate to the registrant that their conduct or behaviour fell below acceptable standards and are an opportunity for insight and learning.

Finally, the Act does not provide any facility for the early disposal of less serious complaints by accepting undertakings or the imposition of more minor sanctions at the screening stage in circumstances where the facts of the complaint are accepted and agreed upon by the registrant.

Currently, only the committee of inquiry may accept a limited range of undertakings at the inquiry stage. Introducing this step earlier in the process could deliver significant efficiencies. However, this would need to be balanced with robust processes to ensure transparency and consistency (PSA, 2017).

4.2.1.4 Inquiry stage

One of the grounds for holding a fitness to practise inquiry is that the registrant is suffering from an impairment of their ability to practise by reason of a physical or mental ailment, for example, alcohol or substance misuse. We believe that our current system for managing health cases, as set out in the Act, is not optimal and needs review.

A discussion document reviewing the disciplinary structures of Irish healthcare professional regulators conducted by the Health, Social Care and Regulatory Forum (HSCRF, 2015) identified a need for a more effective, supportive system for health cases. Concerns were expressed that practitioners suffering from ill health may be reluctant to disclose their illness or seek treatment due to the prospect of adversarial disciplinary proceedings.

The Shipman report highlighted that while it may be appropriate to use a rehabilitative approach for some health cases, it is not always suitable and carries risks that patients and the public will not be adequately protected. Particularly in cases where there might be evidence of conduct capable of amounting to serious professional misconduct with no real evidence of ill health (Smith, 2004).

In response to a recent British government proposal to introduce an alternative parallel process to handle health concerns about healthcare professionals, the PSA raised concerns that this could make it harder for regulators to protect the public and add an additional layer of complication and potential confusion for the regulator, registrant and the public. However, they acknowledged that the fitness to practise process could be streamlined to be faster and less onerous on registrants (PSA, 2021).

As we can see, this is a complex area with several factors to be considered and differing views on best practice. We consider there is a need to explore alternative models for the management of health cases, which should be included in an expert review of fitness to practise.

4.2.1.5 Sanctioning stage: complexity and delay

The final stage of the fitness to practise process is sanctioning. Weaknesses have been identified in how the sanctioning function is set out under the Act. This is examined in section 4.3 on governance below.

4.2.2 Competence assurance of pharmacy professionals

Pharmacists and pharmaceutical assistants must be registered with the PSI to practise in Ireland. This provides a level of assurance to the public that a pharmacist or pharmaceutical assistant has an appropriate qualification and has met the criteria for registration. As outlined above, the Act also gives the PSI the ability to impose conditions on registration through fitness to practise.

The Act places a number of responsibilities on the PSI to oversee the education and training of pharmacists in Ireland, including defining and ensuring standards of education and training and carrying out accreditation of pharmacy degree programmes. The Act also requires the PSI to ensure that all registered pharmacists undertake appropriate continuing professional development (CPD). A separate CPD system for pharmaceutical assistants is currently under development.

The Commission on Patient Safety and Quality Assurance (2008) highlights the importance of lifelong learning and professional development for healthcare professionals:

> *"It is clear that a health professional can no longer be regarded as 'trained for life' upon qualification. Instead what is required are systems of lifelong learning and professional development, with regular competence assurance to ensure that there is a workforce of skilled professionals who are fit for purpose, competent in managing patients' needs, aware of the limits of their own competency and adaptable and capable of responding to changing needs..."*

Although the Act provides for mandatory CPD, it does not set out a framework for the competence assurance of pharmacy professionals. There are limitations to systems based primarily on mandatory CPD, as they do not generally assess the effectiveness of the CPD and whether this leads to good health outcomes for the public (Austin and Gregory, 2017). Other regulators have explicit functions concerning the competence assurance of professionals.

The Ontario College of Pharmacists (OCP) also requires pharmacy professionals to participate in CPD; however, CPD is only one component of their revised Quality Assurance programme, which aims to take a right-touch, risk-based approach and reflect evolving public and patient expectations. While all pharmacists must undertake CPD, pharmacists on the patient-facing register must also periodically undergo online knowledge assessment and practice assessment at their place of practice. These quality assurance activities are designed to help pharmacy professionals deliver safe care to patients and to identify gaps in their practice and validate what they are doing well. There are additional safeguards and competence assurance requirements in place for pharmacists who wish to move from the non-patient-facing register to the patient-facing register (Ontario College of Pharmacists, 2022).

