

COVID-19 OPERATIONAL STANDARDS FOR PHARMACIES



What are the COVID-19 Operational Standards for Pharmacies?

The COVID-19 Operational Standards for Pharmacies (the Standards) outline the standards that the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, expects to see in place in pharmacies in the context of COVID-19¹. The Standards cover a range of relevant areas, such as infection prevention and control, necessary measures to assure the safety of patients and pharmacy staff, and guidance on providing pharmacy and medicines services in an environment where COVID-19 remains present in our communities.

The use of Standards is a new approach for both the PSI and the pharmacy sector; they are a flexible regulatory tool developed to support the profession in delivering safe and quality pharmacy services to patients and the public during the COVID-19 pandemic.

The Standards are intended to guide and support pharmacy owners, pharmacists and pharmacy staff as to what the PSI expects from pharmacies in continuing to ensure safe services and a safe environment for patients, the public and their staff. The Standards are also intended to inform patients and the wider public as to what they can expect from their pharmacy and to provide assurance that their pharmacy is, indeed, a safe and supportive healthcare environment despite the risks arising from COVID-19.

Pharmacists have already made an extraordinary contribution to maintaining the continuity of pharmacy services in the face of unprecedented challenges. The PSI is aware that many pharmacies have already put measures and good practice arrangements in place that will address the majority of the areas covered by these Standards. This is very much welcomed by the regulator. In circumstances where measures had to be put in place at short notice, the PSI believes that the Standards will help ensure pharmacies provide consistently high quality and safe services. The Standards will also help support a co-ordinated approach to dealing with any further changes and challenges which may arise during the course of the pandemic.

¹ The virus is called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and the disease that it causes is called Coronavirus Disease 2019 (COVID-19). For ease of reference throughout the document COVID-19 will be the term used to refer to both.

Introduction

In response to the unprecedented public health emergency resulting from the COVID-19 pandemic, pharmacies have adapted their work practices and how they provide medicines, other healthcare services and counselling to patients. This has presented new challenges for both pharmacists and pharmacies in providing continuity of care to patients whilst the risk of COVID-19 is present in our communities. Pharmacists working in pharmacies continue to play a key role in ensuring the continuity of medicine supply, in providing ongoing care to patients, and in providing professional advice and reassurance to the public.

As the pandemic continues it is important to ensure that a consistent standard of safe and quality care is delivered to patients and the public across pharmacies. The PSI recognises that the delivery of healthcare services and, indeed, how we go about our everyday lives has shifted dramatically as a result of COVID-19. To assist pharmacy owners, superintendent and supervising pharmacists address the resulting challenges, the PSI has developed these Standards to apply across all pharmacies.

What do the Standards cover?

The Standards cover four domains with **Quality** and **Safety** being the overarching principles:

1. Good governance
2. The pharmacy team
3. The pharmacy setting
4. Pharmacy services

Each standard is equally important and will provide concise, outcome focused indicators against which a pharmacy owner, superintendent pharmacist and supervising pharmacist can assess compliance with the Standards. They are not stand-alone standards, but mutually inform and cross-reference each other.

It is important to note that the indicators are indicative rather than prescriptive. It is perfectly acceptable that you may use other indicators to assess how you meet a standard. Indeed, we welcome innovation as regards how pharmacies meet the Standards. Fundamentally, what matters is that all indicators are evidence-based, robust and capable of objective assessment.



Who are the Standards for?

Responsibility for meeting the Standards lies with those who have **statutory governance responsibilities²** within pharmacies. These are:

1. Pharmacy owners
2. Superintendent pharmacists
3. Supervising pharmacists

When 'you' is referenced throughout the Standards this refers to *pharmacy owners, superintendent pharmacists and supervising pharmacists*.

It is essential that those in governance roles fully embrace their leadership responsibilities at all times, but it is of particular importance at a time of crisis. Although there may be different types of governance structures within pharmacies, those with statutory governance roles must ensure that there are appropriate structures and processes in place at all times to enable the pharmacy team to effectively deliver safe and quality care to patients and the public. This is crucially important during this challenging period as COVID-19 has impacted on how healthcare providers operate and this applies to pharmacies just as it does to other healthcare settings.

