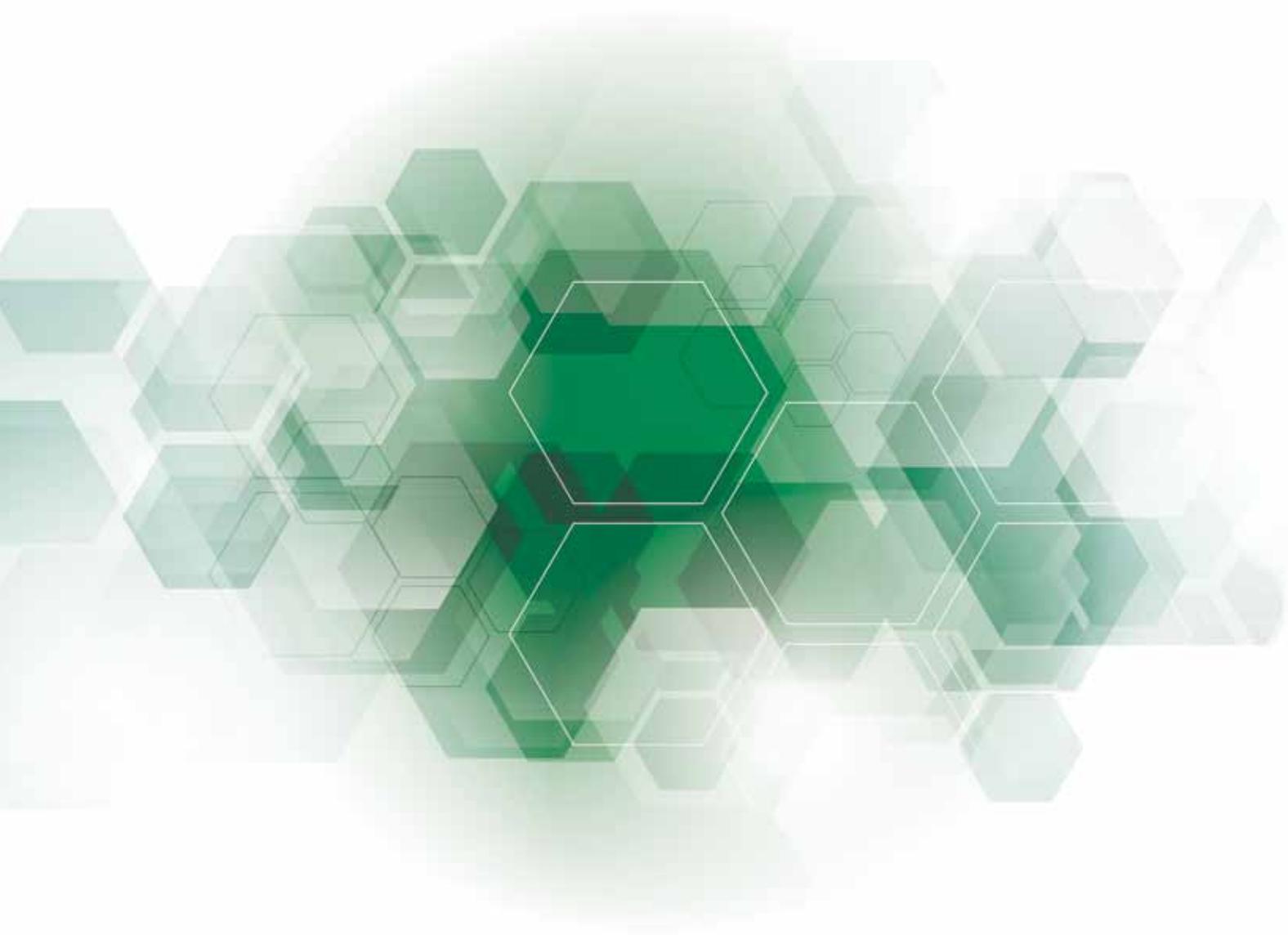




# Corporate Strategy 2013-17



AN RIALTÓIR CÓGAIŚÍOCHTA  
THE PHARMACY REGULATOR



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# Foreword

## from the President

**It is my pleasure to present the Corporate Strategy of the PSI, the Pharmacy Regulator, for the period 2013-2017. This Corporate Strategy follows on from the previous PSI strategy for the period 2010-12, which was principally concerned with the implementation of the Pharmacy Act 2007, and with putting pharmacy services and the regulation of those services in Ireland on a solid foundation.**

During the three-year period covered by the previous PSI strategy, significant achievements were realised by the PSI in areas including Fitness to Practice, the introduction of new pharmacy-provided services in line with the *Pharmacy Ireland 2020* report, the establishment of the new Irish Institute of Pharmacy, and the creation of the National Forum for Pharmacy Education and Accreditation. All of these changes are bringing significant benefits to both patients and the practising profession.

Looking ahead to the next five years, the period covered by this corporate strategy, we see two main strategic objectives for the PSI. Firstly, we must ensure that we complete the important work we have started, and that the full benefits of this work are brought to bear for patients, for the public, and for those working in the healthcare system, including pharmacists, technicians, and pharmacy owners.

Secondly, we recognise that the health services in Ireland are going through a period of unprecedented reform, against a backdrop of significant financial and economic challenges. We also face increasing demographic pressures due to an ageing population and the increasing prevalence of non-communicable diseases such as diabetes and cancers.

Against that backdrop, pharmacists in Ireland and internationally are becoming more centrally involved in the delivery of safe, high-quality, evidence-based healthcare services, and the PSI will continue to support the pharmacy profession to play an enhanced role to meet the needs of patients and the public, in line with national developments. We will also continue to work closely with Government on the implementation of those aspects of the 2012 policy document “Future Health” which relate to pharmacy, recognising that this will facilitate extensions in the scope of pharmacy practice and the capacity of pharmacists to provide additional, valued support to the public.

