ASSURING PUBLIC TRUST IN PHARMACY THROUGH EFFECTIVE REGULATION

Corporate Strategy 2018-2020
Impacting through deeper collaboration and engagement

Promoting professionalism and quality in pharmacy

Building an effective organisation and benchmarking our performance

Regulating effectively for better health outcomes and patient safety

Assure trust in pharmacy through effective regulation
Foreword from the PSI President and the Registrar

Our strategic programme for 2018-2020 centres on our core objective to assure public trust in pharmacy through effective regulation.

This central organisational goal provides our focus and directs the approaches we will take in our work over these three years as we deliver on our responsibility to protect and promote public health, safety and wellbeing through a transparent and collaborative system of regulation of pharmacists and pharmacies.

Our intended actions reflect a theme of development and continuous improvement, both in terms of the expectations placed on the PSI’s regulated professionals and entities, and by way of enhancing our own performance as a regulatory body. Having achieved many milestones since the commencement of our establishing legislation ten years ago, we see this Corporate Strategy as an opportunity to review where we have arrived and to consider how we might best move forward during the next phase of the organisation’s development.

Delivering on this future agenda is not without challenges or, indeed, risks. Many demands and forces will impact on the organisation as we strive to advance our mission within a changing and challenging healthcare environment.

As a public body, we feel very strongly about making a positive contribution to Irish society. We see ourselves as part of a broader system of public services that provide support, raise awareness and collaborate with others to positively influence healthcare provision, equality of access and treatment, and respect for, and recognition of, each individual’s differing needs and human rights.

By adopting a strongly collaborative approach throughout this Strategy, we are committing to create new opportunities and develop new relationships with PSI registrants, to advocate for effective and meaningful patient care and quality health services, and to work with all who are committed to improvement within the wider health, policy and regulatory community.

This Corporate Strategy is the result of extensive deliberation and consultation with a wide range of people and organisations. We are very grateful for the many contributions received and we have strived to accommodate as many of those as possible within the Strategy. We also thank our colleagues on the PSI Council for their input, and recognise the extensive input from the PSI’s staff, whose ongoing commitment and dedication we rely upon as we move forward with implementation.

Rory O’Donnell  
President  

Niall Byrne  
Registrar
The Pharmaceutical Society of Ireland (PSI) is a public body established in law to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland.

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

Commitment to the Public

Our principal function is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007, as amended, established the statutory role and responsibilities of the PSI as the pharmacy regulator, which include:

- Registration of pharmacists, pharmaceutical assistants and pharmacies, in line with statutory requirements;
- Setting standards for pharmacy education and training at undergraduate and postgraduate level;
- Ensuring all registered pharmacists are undertaking appropriate continuing professional development (CPD);
- Promoting good professional practice by pharmacists, through raising standards and sharing information for the benefit of patients and the wider health system;
- Assessing compliance and taking actions to address poor performance, practices and behaviours through our inspection and enforcement functions, by considering formal complaints made against a pharmacist or a pharmacy and through the imposition of sanctions;
- Providing advice, support and guidance to the public, pharmacy profession and Government on pharmacy care, treatment and services in Ireland.

These functions form the basis of the work we do to promote and assure public confidence and trust in pharmacy practice and pharmacy-delivered care and services in Ireland.

Governance

The PSI is a public body, which is independent in the exercise of its statutory functions. For public accountability purposes, the PSI operates under the aegis of the Department of Health.

The PSI is governed by a 21-member Council and each member is appointed by the Minister for Health in accordance with the provisions of the Pharmacy Act 2007. The Council is responsible for overseeing the delivery of the functions of the PSI, in the public interest. This includes setting the strategy for the PSI and making sure that the strategic objectives are achieved. The Registrar (Chief Officer) of the PSI is responsible for leading the day-to-day work and operation of the organisation and seeing that the strategy is implemented efficiently and effectively. The Registrar reports to the Council at each of its meetings on the organisation’s activities and performance.
Our Vision
That the public has access to trusted pharmacy services and that the PSI makes a clear and demonstrable contribution to the availability and quality of those services.

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

Our Values
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.

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.