Whilst pharmacy owners, superintendent pharmacists and supervising pharmacists have overall responsibility for ensuring the Standards are in place, all registered pharmacists (including locum pharmacists) working in the pharmacy, pharmaceutical assistants and other pharmacy staff should be familiar with the Standards. Everyone in the team should play a role in how the Standards are adopted in their pharmacy, be able to demonstrate how the Standards have been implemented in their pharmacy and feel able to raise a concern if they feel their pharmacy is falling short of the Standards.

How were the Standards developed?

The PSI has developed these standards in close collaboration with practising pharmacists, the Irish Pharmacy Union (IPU) and the Health Service Executive (HSE)/Health Protection Surveillance Centre (HPSC), through the formation of a safety collaborative. This type of collaboration brings key stakeholders into a process which is focused on developing the best possible outcomes for patients and the public. The PSI greatly appreciates the contribution of the stakeholders involved in this safety collaborative and we look forward to working with them throughout the process of bringing the Standards into full effect in pharmacies.

The Standards reflect the national public health advice in place to manage the COVID-19 outbreak and they were also informed by approaches adopted internationally³. An internal steering group of the PSI executive has overseen the development of the standards.

² These roles and their responsibilities are set out in the Pharmacy Act 2007 and relevant Regulations.

³ A number of resources and guidance from pharmacy and non-pharmacy regulatory bodies were examined both nationally and internationally, as well as resources from the International Pharmaceutical Federation (FIP).

How do you demonstrate that you are meeting the Standards?

These Standards are intended to be a useful tool in facilitating you to critically review and reflect on protocols or workflow processes implemented during the COVID-19 pandemic and identify where improvements are required. Assessing how you meet the Standards will help you to identify gaps within the provision of your pharmacy services and the provision of a safe working environment for staff. As gaps are identified, you can then act to put measures in place to meet the relevant standard.

Pharmacies vary as to size, location and services provided. The context of each individual pharmacy should be taken into consideration when assessing how you meet the Standards.

In addition to complying with the Standards, you must, of course, also ensure your pharmacy meets all relevant legislative requirements and that you and your staff adhere to guidelines issued by the PSI and other relevant healthcare stakeholders such as the HSE, Department of Health and the HPSC. Compliance with Health and Safety Authority requirements is also important in the context of COVID-19.

Implementation of the Standards

'Use and Learn'

As Standards are a new way of regulating⁴ for both the PSI and the pharmacy sector, a collaborative learning and engagement approach to implementation will be adopted through an initial 'use and learn' period. This flexible period will allow you to have time to reflect upon and adapt your pharmacy practice where needed and share your feedback and experiences on the use and relevance of the Standards before these are finalised later this year. Effective, proactive engagement and communication of the Standards is a core priority for the PSI.

The 'use and learn' period will provide the PSI with an opportunity to pro-actively seek the perspective of those who have been at the forefront during the pandemic. We will be engaging with the pharmacy sector, patients and other relevant stakeholders to hear their views on the Standards, which we expect will take place over the months of August and September 2020. The PSI, with the support and input from a number of pharmacies nationwide, will also be undertaking a field testing programme on the use of the Standards to help test and verify their effectiveness. It will also provide time and opportunity for the PSI to develop an efficient and effective monitoring programme for implementation later in 2020/2021.

Further information about when the 'use and learn' period finishes and how the field testing programme will be carried out, will be communicated in due course.

⁴ Since 2007, the PSI has primarily used the legal provisions of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) to regulate pharmacies. While these provisions, which are focused on conformance with requirements, continue to apply, we are now supplementing these with outcome-based standards which are intended to define what good performance looks like in pharmacies operating during COVID-19.

How are the Standards structured?

The diagram below sets out the Standards under the four domains.



Standard 1.

A clear and effective governance structure is in place which promotes a culture of quality and safety in your pharmacy.



Standard 2.

The pharmacy team is supported and enabled to provide safe and high-quality patient care.



Standard 3.

A safe environment is provided for patients and staff to minimise the risk of spread of COVID-19 and other infections in the pharmacy.



Standard 4.

Pharmacy services are delivered safely, effectively and to a consistently high standard.

Standard 5.

There is effective communication with patients both face-to-face and remotely.



Standard 1: A clear and effective governance structure is in place which promotes a culture of quality and safety in your pharmacy

Under this standard, those in governance roles fully embrace their leadership responsibilities in the interests of patients, the public and their staff during the COVID-19 pandemic. Clear lines of accountability are in place between the pharmacy owner, superintendent pharmacist and supervising pharmacist across all aspects of service provision. An environment is established where responsibilities are clear and transparent, particularly for risk assessment and contingency planning. The focus of leadership is on delivering safe and reliable patient care despite the presence of COVID-19 in our communities.

