

Corporate Strategy 2021-2024

Assuring Public Trust in Pharmacy
Through Effective Regulation

The original period of our Corporate Strategy
(2021-2023) has been extended by one year, to the
end of 2024.*



*At its [2 March 2023 meeting](#), the PSI Council agreed to extend the period of this strategy on the basis that the strategic objectives and development agenda are ambitious and provide enough strategic direction for an additional year, and acknowledging the impact that COVID-19 had on implementing objectives within the original timeframe. 2024 should be inserted where 2023 is currently stated in this document.

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For more information visit
our website www.psi.ie



Foreword from the PSI President and the Registrar

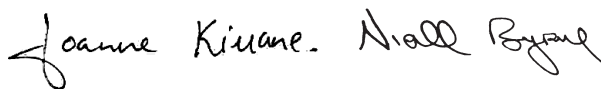
This Corporate Strategy 2021-2023 has been developed against the background of the COVID-19 global pandemic and the significant threat it represents to society and healthcare services in Ireland, including to pharmacists and community pharmacies.

The PSI acknowledges the selfless and dedicated work done by pharmacists and pharmacy teams across all settings during 2020 to support patients and the public throughout this unprecedented time. This remarkable work to reduce the impact of the crisis on the lives of all citizens is a testament to the professionalism and commitment of all involved. This has been the most challenging of years, one which has caused loss, anxiety, and disruption to many people. In these most difficult times, the commitment of our healthcare professionals has been a beacon of hope for all in society and something for which we all are very grateful.

In the PSI, we have worked relentlessly this year to support our registrants and play a full role in the public health response to the pandemic. In parallel, we have developed our Corporate Strategy for the period 2021-2023. One of our aims in this new strategy is to work with stakeholders to help make the pharmacy sector as resilient as possible for the future and to ensure that the learnings identified in confronting the pandemic inform our priorities over the coming years. Additionally, we highlight other meaningful areas where we seek to create an impact in the near future. These include our contribution to the implementation of Sláintecare and the development of integrated healthcare in Ireland. Furthermore, we are committed to continuing our work to reform and develop our regulatory frameworks to be the most effective type of pharmacy regulator – one which adds value for the public without imposing an undue burden.

We appreciate and value the contribution of all who have been involved in the development of this new strategy. This includes our registrants, various partners and other stakeholders, our staff, Council, and all those who contributed through our public consultation process. We hope we have incorporated their key concerns across our various objectives and planned actions.

While we made significant progress under our previous strategy during 2018-2020, we would have liked to have achieved more. This new strategy continues some of the work we already had underway while also setting a course for the next three years and recommitting the PSI to its core mission of ensuring safe and reliable care. In partnership with our stakeholders, we are confident that further and valuable progress on this mission will be made in the coming three years.



Joanne Kissane, MPSI
President

Niall Byrne
Registrar and Chief Officer

December 2020

About the PSI

The Pharmacy Regulator

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, is a public body established under the Pharmacy Act 2007 to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. There are 6,768 pharmacists, and 286 pharmaceutical assistants registered with the PSI. In addition, there are 1,968 retail pharmacies on our register, which includes 75 operating under the governance of hospital pharmacy departments.¹

What we do as the regulator

As the regulator of the profession of pharmacy, the PSI regulates all registered pharmacists, irrespective of where they work, be that in community pharmacies, or hospitals, in other areas of healthcare, or industry, education or regulation. We regulate the profession in accordance with the requirements set out in legislation and in the Code of Conduct – Professional Principles, Standards and Ethics for Pharmacists.² We do this in the public interest, which means that we work to assure the public that pharmacists are always working to high standards of practice and that the public can trust in the professionalism of pharmacists wherever they encounter the profession. In achieving this objective, the PSI works across the full extent of each pharmacist's professional career – from setting the standards for the education courses which lead to registration as a pharmacist to supporting continuing professional development (CPD).

The PSI is also charged with the responsibility to regulate retail pharmacies in Ireland. This is an important aspect of our public protection remit. Pharmacies are a critical part of our healthcare system, and it is essential that, as with all healthcare settings, the public can be assured that they provide a safe and reliable healthcare service. In this role, we are required to ensure that all pharmacies are properly registered and that each pharmacy is operating in accordance with pharmacy and medicines law. As part of our ongoing work to improve how we regulate and respond to the pandemic, we introduced COVID-19 Operational Standards for the retail pharmacy sector during 2020.

By introducing standards, we align pharmacy regulation with how healthcare settings are more generally regulated. We are committed to supporting pharmacies to meet these standards, and the relevant statutory requirements, as part of our ongoing mission to assure the public that pharmacies and pharmacists can be depended upon for safe and reliable healthcare.

As a public interest regulator, the PSI does not advocate for or represent pharmacists or pharmacies. While we have a high degree of respect for the healthcare practitioners, and all who work in the healthcare settings we regulate, we must, as a public interest regulator, also maintain our objectivity and independence. In keeping with this principle, the PSI must be careful not to become involved in the individual concerns of pharmacists, whether as employees or as business owners. Equally, the PSI must maintain an appropriate distance from the commercial interests of pharmacy owners and pharmacy businesses and their contractual relationships with the State and other parties.

However, a critical responsibility of every healthcare regulator is to take timely and effective action where there is a risk to the public. For the PSI, this means taking action in circumstances where it is clear that quality is not being maintained, where there is a clear risk to public safety, or where the behaviour of a pharmacist or pharmacy creates a serious risk to the public. When this happens, we will not hesitate to act in the public interest. In taking action, we will, of course, always act in ways that are fair to all involved, and we will use our statutory powers, both reasonably and proportionately.

¹ While PSI has a remit to regulate the "retail" supply of medicines through hospital pharmacy departments, we do not regulate the many other activities of pharmacy departments. Regulating these other activities is a matter to be considered as part of work ongoing in the Department of Health to develop an appropriate licensing system for hospitals in Ireland.

² Please see our website at https://www.thepsi.ie/gns/Pharmacy_Practice/code-of-conduct.aspx for more details on the Code.

