

Service Plan 2021



“Assuring public trust in pharmacy through effective regulation”

PSI Corporate Strategy 2021 - 2023

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1. Introduction

In December of each year, in accordance with applicable legislation,¹ and in compliance with the provisions of the *Code of Practice for the Governance of State Bodies*,² the PSI Executive develops a Service Plan which, in the context of our current Corporate Strategy, sets out the work programme and priority activities for the coming year. The proposed Service Plan is considered by the PSI Council in December of each year. The Service Plan, once approved by the Council, is a public document and is published on the PSI website.

Our Service Plan for 2021 provides an overview of our strategic development agenda for the year, and it details the projects that will be initiated by the PSI during 2021, together with details of the supporting budget for the year.

The PSI operates on the basis of a three-year Corporate Strategy. In 2021, we will be in year one of our Corporate Strategy 2021-2023. This strategy, which follows on from our previous strategy for 2018-2020, defines our central organisational goal to be: **“Assuring public trust in pharmacy through effective regulation”**. This is the key goal by which we will assess our decisions and actions during 2021 and is a measure against which the public and our stakeholders can hold us to account as a public body.

Our strategic agenda and projects in 2021 are intended to deliver concrete results under each of the three strategic areas set out in our Corporate Strategy. These are:

- Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System
- Evolving a More Effective Regulatory Model for Community Pharmacies³
- Building our Capability and Performance as a Regulatory Organisation

Looking back – Progress made under our 2018-2020 Corporate Strategy

Through the implementation of our previous strategy, we believe that the PSI has made progress towards our goal of enhancing public trust in pharmacy⁴. We have done this by working to ensure that our regulatory activities, across the areas of pharmacist registration and qualification recognition, education, professional development, and the oversight of retail pharmacies, serve to protect the public. We have also worked to encourage ongoing quality development within community pharmacy and to support the provision of quality

¹ Article 22 of Schedule 1 to the Pharmacy Act, 2007.

² As published by the Department of Public Expenditure and Reform (2016/2020)

³ The Pharmacy Act refers to “Retail Pharmacy Businesses”. In this document, we are using the term “Community Pharmacy” to refer to all pharmacies registered with PSI that provide medicines and other pharmacy services to the public at community level.

⁴ Further details on our delivery under the Strategy are set out in our published annual reports for 2018, 2019 and 2020 (forthcoming in May 2021).

and safe healthcare services through community pharmacies in Ireland. We have increased collaboration and engagement with the profession and have continued to build the PSI as an effective organisation. We will further build on this progress and experience as we implement our Service Plan for 2021.

Implementation and oversight

The PSI's Executive Leadership Team keeps the delivery of the Service Plan under regular review during each year. Progress towards achieving the objectives set out in the three-year Corporate Strategy, and progress against this annual Service Plan, are reported at the regular meetings of the PSI Council and of its Advisory Committees.⁵ Recognising that risk is a constant in today's world and represents a critical governance concern, the PSI's Executive Leadership Team also ensures that the organisation is responsive to risk by reviewing, and appropriately managing, our organisational risks throughout the year and, via the PSI Audit and Risk Committee, providing ongoing assurance to the Council in this regard.

Meeting the challenges of COVID-19

As we are all very aware, during 2020 there have been many challenges posed by the COVID-19 pandemic. In PSI, we have worked to play a full part in the public health response to the pandemic while also adapting as an organisation to remote and hybrid working. We are very aware of the ongoing challenges being faced by the pharmacy profession in responding to the challenges of the pandemic. We acknowledge the exceptional dedication of pharmacists, and wider pharmacy teams, during 2020 and their essential role in ensuring that patients have had continued access to care, medicines and influenza vaccination. These challenges and uncertainties are expected to persist well into 2021 and will continue to impact on our scope for in-person engagement activities. Nonetheless, our focus in the PSI will remain on working with all of our stakeholders to play a full part in mitigating the impact of the pandemic and in supporting the roll-out of COVID-19 vaccines.

