

PSI submission to inform the work of the Public Health Reform Expert Advisory Group

About the PSI – the Pharmacy Regulator

As the pharmacy regulator in Ireland, the Pharmaceutical Society of Ireland (PSI), is responsible for protecting the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland and assuring public trust in the quality of pharmacy services through effective regulation.

The PSI regulates all registered pharmacists, irrespective of where they work, be that in community pharmacies, or hospitals, in other areas of healthcare, or industry, education or regulation. We do this in the public interest. In achieving this objective, the PSI works across the full extent of each pharmacist's professional career – from setting the standards for the education and training courses which lead to registration as a pharmacist, assessing through a robust registration process the suitability of a pharmacist to enter the Register of Pharmacists, to supporting continuing professional development (CPD). We work to assure the public that pharmacists are always working to high standards of practice and that the public can have continued trust in pharmacists. In conducting our regulatory responsibilities, it is intended to support pharmacists in their central role to support patients in obtaining optimal outcomes from medicines by maximising the benefits and minimising the potential for patient harm.

The PSI is also charged with the responsibility to regulate retail pharmacies in Ireland. This is an important aspect of our public protection remit. Pharmacies are a critical part of our healthcare system, and it is essential that, as with all healthcare settings, the public can be assured that they provide a safe and reliable healthcare service. In this role, we are required to ensure that all pharmacies are properly registered and that each pharmacy is operating in accordance with pharmacy and medicines law.

1. What were your views on the delivery of these essential public health functions before the pandemic?

Having considered the WHO's essential public health function (EPHF) framework, as both a **healthcare professional regulator** and as a **health care service regulator**, we believe that the EPHFs which are most strongly relevant to our area of work are:

- EPHF 10 - Assuring quality of and access to health services
- EPHF 12 - Ensuring equitable access to and rational use of essential medicines and other health technologies

EPHF 10 - Assuring quality of and access to health services

Pharmacists as healthcare professionals have unique skills and expertise. They are recognised as experts in medicines in the healthcare system, and are a highly trusted and accessible profession. However, as stated in the [PSI Future Pharmacy Practice Report](#), this expertise is currently underutilised. Advances in practice and regulation in recent years have assured a high level of clinical governance within pharmacies with regulatory standards in place for all registered pharmacies. There have been significant developments in the qualification for practice as pharmacists. The mandatory system for CPD as implemented by the Irish Institute of Pharmacy (IIOP) on behalf of the

PSI provides a demonstrable quality assurance system for pharmacists' competence that further enables the realisation of the profession's potential. Overall the picture is of a highly qualified profession that is a unique resource to the health system and patients and which could be capitalised upon to support the enhanced delivery of public health and therapeutic management.

Below, two areas relating to pharmacy are described in further detail. In later questions, these areas are revisited in the context of the significant changes experienced in response to the COVID-19 pandemic.

- **Vaccination services**

Pharmacists have provided influenza vaccinations in community pharmacies since 2011, and the pneumococcal polysaccharide and herpes zoster (shingles) vaccines since 2015. By the time of the COVID-19 outbreak, training pathways for pharmacists to administer authorised vaccinations in community pharmacies were well-established. Previous evaluations of the seasonal influenza vaccination service carried out by the PSI have highlighted that patients find pharmacies an accessible location to access vaccination services in the community.

- **Standards for pharmacies**

Prior to the pandemic, we had committed in our corporate strategy to developing outcome-focused standards for pharmacies, as an additional regulatory tool as part of our approach to regulating pharmacies and were in the process of developing governance and accountability standards for pharmacies. Employed by many healthcare regulators, standards, used by many national and international regulators, are typically more outcome-focused and can articulate what high-quality, safe patient care looks like in practice.

EPHF 12 - Ensuring equitable access to and rational use of essential medicines and other health technologies

- **Prescription regulation amendments – the absence of an ePrescribing solution for Ireland**

The PSI has been very supportive of the implementation of the eHealth Strategy for Ireland, and in particular, the development of a national ePrescribing system, for some time. We are cognisant of the many patient safety benefits this could bring, provided that essential legal and public health safeguards for the proper control of medicines and access to patient health data are maintained.

- **Management of medicines shortages**

As the regulator of pharmacies and pharmacists, the PSI regularly engages with the HPRA on issues of mutual interest including minimising potential stockpiling of medicines during COVID-19 and Brexit to prevent medicines shortages in Ireland.