Partly as a result of the work done by the PSI between 2010 and 2012, the pharmacy profession in Ireland is now much better positioned to meet the challenges of providing effective, safe and high-quality services to patients and the public over the next five years. The PSI Council is of the view that care should be provided to patients at the lowest

level of complexity, in a safe and appropriate manner and environment and as close to the patient's home as possible. Given that pharmacies exist in almost every community in Ireland, the profession is strategically placed to facilitate faster and efficient care for patients, in line with the vision of *Pharmacy Ireland 2020*.

International best evidence has shown that patient outcomes are optimised where a multidisciplinary approach is adopted to patient care. In this regard, the PSI will be working with the HSE and other healthcare providers, with patient advocacy organisations, and with other stakeholders involved in the health system, to ensure that patient care will be optimised through the inclusion of pharmacists in multidisciplinary teams, both at primary and secondary care level. The creation of the Irish Institute of Pharmacy will also allow for academically robust training of pharmacists to fulfil roles that heretofore have been the domain of other areas of the health service, and the PSI will assist the profession in broadening the scope of practice of the profession so that patients will have greater access to services while not compromising on patient safety.

2013 will see Ireland hosting the international FIP Congress, a coming together of over 3,000 pharmacists and pharmaceutical scientists to examine and discuss the latest developments and global best practice within pharmacy. The PSI, as co-hosts of FIP 2013, looks forward to

the opportunity to engage with our colleagues from other countries, and also to showcase the best of what Ireland has to offer.

Finally, I wish to note the PSI's appreciation to Dr Ambrose McLoughlin, who served as our Registrar and CEO from 2005 until April 2012, when he was appointed Secretary-General of the Department of Health. Ambrose's unique vision, professionalism and determination were instrumental in making the PSI what it is today, and we look forward to continued engagement with him in his new national role.

My profound thanks are also due to Noeleen Harvey, PSI President from 2009 to 2011, and to Eoghan Hanly, PSI Vice-President from 2011 onwards, both of whom have contributed very significantly to the PSI and to the profession. Noeleen and Eoghan both worked tirelessly on the implementation of the former PSI Corporate Strategy, and have helped me enormously during my term of office.

I also express my thanks to my colleagues on the Council and on its Committees, and to the staff of the PSI, for their contribution to the development of this Strategy.



**Mr. Paul Fahey**

*President*

# Introduction and Message

## from the Acting Registrar/CEO

**This Corporate Strategy covers the period 2013-2017, and builds upon the substantial work undertaken in the previous strategy period to implement the reforms arising from the 2007 Pharmacy Act.**

As the statutory pharmacy regulator in Ireland, the PSI must remain focused on building and maintaining the confidence of the public, of the pharmacy profession, and of other stakeholders within the healthcare system, regarding the manner in which we operate. Our primary focus is to protect and promote the health, safety and well-being of patients and the public, and we seek to achieve this by:

- Facilitating the development of the profession of pharmacy as an integrated part of the healthcare system, in line with best international practice and evidence;
- Operating robust systems of compliance and fitness to practise, in order to help maximise the quality of service offered by pharmacists to patients and the public;
- Promoting lifelong learning through the implementation of a world-class, robust system of pre- and post-registration education, training and ongoing professional development;
- Maintaining fair and accessible systems of professional registration for pharmacists, druggists and pharmaceutical assistants, and for retail pharmacy businesses;
- Working closely with others in the Irish healthcare system to achieve our objectives, and communicating with our stakeholders openly, honestly and clearly.



Our objectives are set in the knowledge that the broader healthcare environment is changing significantly, both in Ireland and internationally, and we will take a leading role in anticipating and responding to those changes which affect the profession of pharmacy. We will continue to work with Government on the implementation of new policies set out in the 2012 document “Future Health”, and we will remain focused on realising the vision of *Pharmacy Ireland 2020*.

To achieve our goals, we will continue to develop and strengthen the PSI as a regulatory organisation, working within a culture of continuous improvement for staff, for Council members, and for our business processes and systems. Our executive team will continue to provide support to the Council and its Committees, within an effective system of corporate governance, to ensure that we meet our corporate and regulatory objectives.

Collaborative working with other stakeholders in the Irish health system is critical to the PSI’s effective discharge of its responsibilities, and we will continue to work closely with the Department of Health, the HSE, other health service providers, and with other health regulators over the lifetime of this corporate strategy. In setting out our plans for 2013-17, we acknowledge the support and assistance provided by the Minister, the Department of Health, and the pharmacy profession, and we look forward to meeting the challenges and opportunities ahead.

**Ciara McGoldrick**

*Acting Registrar / CEO*

# 1

## The PSI Organisation and Governance

### About the PSI

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007 (as amended). It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies.

### Our Role

The PSI regulates the professional practice of approximately 5,000 pharmacists, 500 pharmaceutical assistants and 1,780 pharmacies.

The main role of the PSI includes:

- registration of pharmacists and pharmacies;
- standard-setting and quality assurance of education and training, including continuing professional development (CPD), for the pharmacy profession at different levels;
- assurance of high quality and safe standards of practice, and the development of pharmacy practice;
- improving the profession of pharmacy;
- supervising compliance with the Act through inspection and enforcement, including the taking of prosecutions under the Pharmacy Act 2007 and other medicines legislation;
- handling complaints and disciplinary matters in relation to pharmacists and pharmacy owners, including the imposition of sanctions;
- provision of advice to the Government on pharmacy care, treatment and service in Ireland.

### Our Responsibilities

Under the Pharmacy Act, 2007, the PSI's main responsibilities are to:

- maintain the registers of pharmacists, pharmaceutical assistants, and pharmacies;
- prescribe the qualifications required for practice and accredit and monitor pharmacy degrees;
- recognise and approve programmes of education and training to assure the ongoing competence of pharmacists;

- ensure compliance by pharmacists, pharmacy owners, and others, with the pharmacy and medicines laws of the State;

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- provide advice, guidance and direction to pharmacists and pharmacy owners when required / appropriate;

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- set standards of professional competence and ethical conduct;

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- receive and act on complaints and concerns about the performance and conduct of pharmacists and pharmacy owners;

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- conduct inquiries into complaints and impose sanctions as appropriate;

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- work with other bodies about matters of mutual concern, patient safety and the public interest;

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- provide information and guidance to the public and to the political system on matters relating to our statutory functions;

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- report and be accountable to the Minister for Health, the Department of Health, and to the Oireachtas.