Our ongoing responsibilities to the public

Our principal purpose as a regulator is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007, as amended, establishes the statutory role of the PSI as the pharmacy regulator. Under this legislation and all other applicable legal and public policy frameworks, the PSI must ensure that, on an ongoing basis, we:

- Operate fair, transparent, and efficient registration procedures for all registrants (pharmacists, pharmaceutical assistants, and retail pharmacies), and maintain the statutory registers,
 - Evaluate, for accreditation purposes, programmes of education leading to qualifications appropriate for practice as a pharmacist in Ireland,
 - Oversee the effective implementation of the mandatory system of CPD for pharmacists,
 - Promote and support professional practice by pharmacists and share information for the benefit of patients and the wider health system,
 - Communicate and engage with the public, the pharmacy profession, and our many other stakeholders to ensure our work is understood and informed by these stakeholders,
 - Assure the public of the quality and safety of community pharmacy services through ongoing programmes of quality assessment and oversight of compliance with essential safety requirements,
 - Undertake investigations into matters of serious concern regarding the actions of pharmacists and/or pharmacies and initiate enforcement actions, including prosecutions, where appropriate,
 - Manage the professional complaints process in accordance with the law, natural justice, and fair procedures,
 - Contribute to the ongoing review of new and existing pharmacy and medicines legislation, and contribute to public policy developments relating to our regulatory remit,
- Comply with our own external compliance obligations and with the Code of Practice for the Governance of State Bodies, which provides assurance that the PSI acts in accordance with best practice in the management and governance of public bodies, and
 - Operate prudent financial management practices and continue to steward all PSI funds so as to maximise the pool of financial resources available to deliver on our statutory functions.

Governance of the PSI

The PSI is a public body, which, by law, is independent in the exercise of its statutory functions.³ While independent, the PSI is also subject to public accountability requirements and, for these purposes, the PSI operates under the aegis of the Department of Health. In keeping with this principle, the PSI is required to report to the Minister for Health on various matters and to seek the consent of the Minister for Health in relation to, for example, the making of statutory Rules under the Pharmacy Act.

A 21-member Council governs the PSI, and the Minister for Health appoints each member in accordance with the provisions of the Pharmacy Act 2007. The Council is responsible for overseeing the delivery of the PSI functions in the public interest. This includes agreeing on the strategy for the PSI and ensuring that the strategic objectives are met.

The PSI Registrar (Chief Officer) is appointed under the Pharmacy Act and is responsible for leading the day-to-day work and operation of the organisation and seeing that the Council's strategy and decisions are implemented efficiently and effectively. The Registrar reports to the Council at each of its meetings on the organisation's activities and performance. All PSI staff are public servants and are recruited in accordance with public service recruitment principles. Staff numbers and grading are subject to oversight by the Department of Health, and staff are managed according to the policies set by the Department of Public Expenditure and Reform.

³ The PSI is self-funded through statutory fees levied on pharmacists and pharmacies.

Our Vision, Mission and Values

Our vision, mission and values that underpin our work in the PSI are set out in the diagram below. Additional information about our role and the work that we do is available on our website at www.psi.ie.

Our Mission

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

Our Values

Our values underpin how we deliver on our mission. They guide our behaviour, the expectations we set ourselves, and the experience of others who engage with us. They provide evidence as to our commitment to equality and human rights in how we fulfil our role.

Our values ensure that we achieve the objectives set in this Corporate Strategy in ways that are properly accountable and which meet with the high standards expected of public bodies and of the public servants who work within them.

More information about our role and the work that we do is available on our website www.psi.ie.

Our Vision

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



Serve the public

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



Everyone Counts

We value, appreciate and respect everyone we engage with.