- **Home delivery of medicines**

Since 2014, PSI has published guidance for pharmacies for the home delivery of medicines which outline the requirements that must be fulfilled when a pharmacy provides a delivery service for dispensed medicines for their patients.

2. Have your views changed in light of the COVID-19 pandemic experience? If so, how have they changed? What are the key lessons from the pandemic?

The COVID-19 pandemic brought unprecedented levels of activity in community pharmacies. Pharmacy rose to the significant challenges presented to it at the onset of the pandemic, responding professionally and adapting quickly to ensure continuity of supply of medicines and treatment and in protecting the public, patients and pharmacy teams. During this time, pharmacists have reported more frequent consultations by the members of the public seeking treatment and advice from their pharmacists, due to either a reluctance or inability to access care in acute or other primary care services. A range of good supplementary practices were introduced that proved beneficial to pharmacy teams and the public we all serve. Pharmacies were also key contacts for many of the more vulnerable members of society and worked well with volunteers and others to ensure essential medicines deliveries were made to those that were sheltering at home. The PSI took a number of steps during the pandemic to support public access to essential pharmacy health services and to support the public health response to the pandemic in pharmacies. This included assisting in the review of draft legislation and rapidly developing guidance, as well as intensive collaboration and the sharing of information with other regulators and key organisations across the health service.

EPHF 10 - Assuring quality of and access to health services

- **Vaccinations**

The PSI played a significant role in ensuring access to vaccination services in pharmacies, firstly, to support a strong uptake of the influenza vaccine (during the 2020/'21 'flu season), and later, working in partnership with the pharmacy profession and other stakeholders to support the safe involvement of pharmacists in the national COVID-19 vaccination programme. PSI also supported extension of services to include influenza vaccination services for children aged 6 months and older, and vaccination services offsite from the pharmacy premises.

The pandemic highlighted the flexibility and adaptiveness of pharmacists, their teams, and the community pharmacy sector through their contribution to providing vaccination services. From the beginning of the roll-out of the national COVID-19 vaccination programme, pharmacists took up critical, senior roles within centralised vaccination centres and specialised clinics, both in a medicines management capacity, and as vaccinators. Following the identification of a need to expand the accessibility of vaccination services, within a very short period of time, the provision of COVID-19 vaccines was expanded to community pharmacies in June 2021, and by February 2022, over 813,000 vaccines had been administered by pharmacists in community pharmacies. The PSI's role in supporting safe vaccination services during the pandemic involved a number of work strands:

- A range of guidance to support the delivery of the national influenza vaccination programme in pharmacies.
- Assisting and reviewing changes to legislation to provide for the COVID-19 vaccination programme. During 2021, a total of 16 statutory instruments were drafted by the Department of Health with the PSI providing assistance and review.
- Working in partnership with the HSE and IPU to identify the key regulatory and operational components necessary to support the safe roll-out of vaccination

services within community pharmacies and to develop guidance for pharmacists on providing a COVID-19 vaccination service in community pharmacies.

- Communications to those in governance roles to highlight key aspects of governance and clinical leadership
- Review and approval of NIO training for pharmacists for each of the approved COVID-19 vaccines by an expert Assessment Team convened by the PSI. This was required in order to allow pharmacists to supply and administer COVID-19 vaccines.

- **COVID-19 Operational Standards for Pharmacies**

In 2020, in response to the COVID-19 pandemic and in the context of rapidly changing public health advice and the evolving nature of the outbreak, we developed [COVID-19 Operational Standards for Pharmacies](#), intended to provide guidance and support during the pandemic to those in governance positions in pharmacies in continuing to ensure safe services for patients, the public and pharmacy teams. The standards were collaboratively developed with input from a range of stakeholders including the Department of Health, the HSE and the Health Protection Surveillance Centre, the IPU and representatives from the community pharmacy sector. We believe that standards have much to offer as a component element in how we regulate healthcare services provided through community pharmacies. The pandemic presented us with an immediate requirement to move into this area (which had been identified as an action under our Corporate Strategy 2018-2020) and we believe our response is demonstrating the value and relevance of standards to pharmacy regulation.