More information about our role and the work that we do is available on our website www.psi.ie.
Looking Back –
Achievements under our
2013-2017 Corporate Strategy

Ensuring Fair Registration Procedures

We maintained growing registers of pharmacists and pharmacies, providing timely, fair and appropriate access to the registers, in line with statutory requirements.

We sought feedback on our registration process from those using our services, and we increased use of the online portal for annual renewal of registration of pharmacists. This reduced paper-based administration and improved access and efficiency for all involved.

Continuing to Assure High Standards of Patient Care and Good Pharmacy Practice

We developed guidance documents and provided information and other resources to support and promote compliance with pharmacy and medicines legislation. We also published important information about medication and patient safety issues, good pharmacy practice and the standards of care which the public can expect of professional pharmacists.

During the Strategy period, we supported an increase in the uptake of seasonal influenza vaccinations provided in pharmacies and expansion in the types of vaccinations that can be administered by pharmacists. We also worked with the Department of Health to facilitate wider access to emergency medicines through pharmacies, such as adrenaline in the case of anaphylaxis (acute allergic reaction).

Continuing to Facilitate Lifelong Learning

Following extensive consultation and engagement, we implemented a reformed five-year programme of education and training for pharmacy students – the integrated Master of Pharmacy degree (MPharm), which commenced in 2015 in the three Schools of Pharmacy in Ireland. This programme provides a high standard of education that includes both academic and experiential learning, and ensures that students have the knowledge, skills and experience needed for their future role as healthcare professionals. Students now have the opportunity to experience each of the main pharmacy practice settings – community, hospital and industry – as part of attaining their qualification.

Arising from the expanding role of pharmacists and the requirement under the Pharmacy Act for a mandatory system of continuing professional development (CPD), we established the Irish Institute of Pharmacy in 2013 to manage and deliver the CPD system for registered pharmacists on behalf of the PSI. The review of pharmacists’ CPD e-portfolios commenced during this period.
Our previous Corporate Strategy covered the period 2013 to 2017. During that time, we worked to achieve objectives under ten key development areas. We have reviewed our activities and significant achievements over that period, as part of planning for our 2018-2020 Strategy.

Facilitating the Development of Pharmacy as a Profession in Ireland

We carried out extensive research, and undertook significant stakeholder engagement, to determine the future needs of patients and the role that pharmacy, in both the community and hospital setting, could play in meeting those needs. The ‘Future Pharmacy Practice Report – Meeting Patients’ Needs’ was published in 2016. This major report identified the benefits to the public from the greater integration of pharmacists within the wider healthcare system. We will continue to work with key stakeholders as part of this 2018-2020 Strategy to advance the recommendations of the report.

Engaging with Stakeholders

To inform the public about what they can expect from their community pharmacist and to help increase understanding of the role of pharmacists in healthcare, we published a Patient Charter in 2016. This Charter was developed following extensive consultation with our stakeholders. We also carried out a representative survey of the public to assess their trust in, and attitude towards, pharmacy-delivered care in Ireland.

To ensure our work is informed by the people who are affected by it, we carried out over 20 public consultations on different aspects of our regulatory work.

We contributed to, and informed, the work of other regulatory bodies, policy makers, the Department of Health and patient advocacy organisations. We developed memoranda of understanding with several organisations and partnered with the Medical Council of Ireland in the development of guidelines relating to the practice of both doctors and pharmacists in the prescribing and dispensing of controlled drugs.

Delivering an Effective Compliance System

By 2014 we had inspected all community pharmacies, had undertaken follow-up actions where needed, and published compliance findings on our website.

As a next step, we began moving towards a more risk-based approach to inspection through a revised inspection policy. As part of this, we introduced the Pharmacy Assessment System, which involves a self-audit to help pharmacies review and improve their own standards and practices on an ongoing basis. The system also provides a way in which pharmacies can readily record and demonstrate compliance with statutory requirements.

During the 2013-2017 period, we received and dealt with over 200 formal complaints in relation to pharmacists and pharmacies, and considered over 530 concerns.
## Looking Back – Achievements Under our 2013-2017 Corporate Strategy (continued)

### Getting our Message Out

In response to feedback from our stakeholders about our communications channels, we developed a new PSI e-newsletter and made significant changes to our website to improve its accessibility.