Indicators that your pharmacy service is meeting this standard are likely⁵ to include:

- 1.1 You ensure that all statutory governance roles such as superintendent and supervising pharmacists are appointed in accordance with legislation, and that there are appropriate communication channels implemented.
- 1.2 You have effective supervision structures in place in your pharmacy. You hold yourself to a high and consistent standard of performance and you hold those who report to you accountable for their performance, particularly as it relates to quality and safety.
- 1.3 You and the pharmacy team display professionalism in every point of contact with patients and the public. During times of national crisis it is essential that superintendent, supervising and other registered pharmacists follow the [PSI Code of Conduct for Pharmacists](#). As a pharmacy leader, you exercise your professional judgement and practice ethically in challenging conditions and you also support and encourage other pharmacy staff to do the same⁶.
- 1.4 You can demonstrate that the pharmacy adheres to the most up-to-date national measures and public health advice in relation to COVID-19 from the Government and the Department of Health, HSE and HPSC.
- 1.5 You have an up-to-date risk assessment in place for the pharmacy and for all services provided in the context of COVID-19. This identifies all necessary updates required for procedures and workflow processes. You audit your risk assessment at appropriate intervals to ensure it reflects current public health advice. You have actioned any additional mitigation measures and you monitor these at appropriate intervals. Pharmacy staff receive training on any updated procedures and workflow processes.

⁵The indicators are indicative rather than prescriptive.

⁶ The PSI has an [Ethical Decision Making Tool](#) available which is designed to support pharmacists as a guide in decision making when they are presented with an ethical dilemma or issue.

- 1.6 You have a written business continuity plan for the COVID-19 pandemic including emergency business continuity planning for any potential temporary closure(s) identifying one or more local pharmacies which can support and maintain continuity of services to your patients, whilst the pharmacy is closed. This is actively reviewed by the pharmacy owner and/or superintendent pharmacist and the relevant supervising pharmacist and pharmacy staff are aware of this plan⁷.
- 1.7 You review and facilitate staff training and professional development to reflect up to date national public health advice in the context of COVID-19. You pay particular attention to the induction of new pharmacy staff and those pharmacists returning to work under Section 77 of the Pharmacy Act 2007⁸. All pharmacy staff are aware of their responsibilities in helping to prevent the spread of COVID-19 in their workplace.

⁷ The PSI and HSE have issued joint guidance on [Business Continuity Planning for Community Pharmacies during the COVID-19 Pandemic](#).

⁸ Restorations to the Register made under COVID-19 Section 77 of the Pharmacy Act 2007 are temporary registrations and registration will automatically cease after the COVID-19 pandemic emergency has been declared to have passed by Government.

Standard 2: The pharmacy team is supported and enabled to provide safe and high-quality patient care



The pharmacy team is likely to be under additional pressures and anxieties due to the COVID-19 pandemic and changing work practices. Pharmacy owners, superintendent and supervising pharmacists provide leadership to the pharmacy team and promote a supportive and safe work environment which meets the requirements set out in the Government's Return to Work Safely Protocol: COVID-19 Specific National Protocol for Employers and Workers⁹.

Indicators that your pharmacy service is meeting this standard are likely to include:

- 2.1 Your pharmacy team is trained and empowered to promote COVID-19 infection prevention and control measures in order to protect the pharmacy team. At a minimum, staff training should include hand hygiene, respiratory hygiene and cough etiquette, social distancing measures, appropriate use of Personal Protective Equipment, waste disposal procedures and environmental cleaning.
- 2.2 You ensure that sufficient staff of an appropriate skill mix are available to provide safe and high-quality patient care. You identify steps which may need to be taken if staffing levels of an appropriate skill mix are reduced in the context of your pharmacy's business continuity plan. In so far as possible, you ensure pharmacy staff work within their scope of roles and responsibilities.
- 2.3 You address the level of risk associated with the individual roles that pharmacy staff perform, and implement control measures to reduce the risk of exposure to COVID-19 in the pharmacy. You consider individual staff risk factors¹⁰, e.g., underlying health conditions, when implementing control measures.
- 2.4 You ensure that staff are educated on the signs and symptoms of COVID-19 and monitor their own wellbeing and self-isolate at home and contact their GP promptly for further advice if they display any signs or symptoms. It is also important that staff report to management immediately if any symptoms develop at any time.