Other activities and lessons learned:

- **PSI COVID-19 response group**

At the beginning of March 2020, we established a COVID-19 response group to manage the PSI's external response during the COVID-19 pandemic and to coordinate the key strands of activity arising for the PSI. This group was the primary mechanism to ensure that the multiple issues arising during the pandemic were addressed across the organisation. This involved extensive liaison with multiple stakeholders within the pharmacy and wider health sector, including the Department of Health and the Health Service Executive (HSE).

- **Supporting business continuity planning and workforce availability**

One of the primary concerns very early in the pandemic was ensuring that pharmacies could remain open to the public so that patients would have access to pharmacy services. The PSI and HSE issued joint guidance on business continuity planning for community pharmacies to help support the community pharmacy sector in maintaining pharmacy services and ensuring that patients could continue to access their ongoing treatment and 'regular' medicines. This included having a coordinated approach to making contingency plans and supporting collaborative working with other local pharmacies.

In line with the approach taken by other regulators nationally and the Emergency Measures in the Public Interest (COVID-19) Act 2020, PSI also established a process for former PSI registrants, who either voluntarily withdrew from the register or were removed due to non-payment of registration fees, to have their registration restored for a temporary period.

Return to practice resources were also developed to aid those returning to practice in ensuring their practice was up to date.

- **Digital Transformation to support registration processes**

From the onset of the pandemic, we adapted our processes in relation to first time registration and continued registration of pharmacists and pharmacies to allow for these functions to be conducted, largely, on a remote basis. This was further enhanced through the launch of our new online registration portal in September 2021, as part of our ongoing Business Transformation Programme. This has moved the majority of registration processes to a secure fully digital environment, removing reliance on paper, streamlining processes, and providing enhanced access for applicants and registrants to engage with the PSI on registration-related matters.

EPHF 12 - Ensuring equitable access to and rational use of essential medicines and other health technologies

- **Prescription regulation amendments**

To ensure continuity of care and access to treatment for patients during the pandemic, the Department of Health introduced statutory instruments to amend relevant medicines legislation. PSI provided review of these draft legislative changes. These changes enabled pharmacists to make additional supplies of prescription-only medicines to patients during the pandemic without obtaining a new prescription from the prescriber, where in the pharmacist's professional judgement it is safe and appropriate to do so. The amendments allowed for the Electronic Transfer of Prescriptions (ETP) between prescribers and pharmacies, removing the need for a paper equivalent, which up to that point, in the absence of a national ePrescribing system, was not possible.

To assist pharmacists and prescribers, the PSI, Medical Council and HSE worked collaboratively to publish joint guidance and frequently asked questions to support pharmacists and prescribers in complying with the amended legislation.

The introduction of ETP via Healthmail, as one of the most significant changes, has been a critical facilitatory tool in addressing the pressures brought by the pandemic in ensuring continued access to medicines for patients. This development revolutionised the communication between GPs and pharmacists in particular, as well as reducing the footfall of patients between both sectors. It has also led to a more efficient transfer of patient information between care settings as it has allowed for greater electronic interaction between community pharmacies, GP's & hospitals. A particular benefit that was not foreseen was how this innovation provided for much better communication between the doctor and the pharmacist directly. However, it is important to stress that this was always understood to be an interim solution and while it had delivered many benefits, it has further highlighted the need for a fully integrated e-prescribing solution with all required functionality and necessary safeguards.

- **Management of medicines shortages - medicines availability during the COVID-19 pandemic**

The PSI engaged with stakeholders including the Department of Health and the HPRA to help prevent medicines shortages from occurring and to reduce the impact of shortages on patients and healthcare professionals.

Liaising with the HPRA, who monitors the medicines supply chain, ascertained that Ireland was unlikely to face general medicine supply issues if normal use of medicines continued. To support pharmacists in ensuring continued medicines supply and continuity of care for all patients, PSI shared advice on managing medicine supply during the pandemic including encouraging pharmacies not to stockpile medicines.

- **Home delivery of medicines**

In the initial stages of the pandemic many vulnerable people were cocooning at home and were reluctant to attend their GP or pharmacy in person. The PSI and the HSE published joint guidance to support pharmacies and volunteers in ensuring safe and equitable access to medicines deliveries for those cocooning. While some pharmacies had previously routinely provided delivery services, it was a new development for many pharmacies. It also provided guidance for patients about ordering and receiving medicines to their home and outlined what they should expect when they engaged with their pharmacy in this way.