Work Together

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



Lead by example

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



Embrace Change

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

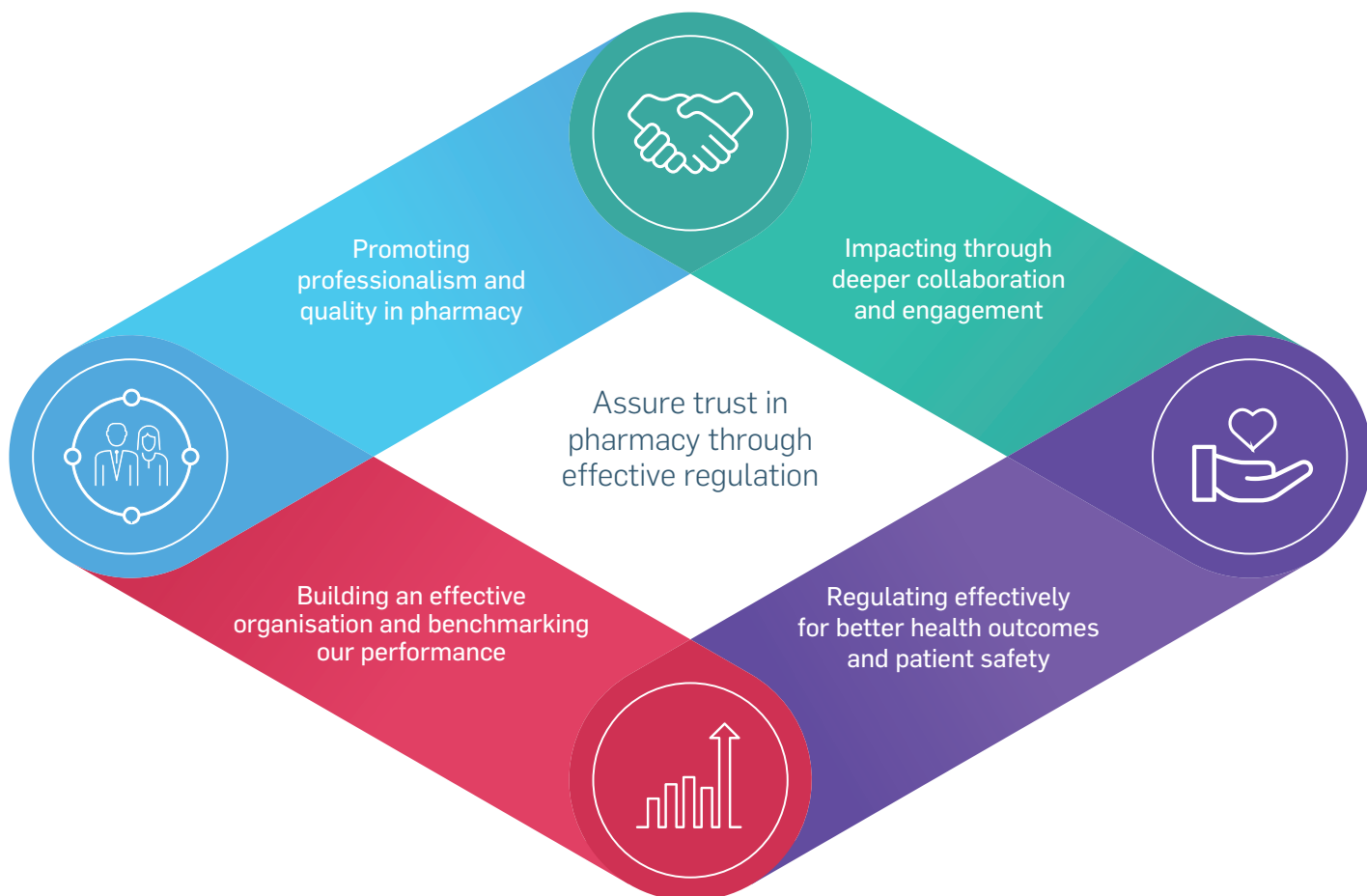
Looking Back

Progress made under our 2018-2020 Corporate Strategy

Why look back?

The PSI made a range of commitments in its 2018-2020 Corporate Strategy. Now that we are at the end of that three-year period, it is important and relevant to look at what progress we made and what we learned as a regulatory organisation over this period. This process of review is part of how the PSI reports back to its community of stakeholders, including the public. As with any plan, not everything developed over 2019-2020 as we anticipated when planning back in 2017. Nonetheless, and notwithstanding the impact of COVID-19 during 2020, we believe that we made substantial progress on our strategic change agenda over the last three years.

In Appendix 1, you can read our review of our progress under each of the four strategic results areas set out in our 2018-2020 Corporate Strategy.



Developing our Corporate Strategy 2021-2023

This Corporate Strategy 2021-2023 has been developed against the background of the COVID-19 global pandemic and the significant threat it represents to society and healthcare services in Ireland.

As the scope and potential impact of COVID-19 became apparent in early 2020, the Council noted at its meeting on 23 April 2020 that COVID-19 would significantly impact the strategic development process and on the PSI's operating environment. Nonetheless, the Council believed that it was still important for a strategy to be developed for adoption in December 2020. The Council also recognised that there were significant objectives under the 2018-2020 strategy to be carried forward into the next strategic planning period. Hence, the Council agreed that a follow-on to the 2018-2020 strategy, rather than a radical re-working, would be an appropriate and pragmatic approach for Council to adopt in the circumstances. It is

on this basis of a high degree of strategic continuity, rather than radical strategic change, that this Strategy has been formulated.

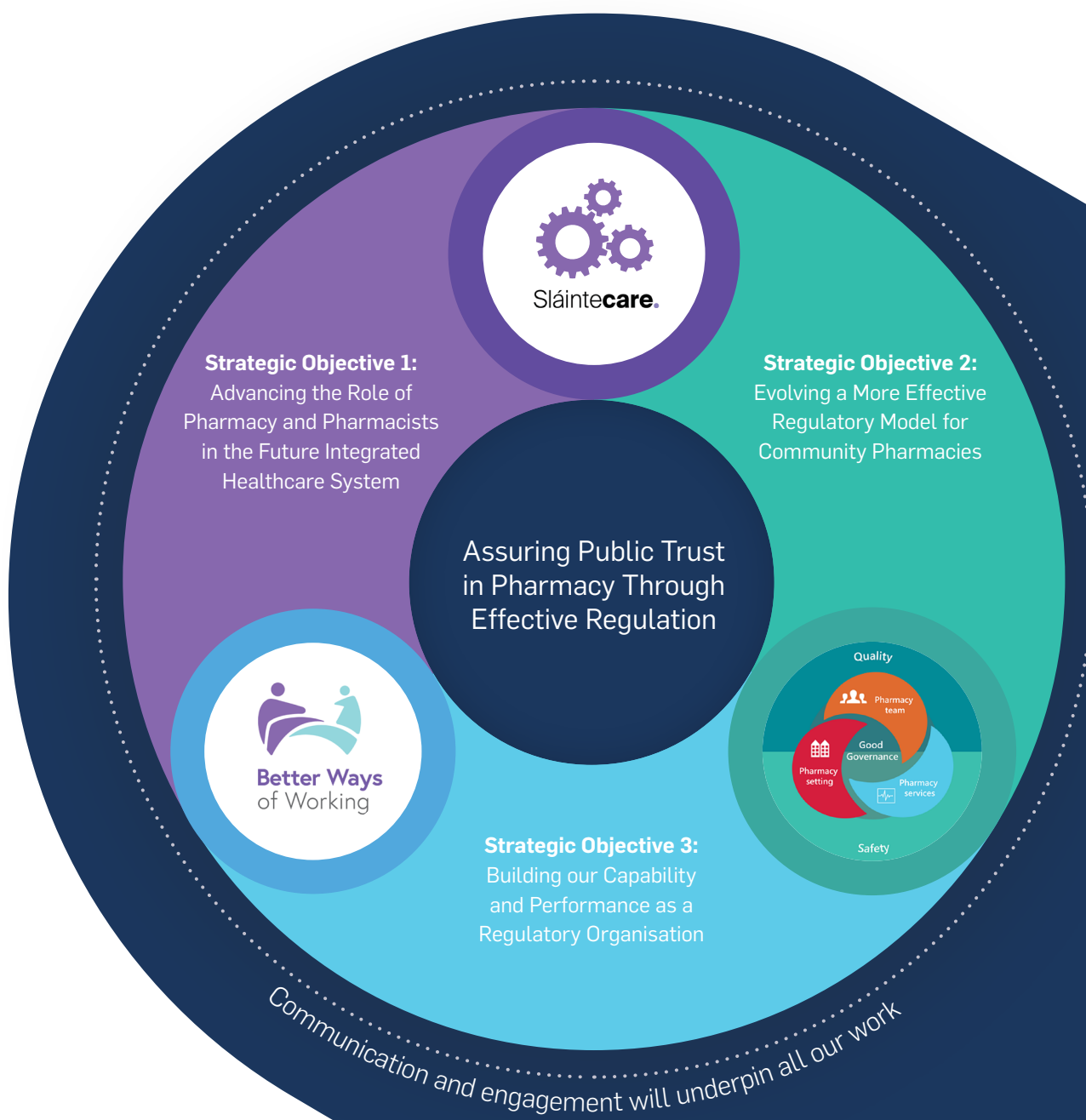
The PSI is grateful to all stakeholders who took the time to respond to the public consultation that we carried out during August 2020. More than 150 submissions were received in response to the consultation invitation.⁴

We have used the strategic planning tools PESTLE and SWOT in drafting this Strategy. Please see Appendix 2 for the environmental analysis that the PSI Council considered in drafting the strategy and further details on the strategy development process.