⁹ Department of Business, Enterprise and Innovation Return to Work Safely Protocol: COVID-19 Specific National Protocol for Employers and Workers. Retrieved from <https://www.gov.ie/en/publication/22829a-return-to-work-safely-protocol/>

¹⁰ The HSE has 2 categories of those at a higher risk to COVID-19, further information on this can be found at <https://www2.hse.ie/conditions/coronavirus/people-at-higher-risk.html>

- 2.5 You ensure that all staff, including all pharmacists, take appropriate work breaks to safeguard their health and welfare and also to ensure the safe operation of the pharmacy, including the safety of patients and the public.
- 2.6 Your lead worker representative¹¹ assists those in governance roles to oversee the implementation, monitoring, evaluation and communication of risk controls implemented in response to COVID-19.
- 2.7 You ensure structures and processes are in place to support staff suffering from anxiety or work-related stress, for example, access to your business employee assistance programme or to supports and advice available from the [HSE](#).
- 2.8 You ensure that a proactive safety culture exists, where issues relating to staff and patient safety are critically reviewed and discussed. You promote an environment of continuous learning and improvement to enhance patient experience, patient safety and staff engagement.

¹¹ The Return to Work Safely Protocol requires employers to appoint at least one lead worker representative whose role is to work collaboratively with the employer to assist in the implementation of measures and monitor adherence to the measures to prevent the spread of COVID-19.

Standard 3: A safe environment is provided for patients and staff to minimise the risk of spread of COVID-19 and other infections in the pharmacy



To ensure the safe and efficient operation of pharmacy services during the COVID-19 pandemic, it is important that a safe and clean physical environment is provided where there is a focus on key infection prevention and control (IPC) practices in line with public health advice and best practice for the prevention and control of COVID-19. This includes appropriate environmental control and staff protection. IPC practices are maintained to as high a standard as possible, and in a visible manner which instils staff and patient confidence.

Indicators that your pharmacy service is meeting this standard are likely to include:

- 3.1 You ensure that good infection prevention and control practice is part of everyday pharmacy practice and based on the best available evidence.
- 3.2 The physical environment, including the patient consultation area is maintained to as high a standard as possible, is clean and complies with infection prevention and control best practices as per HSE and HPSC advice.
- 3.3 You make reasonable adjustments to maximise social distancing in accordance with current public health advice, and where this is not possible you implement mitigating/control measures as identified in your risk assessment.
- 3.4 You ensure that the pharmacy premises is accessible to the public and patients, and that accommodation is made in order for members of the public and patients to access the premises given the social distancing measures that have been implemented at the pharmacy.
- 3.5 You implement contemporaneous national guidance to promote and encourage effective hand hygiene practices. Appropriate handwashing facilities, with access to alcohol-based hand sanitiser or soap and water, are available to people attending the pharmacy and to accommodate staff adhering to hand hygiene measures in the course of their duty.
- 3.6 You provide appropriate space for staff to have breaks, and this area is arranged so that social distancing is maintained. You ensure staff are informed on the use of the space and the cleaning requirements after use, and maintain cleaning records.
- 3.7 You support members of the public in complying with high standards of hygiene, and any measures implemented are in line with best practice advice as per the HSE and HPSC. Social distancing, respiratory hygiene and cough etiquette and hand hygiene are promoted to prevent the spread of COVID-19.

- 3.8 You have a documented response plan to deal with a suspected case of COVID-19 in a staff member that may arise during the course of the working day.
- 3.9 In the context of COVID-19, you have proper arrangements in place for the appropriate segregation and disposal of domestic and healthcare risk waste.
- 3.10 You ensure that all medical equipment and devices that come into direct contact with patients are cleaned and decontaminated between patients, and this is carried out in accordance with manufacturer's recommendations.



Standard 4: Pharmacy services are delivered safely, effectively and to a consistently high standard

Despite changing circumstances and resource challenges to COVID-19, it is essential that pharmacy services continue to meet high standards of patient safety and person-centred care. Services must be managed and delivered to achieve the best possible health outcomes for patients, with minimal close contact but without compromising on patients' dignity, confidentiality and continuity of care.