We also developed a new Communications Strategy to modernise and progress how, where and when we convey information to our various target audiences.

### Corporate Governance

We commissioned independent governance reviews to ensure our governance structures remain effective and to ensure we are properly complying with our obligations under the revised Code of Practice for the Governance of State Bodies (2016). The Council and its Committees also reviewed their own performance against their respective terms of reference.

To ensure our risk management practices remain robust, effective and in keeping with good practice, we commissioned an independent review and introduced a revised risk management framework.

Our Internal Auditors also carried out 21 audits to ensure our internal controls are comprehensive and provide the requisite assurances, through the PSI Audit and Risk Committee, to the Council and, ultimately, to the Minister.

### Ensuring the Delivery Capacity of PSI

During 2017, we carried out a major organisation resourcing review examining our funding needs, our current human resource capacity and our future development requirements. The aim of this work was to gain an objective view of the resources required to deliver on our statutory responsibilities to the standard necessary to protect the safety and welfare of the public. The findings of this review will play an important part in how PSI, as an organisation, develops during the course of this new Strategy.

To ensure that our ICT infrastructure is fit to address our current and ongoing management of information, customer service and business intelligence needs, we conducted an ICT Environment Review which identified key areas for improvement. The recommendations from this review will be advanced, subject to resourcing, as part of our 2018-2020 Strategy.
The Wider Environment

We implemented various changes to our regulatory processes and procedures as a result of changes emanating from national and European legislation.

We took on new responsibilities in the regulation of the online supply of non-prescription medicines in Ireland and in monitoring pharmacists’ compliance with interchangeable medicines and reference pricing legislation.

We also updated our regulatory rules and policies arising from changes to the EU Professional Qualifications Directive and its transposition into Irish law.

Acting to protect and promote the health, safety and wellbeing of patients and the public
Looking Forward –
Developing our Corporate Strategy 2018-2020

Our Corporate Strategy for 2018-2020 sets the development agenda for the organisation over the next three years. It provides the various actions which the PSI will take to ensure our work provides ongoing assurance to the public as to the safety and reliability of both pharmacists’ practice and the operation of pharmacy services. Through our implementation of this Strategy, we will enhance public trust in pharmacy by ensuring that our regulatory approaches protect the public and also encourage improvement and ongoing quality development within pharmacy practice in Ireland.

Over the last ten years, PSI has worked to implement an effective system of pharmacy regulation in Ireland, as prescribed under the Pharmacy Act 2007. This system covers the full range of our regulatory responsibilities – registration to practice, education, continuing professional development, conduct and fitness, registration and monitoring of retail pharmacy businesses, guidance development, etc. We have seen significant achievements and key projects completed during this time. This new Strategy gives us an opportunity to renew our focus and to build on the work we have done to date, while also affording us the opportunity to reflect on how our established regulatory approaches compare with current good practice in regulation both in Ireland and further afield. We are keen to improve and renew how we work and to ensure that the PSI is capable of meeting future challenges.

Our work as a public interest regulator is influenced and affected by the many events and uncertainties arising in our operating environment. In developing this new Strategy, we have considered various current, and future, opportunities as well as challenges. We have carefully considered the implications of these as we define our strategic direction and regulatory approach for the coming three years. What follows is a summary of our analysis across six key areas of our current and anticipated future operating environment.

1. Changing Health Landscape and Patient Need
In common with most developed countries, demand for healthcare services in Ireland is increasing. This reflects our ageing population (proportion of individuals over 65 has increased from 10.9% in 2006 to 13.4% in 2016) as well as increasing life expectancy (from 76.7 to 79.6 for men and from 81.3 to 83.4 for women between 2005 and 2015). While highly welcome for society as a whole, these improvements are also associated with an increase in the burden of chronic illness and a growing reliance on medicines and support services. In addition, our general population increased by over 520,000 between 2006 and 2016 and Ireland enjoys the second highest fertility rate in the EU. All of these factors, plus many others, generate increased demand for pharmacy services across all stages of the life span.