### Organisation and Governance

The PSI is governed by a 21 member Council, with a non-pharmacist majority, appointed by the Minister for Health. The primary role of the PSI Council is protection of the public interest through the effective regulation of the profession and practice of pharmacy. An executive staff at the PSI offices in Dublin supports the work of the Council. Our main operating units are:

- Office of the Registrar / Chief Executive Officer, including Corporate Governance;

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- Fitness to Practise and Legal Affairs;

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- Professional Development and Learning;

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- Registration and Qualification Recognition;

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- Pharmacy Practice Development;

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- Inspection and Enforcement, including registration of pharmacies;

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- Administration and Finance;

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- Information and Communications Technology (ICT); and

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- Communications and Public Affairs.



## 2 Mission, Vision and Values of the PSI

### **Our Mission**

The PSI, as the pharmacy regulator, acts to protect and promote the health, safety and well-being of patients and the public.

### **Our Vision**

We aim to ensure that pharmacy services are delivered in a competent, professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice, and well-being of patients and the public.

### **Our Values**

The PSI's values are to operate with:

- Commitment to the safety of patients and the public, as our highest priority;
- A focus on supporting excellence in pharmacy education and practice;
- Accountability and responsibility;
- Independence, integrity and high professional and ethical standards;
- Openness, accessibility and transparency;
- Consistency, fairness and equity;
- Excellence and professionalism;
- An ethos of continuous learning, including commitment to the development of PSI staff and of Council and Committee members.

## 3 Key Challenges for 2013-2017

### Setting Our Objectives for 2013-17

The previous Corporate Strategy was the first such formal strategic plan developed by the PSI, and covered the period 2010-12. At that time, the PSI was heavily engaged in implementing the various provisions of the Pharmacy Act 2007, and as such many of the objectives and actions set down in the plan reflected the relatively short term nature of that implementation work.

This new Corporate Strategy covers a longer timeframe, and runs for the five year period 2013-17. Accordingly, we have structured this document to reflect both short to medium-term objectives (typically, those relating to work to be done in the first half of the period), and medium to long-term objectives (for the second half). Naturally, there will be some overlap and some fluidity within these timeframes, reflecting both the dynamic nature of the PSI's work in 2013-17 and the fact that some initiatives will continue over the full life of the Corporate Strategy. It should also be noted that as a mid-term review of the Corporate Strategy will be conducted in 2015, this will afford the opportunity for the plan to be updated as necessary.

Where possible and relevant, we have aimed to structure this Corporate Strategy in a similar manner and format to the previous strategic plan for 2010-12, as many of the issues continue to be live and as the broad framework for setting our objectives and targets remains valid. The content of this Corporate Strategy also forms the basis for the PSI's annual service plans, and provides a basis on which our delivery against objectives and targets can be evaluated.

### The Overall Challenge For The PSI

The Pharmacy Act 2007 provides for a modern and robust system of regulation of the pharmacy profession in Ireland. The Act places very clear responsibilities upon the PSI in respect of its independent regulatory role and its involvement in the development of the pharmacy profession in the interests of patient safety.

We also recognise that the environment in which pharmacy operates is changing considerably, as a result of the introduction of new technology and new medicines, changes in consumer preferences, changing clinical needs, and evolving EU and Government policy. It is essential that the PSI has the capacity to take a leading role in anticipating and responding to these changes. In doing so, we recognise that present economic circumstances are challenging for the Government, pharmacies and patients alike.



Since 2007, the PSI has undertaken extensive work to strengthen the system of regulation, in which features such as fitness to practise, continuing professional development and the development of professional standards are increasingly prominent, with defined lines of professional accountability. As the regulator, the PSI has also proactively facilitated the introduction of new and novel pharmacy services, including the administering of the flu vaccination by pharmacists, the provision of emergency hormonal contraception, and the development of guidance on storage and supply of medicinal products containing codeine. At a strategic level, we have been working with Government to implement new policies set out in the 2012 document “Future Health”, and continuing to focus on realising the vision of *Pharmacy Ireland 2020*.

This work has helped to bring about greater compliance with pharmacy and medicines legislation and the requirements of good pharmacy practice, and adherence to the statutory Code of Conduct for Pharmacists. The overall challenge for the PSI is to continue to build on this work, and to promote and enhance the culture of continuous improvement within pharmacy in Ireland.

#### **Overall Objectives for 2013-17:**

The key challenge for the PSI over the period 2013 to 2017 will be to build on its achievement of the implementation of the Pharmacy Act 2007, and to continue to provide effective leadership and regulation of the practice of pharmacy, taking account of the changing economic and health policy environment.

We will continue to seek the safe and optimal use of medicines, and to ensure that pharmacists and pharmacies are in a position to meet the evolving needs of patients and the public.

In line with *Pharmacy Ireland 2020*, we will continue to support the development of new and novel pharmacy services through effective regulatory processes, and to facilitate enhanced accessibility of pharmacy services by patients.

## Promoting Lifelong Learning

The reform of pharmacy education is the lynchpin of the *Pharmacy Ireland 2020* initiative that positions pharmacy to offer safe, accessible and economical alternatives to traditional ways of delivering healthcare. In recent years, the PSI has commissioned a substantial body of work, utilising international expertise, to inform and support the reform and development of the education system for pharmacists. This work has been designed to facilitate the further development of the profession and to enable pharmacists to be positioned to take on new roles and to deliver a wider range of high quality health services, more suited to the emerging needs of the Irish public and the profession itself.

Work completed during the period of the previous PSI Corporate Strategy, 2010-12, includes the Pharmacy Education and Accreditation Reviews (PEARs) project, which entailed the root and branch review of the entry to practice qualification, and a comprehensive project to review international CPD models and systems.