⁴ The consultation report can be found on our website <https://www.thepsi.ie/consultations.aspx>

Strategy Overview

Our Strategic Goal remains to assure public trust through effective regulation. We plan to advance achievement of this Goal through actions under three strategic objectives.



Objectives and Actions 2021-2023

This Corporate Strategy consists of four elements:

A central organisational goal,

which provides the focus for our work over the next three years – *assuring public trust in pharmacy through effective regulation, and*

Three strategic objectives,

each with defined actions designed to advance the achievement of our central goal over the next three years – each is described below.



Strategic Objective 1: Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System

The development of an integrated healthcare system, as advocated under Sláintecare, is a core policy objective of healthcare reform in Ireland. Compounded by the impact of COVID-19, there will continue to be increased demand placed on the health service and healthcare provision by pharmacists and pharmacies. The means of providing safe healthcare and services will evolve over the coming years in the face of opportunities and challenges, some known and some unknown.

We will continue to work with others to ensure that the regulator facilitates pharmacists across all healthcare sectors to play a full role within the future integrated healthcare system. We will work with all relevant stakeholders to ensure that pharmacists' education, including continuing professional development (CPD) and practise standards, evolve to meet these changes. We will ensure that changing approaches to pharmacy practice will continue to be underpinned by regulatory safeguards that are proportionate while assuring ongoing public confidence and trust in pharmacy practice. We will utilise our knowledge and research to inform policy development and support legislative changes relating to pharmacy and healthcare reform into the future.



Actions

- Engage with the Department of Health on Sláintecare implementation with a focus on actions to facilitate evidence-based practice by pharmacists and advanced practice, where this is required by patient need and public policy.
- Engage and collaborate with the Department of Health on other policy developments relating to pharmacy, such as the national response to COVID-19, national patient safety strategies, national policy on anti-microbial resistance and the forthcoming strategic review of the current community pharmacy contract.
- Work with the HSE to ensure that pharmacy at community level is integrated into the work on developing community healthcare networks.
- Collaborate with pharmacists, pharmacies and other stakeholders on patient safety and quality initiatives, including ensuring positive work environments for pharmacists.
- Work to identify, and respond to new risks and challenges for pharmacists as emerging service delivery models bring about potential new pharmacy services using new technologies.
- Review our model of CPD to ensure it supports future pharmacist practise in all settings, that it is agile, adaptive and sustainable, and that it delivers value for money.
- Take steps to identify and mitigate risks to the continued availability of the professional pharmacist workforce, particularly within the community pharmacy sector.
- Research and design a rolling patient experience programme to ensure we hear patient voices and understand key patient needs so that the PSI can help improve the quality and safety of pharmacy services provided to patients in Ireland.
- Stand ready to engage with any feasible and sustainable initiative to develop a professional and independent leadership framework or body for Ireland's pharmacy profession.

Strategic Objective 2: Evolving a More Effective Regulatory Model for Community⁵ Pharmacies

Community pharmacies are a highly accessible part of the healthcare system. There are 20+ million visits to pharmacies each year, and 80+ million items are dispensed annually. In addition, other essential healthcare services, such as vaccinations and the provision of professional advice by pharmacists, are provided through community pharmacies. As the regulator of community pharmacies, the PSI has a statutory responsibility to ensure that all of this vital healthcare activity is regulated to a high and consistent standard.

We are keen to see further and ongoing change and development in the model of regulation in pharmacies. We intend to increase the information published as a result of our work in regulating pharmacies so that everyone can learn from the regulatory process, both pharmacists and the public. We also want to work with the Department of Health to ensure that the regulatory data and learnings arising from our work across community pharmacies are used to inform policy monitoring and ongoing policy development. We plan to continue our work on developing regulatory standards in consultation with stakeholders and to build awareness among the public of the quality of service that can be expected by all who receive healthcare advice and treatment in a community pharmacy.



Actions

- Develop a standards-based regulatory model for community pharmacies that, subject to Department of Health agreement, will be supported by revised and updated Retail Pharmacy Regulations and/or amendments to the Pharmacy Act, 2007.
- Further develop regulatory standards to support those in key governance roles across the community pharmacy sector (owners, superintendent, and supervising pharmacists) to deliver safe and reliable services, particularly during the COVID-19 pandemic.
- Develop new ways to report to stakeholders on the learnings and data gathered through our regulatory work in pharmacies, and inform the public as to how pharmacies are performing against the PSI standards.
- Propose a prioritised programme of reform of the current Pharmacy Act to the Department of Health and work on its progression over the life of this Strategy.
- Operationalise our regulatory risk statement policy as a key tool in managing incoming information, intelligence, and strategic learning to help identify, and respond to risks to patient safety and/or serious concerns as to the quality of community pharmacy services.
- Recognising the importance of supporting a strong culture of safety and learning across the community pharmacy sector, work with stakeholders to ensure a clear focus on the role of incident management, quality audit and inter-professional communication in providing safe and reliable services to patients.
- Promote positive understanding among pharmacists of the Code of Conduct and work to ensure that pharmacists adopt the essential principles set out in the Code in their routine practice.
- Engage with other regulators on developing a community of practice for regulators in Ireland.

⁵ The Pharmacy Act refers to "Retail Pharmacy Businesses". In this document, we are using the term "Community Pharmacy" to refer to all pharmacies that provide medicines and other pharmacy services to the public at community level.

Strategic Objective 3: Building our Capability and Performance as a Regulatory Organisation

In common with all organisations, the PSI must continuously strive for improvement and to innovate. We must also work in a coordinated fashion to make the most effective use of our resources, people, and time. Following on from our previous Corporate Strategy, we will continue to focus on building our capability and performance as a regulator. This will see us completing our current business transformation programme during the life of this Strategy and moving to utilise new systems, data, and digital tools to support our regulatory mission.