1 Central Statistics Office (CSO). Available at: www.cso.ie
While national healthcare policy is centred on maintaining health and preventing illness, there is also a parallel focus on ensuring the best use of acute and non-acute facilities through more effective, and earlier, access to primary care interventions and supports. The OECD reports that Irish hospitals are working at near full capacity, with occupancy rates for our acute hospital beds at 93.8% versus an OECD average of 77.3%. Ireland also has the highest rate of hospital admission for asthma and chronic obstructive pulmonary disease (COPD) among all OECD countries despite asthma being a long-term condition that can be effectively managed in primary care.\(^2\) These statistics demonstrate the potential contribution that pharmacy could make to the achievement of national health objectives.

Medicines are the most common healthcare intervention within the health system and both the use and the complexity of medicines is increasing. Parallel to increased usage is an increasing risk of both waste and potential harm through the inappropriate, or unnecessary, use of medicines. A particular concern, and one of increasing global significance, is the problem of antimicrobial resistance – an area where pharmacists can play a vital stewardship role, both in hospital and community settings.

In PSI, we recognise that our regulatory approaches must not stand in the way of innovation and developments that can facilitate improved healthcare outcomes for people receiving pharmacy care and advice. We are aware of the innovative developments and patient-centred activities happening in hospitals, community and out-reach services, and community pharmacies.\(^3\) We also know that adaptability must become one of our core organisational competencies. Changes in patient needs, and in our operating environment, mean that the PSI can only be successful into the future if we continually reflect on our current approaches to regulation and adapt these as required by changing circumstances. This competence will ensure that we remain patient-focussed, cost effective and capable of responding to unanticipated developments. We can do this most effectively through a collaborative approach and we look forward to meeting with, and hearing from, pharmacists working in all practice environments, so that we are informed as to the challenges and vulnerabilities facing their patients.

While this Strategy is primarily focused on patients, it also considers all of the people, businesses and organisations who are affected by what we do. It also reflects health-related strategic planning documents published by the Government and the Oireachtas. We are committed to contributing to wider health initiatives, and will reflect on the part we can play, for example, to help support the Healthy Ireland Strategy, implementation of the Sláinte Care recommendations and in relation to eHealth developments.

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\(^2\) OECD. Health policy in Ireland. February 2016. Available at: www.oecd.org/health

Over the next 3 years, we will continue to work with the Department of Health, HSE, patient and pharmacy representative organisations, education and training bodies and others to help address the significant healthcare challenges facing our country. We will facilitate proposed expansions in pharmacy services by revising standards, further developing the education of pharmacists and by promoting the full engagement of the pharmacy profession with continuing professional development. This will be our primary contribution as regulator to ensuring that pharmacists in patient-facing roles are, and remain, competent to offer individualised advice and treatment to patients and the public into the future.

2. Technology and Society
People’s needs and expectations as to how they manage their own health are changing, with many people now independently accessing online information about their own treatment and care. A more informed population presents many benefits for the health system, as well as new challenges particularly in relation to the potential for online information resources to be incorrect and/or misunderstood. The public also now expects higher levels of performance and accountability from those in positions of professional responsibility, including pharmacists.

The PSI must be mindful of its role in this area, not least because of the potential ethical dilemmas and other professional issues that can arise in the face of new demands being placed on pharmacists.

As healthcare professionals, there is always a need for each pharmacist to manage potential conflicts which may arise between business and organisational goals, and their own professional ethics.

E-health initiatives are a current priority within our health system. Community pharmacists and pharmacies are among the key touchpoints for the public and are potential enablers of a wide range of patient-benefit initiatives. During the life of this Strategy, we anticipate the introduction of new hospital and community pharmacy initiatives using unique patient identifiers and operating within a robust data protection and privacy framework. Through proactive collaboration and engagement, we will work with stakeholders to raise awareness, support technical and associated practice changes and remove barriers to progress so as to benefit everyone who uses pharmacy services.

Within our own working environment, we plan to extend our use of digital technology to support the business of the PSI. Through investments in improved technology and information management infrastructure, and through our new Communications Strategy, we will enable greater online access to the information we hold. We plan to streamline our registration methods and enhance our communications through a range of traditional and digital channels. Our intention is to improve our business efficiency and reduce unnecessary administrative burden on regulated businesses through the creative, convenient and secure use of online technologies.
3. European Union and International Developments

As a country and as a public body we are impacted by legislation, regulations and associated frameworks that emanate from our membership of the EU.