Niall Byrne
Registrar & Chief Officer
December 2020

⁵ The Performance & Resources Committee and the Regulatory & Professional Policy Committee.

Our mission, vision and values

Our vision, our mission and the values that underpin our work in the PSI are set out in the diagram below.



2. Planned activities and priorities for 2021

This 2021 Service Plan should be read in conjunction with the PSI Corporate Strategy 2021-2023, which sets out our strategic agenda for the next three years and which provides the broader context for our programme of strategic change and ongoing development.

Below is an overview of our priorities for 2021, first detailing our ongoing regulatory work, and then our policy priority initiatives and our strategic development projects for 2021.

Our ongoing regulatory work

As well as pursuing a clear strategic agenda and envisioning new projects and fresh ways of working, the PSI must, at all times, ensure that we fulfil our primary statutory functions. The Pharmacy Act 2007 provides for a system of statutory regulation of pharmacists and of retail pharmacies in Ireland. The Act, together with its supporting secondary legislation, and related medicines law, places a clear responsibility on the PSI to regulate the pharmacy profession and community pharmacies in the interests of patient safety. Critical to our work, and central to our mission, are our ongoing areas of activity which we will continue to deliver upon to a high standard during 2021.

During 2021, we will continue to:

-  operate fair, transparent, and efficient registration procedures for all registrants (pharmacists, pharmaceutical assistants, and retail pharmacies), and maintain the statutory registers,
-  evaluate, for accreditation purposes, programmes of education leading to qualifications appropriate for practice as a pharmacist in Ireland
-  oversee the effective implementation of the mandatory system of continuing professional development (CPD) for pharmacists,
-  promote and support professional practice by pharmacists and share information for the benefit of patients and the wider health system,
-  communicate and engage with the public, the pharmacy profession, and our many other stakeholders, to ensure our work is understood, and informed, by these stakeholders,
-  assure the public of the quality and safety of community pharmacy services through ongoing programmes of quality assessment and oversight of compliance with essential safety requirements,
-  undertake investigations into matters of serious concern regarding the actions of pharmacists and/or pharmacies and initiate enforcement actions, including prosecutions, where appropriate,

-  manage the professional complaints process in accordance with the law, natural justice, and fair procedures,
-  contribute to the ongoing review of new and existing pharmacy/medicines legislation and contribute to public policy developments relating to our regulatory remit,
-  comply with our own external compliance obligations and with the Code of Practice for the Governance for State Bodies which provides assurance that the PSI acts in accordance with best practice in the management and governance of public bodies, and
-  operate prudent financial management practices and continue to steward all PSI resources to maximise the resources available to deliver on PSI's statutory functions.

Our priority policy initiatives

In addition to our core statutory responsibilities and our ongoing assurance work, as outlined above, we will also pursue initiatives that are framed by the three elements of our Corporate Strategy 2021-2023. In planning for 2021, we are also very aware of three key aspects of our current operating environment:

- The COVID-19 pandemic and the necessity for a clear external and internal response by the PSI;
- The policy objectives of healthcare reform, Sláintecare implementation and related initiatives;
- The consequences for Ireland of Brexit.

During 2021, we will seek to progress the following initiatives in cooperation with other stakeholders. We will, of course, also engage with initiatives sponsored by Government, other public bodies, and our other stakeholders, where these are appropriate to our role as the public interest regulator of pharmacists and pharmacies. During 2021, we plan to:

- Engage with the Department of Health and HSE on Sláintecare implementation, standing ready to facilitate advanced practice by pharmacists where this is required by patient need and public policy;
- Engage and collaborate with the Department of Health on other developments relating to pharmacy such as the public health response to COVID-19 and the development of a new community pharmacy contract;
- Manage the risks related to Brexit, in collaboration with other public bodies and relevant stakeholders;
- Assure the safe supply of medicines from pharmacies into residential care settings by engaging with other relevant regulatory bodies and by ensuring that the regulatory

requirements falling on pharmacists and pharmacies involved in this area of supply are clear;

- Examine how the PSI can contribute to the development of strategies that will reduce the overuse of benzodiazepine medicines, in collaboration with relevant public bodies and other stakeholders.