We remain committed to our ongoing programme of organisational development and building on our work to date in this area, including creating a positive work environment for staff and creating an organisational structure that works to help us achieve our mission and our strategic objectives. We are also committed to retaining and building upon our current 4-Star quality recognition under the European Foundation for Quality Management. These initiatives will ultimately benefit all who engage with us.



Actions

- Complete our current programme of business transformation.
- Utilise our new digital systems to support our regulatory purpose and mission.
- Implement revised organisation and management structures to support the achievement of our strategic goals.
- Complete our strategic financing review.
- Invest in our website and social media communication channels.
- Take actions to be a workplace of choice.
- Maintain our current 4-star recognition with the European Foundation for Quality Management (EFQM).
- Ensure we continue to be a safe and caring employer, particularly, in the context of COVID-19.

Communications and Engagement

Underpinning our strategy will be our commitment to communicate widely and to work extensively with others. In keeping with our approach under our 2018-2020 strategy, we will continue our practice of regularly engaging with the Department of Health, HSE and other public bodies, other regulators, pharmacy service users, the public and our registrants. This engagement will also include partnering with others to advance our mission and achieve efficiencies in our regulatory functions.

This engagement is central to the PSI's remit in providing opportunities to learn from others and to inform our work. We also look forward to building greater awareness of our role as the pharmacy regulator so that people are aware of the standards they can expect from pharmacists and pharmacies. We want to ensure that we are a relevant regulator which plays a positive role in supporting the overall healthcare system in Ireland to deliver safe, reliable and cost-effective care.



Key Outcomes 2021-2023: How will we know we have succeeded?

Strategic Objective 1: Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System

- The PSI has facilitated initiatives arising from Sláintecare implementation and other initiatives relating to pharmacy, such as the national response to COVID-19, proposals for advanced practice for pharmacists and the pharmacy component of community healthcare networks.
- Effective partnerships are in place with our stakeholders and result in the required initiatives to increase patient safety and quality in pharmacy practice.
- A new CPD model that ensures good professional practice and ongoing learning is in place, and an appropriate CPD process for pharmaceutical assistants is in operation from October 2022.
- The risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy in Ireland are assessed, and mitigating actions agreed with relevant stakeholders are being implemented.
- A rolling patient experience programme is in place, and the experiences of the patient are monitored, analysed, and used for the required actions and adaptations of practice.
- The PSI has facilitated, if possible, the development of a professional and independent leadership framework or body for the pharmacy profession in Ireland.

Strategic Objective 2: Evolving a More Effective Regulatory Model for Community Pharmacies

- The COVID-19 Operational Standards and other relevant Standards operate on a statutory basis, are adopted by the pharmacy sector, are seen as of value, and are supported by revised Retail Pharmacy Business Regulations.
- The PSI is acknowledged as having supported those in key governance roles across the community pharmacy sector throughout the COVID-19 pandemic.
- Transparency and learning are strengthened by the increased publication of information from the PSI's work in regulating pharmacies.
- A review of models of pharmacy regulation and other relevant healthcare services is conducted, and a proposal for Reform of the Pharmacy Act, 2007, is presented to the Department of Health.
- Our Regulatory Risk Statement is fully operationalised, and all risk analysis, response processes and procedures are in place.
- Engagement with pharmacists demonstrates that the Code of Conduct is understood and adopted by pharmacists as a matter of routine practice.

Strategic Objective 3: Building our Capability and Performance as a Regulatory Organisation

- The PSI is a "digital-first" regulator with a "Single Customer View".
- A new organisation and management structure that supports the digital-first model and the achievement of our strategic goals is implemented in the PSI.
- A finance model is in place that will encompass an agreed expenditure model to underpin the 2021-2023 Corporate Strategy.
- A new, contemporary, and flexible PSI website that will support and facilitate all of the PSI's digital offerings and enhance visitor engagement contributes to awareness-raising about the PSI's roles for all customers.
- The PSI retains its 4-Star recognition with the European Foundation for Quality Management.
- The PSI is a workplace of choice proven by focused programmes of being a safe and caring employer, not least during the COVID-19 pandemic.
- A community of practice for regulators in Ireland is established, with the PSI having played a lead role.

Implementing the Strategy and Monitoring Progress

This strategy will be implemented over three years, from January 2021 to December 2023.

As the Strategy represents an integrated three-year programme, some actions will be implemented over more than a single year. We will set out the specific actions to be progressed each year in our Annual Service Plan and, as the Strategy progresses, we will also show which actions are being carried out on a multi-year basis.

Progress will be monitored on an ongoing basis through oversight arrangements via the PSI Advisory Committees and will be reported to the PSI Council at each of its public meetings. Full details will also be published in each year's Annual Report.



Acting to protect and
promote the health, safety
and wellbeing of patients
and the public

Looking Back

Progress made under our 2018-2020 Corporate Strategy

Why look back?

The PSI made a range of commitments in its *2018-2020 Corporate Strategy*. Now that we are at the end of that three-year period, it is important and relevant to look at what progress we made and what we have learned as a regulatory organisation over this period. Undertaking this review is part of how the PSI reports to its community of stakeholders, including the public. As with any plan, not everything has developed as we anticipated. While our plans for 2020 have been significantly impacted by the COVID-19 pandemic, we believe that there has, nonetheless, been substantial progress on our strategic change agenda.

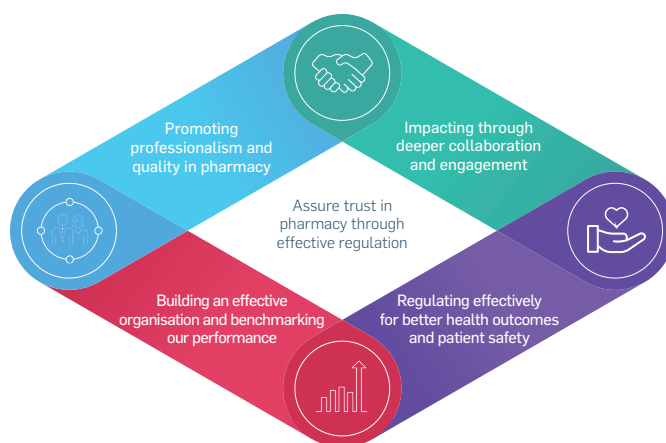


Our 2018-2020 Strategy

Our Corporate Strategy for 2018-2020 consisted of five key elements:

- One organisational goal. This statement was intended to make a clear commitment that the PSI would work to "Assure trust in pharmacy through effective regulation" over the three years of the Strategy.
- Four strategic results areas under which we committed to delivering specific results which, when taken together, would see us make significant progress towards our central goal. Our intention, as an organisation, was that by 2021, the PSI would be more developed, more effective, more capable and would be able to demonstrate that its work had impacted positively on assuring trust in pharmacists, in pharmacy services and had resulted in better health outcomes for the public

In the following paragraphs, we review our progress under each of the four strategic results areas.