The forthcoming implementation of the EU Falsified Medicines Directive, to safeguard and authenticate medicines within the legitimate supply chain, is one such change arising for the sector during the lifetime of this Strategy.

In addition, the decision of the United Kingdom to leave the EU will require us to devote resources to deal with the, as yet unclear, implications of ‘Brexit’. For the PSI, these particularly relate to the registration of pharmacists who qualified in, or are working in, the United Kingdom, including Northern Ireland. They also relate to the free movement of pharmacists more generally and to the facilitation of cross-border healthcare. As the Brexit process unfolds, we will maintain close ties with the Department of Health, professional healthcare regulators in Ireland and across Europe, as well as with other relevant parties to minimise the negative impact on Ireland.

We have already commenced work to address the data protection reforms coming into effect under the EU General Data Protection Regulation (GDPR) from 25 May 2018. The GDPR will provide large-scale transparency, security and accountability for all European citizens and will strengthen data privacy rights by placing strict requirements on everyone who gathers, holds and processes personal data. In common with other public bodies, we are required to comply with those changes and we will dedicate resources to fully review our processes and practices pertaining to personal information. These measures will ensure that we are properly safeguarding the information that we gather for our regulatory purposes and that the exercise of our public interest functions is not compromised.

4. Our Regulatory Approach and Accountability

Our commitment is to protect the health and safety of the public through the effective regulation of pharmacists and pharmacies in Ireland. We regulate against the requirements set out in the Pharmacy Act 2007, against regulations made under the Act and against the requirements of related medicines legislation. Discharging these responsibilities requires us to put in place a regulatory system that promotes and assures public trust in the profession of pharmacy. Across the health and social care professions in Ireland, there has been significant progress since 2007 in establishing and reforming statutory regulation to assure and support good professional standards and to create robust systems of professional accountability. In keeping with these developments, our system of regulation in PSI must be effective, proportionate, applied consistently and be adapted to changing circumstances. These principles of good regulatory practice are also in keeping with findings and recommendations published in recent years by the OECD in relation to regulatory governance and reform4, 5.

Looking Forward –
Developing our Corporate Strategy
2018-2020 (continued)

Fundamental to our Strategy over the next three years is to ensure that the most effective and proportionate approach is taken by the PSI to the regulation of pharmacists and pharmacies. We see this Strategy as one that starts at a crossroads to change. Having established clear structures of regulation in the past ten years, we now want to embed what we have learned, consolidate our data and make sure that our regulatory approaches are based on measures that guarantee a positive impact on health outcomes and patient safety, whilst also minimising unnecessary compliance costs on the professionals and pharmacies we regulate. The road we plan to take includes some significant development projects. These include:

- seeking substantial revisions to the scheme of regulation set out under the current Pharmacy Act,
- moving to a standards-based and outcomes-focused approach to assessing quality in pharmacies,
- exploring the merits of publishing new formats of inspection reports, which will give credit for the many good practices found during inspections as well as clearly identifying those pharmacies which fail to deliver high quality services, and
- exploring alternative approaches to the management of professional conduct complaints so as to deliver clear outcomes while also reducing costs on PSI and on registrants.

As a public service body, we aim to operate transparently and to be fully open to public scrutiny, which includes being held to account by the public for our own actions or inactions. As a body funded by fees paid by pharmacists and pharmacies, we must show that value has been created from these funds and that we are operating efficiently. During the coming three years we will respond to these external accountability demands by examining our own internal processes and by engaging independent assessors to provide objective evidence that we are, indeed, operating to high standards of performance, and delivering value-for-money.

5. Funding and Resourcing

Regulation is not without cost. The PSI is among the few professional healthcare regulators that has responsibility for the regulation of both individual professionals and the working environment within which the majority of pharmacists work. This context requires a regulatory approach which includes an effective registration system to ensure that only those individuals who are competent, and entities that are compliant, are granted the privilege of first-time and ongoing registration. It also requires an inspection and enforcement regime, and a fitness to practise process, to verify that registrants, whether pharmacists or pharmacies, are demonstrating through their actions that they deserve to remain registered. We also set standards for education and training, and develop guidance to support compliance with relevant legislation so that pharmacists can properly support the public’s healthcare needs. This work is self-funded through the registration fees levied on PSI registrants. During 2017 we undertook a significant project to determine the core funding and resource requirements to effectively deliver on our statutory remit.
The recommendations from that review, subject to direction from the PSI Council, will critically influence how the PSI develops and operates over the lifetime of this Strategy.