There is currently 'no single "gold standard" quality assurance mechanism to ensure maintenance of competence of practitioners' (Austin and Gregory, 2017), and 'this continues to be an area in which 'good' or 'best' practice is still emerging' (Medical Council of New Zealand, 2018). However, there are limitations to systems based primarily on mandatory CPD. We see the need to commission an expert review to explore competence assurance mechanisms under a reformed Act and how these could provide continued assurance that patients receive safe and high-quality pharmacy care and services, now and into the future.

The case for Reform - Regulation of pharmacy professionals

Fitness to practise structures and processes

Lengthy and complex fitness to practise procedures present risks to patient safety. They can act as a deterrent to the public, healthcare professionals and employers from making complaints and ultimately undermine public confidence in the regulatory system.

The fitness to practise system is a long, inflexible process with duplication of decision-making and unnecessary complexity across a number of areas:

- The interim suspension process, where PSI is concerned that a pharmacist or pharmacy presents an immediate safety risk to the public is unsuitable when responding to urgent risks to patient safety.
- The Act provides a limited set of tools to triage or investigate complaints at the screening stage of the process. The effect of this is that the bulk of the investigation and decision-making happens much later. There are no provisions under the legislation to take an alternative action such as issuing advice or warning letters to the registrant who is the subject of a complaint.
- We have concerns that the current process for managing health cases is overly adversarial. In turn, this could present a risk to patient safety as it may discourage pharmacists from seeking support or an employer or colleague from raising a concern to the regulator about the health of a registered pharmacist.

Fundamental reform of our entire fitness to practise system is urgently needed from the screening to the sanctioning stage to safeguard the public interest and protect patients from harm. We believe that reform should be supported by an expert review in this area and that this should include an exploration of alternative models for the management of health cases.

We consider that the following research question should be examined and developed further as part of commissioning an expert review in this area.

1. **Describe the approaches used in the fitness to practise processes of health and social care regulators in other jurisdictions including but not limited to:**
    a. Mechanisms for the management of immediate safety risks
    b. Processes in place for the screening and triaging of complaints
    c. How health cases are managed
    d. Sanctioning processes
    e. Effectiveness of the fitness to practise system

Competence assurance of pharmacy professionals

The Act places a number of responsibilities on the PSI to oversee the education and training of pharmacists in Ireland and to ensure that all registered pharmacists undertake appropriate CPD. There are limitations, however, in what mandatory CPD systems can achieve in relation to the continued competence of healthcare professionals.

We see the need to commission an expert review to explore competence assurance mechanisms under a reformed Act and how these might provide continued assurance that patients receive safe and high-quality pharmacy services, now and into the future.

We consider that the following research question should be examined and developed further as part of commissioning an expert review in this area.

1. **Describe the mechanisms used by health and social care regulators in Ireland and in other jurisdictions to assure the continued competence of health and social care professionals.**

4.3 Governance structure and role of Council

The PSI is governed by a 21-member Council responsible for setting and overseeing PSI strategy and governing the functions of the PSI in the public interest. The Act sets out the role, structure and functions of Council and has put in place a number of fundamental components of good governance, including a non-pharmacist majority, audited accounts and annual reporting to the Minister. The Act also sets out procedures on how often Council must meet and how it should carry out its functions.

A 2016 review of PSI governance by the Charted Institute of Public Finance and Accountancy (CIPFA, 2016) highlighted several areas of good governance practice, including openness and transparency, governance policies and procedures, leadership capacity and risk management (CIPFA, 2016). The requirement for the PSI Council to submit a statement of strategy, business plan and annual report to the Minister as prescribed by the Act was highlighted by the Commission on Patient Safety and Quality Assurance (2008) as a positive measure to strengthen our accountability to the Government. The PSI implementation of the Code of Practice for the Governance of State Bodies (The Department of Public Expenditure and Reform (DPER), 2016) provides additional corporate governance assurances to the public in terms of the underlying principles of good governance: accountability, transparency, probity and a focus on the sustainable success of the organisation over the longer term.

The Commission on Patient Safety and Quality Assurance (2008) highlighted strengthening governance and accountability arrangements across the health system as a significant element of health service reform. The Code of Practice also emphasises that all State bodies, including regulatory bodies, are responsible for implementing good corporate governance standards.