Indicators that your pharmacy service is meeting this standard are likely to include:

- 4.1 You enable patients and members of the public to safely access pharmacy services. You communicate clearly how patient services, including close contact services, can be accessed safely and any relevant changes to their normal operation.
- 4.2 You continue to supply medicines and patient services in line with up-to-date legislation and PSI guidance, using your professional judgement and working with the patient and prescribers to ensure person-centred care, access to treatment and the safe and appropriate use of medicines. You ensure safe and equitable access to medicines and prevent stockpiling during the COVID-19 pandemic.
- 4.3 You continue to enable and support patients to make informed decisions about their care. You ensure consent for a treatment or service is always informed by providing accurate, honest information about a treatment's expected benefits, efficacy and any potential risks or interactions.
- 4.4 You ensure that vulnerable patients receive a high standard of patient care, including patients in residential care settings and patients who may be unable or may not wish to physically access the pharmacy, for example due to cocooning measures. You take proactive steps to enable these patients to regularly discuss their care and to receive their medicines safely, including through any delivery services operated by the pharmacy.
- 4.5 You actively encourage and learn from patient, peer and staff feedback and use it to improve the quality and safety of pharmacy services. You regularly assess the pharmacy services you provide to ensure that they are managed and delivered to achieve the best possible health outcomes for patients, in line with current guidance from the PSI and other relevant bodies¹².
- 4.6 You clearly communicate to patients and members of the public if you are no longer able to provide a pharmacy service and ensure continuity of care for existing patients. You work with patients and other healthcare professionals to find an appropriate alternative service and to achieve the best possible patient outcomes.

¹² As well as the PSI, relevant bodies may include the Government, Department of Health, the HPSC and the National Immunisation Office (NIO)

- 4.7 When providing close contact services¹³ you adopt measures to minimise contact time with patients attending the pharmacy without compromising on patients' privacy, dignity and confidentiality. You consider what requirements of the service could be safely carried out either remotely before the patient arrives at the pharmacy or in an area of the pharmacy where recommended social distancing can be maintained.
- 4.8 In the context of COVID-19, you have proper arrangements in place for the appropriate segregation and disposal of patient returned medicines. When accepting patient returned medicines you ensure that staff complete hand hygiene immediately after handling and disposing of the returned medicines.

¹³ Close contact services are those where the pharmacist must be closer to the patient than 2 metres, such as vaccinations, parenteral administration, point of care testing including blood pressure and diabetes monitoring, INR and cholesterol testing.

Standard 5: There is effective communication with patients both face-to-face and remotely



Pharmacy services

There are more barriers than usual in terms of ensuring good communication with patients, with infection prevention and control procedures and other essential safety measures in place to protect both patients and staff.

In addition to extra pressures on staff, patients themselves may feel anxious to visit the pharmacy, but it is important that patients understand how to take their medicines correctly and safely and have an opportunity to ask questions.

Pharmacies must continue to respect patient confidentiality and privacy, while also abiding by infection prevention and control and social distancing measures. Patient counselling that is carried out remotely should insofar as possible meet the same standards of care as face to face counselling.

Indicators that your pharmacy service is meeting this standard are likely to include:

- 5.1 Your staff are enabled to provide evidence-based information and advice to patients and the public, within the scope of their roles and responsibilities, including information relating to COVID-19. Patients should be signposted to up-to-date and reliable sources of trusted public health information.
- 5.2 You have arrangements in place to ensure that patients are informed in advance that they are not to attend the pharmacy if they have COVID-19 symptoms, have been recently diagnosed with COVID-19, or are awaiting testing or test results, if they are a close contact of a confirmed case of COVID-19, or have been advised to self-isolate.
- 5.3 You take all reasonable steps to safeguard and maintain patient dignity, privacy and confidentiality, having regard to social distancing and infection prevention and control requirements introduced in response to COVID-19. Patients are facilitated and encouraged to speak privately with the pharmacist about their health and treatment.
- 5.4 You continue to ensure that care, advice and patient counselling are provided under the personal supervision of a registered pharmacist and they meet all legal and professional requirements while also assisting and empowering patients to care for their own health.
- 5.5 You consider the impact of personal protective equipment (PPE) and other physical barriers on the provision of effective patient counselling for the safe and appropriate use of medicinal products. You ensure that patients can hear and understand the information provided and have the opportunity to ask questions.