The implementation of the recommendations contained in the PEARs Report, the main one being the introduction of a five year fully integrated Masters degree in pharmacy, are being pursued with the assistance of the National Forum for Pharmacy Education and Accreditation, which was established by the PSI Council in 2011 to advise and assist in its oversight of the development and ongoing delivery of the new five-year fully integrated degree programme in pharmacy. The membership of the National Forum, which is led by the PSI, comprises all relevant stakeholders with nominees from the PSI, government agencies (Health Service Executive, the Higher Education Authority, IDA Ireland), the higher education institutions, representation from the main pharmacy practice settings of community, hospital and industry and on behalf of patients and students.

Reforming the academic qualification is essential to prepare pharmacists for their evolving and future roles. The PSI will work with all parties to ensure that the fully integrated degree is commenced for pharmacy students during the period covered by this Corporate Strategy.

The implementation of the CPD model, the establishment of the Irish Institute of Pharmacy, and the commencement of its operations, are the other key educational development activities arising from the recommendations of the Review of International CPD Models that the PSI will oversee over the period of this Strategy.

The Institute – being set up with the assistance of the Royal College of Surgeons in Ireland (RCSI), which has been contracted by the PSI to manage its activities – will be the mechanism to provide pharmacists with a structured approach to engage with CPD, and will facilitate the quality assurance and the effectiveness of the system. The PSI will engage with the profession to facilitate the transition to this new approach.



**Work to be undertaken by the Institute within the next 2-3 years includes:**

- Establishment of a CPD portfolio system and a dedicated information and learning portal to allow pharmacists to identify, record and reflect on learning obtained and required;
- Development and piloting in 2014 of a competency-based Quality Assurance process. This QA process, incorporating a review of learning portfolios and a practice review process, will be peer-led, -designed and -assessed, the purpose of which is to validate and support each pharmacist's engagement with CPD on a regular basis through the feedback mechanism, and to generate an evidence base of the profession's competency development. Full roll-out of the system is anticipated by the end of 2015.

The significance of these reforms is that they will enhance and provide an evidence base of the competencies of Irish pharmacists and will bring Irish pharmacy into line with internationally benchmarked standards. This will further facilitate the expansion of pharmacy services and will add value by improving integrated care services for patients.

**Short/Medium Term Objective:**

We will continue to facilitate lifelong learning through the implementation of a world-class, robust system of pre- and post-registration education, training and ongoing professional development for pharmacists.

**Medium/Long Term Objective:**

During the period 2015-17, we will review progress to date with the implementation of the five-year fully integrated Masters degree in pharmacy and the Irish Institute of Pharmacy and its various initiatives and developments, and will evaluate the need for any changes or enhancements.

## Continuing To Assure High Standards Of Patient Care And Good Pharmacy Practice

The rational use of medicinal products makes a major contribution to the safe, appropriate and cost-effective care and treatment of patients. The direct interaction between pharmacists and patients regarding the use of their medicines, and the application of good pharmacy practice, will ensure this safe and rational use of medicines, the effect of which is to improve the quality of patient care with better treatment outcomes.

Pharmacists have a vital role to play in the provision of clinical advice and ensuring the safe and rational use of medicinal products, and it is essential that patients should be provided with the necessary counselling on medication management and assistance in managing their acute and chronic medical conditions. Patients and the public have an expectation that pharmacists will provide appropriate interventions and guidance, including advice on the safest and most cost-effective therapeutic regimes.

The PSI recognises the provision of better and safer care for patients will depend heavily upon a number of critical features:

- Collaborative, patient-centred care delivery involving healthcare professionals working together for the common good of the patient, across the various interfaces within the evolving Irish health system;
- Pharmacists working with patients to educate and inform them regarding their medication regimes, to advise them of the benefits of adhering to prescribed courses of treatment and to aim towards greater compliance;
- Enhanced patient safety through effective medicines reconciliation, as recommended in the report of the Madden Commission on Patient Safety and Quality Assurance in 2008.

The PSI remains fully committed to all aspects of this collaborative work and will play its part fully at both national and local levels, to ensure that the role of pharmacists can be optimised in realising better and safer care, within both primary and acute care settings, and at the interfaces of professional collaboration.

Linked to this, we also recognise that there is a particular challenge within hospital pharmacy, with a requirement – as identified in the Hospital Pharmacy Baseline Study commissioned by the PSI and completed in 2012 – for greater uniformity of practice to facilitate hospital pharmacists to play a full role in the provision of care to patients and enhancing patient safety.

The PSI will continue its efforts to ensure that all pharmacists and pharmacy owners and operators fulfil their respective obligations to conduct patient medication reviews, and counsel patients in their use of both prescribed and non-prescribed medicines. In order to achieve this, the PSI is mindful that there needs to be sufficient pharmacist personnel available in each pharmacy to enable the necessary reviews, patient counselling and sale/supply supervision to be appropriately carried out.



**Overall Objective:**

During the life of this Corporate Strategy, we will play a full part at both national and local levels to enhance collaborative, patient-centred care delivery involving healthcare professionals working together across the various interfaces within the evolving Irish health system.

We will support and facilitate pharmacists to work with patients to educate and inform them regarding their medication regimes.

We will continue to develop evidence-based standards of good pharmacy practice in all settings, in line with evolving changes in the delivery of healthcare services. We will work with other healthcare and patient organisations to ensure the best standards of care for patients.

**Short/Medium Term Objective:**

We will work closely with hospital pharmacists, and with other stakeholders within the hospital sector, to ensure that the contribution of hospital pharmacists to patient care can be optimised.

We will complete the suite of guidelines to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008.

## Facilitating The Development Of Pharmacy As A Profession In Ireland

Pharmacists have a vital role to play in the provision of integrated care services, for the benefits of patients and the public. The PSI remains committed to developing the profession of pharmacy as an integrated part of the healthcare system.

As part of that commitment, the PSI's 2008 report on the *Pharmacy Ireland 2020* initiative contained a series of recommendations to enhance the role of pharmacists across a range of clinical service areas. Some of the recommendations arising from the *Pharmacy Ireland 2020* initiative were achieved in the lifetime of the PSI's previous Corporate Strategy 2010-12, in important areas which included:

- the introduction of the seasonal influenza vaccination in pharmacies;

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- provision of emergency hormonal contraception;

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- the development of guidance on storage and supply of medicinal products containing codeine;

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- chronic disease management;

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- the reclassification of medicines from prescription control to pharmacist supply.