Despite many strengths in the governance structure and corporate governance processes of the PSI, the Act presents a number of challenges for the PSI Council in carrying out its responsibilities, including challenges relating to the size, structure and role of Council.

Key issues discussed in this section include:

- The relatively large size of the PSI Council presents a number of challenges in terms of managing meetings and achieving a quorum. As part of more recent wider regulatory reform to improve coordination, communication and greater overall effectiveness of decision-making, there has been a shift towards smaller boards and competency-based appointments.
- Furthermore, Council's role in the fitness to practise system often duplicates decision-making. It creates additional delays in cases being concluded and impacts Council's strategic performance and time to devote to its other functions, including developing policy, strategy, and governance.

4.3.1 Size and structure of the PSI Council

The PSI is governed by a 21-member Council with a non-pharmacist majority. All Council members are appointed by the Minister for Health in accordance with the Act. As shown in Figure 13 below, some Council members are appointed through the State Boards appointment process (as managed by the Public Appointments Service), and others are elected by pharmacist registrants.

The Act requires the chair of Council, the PSI President, to be a pharmacist member of Council and to be elected by Council members each year. The same process applies for the Vice-President. The term of the President is one year, subject to re-appointment for a maximum of two years, which presents challenges for continuity of leadership on the Council.

The relatively large size of the PSI Council presents a number of challenges in terms of managing meetings and achieving the quorum of 11 members required for meetings and decision making on a regular basis. This means that under the current Act, Council's progress on its remit can often be dependent to an extent on the scheduling of meetings. Among professional regulatory bodies in the UK, for example, there has been a clear shift towards smaller boards (PSA, 2013) as part of regulatory reform in an attempt to improve coordination, communication and greater overall effectiveness of decision-making and scrutiny (Council for Healthcare Regulatory Excellence (CHRE, 2011)).

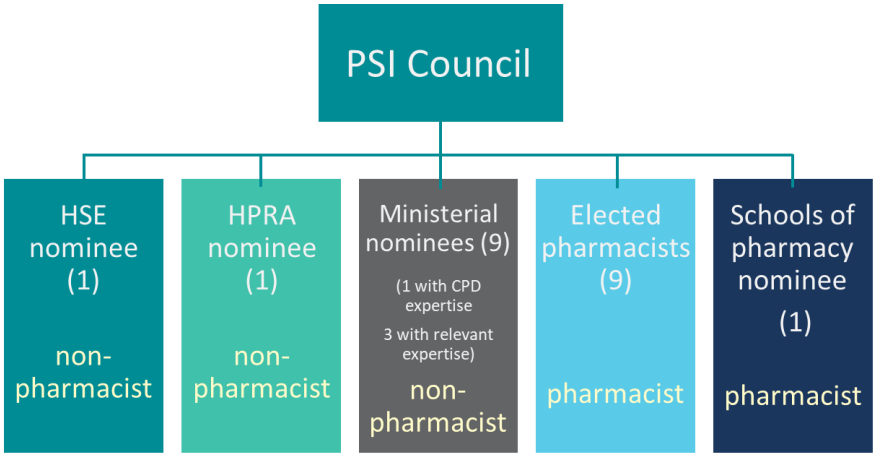

Figure 13 - Structure of the PSI Council, PSI Corporate Governance Framework, 2019.

The CIPFA Report on PSI governance concluded that:

> *'…the Council is too big to function at maximum effectiveness. In relation to decision-making, relationship-building, conducting business etc. Without being privy to the rationale and determination of the Council size by the Department of Health/Oireachtas when legislating, our preference would be to have a smaller Council but without diluting or changing the composition of the Council (for example, the balance of pharmacists and independents). This should be considered by the Department of Health/Oireachtas.'*

Similar findings were identified in a review of the governance structures of NMBI (Crowe Horwath, 2015), whose governance structures are broadly similar to the PSI. This report states that:

> ‘the size of the NMBI Board, at 23 members, is unwieldy. Best practice within corporate governance would suggest that the optimum size of a board should not exceed 10 or 11 members; some academic studies have suggested that the optimum size should be between 6 and 8…’

The Professional Standards Authority and UK Law Commission have both noted the shift towards boards that are smaller, non-representative of any particular group or constituency and where members are appointed against competencies rather than through election as a way of delivering more effective governance (PSA, 2013 & UK Law Commission, 2014).

The Commission on Patient Safety and Quality Assurance (2008) suggests that a lay majority Council and model where members are appointed rather than elected by peers could address ‘concerns about the tension that can arise in governance of these bodies between protecting self-interest and promoting public accountability’.