Promoting professionalism and quality in pharmacy

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



One of our principal achievements in this area was the publication in 2019 of the revised Code of Conduct for Pharmacists. This was the result of extensive research and consultation. The Code is a critically important document for all pharmacists, particularly those who practise in patient-facing roles. We also promoted the recommendations of our *Future Pharmacy Practice Report* to policymakers and ensured we made clear the linkages to the recommendations of the *Sláintecare Report*. We oversaw the implementation of CPD for pharmacists and the roll-out of the reforms underpinning the 5-year integrated Master's Degree in Pharmacy (MPharm). We reviewed the current Core Competency Framework for pharmacists. We were, and continue to be, involved in various activities relating to Brexit and its implications for pharmacy and pharmacists in Ireland.

COVID-19 impact: As part of the response to the pandemic, we have worked during 2020 to support the Department of Health and the HSE, putting in place measures to protect public health, including extending the range of locations where pharmacists can administer vaccinations. Among other activities, we facilitated the temporary restoration of pharmacists and pharmaceutical assistants to the registers and revising statutory Rules to streamline processes to ensure as many pharmacists as possible are available to meet public health needs. We issued guidance to the profession to support pharmacists in extending influenza vaccination to children.



Impacting through collaboration and engagement

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

During 2018-2020, we have increased positive collaboration with pharmacists and the retail pharmacy sector. We recognise that this remains a work-in-progress, as is generally the case for regulators of all types. We took steps to increase levels of engagement with the profession, particularly during the review of the Code of Conduct. We also undertook a series of regional seminars during 2018 to meet with superintendent pharmacists and engage with them on our strategic objectives. We established a collaborative process to develop governance and accountability standards for retail pharmacies. Our experience is that the pharmacy profession is very willing to engage with the regulator once we are clear that the topics are relevant and important to their roles as healthcare practitioners. We also recognise the importance of our ongoing involvement with representative bodies and their role concerning change and quality improvement in pharmacy.

COVID-19 impact: The PSI has worked with its stakeholders to mitigate the impact of the crisis. It was a PSI initiative that led to the establishment of the Community Pharmacy Contingency Planning Forum in late April 2020. We developed and published planning guidance in cooperation with the HSE and guidance to support the safe delivery of medicines to people shielding at home. We have also had extensive engagement with the Department of Health throughout the crisis.



Regulating effectively for better health outcomes and patient safety

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



Regulatory reform and ongoing review are an important matter for all regulators. From 2018 to 2020, we have worked to make the case to the Department of Health that reform of the Pharmacy Act is now required. We believe we have made progress on this, but, unfortunately, further progress during 2020 has been seriously impacted by the COVID-19 crisis. Nonetheless, this remains a significant ongoing objective for inclusion in our next strategy. We made meaningful progress on developing Standards for Governance and Accountability in Retail Pharmacies (see under COVID-19 impact), and we evolved and published our Regulatory Risk Statement. We invested in our internal learning as a regulator and in training and developing key staff in areas such as regulatory design and healthcare quality and safety.



COVID-19 impact: In recognition of the threat that COVID-19 poses to the ongoing provision of healthcare via retail pharmacies, we undertook a rapid process to develop our COVID-19 Operational Standards for Pharmacies. This was done in close collaboration with stakeholders, including practising pharmacists.

We believe this is an excellent example of flexible and adaptable regulation, demonstrating that the PSI is a relevant and engaged regulator. We plan to build on this positive experience to progress further initiatives under our next Strategy.



Building an effective organisation and benchmarking our performance

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

During 2018-2020, we undertook work to examine our organisational structures to ensure these could effectively support the implementation of our strategy. Subsequently, we engaged consultants to assist us in developing the kind of structures we need for the future – a process that will take us into 2021. This process will also integrate with the extensive work we have been undertaking since 2018 to transform the PSI into a 'digital first' organisation. This work will begin to deliver results later in 2021 and represent a critical investment of PSI funds in the organisation's future effectiveness. We have developed the PSI as a positive and supportive workplace, where all staff work towards achieving our public-interest mission. We have a HR strategy in place to guide us in this work. New roles have also been developed, which are enhancing our capacity to deliver our Corporate Strategy. These roles are all critical assets as we move into 2021-2023. As testimony to our commitment to quality, we worked during 2018 and 2019 to meet the standards for accreditation under the European Foundation for Quality Management (EFQM). We were awarded 4-Star Recognition in late 2019.

COVID-19 impact: In response to the pandemic, and in accordance with Government policy, all PSI staff moved to home working from 19 March 2020. Despite the redeployment of some staff to national COVID-19 related activities, the organisation has continued to operate to a high standard of efficiency. PSI staff has urgently redirected their resources to new priorities at short notice with a resultant impact on the achievement of planned objectives. PSI staff have successfully responded to these pressing matters while also working to maintain our essential regulatory processes.



Appendix 2

Developing our Corporate Strategy 2021-2023

Coronavirus
COVID-19



Consultation to inform this Strategy

The PSI Corporate Strategy 2021-2023 has been developed in consultation with our stakeholders, including PSI registrants, patients and healthcare advocates, the Department of Health, representative organisations, the PSI Council and Committee members. Our process commenced with the appointment, at its meeting on 13 February 2020, of a subgroup of the PSI Council to work with the Executive on the development of the Corporate Strategy.

The PSI Council and Executive adapted to remote working over the year. The subgroup and wider Council met on a number of occasions to discuss the draft strategy. A public consultation process was open from 30 July until 21 August 2020, and more than 150 submissions were received. The Department of Health was also consulted on the draft strategy and contributed significantly in November 2020.