Over the life of this Corporate Strategy 2013-17, we will continue our work on the implementation of the recommendations of the *Pharmacy Ireland 2020* initiative. We will pay close attention to the continued development of a strong evidence base for all branches of pharmacy, with a view to the achievement of the highest standards of professional practice. We will also seek to share our learning with other healthcare professions, and to learn from their research on a collaborative basis.

Linked with *Pharmacy Ireland 2020*, the establishment of the Irish Institute of Pharmacy provides an active focus for leadership, development and research within the profession, and further strengthens the PSI's commitment to collaboration.

The two Baseline Studies commissioned by the PSI (for community pharmacy, completed in 2011, and for hospital pharmacy, completed in 2012) showed clearly that whilst some pharmacists have developed highly innovative, professional services for their patients in recent years, others continue to operate on more traditional lines. Within hospital pharmacy in particular, there is significant potential for the role of pharmacists to be developed and enhanced, with wide differences in practice seen between hospitals.

Over the period of this Corporate Strategy, the PSI will continue to encourage and support research into the development of pharmacy as a profession in Ireland, and to engage with other stakeholders to help optimise the role of pharmacists, and thereby achieve improvements in quality of care to patients.

These changes will require policy-makers to be more cognisant of the enhanced and significant contribution that pharmacy can make to the quality of patient care and cost-effectiveness, and also to the well-being of the wider population.

### Overall Objective:

During the life of this Corporate Strategy, we will continue our work on the implementation of the recommendations of the *Pharmacy Ireland 2020* initiative, in order to continue to strengthen the profession in line with international best practice, with particular focus on benchmarking and continuous learning.

### Short/Medium Term Objective:

Through the Institute of Pharmacy, we will seek to enhance the development of the profession to ensure that its contribution to safe and effective patient care is optimised.

We will engage with other stakeholders to determine how best the findings of the Hospital Pharmacy Baseline Study can be taken forward, in order to assist with the development of hospital pharmacy and optimise the role of hospital pharmacists.

### Medium/Long Term Objective:

During the period 2015-17, we will examine closely the emerging and future trends for all branches of pharmacy, in order to help identify the type of regulation and support required by the profession in 2018 and beyond.

## Ensuring Fair Registration Procedures

The Pharmacy Act 2007 currently requires that the PSI keeps and maintains registers of pharmacists, druggists and pharmaceutical assistants and retail pharmacy businesses (pharmacies). This is one of the core activities by which the PSI ensures that those practising the profession of pharmacy and delivering pharmacy services are suitably qualified, and recognised as such to do so.

There are currently three applicable routes to recognition and registration as a pharmacist in Ireland: the national route, the EU/EEA route and the Third Country Qualification Route. Irrespective of access route, the requirement that the registrant holds a recognised qualification appropriate for practice is one of the criteria which safeguards the health and safety of the public.

Changes proposed by the European Commission in late 2011, if ratified, will have significant implications regarding the procedural mechanisms by which individuals may register as pharmacists in Ireland via the EU/EEA route, and will require legislative, procedural and technological changes to be recognised, developed and implemented.

Commitment to the key concept of lifelong learning will play an important part in safeguarding the fitness of a registrant at the annual renewal of their registration. The PSI will take forward development of guiding principles which link the system of continued registration with the registrant's participation in CPD and associated assurance processes. These principles must also be appropriately disseminated to the practising profession. The use of appropriate technologies will be an important consideration in the responsible meeting of this objective.

Pharmacists and evolving pharmacy practice have the potential to help develop the delivery of primary and self care, which in turn can serve to optimise the effectiveness and efficiency of the secondary and tertiary health systems. The contribution of other non-registered team members such as pharmacy technicians is vital. The possible recognition and registration of these practitioners, either on a voluntary or legislative basis, will be explored.

**Overall Objective:**

To operate in a transparent, objective manner, ensuring the responsible application of resources in the fulfilment of the core registration functions.

To optimise on an on-going basis the utilisation of appropriate technology, in delivery of registration services, engagement with registrants, and monitoring of qualified registrants

To review, monitor and apply fair registration procedures in accordance with relevant legislation at both initial and continuing registration application stage.

**Short/Medium Term Objective:**

We will develop guiding principles which link the system of continued registration with the registrant's participation in CPD and associated assurance processes.

We will disseminate these principles to the practising profession.

**Medium/Long Term Objective:**

To participate, lead where appropriate, and contribute to the identification, development and application of required legislative and policy change, incorporating the creation and application of regulations, standards and guidelines in identified issues pertaining to the registration of pharmacy personnel and pharmacies.



## Delivering An Effective Compliance System

The Pharmacy Act 2007 gives the PSI significant powers of inspection, investigation and enforcement. Authorised Officers of the PSI inspect new and existing retail pharmacy businesses, to assess compliance with the Act, and with other pharmacy and medicines legislation, and with the statutory Code of Conduct for pharmacists.

The PSI is tasked with ensuring that all pharmacists and pharmacy owners embed standards of good pharmacy practice within their day-to-day work, thereby delivering clear benefits to patients and the public. However, whilst standards continue to improve across the profession, there will always be a requirement to protect patients and the public from adverse consequences arising from poor or unacceptable standards of practice.

Accordingly, the PSI will continue to refine its risk assessment methodologies with a view to allocating inspection and enforcement resources in the most effective manner, and to facilitate compliance with best practice.

A key focus of the evolving system will be the recognition of the important role played by pharmacy owners. The PSI must engage effectively with owners to ensure their ongoing commitment to, and accountability for, the application of regulations and good practice standards.

Anticipated changes within pharmacy and within the broader healthcare landscape in Ireland will place additional responsibilities on the PSI inspection and enforcement regime which will have to be closely monitored over the lifetime of this Corporate Strategy.

### Short/Medium Term Objective:

By mid-2015, every community pharmacy in the State will have received at least one formal inspection by an Authorised Officer of the PSI, with appropriate and relevant follow-up action put in place with those pharmacies and pharmacists found not to be compliant with the regulations and with good practice guidelines.