The Shipman inquiry found that one of the fundamental problems for the UK’s General Medical Council was the perception among doctors that elected members of Council were ‘representing’ them’ and that this created difficulties for council members to put the public interest first (Smith, 2004). Smith recommended that medical and lay members of Council should be selected for nomination by the Public Appointments Commission following open competition (Smith, 2004). The GMC have since moved to a smaller board with a balance between professional and public members, who are all appointed against competencies based on technical and public interest attributes by the UK Privy Council, including the Chair (GMC, 2019).

The CIPFA review of PSI governance in 2016 recommended that the PSI consider a smaller board where all members are appointed through the Public Appointment System (PAS), including those of the President and Vice-President (CIPFA, 2016). CIPFA strongly believed that having practising pharmacists on the Council is essential, however, it expressed concerns that the election process that determines pharmacy representatives on the Council leads to inherent risks and weaknesses. CIPFA recommended that, instead, appointments to the Council should be through the public appointment process using the required essential criteria.

4.3.2 Council’s involvement in sanctioning

As part of the post-inquiry phase of the fitness to practise process, the Act requires Council’s involvement in sanctioning. After the committee of inquiry has heard evidence, made findings and recommended sanctions, the Report of the Committee is then considered at a private meeting of the PSI Council, and Council decides what sanction to impose. As part of the process, all inquiry papers and transcripts are provided to the Council and oral/written submissions from legal representatives on both sides.

This duplication of decision-making in the fitness to practise process is time-consuming and adds additional complexity and delay to the process. A Better Boards review of PSI governance (2018) took the view that Council’s role in fitness to practise requires ‘extensive review’ as it impacted on Council’s strategic performance and that this requirement should be removed.

The HSCRF discussion document reviewing the disciplinary structures across all of the Irish healthcare professional regulators highlighted that sanctions hearings were occupying over 50% of each council’s meeting time, limiting the time that the councils could devote to their other functions

such as developing policy, strategy and governance, and that council hearings also involved significant legal and administrative costs. The discussion document concluded that 'councils should not be involved in sanctioning' (HSCRF, 2015).

The UK Law Commission also recommended that Council members of professional regulators should not be involved in the decision-making relating to the fitness to practise process (Law Commission, 2014).

The 2014 PSA fitness to practise review for the NMBI also observed that this additional layer of decision-making did not add any 'additional or meaningful layer of public protection', that an expert committee is well able to assess the evidence and come to an appropriate conclusion as to sanction and that the current process contained potential risks (PSA, 2014).

Both the PSA and the HSCRF considered that inquiry committees are better placed to decide what sanction should be imposed, given that they have heard all of the evidence in the case. They also highlight how the registrant has a route of appeal to the High Court for more serious sanctions, providing an additional layer of protection to the registrant's rights (PSA, 2014).

In summary, although there are many strengths in the governance arrangements set in place by the Act, there is a clear opportunity to streamline our governance structures and processes to ensure that Council can effectively deliver on its strategic remit and its role in protecting patients and the public.

Case for Reform - Governance structure and role of Council

In summary, despite many strengths in the governance structure of the PSI, the Act presents a number of challenges for the PSI Council in carrying out its responsibilities, including challenges relating to the size, structure and role of Council.

- The relatively large size of the PSI Council presents a number of challenges in terms of managing meetings and achieving a quorum. As part of more recent wider regulatory reform to improve coordination, communication and greater overall effectiveness of decision-making, there has been a shift towards smaller boards and competency-based appointments.
- Furthermore, Council's role in the fitness to practise system often duplicates decision-making. It creates additional delays in cases being concluded and impacts Council's strategic performance and time to devote to its other functions, including developing policy, strategy, and governance.

We believe that the governance structure and role of the PSI Council needs to be examined as part of a reformed Act, notwithstanding that this is an area that the Department of Health may wish to examine in a broader context across other health and social care professional regulators.

We consider that the following research question should be examined and developed further as part of commissioning an expert review in this area.

1. **Describe the approaches used in the governance of health and social care regulators in Ireland and in other jurisdictions including but not limited to the:**
    a. Size and structure of the governance board
    b. Appointment process for board members
    c. Role and responsibilities of the governance board, including any involvement in fitness to practise processes
    d. Effectiveness of the governance structures in place

5. Conclusion

This paper has drawn on our analysis and research on international regulatory principles and practices and our experience of implementing the provisions of the Act for almost fifteen years.