Our strategic development projects

In addition to the above, the following tables provide a summary of our planned strategic development projects for 2021. Our operating environment for the first part of 2021 (at least) will be significantly impacted by the COVID-19 pandemic, and remote or hybrid working is expected to continue. Consequently, projects that include wider consultation, engagement and analysis will continue into 2022 to allow the impact of remote working on these activities to lessen. Some projects are, of necessity, multi-annual, and will run across the period from 2021-2023.

The tables also show which of the strategic objectives in our Corporate Strategy will be impacted by each project and describes the expected outcomes for each project in 2021.

In Table 1, we have identified **eight priority projects for 2021**, including our digital transformation project which commenced in November 2019. In addition, we are including **six multi-annual projects to commence in 2021** and which will run over subsequent years of our strategic planning cycle - these are shown in Table 2.

Objective 1: Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System	Objective 2: Evolving a More Effective Regulatory Model for Community Pharmacies	Objective 3: Building our Capability and Performance as a Regulatory Organisation
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Table 1 – Priority projects for 2021

Project description	Objective impacted by this project			Planned timeframe			Principal outcomes in <u>2021</u>
	Objective 1	Objective 2	Objective 3	2021	2022	2023	
Ensure registration of pharmacists from the UK continues after Brexit in keeping with Government policy	✓			✓			<ul style="list-style-type: none"> Operationalise our new Third Country Qualification Route (TCQR) process Initiate a comprehensive review of the Rules governing the registration of pharmacists
Advance reform of the Pharmacy Act		✓		✓			<ul style="list-style-type: none"> A review of models of regulation of pharmacy and other relevant healthcare services will be scoped and commissioned Possible review of the current Retail Pharmacy Businesses Regulations will be informed by the results of the above exercise
Encourage adoption of COVID-19 operational standards across all community pharmacies		✓		✓			<ul style="list-style-type: none"> COVID-19 operating standards for pharmacies tested, refined and adopted in practice by pharmacies Overview reporting of how pharmacies are meeting the Standards commenced

							<ul style="list-style-type: none"> Legislative underpinning for these, and standards more generally, progressed with the Department of Health
Operationalise our Regulatory Risk Statement		✓	✓	✓			<ul style="list-style-type: none"> All necessary risk analysis and response processes and procedures are in place Learnings are incorporated into our Business Transformation Programme
Deliver the year two objectives of our Business Transformation Programme			✓	✓	✓	✓	<ul style="list-style-type: none"> Full implementation of the new registration system and technology platform that enables our registrants and applicants to engage with the PSI in an efficient and streamlined manner Development commenced on the technology platform within the 'Single Customer View' to facilitate the PSI's management of regulatory risk Enhanced ways of working for our staff within a new target operating model
Review and reform our organisation and management structures to better support strategy implementation			✓	✓	✓		<ul style="list-style-type: none"> Develop and adopt a new target operating model Enable the change process through: <ol style="list-style-type: none"> Change readiness assessment and engagement of staff Ongoing development of staff through facilitation and coaching Assessment and integration to ensure change competency transfer

Enhance our customer services and engagement with key stakeholders by developing an improved website and improve our use of social media platforms			✓	✓			<ul style="list-style-type: none"> • Implementation of a contemporary and flexible PSI website that supports and facilitates all PSI digital offerings • Enhanced and increased engagement with all our customers through social media
Commence a Strategic Financing Review for the PSI			✓	✓			<ul style="list-style-type: none"> • Identify the key issues problem - scoping/analysis of the scale, nature and extent of the strategic finance issues, key assumptions, etc. • Proposals as to necessary next steps brought to the PSI Council