During the period 2013-15, we will continue to refine and develop the system of inspection and enforcement across all types of pharmacy, combining the requirements of the legislation with the nature of pharmacy practice within each sector.

### Medium/Long Term Objective:

During the period 2015-17, the PSI will develop its quality and risk system for inspecting community pharmacies which looks holistically at the pharmacy, incorporating the roles and responsibilities of pharmacists, owners, and the wider pharmacy team.

We will also consider the feasibility of introducing a system of self-assessment for pharmacies, as part of the wider quality- and risk-based system of inspection.

## Ensuring The Delivery Capacity Of The PSI

The PSI prioritises patient safety and public protection, and must ensure that patients, the public, policy-makers, and other statutory bodies maintain their confidence and trust in pharmacists and in the profession of pharmacy.

As resources and funding continue to be constrained as a result of the economic downturn which commenced in 2008, the PSI must remain cognisant of its responsibilities to manage its resources cost-effectively and prudently, recognising that its funding is derived wholly from fees paid by the profession. We will co-operate with other regulators within the healthcare sector in order to examine the potential to maximise efficiencies.

At the same time, we have also been undertaking a growing workload arising from the new roles for the PSI set out in the 2007 Act and other legislation, and it is expected that this workload will increase over the lifetime of this Corporate Strategy.

Over the period 2013-17, additional resources – in terms of both highly-qualified and experienced staff, new information technology systems, and facilities within our new central Dublin offices – will be required to ensure that the PSI meets these requirements. Business processes and procedures will be regularly updated in line with improved standards for the performance of regulatory bodies, reflecting the independence of the PSI, and the leadership that this entails. We will also work to ensure that we recruit and retain the best and brightest staff, offering a highly attractive professional career path and work environment.

The PSI must continue to ensure that it has the necessary range of qualifications, skills and experience at its disposal to effectively address the challenges ahead both within the pharmacy profession and across the wider healthcare sector.

### Short/Medium Term Objective:

We will review, and revise as necessary, the executive structure of the PSI, and the competency and skill mix, to ensure that we are focused on the present and emerging challenges facing the regulation of pharmacy in Ireland.

We will continue to develop the organisation, with particular focus upon the recruitment and retention of highly-qualified and motivated staff, on the development of attractive career paths, and on the strengthening of our IT infrastructure.

We will work closely with other healthcare regulators in order to examine the potential to maximise efficiencies, with a view to identifying possible target actions during 2013-15.

### Medium/Long Term Objective:

During the period 2015-17, it will be necessary to review the organisation in terms of its size, structure, skills, and infrastructure, in order to prepare the PSI to meet the regulatory challenges of 2018 and beyond.



## Corporate Governance

Critical to the effectiveness of the PSI is the need for it to operate, and be seen to operate, as the independent regulator of pharmacy in the discharge of its functions. The PSI must operate in an ethical and fair manner, with high standards of transparency and accountability, and comply in full with the Code of Practice for the Governance of State Bodies, including the Ethics in Public Office Acts.

The PSI will continue to be guided by its published Corporate Governance Framework, which will be reviewed during 2013.

We will work to ensure that our policies on Conflicts of Interest involving PSI Members and staff are as robust as possible, and in line with good governance practice.

### Overall Objective for 2013-17:

The key challenge for the PSI – its Council, its Committees and its executive staff – over the period 2013 to 2017 will be to continue to operate, and be seen to operate, in an independent and objective manner, in the interests of the safety of patients and the public.

We will continue to develop and review our corporate governance framework, including our policies on Conflicts of Interest.

## Engaging With Stakeholders

We recognise that very substantial change is taking place within the Irish healthcare system: during the lifetime of this Corporate Strategy, Government policy is that the Health Service Executive will cease to exist, the Department of Health will assume greater control over the delivery of health services, new health agencies will be created, mechanisms to improve the quality of care will be strengthened, and – ultimately – a system of Universal Health Insurance will be introduced. All of these changes will have a profound effect upon the contribution to be made by the pharmacy profession in Ireland.

The PSI will continue to play a central part in the Irish healthcare system, through ongoing and increasing engagement with stakeholders, through proactively facilitating the changes in the context of its own regulatory responsibilities and the requirements of patients and the public, and through continuing involvement in the initiatives arising from the strategic document “Future Health” issued by the Government in 2012

The establishment of the new Institute of Pharmacy will also provide the PSI with a further opportunity to contribute to the leadership of the profession in Ireland, and a sound platform for enhancing engagement with stakeholders within the healthcare system.

**Short/Medium Term Objective:**

We will actively work with stakeholders within the Irish healthcare sector, strengthening these vital relationships to ensure that the regulation of pharmacy and the provision of safe and effective pharmacy services occupy a central position in the changing structures of the health service.

We will work closely with other health regulators to ensure that quality of service to patients and the public remains pharmacy's priority.

**Medium/Long Term Objective:**

During the period 2015-17, we will continue to examine the impact of the changing healthcare landscape on pharmacy, and to make such changes to our services and structures as are deemed necessary.

**Getting Our Message Out**

In line with the PSI's duties and responsibilities under the 2007 Act, it is vitally important that the role of the PSI as the pharmacy regulator is effectively and proactively communicated to the public, the pharmacy profession, and other stakeholders.

The PSI has a duty to communicate to the profession of pharmacy its ethical and professional obligations to patients and the public in a clear and concise manner. The PSI has a duty to the public and to patients to communicate what they should expect from pharmacy services and from their interaction with pharmacists.

In 2012, the PSI Council approved a new Communications Strategy for the organisation, in order to help develop and implement a cohesive and coherent communications programme that supports the PSI's commitment to the safety of patients and the public.

In August/September 2013, the International Pharmaceutical Federation (FIP) will host its Annual Congress in Dublin, providing the PSI with an excellent opportunity to develop and present its profile, and that of modern pharmacy practice in Ireland, on a global stage.