- 5.6 You exercise your professional judgement in providing care and advice to patients remotely. You weigh the benefits of using available technology platforms against the risks to patient confidentiality and privacy. You make every effort to deliver the same high standards of person-centred care for counselling and advice that is provided remotely, that would be provided in person.
- 5.7 You have clear policies and procedures in place for the provision of video and audio consultations. You consider patient suitability for remote consultations, the need to obtain consent, the devices and technology used, the environment where consultations are provided and the documentation and record keeping required. You consider data protection legislation and ensure your data protection arrangements cover the steps to be taken if a data breach should occur¹⁴.
- 5.8 You ensure that the video and audio consultations you conduct with patients are structured and patient-centred. You consider using a structured consultation guide e.g. the [National Healthcare Communication Programme: Calgary-Cambridge guide to telephone consultations](#) to ensure a consistently high standard of patient consultations¹⁵.

¹⁴ Further information on Data Protection is available on the Data Protection Commission Website www.dataprotection.ie.

¹⁵ The National Healthcare Communication Programme have also provided additional references to help you communicate with patients and their families during COVID-19 <https://www.hse.ie/eng/about/our-health-service/healthcare-communication/nhcp-covid19-response-toolkit.pdf>.

More Information

Information on Public Health

- Government of Ireland:
<https://www.gov.ie/en/publication/22829a-return-to-work-safely-protocol/>
- Health Service Executive:
<https://www2.hse.ie/coronavirus/?source=banner-www>
- Health Protection Surveillance Centre (HPSC):
<https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/> is the central hub for nationally approved infection prevention and control guidance relating to COVID-19.
- Irish Institute of Pharmacy (IIOP): COVID Hub
<https://iiop.ie/content/covid-hub>
- HSE/PSI Pharmacy Contingency Planning Guidance
https://www.thepsi.ie/Libraries/COVID/Continuity_Planning_for_Pharmacy_Covid_19_Version_2.sflb.ashx
- Health & Safety Authority:
www.hsa.ie

PSI Information

- PSI Website: COVID-19 Information and Updates for Pharmacists and the Public
<https://www.thepsi.ie/tns/news/Coronavirus.aspx>

This document is subject to review and updates. Updates will be communicated when available. For more information on the Standards and the 'use and learn' period please see the PSI website.

Membership of the Safety Collaborative Group

The PSI wishes to thank the members of the Safety Collaborative Group for contributing their expertise and experience during the development of the Standards and supporting the main aim of achieving the best possible outcomes for patients and the public during the pandemic.

Organisation	Group Member
Health Protection Surveillance Centre (HPSC) - Antimicrobial Resistance and Infection Control (AMRIC) Division	Ms Marie Philbin MPSI, Chief Antimicrobial Pharmacist
Health Service Executive - Primary Care Reimbursement Service (PCRS)	Ms Kate Mulvenna MPSI, Chief Pharmacist
Department of Health - Medicines, Controlled Drugs and Pharmacy Legislation Unit	Ms Maria Egan, MPSI
Irish Pharmacy Union (IPU)	Mr Darragh O'Loughlin MPSI, Secretary General
Irish Pharmacy Union (IPU)	Ms Pamela Logan MPSI, Director of Pharmacy Services
Community pharmacist/Superintendent	Ms Caoimhe McAuley MPSI, Director of Pharmacy & Superintendent Pharmacist, Boots Ireland
Community pharmacist/Superintendent	Dr Denis O'Driscoll MPSI, Superintendent Pharmacist, Lloyds Pharmacy
Community pharmacist/Superintendent	Ms Emily Kelly MPSI, Superintendent Pharmacist, Sam McCauley pharmacy group
Community pharmacist/Pharmacy Owner	Mr Liam Butler MPSI, Superintendent, Supervising Pharmacist and Pharmacy Owner
Community pharmacist/Pharmacy Owner	Mr Dermot Twomey MPSI, Superintendent Pharmacist and Pharmacy Owner
PSI Council	Ms Joanne Kissane MPSI, PSI President
PSI Regulatory and Professional Policy Committee	Ms Muireann Ní Shuilleabháin MPSI, Chair
PSI Executive	Mr Niall Byrne, CEO & Registrar

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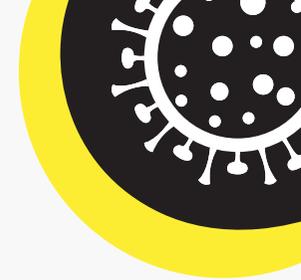


PSI House, Fenian Street,
Dublin 2, D02 TD7

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

 **PSI**
The Pharmacy Regulator
An Rialtóir Cógaisíochta

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