Table 2: Multi-Annual Projects to Commence in 2021

Review the CPD Model for pharmacists	✓			✓	✓		<ul style="list-style-type: none"> • Scale and extent of the necessary review scoped • Proposals as to necessary next steps brought to the PSI Council • Preliminary work commenced on separate CPD model for Pharmaceutical Assistants
Assess emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy in Ireland	✓			✓	✓	✓	<ul style="list-style-type: none"> • Identify the key issues - scoping/analysis of the scale, nature, and extent of this risk to identify emergent issues, impact, and landscape of issue • Proposals as to necessary next steps brought to the PSI Council

Develop revised Core Competency Framework (CCF) for Pharmacists	✓			✓	✓		<ul style="list-style-type: none"> Follow up on the recommendations in the report on the Core Competency Framework as approved by Council on 10 October 2020 Initiate further work on a CCF allowing for demonstration of evolving levels of competence
Develop a rolling patient experience programme capable of capturing/tracking the experience of people using community pharmacies		✓		✓	✓	✓	<ul style="list-style-type: none"> Exploration of research and best practice in other patient experience programmes nationally and internationally Scoping of programme content and process for a programme across community pharmacies
Develop and commence delivery of a new HR Strategy 2021-2023			✓	✓	✓		<ul style="list-style-type: none"> Implementation of a new performance model and a learning and development (L&D) framework that support all our people to achieve their potential in pursuit of our shared vision and mission and in context of our “Better Ways of Working” business transformation programme A collaborative working environment where the employee voice is involved in all matters impacting on our staff A productive and safe workplace that meets the needs of the organisation and our people in the context of a distributed workforce
EFQM – Embed the discipline and approaches underpinning Excellence throughout the PSI			✓	✓	✓		<ul style="list-style-type: none"> Action the recommendations of our EFQM assessment report Adopt the revised EFQM Model Achieve for re-certification in 2022

How we will deliver on our strategic projects for 2021

Communication and engagement play a vital part in all aspects of our work and will be adapted to remote and hybrid working, as necessary. We will continue to work to ensure that our work priorities and our decisions are based on consultation with PSI registrants, pharmacy students, higher education institutions, patients, the healthcare sector, and the general public. We will continue to develop our channels of engagement so that we are learning from a broad community, and gaining from their input, as well as finding new ways of raising awareness about our role and that of pharmacists and of pharmacy services in Ireland. We will also continue to work closely with other regulators and public bodies to ensure that we share relevant information, achieve ongoing efficiencies in service delivery, support quality improvement within healthcare and play a full part in safeguarding public health and welfare.

3. Expected financial position and budget for 2021

Funding direction

During 2021, the PSI will continue to operate in a prudent manner to ensure its resources are fully, and properly, utilised to meet its statutory functions. We will implement the objectives of the Corporate Strategy 2021-2023 within the context of Government policies for healthcare regulation and for the management of public bodies in the health sector.

The PSI will continue to manage its resources carefully and will ensure it has the funding and reserves available to meet its expenditure commitments. Reserve funds will also be managed and invested appropriately, and in line with Council policy, to ensure that future liabilities can be funded as they arise.

The 2021 budget has been drafted with a view to meeting, to the optimum level, the statutory obligations of the PSI within the constraints of resources available. In summary, the income budget for 2021 is **€7.988m** and the total proposed expenditure budget for 2021 is **€8.842m** of which it is proposed that **€501k** is eligible to be funded from the reserves thereby projecting a deficit arising from operating activities of **€353k**.

Overview of principal components of 2021 budget

The following sections set out a brief description of the activities covered in the draft 2021 budget.

Income

For the 2021 income budget, we have budgeted a net increase in the registration numbers for both retail pharmacy businesses (1%) and pharmacists (3%). The total income from registration fees and other related fees is expected to be €7.998m, an increase of €256k or 3% above the 2020 budget.