This Strategy recognises that the PSI, as a public interest regulator, must remain effective, efficient and trusted. We have a responsibility to maintain a cost base that does not place excessive burden on regulated persons and pharmacy businesses, while also ensuring we have the necessary resources to regulate to the standard which the public deserves. During the term of this Strategy, we will review many of our internal processes, with the aim of streamlining services and customer interactions for the benefit of all who engage with us. In time, possible reforms to the Pharmacy Act will also provide new tools and approaches to drive our efficiency and help realise additional outcomes for registrants and for the public. Over the next three years, we will, among other objectives, also seek to develop and build organisational capacity within the PSI to ensure that we are attracting and retaining the type of capable and committed staff whose work will ensure we can deliver on our objectives to the high standards expected of us by the public. We will also explore the scope for participating in, and developing, shared service arrangements with other public bodies.

6. Working and Communicating with Others

The PSI’s value and contribution to public safety, health and wellbeing sits within a broader context that relies on us sharing and receiving insights and information to realise better public health outcomes. Effective, extensive and proactive communication is a core concern for any modern regulatory body. Over the course of this Strategy, we will continue to work openly and transparently, and in collaboration with a wide network of stakeholders and partners, in Ireland and abroad, to achieve our purpose across all our areas of responsibility. We will listen and learn from the feedback that we receive, and this will help us build trust, confidence and credibility in our work. We plan to clearly communicate the findings of our work so that the public and the sector understand the regulatory structures that are in place, and how these operate to help assure public trust in pharmacy.
Consultation to Inform this Strategy

The PSI Corporate Strategy 2018-2020 has been developed in consultation with our stakeholders including PSI registrants, patients and healthcare advocates, the Department of Health, HSE, members of the public, representative organisations, PSI Council and Committee members, and PSI staff.

The purpose of these consultations was to ensure that our strategic objectives are properly defined and relevant to the needs of the public and our various stakeholders. Our strategic priorities over the next three years are based on these consultations and we are confident that they reflect the needs of our diverse stakeholders.

Some of the actions in our Strategy are extensive in scope and will not be fully completed within the next three years. However, we will commence the groundwork for change now and we are confident that this will deliver results in the years that follow. As a public interest regulator, we intend to remain focussed on real patient outcomes and benefits by placing pharmacy service users at the heart of each decision we make.
Our Objectives and Outcomes for 2018-2020
This Corporate Strategy consists of five key elements:

**One central organisational goal**

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

**Four strategic results areas**

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

The following four sections describe each of our strategic results areas and indicate the actions we plan to initiate and complete under each.
We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.

Our actions in this area will include:

1. Partnering with the relevant statutory agencies within the health system to support them in adopting the recommendations of the Future Pharmacy Practice Report⁶. This includes removing regulatory barriers to necessary innovation in pharmacy practice and utilising our knowledge and research findings to inform policy development and support legislative changes relating to pharmacy and healthcare reform into the future.

2. Designing, through collaboration with pharmacists and other stakeholders, new types of standards (incorporating learnings from complaints and fitness to practise reports), which will support practitioners who are committed to best professional practice and the delivery of best outcomes for the public.

3. Engaging with our educational partners and other healthcare regulators to ensure that pharmacists’ education standards and any new practice standards, including our Core Competency Framework, evolve in line with changing needs of the public and the expanding role of pharmacy. This includes encouraging a greater focus on interprofessional learning within undergraduate and postgraduate education as a proven way of ensuring that patients benefit from integrated care and better health outcomes.

4. Managing and supporting the challenges arising from the Brexit process, as they relate to our remit, including the recognition of UK-gained qualifications, free movement considerations in the context of availability of pharmacist manpower, and practical patient issues including medicine availability and the facilitation of cross-border healthcare.