Consideration of COVID-19

The Corporate Strategy 2021-2023 has been developed against the background of the COVID-19 global pandemic and its significant threat to society and healthcare services in Ireland, including pharmacists and community pharmacies. The PSI recognises the contribution that continues to be made by pharmacists working across our healthcare services as well as those working in industry, research, education, regulation, and all other sectors. The PSI also acknowledges the notable contribution of the other pharmacy team members, including pharmaceutical assistants and technicians, who work as part of the team in community and hospital pharmacies, and in healthcare sectors across Ireland. Part of our intention in this new strategy is to work with stakeholders to help make the pharmacy sector as resilient as possible for the future and to ensure that the learning from confronting the pandemic informs our objectives over the coming years.

Analysing our environment

As set out in the previous section of this document, we have reviewed the actions we have taken over recent years, and particularly under our “Corporate Strategy 2018-2020”, to develop an effective system of public-interest regulation covering both pharmacists and pharmacies. We have considered how we have developed as an organisation and what we still need to do to become the most effective regulator. In the following paragraphs, we reflect on how we think our operating environment will develop over the coming three to five years. Undoubtedly, the impact of the pandemic, and how it may yet evolve, creates significant uncertainty, and this is a fact which we need to reflect in our overall assessment.

In considering what operating environment the PSI may face over the coming period, we must reflect on our anticipated external and internal environments, our purpose as set out in legislation, our organisation values, our mission, and our vision. As a public body involved in healthcare regulation, we must also ensure that our strategy and objectives align with those of the Department of Health, particularly regarding the continued implementation of the *Sláintecare* reform programme and the priorities set out in the recently-published *Programme for Government*. We are also mindful of our statutory public sector duty to equality and human rights in the conduct of our functions and our strategic planning, as required under section 42 of the Irish Human Rights and Equality Commission Act, 2014.

Two useful tools often used in strategic planning are the PESTLE⁶ and SWOT⁷ analyses. In drafting this Strategy, the Council has considered the analysis set out in the following two tables.

PESTLE Theme	Factors
Political	<ul style="list-style-type: none"> • COVID-19 national health emergency • Government and Ministerial change and new Programme for Government • Healthcare quality and safety – accountability and clinical governance • Sláintecare implementation – Community healthcare networks • National, coordinated pharmacy policy • New HSE pharmacy contract negotiations and outcomes • Response to and impact of Brexit (multi-factor) • Regulatory expectations and demands – attitudes to regulation – service governance
Economic	<ul style="list-style-type: none"> • Strategic funding • Pandemic-related global recession • Evolving pharmacy provision of care/delivery • Pharmacy ownership changes - impacts for registration and funding
Social	<ul style="list-style-type: none"> • Pharmacist workforce issues – career prospects, community pharmacist retention and ongoing provision of patient care • Public health need and enhanced pharmacist provision of care • Pharmacist specialism or evolution – legal and regulatory considerations • Demographic impactors – broad population and pharmacist population plus across other relevant healthcare professions, for example, GPs
Technological	<ul style="list-style-type: none"> • E-health delivery model and timeframe • Electronic interfaces and changed expectations (COVID-19 related) • Automation in pharmacy dispensing • Advances in pharmaceutical science and medicines • Digital-first provision of services in the public sector • Digital security threats
Legal	<ul style="list-style-type: none"> • Implementation of relevant provisions under the Regulated Professions (Health and Social Care) (Amendment) Act 2020 • Reform of current legislation – an adaptable and sustainable model of regulation within a good-practice corporate governance framework • Clarity about the regulation of Retail Pharmacy Businesses under the governance of hospitals • Patient Safety Bill and mandatory disclosure • Meeting compliance expectations for public bodies
Environmental	<ul style="list-style-type: none"> • Pandemic response and future preparedness • Internal and externally sustainable practices • Business continuity planning and workplace safety • Evolving international regulatory trends and practices

⁶ Refers to Political, Economic, Social, Technological, Legal and Environmental factors that are relevant to the organisation.

⁷ Refers to the Strengths, Weaknesses, Opportunities and Threats relevant to the organisation and its environment.

Strengths

- Council commitment to the strategic mission
- Strong belief in public interest purpose amongst PSI staff and commitment to necessary organisational change
- Strong belief in our values
- Good working relationships with the Department of Health
- Good IT infrastructure developed and in the process of development
- Ongoing investment in staff development with a focus on the strategic direction of the PSI
- Flexible approach and ability to adapt (COVID-19 demonstrated this capability)
- Established regulatory approaches and a good record of delivery of these
- Positive financial position
- The eagerness of pharmacists and sector to evolve and develop professionally
- EFQM recognition achieved at 4-Star level

Opportunities

- Opportunities and learnings arising from COVID-19 – safety collaboration, Operational Standards, HSE Continuity Planning Forum
- Advancing a new legislative model for better and more effective regulation
- Opportunity for new service provision led by patient and policy need, including via new contract negotiations
- Sláintecare implementation – Community Healthcare Networks and integrated care developments
- Scope to work with the Department of Health to influence pharmacy policy at national level
- E-health and technology changes
- Collective/shared regulatory development with other regulatory bodies – learning and development opportunities
- Business and digital transformation
- Regulatory risk- better use of PSI data and information
- Scope to build enhanced relationships with registrants

Weaknesses

- Constrained by legislation to respond to changes in sector/ adaptability of current legislation to modern regulation
- Aspects of the Council's governance structures
- Recruitment challenges - the speed of sanction and limitations as to flexibility within a small public service organisation
- Lack of experience from other domains of regulation
- Weaknesses in the alignment of organisational structure to the strategic direction
- Paper-based business processes still operating
- Perceptions of, and awareness of, pharmacy within the health system and by public
- Weak engagement with pharmacy users/public
- Cost and structure of the current CPD model
- The difficulty of demonstrating the impact of our regulatory work

Threats

- Our relevance as regulator may be questioned if pharmacies are inconsistent in their responses to COVID-19
- Global recession and public funding impacts as a result of the pandemic
- Uncertainties arising from possible unknown evolution of the pandemic
- Changing Government and Ministerial priorities
- Managing expectations of all stakeholders
- Delays in healthcare service delivery changes
- Changed services and keeping regulatory pace
- Satisfaction levels in pharmacist workforce
- PSI staff changes and potential loss of corporate knowledge
- The PSI need to carefully observe all COVID-19 workplace safety issues
- Brexit impacts – potential for unknown and/or unexpected events during 2021/2022
- Cybersecurity/data loss threats

Arising from this analysis, we have further considered a number of other relevant matters in developing this Strategy. These include:

- The role of pharmacy within the patient journey (see diagram below).
- The stated public policy position regarding investment in community pharmacy by the State, which is that this must address unmet public healthcare needs, improve access to existing public health services, provide better value for money or patient outcomes, and must be evidence-based.
- The benefits of future pharmacy care for patients as set out in the PSI's published report on Future Pharmacy Practice: Meeting Patients' Needs (2016).