**Overall Objective for 2013-17:**

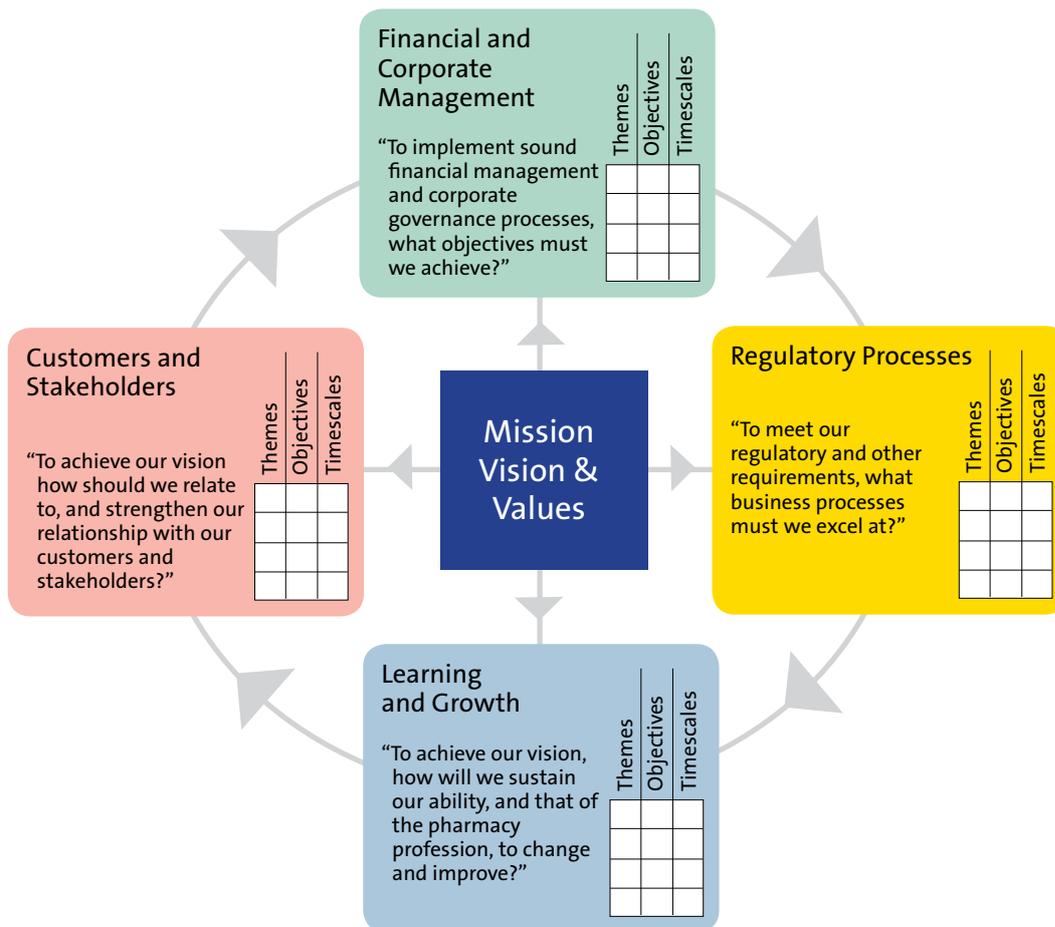
Over the lifetime of this Corporate Strategy, we will implement the Communications Strategy in full, ensuring that we maximise the effective delivery of our message to all stakeholders.

# 4

## PSI Balanced Scorecard

### Translating Our Strategic Objectives into Service Delivery

To measure our corporate performance over the period 2013-17, the PSI will continue to use the existing Balanced Scorecard system, which sets out our key objectives and timescales over four quadrants, representing the main areas of the PSI’s corporate focus – our regulatory responsibilities, our plans for learning and growth within pharmacy, our relationship with customers and stakeholders, and our arrangements for financial and corporate management and governance. Use of the scorecard provides both the PSI and its external stakeholders with a clear and straightforward mechanism for measuring our performance in the areas which are of greatest strategic importance.



The Strategic Objectives presented in Section 3 above have been grouped under themes within the four quadrants (depicted above), with a short series of targeted actions or initiatives identified as objectives, alongside clear timescales, in order to facilitate ongoing monitoring of progress and measurement of our corporate performance.



Responding to the challenges set out earlier, the PSI's strategic objectives for 2013 to 2017 are:

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
The Overall Challenge for the PSI <i>[Regulatory Processes]</i>	1	To build on our achievement of the implementation of the Pharmacy Act 2007, and to continue to provide effective leadership and regulation of the practice of pharmacy, taking account of the changing environment.	
	2	To continue to seek the safe and optimal use of medicines, and to ensure that pharmacists and pharmacies are in a position to meet the evolving needs of patients and the public.	
	3	In line with <i>Pharmacy Ireland 2020</i> , to continue to support the development of new and novel pharmacy services through effective regulatory processes, and to facilitate enhanced accessibility of pharmacy services by patients.	
Continuing to Facilitate Lifelong Learning <i>[Learning and Growth]</i>	4	Continue to facilitate lifelong learning through the implementation of a world-class, robust system of pre- and post-registration education, training and ongoing professional development for pharmacists.	
	5		Review progress to date with the implementation of the five-year fully integrated Masters degree in pharmacy and the Irish Institute of Pharmacy and its various initiatives and developments, and evaluate the need for any changes or enhancements.

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Continuing to Assure High Standards of Patient Care and Good Pharmacy Practice <i>[Learning and Growth]</i>	6	Play a full part at both national and local levels to enhance collaborative, patient-centred care delivery involving healthcare professionals working together across the various interfaces within the evolving Irish health system.	
	7	Support and facilitate pharmacists to work with patients to educate and inform them regarding their medication regimes.	
	8	Work towards the introduction of effective medicines reconciliation, as recommended in the report of the Madden Commission in 2008.	
	9	Continue to develop evidence-based standards of good pharmacy practice in all settings, in line with evolving changes in the delivery of healthcare services. Work with other healthcare and patient organisations to ensure the best standards of care for patients.	
	10	Work closely with hospital pharmacists, and with other stakeholders within the hospital sector, to ensure that the contribution of hospital pharmacists to patient care can be optimised.	
	11	Complete the suite of guidelines to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008.	