It is expected that the Department of Health will continue to fund the operation and further development of the Irish Institute of Pharmacy's services in 2021, up to an annual amount of €600k.

Expenditure

The projected expenditure in the 2021 budget provides for the continuation of the core functions and services as in previous budgets, any continued cost of projects commenced in prior periods, as well as newly planned activities for the year 2021.

Pay budget (€4.190m)

The total pay budget 2021 is €4.190m, being an increase of €0.342m or 8.2% on the 2020 budget. This increase of 8.2% in payroll, year-on-year, is as a result of the ending of the Haddington Road Agreement, through the Lansdowne Road Agreement, and its extension and the associated public sector pay restoration implications, including a 2% pay increase which was awarded to all public service staff, including PSI staff, in October 2020. The staffing and pay levels are in line with public sector pay policy and include the workforce matters approved by Council in 2017. It is the intention that the PSI will have the full complement of employees in post by the end of 2021.

Non-pay budget (€4.652m)

The non-pay budget covers the costs of all goods and services expected to be incurred by the PSI during the year. It includes the regular contracted services and agreed development projects funded from the reserves.

Management of 2021 budget

Procurement planning

The PSI will continue to search for efficiencies, value for money and use ICT solutions and Office of Government Procurement (OGP) frameworks, wherever possible. The PSI will ensure that its procurement policies and procedures are implemented, and that competitive

tendering is undertaken for goods and services procured. The PSI will carry out its annual procurement activity in line with its Corporate Procurement Plan.

Financial management

Each budget holder in PSI is responsible for managing their own budget. Regular reports will be issued to the Heads of Departments and Unit Managers by the finance team. Monthly meetings will take place with each budget-holder to discuss progress and any resulting variances. All variances will be considered by the Executive Leadership Team and remedial actions taken as required. The Council will review quarterly financial reports, and these will also be reviewed by the Performance and Resources Committee and by the Audit and Risk Committee.

Treasury management

The PSI invests its funding as per its approved Treasury Management Policy. The PSI will continue to manage its funding and cash flows to ensure availability and access to funding in order to service the requirements placed on it in legislation and any future developments that may so arise. PSI funds are currently invested with Ulster Bank, AIB Bank, Bank of Ireland and KBC bank. In the Irish deposit market, negative interest rates are now a reality. We will endeavour to maintain the value of the PSI reserves as far as possible, and as per the PSI Treasury Management Policy.

Property/facilities management

In 2021 the PSI will be entering its ninth year of residency in PSI House. The premises continue to provide efficiency of resources with the ability, COVID-19 restrictions allowing, to hold all meetings, fitness to practise inquiries, and events in-house, as well as the ability to support regulatory colleagues and other stakeholders in the provision of modern meeting facilities.

The PSI will continue to maintain the property to a high standard and deal promptly with maintenance issues as they arise. Nonetheless, it must be recognised that future provision is required for additional and proactive maintenance as the premises and building infrastructure begin to age. It is envisaged that the Strategic Financing Review will examine all options regarding PSI House. There is a project planned for 2021 – PSI House Life cycle Review – which will examine the life cycle costs of PSI House and make recommendations regarding future costs.

Summary budget 2021

	€M	€M
Income 2021		
Registration of Pharmacists	2.794	
Registration of Retail Pharmacy Business (RPB)	4.511	
Administration charges and other registration costs	0.088	
Bank interest received	(0.006)	
Department of Health funding to the Irish Institute of Pharmacy (IIOP)	0.600	
Total Income		7,988
Expenditure 2021		
Pay costs	4,190	
Operational costs	3.182	
IIOP	1.300	
Organisation-wide projects	0.170	
Total expenditure		8.842
Operating Surplus/(Deficit)		(0.854)
Add back projects funded from Reserves		0.501
Adjusted Surplus/(Deficit) for the year		(0.353)