5. Engaging with stakeholders in a strategic review of the future of the Irish Institute of Pharmacy to ensure that its longer-term mission is clear and that its structure, governance and financing is on a secure and stable footing.

6. Publishing an updated Code of Conduct for pharmacists and engaging with the profession to highlight the ethical expectations of the Code and to ensure its guiding principles form the basis on which pharmacy is practised into the future.

7. Reviewing whether governance and management structures within retail pharmacy businesses are working to protect the public, and defining, with stakeholders, the high standards of leadership and accountability that must be practised by those holding key governance positions. This accountability framework will apply to supervising and superintendent pharmacists as well as those responsible for the overall governance of pharmacy businesses, for example, the senior management and the boards of corporate entities.

Strategic Results Area 2
Impacting through deeper 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.

Our actions in this area will include:

1. Communicating widely and working extensively with stakeholders – the Department of Health, government agencies, regulators and our registrants – to promote mutual learning, to co-design regulatory improvements and to exchange information that informs both our work and wider health policy development.

2. Developing a network of public and patient advocates to inform our work at all levels, and to partner with, on patient-centred initiatives.

3. Promoting our Patient Charter so that the public knows what they can expect from a high-quality community pharmacy and what to do if they are not satisfied.

4. Collaborating with other professional healthcare regulators to ensure that our regulatory approaches are grounded in evidence, and working with these partners to progress coordinated legislative reform in areas of mutual benefit or concern.

5. Developing and publishing more extensive information on the results of our field work in pharmacy businesses so that there is greater understanding of our role, improved public understanding of what good pharmacy practice looks like, and increased awareness of the standards that should be expected by all who receive care, advice and treatment from pharmacists.

6. Enhancing the capabilities of our website and implementing a Communications Strategy aligned to this Corporate Strategy to enable improved communications and to maximise our engagement opportunities.
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.

Our actions in this area will include:

1. Recognising that the current Pharmacy Act was passed in 2007, we will work with the Department of Health and other stakeholders in the pharmacy sector to advance a regulatory reform programme across primary and secondary legislation. This will include proposals to streamline requirements which create regulatory burden without addressing safety and to replace these with provisions which will support the PSI in taking a risk-led approach to the regulation of pharmacists and pharmacy businesses.

2. Developing outcomes-based, responsive, targeted and proportionate regulatory approaches which are designed to assess the true quality of pharmacy practice and services and which assure the public that these services can be trusted. This includes developing our Pharmacy Assessment System further as a positive driver for quality improvement within pharmacy businesses.

3. Reviewing how effective our current approaches are in identifying and responding to key safety issues and facilitating the development of new and inclusive safety collaboratives to address these areas of risk.

4. Exploring how mediation and the giving of undertakings can be used to resolve and manage some types of professional complaints without compromising the safety and welfare of the public.

5. Exploring how new thinking in regulation, such as behavioural economics or earned recognition, can be safely applied by PSI to advance our mission while keeping costs to PSI and to registrants at a sustainable level.

6. Reviewing how we can make the system of regulation as understandable, simple and transparent as possible so that compliance is facilitated and compliance costs are minimised. This includes clarifying how pharmacy regulation works in complex environments such as hospitals.

7. Designing and conducting themed programmes of inspection in key areas of pharmacy practice (for example, the high-tech drugs scheme, management of controlled drugs, supply into residential care services, etc.) and producing overview reports which will provide assurance to the public that standards for pharmacists and pharmacies in these areas are being met. Publication of the reports will recognise, encourage, guide and support ongoing quality improvement and innovation by pharmacy owners and pharmacy businesses.

8. Developing, through consultation, new types of pharmacy inspection reports that will be published to give clear credit for the many good practices and quality outcomes which our inspectors find in practice. These reports will also fulfil the important public service of highlighting pharmacies that are not meeting key requirements, represent real safety risks and which fail to discharge their duty of trust to the public.
Strategic Results Area 4
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.

Our actions in this area will include:

1. Investing in organisation development and transformation as a strategic priority and as a key enabler of the delivery of our other three strategic results areas. Building organisational agility, cross-working and a culture of ongoing change and improvement is critical to our future success.

2. Building our capacity in the areas of policy development, research and knowledge management, methodology development and process review.