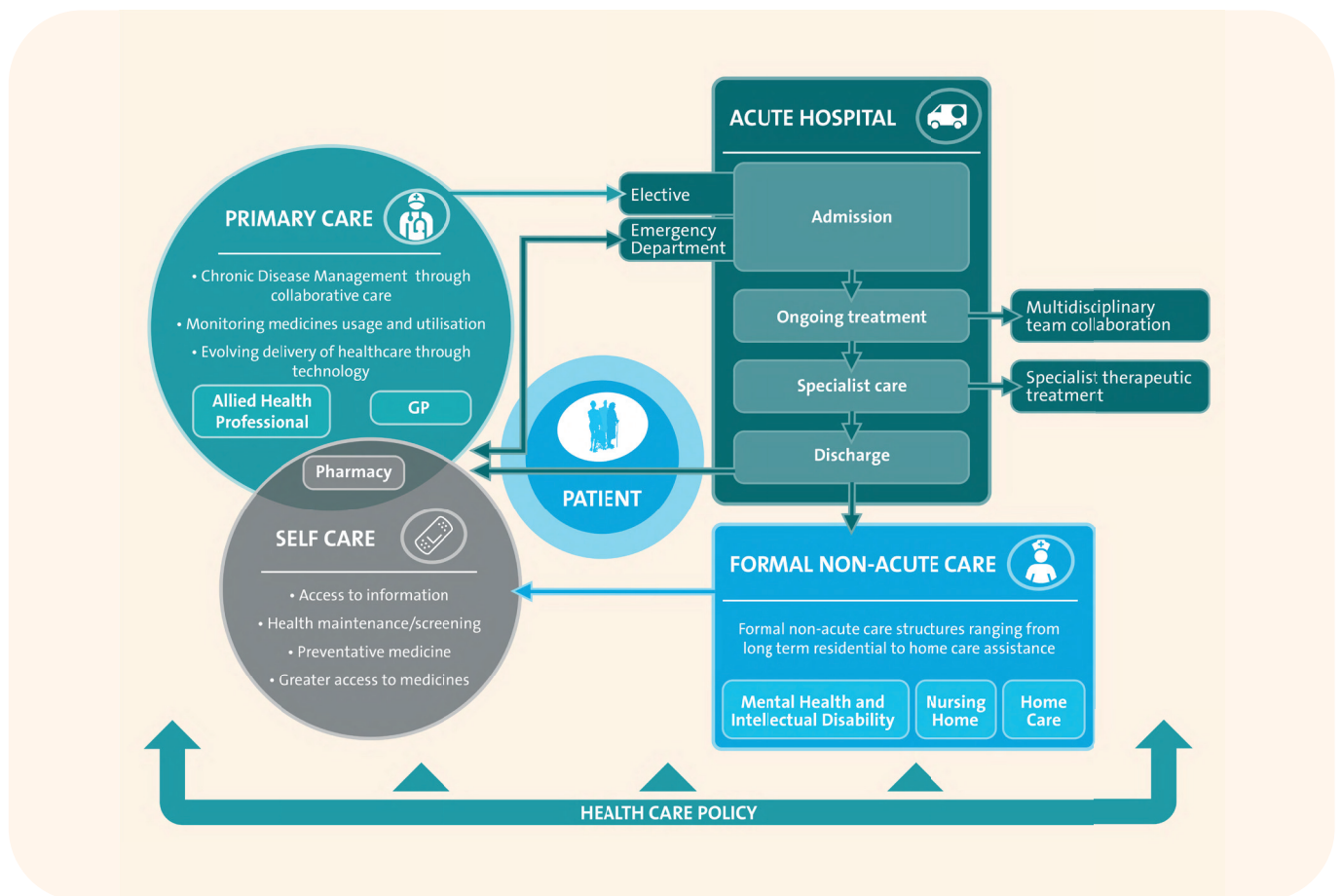
- The focus on integrated care in the Sláintecare Report, defined as:

'Healthcare delivered at the lowest appropriate level of complexity through a health service that is well organised and managed to enable comprehensive care pathways that patients can easily access and service providers can easily deliver. This is a service in which communication and information support positive decision-making, governance and accountability; where patients' needs come first in driving safety, quality and the coordination of care.' (Sláintecare Report p17).

- The important work being carried on by the HSE to develop Community Healthcare Networks in the context of the Sláintecare reforms and what this means for pharmacists and pharmacies.
- The driving forces influencing future skills and competencies of the health workforce.⁸

⁸ European Commission, Health Workforce https://ec.europa.eu/health/workforce/overview_en

Outline of patient care journey,
Future Pharmacy Practice Report



Strategic objectives and actions

In consideration of the preceding analysis, there are many worthwhile objectives that the PSI could choose to pursue in the coming three years. In deciding what objectives the PSI should commit to in the next three years, we have considered each objective from three perspectives by asking the following questions:

1. What public value is represented by the objective? Are we clear that there is a substantive value to the public interest, and are we clear what we are trying to achieve by pursuing the objective?

2. Do we have legitimate authority to pursue this objective? Is it politically achievable, is it in accordance with broad public policy and will we have the support necessary to accomplish the objective?
3. Do we have the internal capacity to deliver the objective? Is it operationally feasible in the light of available (or likely) resources?

Those objectives (and supporting actions) that we believe meet the foregoing test are described in the main body of this document.

A photograph of a pharmacist in a white lab coat, holding a medicine box in their right hand and a stack of medicine boxes in their left hand. The image is overlaid with a semi-transparent purple filter. The pharmacist's face is partially visible, looking down at the medication. The background is blurred, suggesting a pharmacy setting.

Assuring public trust
in pharmacy through
effective regulation



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