The most significant weaknesses that we have identified in the Act fall under three main areas:

- regulation of pharmacies
- regulation of pharmacy professionals
- governance structures and the role of PSI Council.

The legislative framework governing pharmacy service regulation is overly centred on the safe management of medicines when it should be centred on the patient and the safety and quality of the wide range of health services provided by pharmacies in the community, including the safe management of medicines. There is an urgent need for broader, revised regulations supported by outcomes-focused standards and strengthening of the governance and accountability structures for pharmacies.

Reform should also examine the use of a mandatory national system to report errors and incidents which occur in pharmacies. The lack of a such a system is a significant gap in the current regulatory model for pharmacies. In addition, the Act and the regulations place very limited statutory obligations on pharmacies to provide solicited information (information a service provider is required to provide under statutory obligations) to the PSI.

We have described how fundamental reform of our fitness to practise system is needed from the screening to the sanctioning stage to safeguard the public interest and protect patients from harm. Lengthy and complex fitness to practise procedures present risks to patient safety and can ultimately undermine public confidence in the regulatory system.

Finally, the Act presents a number of challenges for the PSI Council in carrying out its functions, including challenges relating to the size, structure and role of Council.

The issues set out in this paper are issues that we believe can only be addressed through legislative reform. As the pharmacy regulator, we have a duty to ensure that our regulatory system continues to be fit for purpose. Pharmacy practice developments and wider health system reforms continue to bring new regulatory demands and risks and require a more proactive, risk-based regulatory response. It is essential that how we regulate pharmacy in Ireland in the future is in line with national and international quality and patient safety recommendations and insights from key healthcare inquiries.

Ultimately, we believe that a fundamental review and reform of the Act is needed to ensure that the legislation which underpins the regulation of pharmacies and pharmacy professionals in Ireland is fit for purpose in protecting, maintaining and promoting the health and safety of patients and the public and that it supports effective pharmacy regulation now and into the future.

6. Next Steps - Development of policy proposals for reform

We envisage that the next stages in advancing the reform of the Act would involve the PSI commissioning in-depth evidence reviews/expert reviews to inform the development of evidence-based policy proposals for reform of the Act and that this would take place under the guidance of an advisory group comprising expertise from a number of key stakeholders, including external experts, registrants and patient representatives.

We also envisage that further stages of the project would involve significant public consultation.

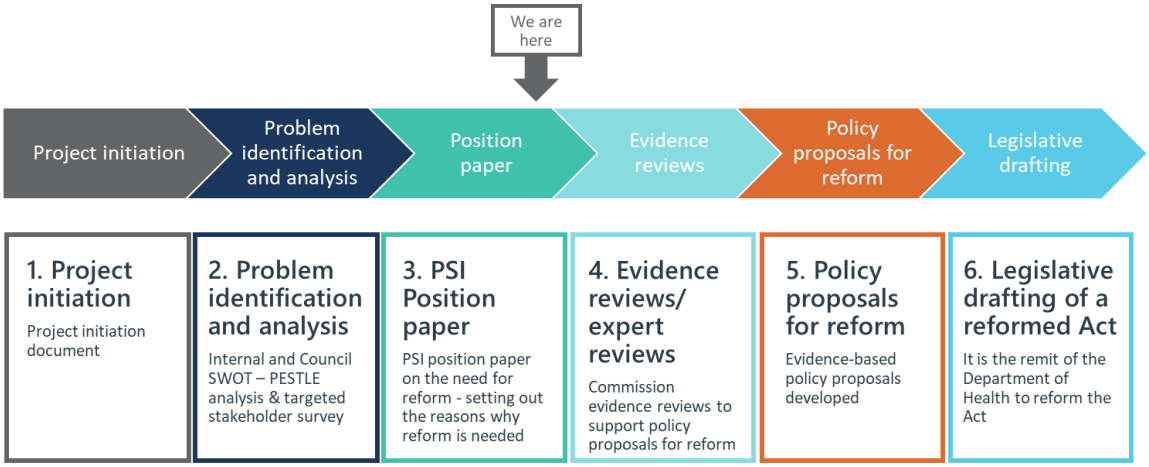

Figure 14 – Regulatory reform journey

We are committed to working in partnership with the Department of Health to determine the best way to advance the reform of the Pharmacy Act in the public interest.

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