3. Working to advance the approved recommendations from the 2017 core funding and resourcing project to ensure we have the financial and human resources necessary to deliver on our functions to the standard expected by the public.

4. Reviewing and adapting our organisation and management structures to support the delivery of our strategic objectives and to enable us to manage all corporate and regulatory risks effectively.

5. Examining the role and governance remit of all sub-Council structures (Advisory Committees and sub-groups) to ensure these are contributing in the best way to the future development of the PSI.

6. Developing a future HR strategy focused on creating a positive work environment, with equality of access, opportunity and treatment for staff, so that PSI is seen an employer of choice and can attract, and retain, the calibre of people needed to deliver on our public service mission. This also involves seeking external accreditation for our HR processes.

7. Building our capacity and performance by investing in formal quality assessment via the EFQM Excellence Model (www.efqm.org). This will see us critically reviewing our own processes, looking at how we use the data that we gather and how we create best value from the resources available to us. External assessors will evaluate how our processes, performance and results compare with those of other high-performing organisations.

8. Implementing an ICT Development Strategy to support the PSI’s business processes and service user needs by providing better management information and increased business intelligence. This will lead to better decision making, increased efficiency in our use of resources and will ultimately impact the people, businesses and organisations engaging with us.

9. Reviewing our business processes to ensure we are operating as cost-effectively as possible, including exploring opportunities to share resources and costs with other public bodies.
Key Outcomes 2018-2020
How will we know we have succeeded?

**Strategic Results Area 1**
Promoting professionalism and quality in pharmacy

- The potential contribution of pharmacy practice is informed through our research and knowledge and valued by policy makers and commissioners of services as a key enabler of better health outcomes for the public.

- Change and innovation within pharmacy services is facilitated by the PSI through new initiatives in standards development.

- An updated Core Competency Framework for pharmacists is published, acknowledging the expanding role of pharmacy.

- Education, training and CPD processes are in place that are effectively contributing to, and underpinning, good professional practice and ongoing learning.

- Changes relating to our functions that arise out of the Brexit process are managed so as to minimise the impact on pharmacy services in Ireland.

- A revised Code of Conduct is published with its key changes and intent clearly communicated to all registrants.

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

**Strategic Results Area 2**
Impacting through collaboration and engagement

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

- There is increased public awareness and understanding of the PSI’s role and of how the pharmacy regulatory system in Ireland protects the public, assures trust and supports professionalism.

- The PSI is a force for positive change and for collaboration and learning within the pharmacy sector as well as being seen an efficient regulator which operates to high standards of openness and accountability.

- The PSI is recognised as a leader in effective healthcare regulation and is a contributor at key health, patient safety and regulatory fora at national and EU level.
Strategic Results Area 3
Regulating effectively for better health outcomes and patient safety

- A programme of reform is commenced to address changes to our primary and secondary legislation, to allow for more meaningful regulation that is focussed on patient outcomes and key risk areas.

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

- Robust and streamlined registration and fitness processes are in operation, which ensure registered pharmacists and pharmacies are safe and that timely action is taken to address deficits.

- Pharmacies are experiencing the benefits of risk-based pharmacy regulation that is up-to-date, transparent, highlights outcomes achievement and targets those who consistently fail to meet clear standards of quality and performance.

- Better information is available to the public and to pharmacies about the standard of pharmacy services in Ireland and there is greater assurance as to the safety and reliability of those services.

Strategic Results Area 4
Building an effective organisation and benchmarking our performance

- Our organisation and management structures support the implementation of our Corporate Strategy, the effective management of risk and a high standard of organisational performance.

- PSI is a positive, people-focused and HR-accredited workplace that embraces ongoing change and demonstrates continuous improvement.

- Our funding streams and workforce development strategy are aligned and are supporting delivery of our statutory and other functions and we are demonstrably carrying out our regulatory mission to the standard expected by the public.

- ICT systems are in place that effectively support our internal processes, our delivery of results and provide new online user services to streamline how our stakeholders engage with us.

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

This Strategy will be implemented over three years from January 2018 to December 2020. 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 an 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 and will be reported to the PSI Council at each of its meetings. Full details will also be published in each year’s Annual Report.
Ensuring that pharmacy services are delivered in a competent, professional and ethical manner