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Facilitating the Development of Pharmacy as a Profession in Ireland <i>[Learning and Growth]</i>	12	Continue our work on the implementation of the recommendations of the <i>Pharmacy Ireland 2020</i> initiative, in order to continue to strengthen the profession in line with international best practice, with particular focus on benchmarking and continuous learning	
	13	Seek to enhance the development of the profession to ensure that its contribution to safe and effective patient care is optimised.	
	14	Engage with other stakeholders to determine how best the findings of the Hospital Pharmacy Baseline Study can be taken forward, in order to assist with the development of hospital pharmacy and optimise the role of hospital pharmacists.	
	14		Examine closely the emerging and future trends for all branches of pharmacy, in order to help identify the type of regulation and support required by the profession in 2018 and beyond.

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Ensuring Fair Registration Procedures <i>[Regulatory Processes]</i>	15	To operate in a transparent, objective manner, ensuring the responsible application of resources in the fulfilment of the core registration functions.	
	16	To optimise on an on-going basis the utilisation of appropriate technology, in delivery of registration services, engagement with registrants, and monitoring of qualified registrants.	
	17	To review, monitor and apply fair registration procedures in accordance with relevant legislation at both initial and continuing registration application stage.	
	18	To develop, and disseminate to the practising profession, guiding principles which link the system of continued registration with the registrant's participation in CPD and associated assurance processes.	
	19		To participate, lead where appropriate, and contribute to the identification, development and application of required legislative and policy change, incorporating the creation and application of regulations, standards and guidelines in identified issues pertaining to the registration of pharmacy personnel and pharmacies.

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Delivering an Effective Compliance System <i>[Regulatory Processes]</i>	20	Ensure that by mid-2015, every community pharmacy in the State will have received at least one formal inspection by the PSI, with appropriate and relevant follow-up action put in place with those pharmacies and pharmacists found not to be compliant with the regulations and with good practice guidelines	
	21	Continue to refine and develop the system of inspection and enforcement across all types of pharmacy, combining the requirements of the legislation with the nature of pharmacy practice within each sector.	
	22		To develop our quality and risk system for inspecting community pharmacies which looks holistically at the pharmacy, incorporating the roles and responsibilities of pharmacists, owners, and the wider pharmacy team.
	23		To consider the feasibility of introducing a system of self-assessment for pharmacies, as part of the wider quality- and risk-based system of inspection.

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Ensuring the Delivery Capacity of the PSI <i>[Financial and Corporate Management]</i>	24	Review, and revise as necessary, the executive structure of the PSI, and the competency and skill mix, to ensure that we are focused on the present and emerging challenges facing the regulation of pharmacy in Ireland.	
	25	Continue to develop the organisation, with particular focus upon the recruitment and retention of highly-qualified and motivated staff, on the development of attractive career paths, and on the strengthening of our IT infrastructure.	
	26	Work closely with other healthcare regulators in order to examine the potential to maximise efficiencies, with a view to identifying possible target actions during 2013-15.	
	27		Review the organisation in terms of its size, structure, skills, and infrastructure, in order to prepare the PSI to meet the regulatory challenges of 2018 and beyond.

Theme	Objective	Short/Medium Term (2013-15)	Medium/Long Term (2015-17)
Corporate Governance <i>[Financial and Corporate Management]</i>	28	To continue to operate, and be seen to operate, in an independent and objective manner, in the interests of the safety of patients and the public.	
	29	To continue to develop and review our corporate governance framework, including our policies on Conflicts of Interest.	
Engaging With Stakeholders <i>[Customers and Stakeholders]</i>	30	Actively work with stakeholders within the Irish healthcare sector, strengthening these vital relationships to ensure that the regulation of pharmacy and the provision of safe and effective pharmacy services occupy a central position in the changing structures of the health service.	
	31	Work closely with other health regulators to ensure that quality of service to patients and the public remains pharmacy priority.	
	32		Continue to examine the impact of the changing healthcare landscape on pharmacy, and to make such changes to our services and structures as are deemed necessary.
Getting Our Message Out <i>[Customers and Stakeholders]</i>	33	Implement the Communications Strategy in full, ensuring that we maximise the effective delivery of our message to all stakeholders.	

## 5

## Risk Management

### Translating Our Strategic Objectives into Service Delivery

The strategic objectives included within our Balanced Scorecard set out the priorities for the PSI over the next five years, and reflect the ambition and intent of the PSI Council and Senior Management Team to deliver on its challenging mandate. In preparing this Corporate Strategy, a range of significant / strategic risks facing the PSI were identified. The risks are reflective of the uncertainty facing both the health sector and the wider public sector in Ireland, and in particular address the challenges as outlined in the Corporate Strategy.

Risk Type	Nature of Risk
<b>Legal and regulatory</b>	Failure by the PSI to meet or deliver on its legal and regulatory obligations both as a regulator with a mandate for patient safety, and as a public service body, subject to the governance obligations of the 2009 State Body Code, employment legislation, freedom of information regulations, data protection regulations, etc.
<b>Reputational</b>	Impairment or loss of reputation of PSI as an effective regulator in the public interest, or loss of confidence of the public or Government, in the work of the PSI.
<b>Personnel</b>	Insufficient or inadequate knowledge, skills and competencies within the organisation, particularly in the context of the public service recruitment embargo.
<b>Budgetary and financial resources</b>	Insufficient or inadequate budgets to meet revenue and capital obligations in context of service plans and contingency funds required.
<b>Inter-agency relationships</b>	Failure to achieve joined up approaches to address cross-cutting issues. For the PSI to be fully effective, it needs to foster robust relationships with the Department of Health, the HSE, other State agencies, other regulators, and all those with whom it has service level agreements and/or memoranda of understanding.
<b>Policy and Operational</b>	Failure to ensure that the strategic and operational policies of the PSI are properly developed and implemented, and that targets are met.

The PSI will, over the life of this Corporate Strategy, evaluate the above risks and will ensure that all actions and initiatives undertaken manage these challenges proactively, with risk mitigation/minimisation actions being identified and implemented without delay, so that our statutory mandate can be pursued and effectively delivered.



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