3. During the COVID-19 pandemic response, what do you think were success stories of new partnerships, models, or innovations that could provide scalable solutions to current system barriers?

- **HSE Community Pharmacy Contingency Planning Forum**

The PSI has been a member of the HSE's Community Pharmacy Contingency Planning Forum since its establishment by the HSE in 2020 to discuss contingency planning and issues arising for community pharmacy services during COVID-19. The forum includes members from the HSE, Department of Health, PSI, Irish Pharmacy Union (IPU), the Irish Institute of Pharmacy (IIOP) and a number of community pharmacists. The forum was a new and very effective way of working collaboratively and sharing information with a range of key stakeholders to address the many complex issues which arose during the pandemic in a timely manner. It also ensured that key messages could be centrally agreed and reported on, and, via the Forum's membership, then conveyed in a timely fashion to those working on the frontline or impacted by the changes occurring at pace in the healthcare environment. It is encouraging, and endorsed by the PSI, that this group will continue to meet post-pandemic to discuss and progress community pharmacy services within this collaborative forum. The HSE also formed a subgroup comprising the HSE, PSI and IPU to address the roll-out of the COVID-19 vaccination programme to community pharmacies, which continues to meet regularly.

- **COVID-19 Information Hub via the IIOP**

Due to the evolving nature of the pandemic, the PSI identified the need for a dedicated information resource for pharmacists and requested that this be developed and hosted by the Irish Institute of Pharmacy (IIOP). The intention of the hub was to provide a single source 'one-stop location' of up-to-date and comprehensive information on COVID-19 for pharmacists, to simplify access to key

evidence-based information in a streamlined manner. This measure proved to be very useful in reducing the burden of information on registrants, and also placed significant focus on providing information and signposting on mental health and wellness resources for pharmacists. A 'return to practice' resource was also developed to support those who were returning to the register under 'Section 77' provisions. The IOP also developed and delivered a series of webinars for the first time, initially on topics specific to the pandemic, with these expanding over time to other topics of interest and relevance to pharmacists. This has proved to be a popular format of delivering information and training, and will likely continue to be a format that will be utilised post-pandemic. The PSI also had a dedicated COVID-19 section on our website to gather all information in one place for registrants and the public to access.

4. From your perspective, what key areas in the public health system need strengthening over the next 3-5 years? What tangible actions could be taken to address these?

Pharmacies played an essential role in the delivery of health care throughout the pandemic and were a key vaccination provider during the COVID-19 vaccination programme. Pharmacists are one of the most accessible health care professionals and further consideration should be given to the planning and delivery of health services in community pharmacies as part of an integrated primary care system. Community pharmacies have embraced the advances of technology and continue to incorporate it as part of the health services they provide to the public. These developments have facilitated pharmacy services to be available throughout the pandemic. The availability of virtual, remote counselling, ability to electronically submit prescriptions to pharmacies has made the community pharmacy a core and resilient healthcare service that remained open and accessible to the public. As the pharmacy sector was able to demonstrate its resilience during the pandemic, further integration of pharmacy services to support other primary care health initiatives should be continued and supported by government.

The PSI has committed in our corporate strategy to engaging with the Department of Health on the implementation of Sláintecare. The PSI believes that the full implementation of Sláintecare is essential in the development of an integrated healthcare system and greater outcomes for patients. The PSI [Future Pharmacy Practice in Ireland: Meeting Patients' Needs report](#) identified key areas of patient and health system needs and identified priorities for the use of pharmacists' skills and expertise in supporting patients in the management of their medicines and their health. It also emphasises the value of strengthening healthcare services in the community as a key tool to prevent illness and maintain health in the community. Pharmacists have proven in Ireland throughout the pandemic how they play a vital role in public health. The contribution of the community pharmacy sector to complement and enhance healthcare services provided in the community should be explored and developed further so that it can reach its full potential in the delivery of improved patient outcomes.

Pharmacies are the gatekeepers to the public receiving medications and this entry point should be capturing vital healthcare information such as public health outbreaks, service needs based on local population, etc. This information could also be captured through unique patient identifiers that feed

into integrated technology health platforms supporting the ethos of Sláintecare for an integrated primary care health system.

The PSI has been very supportive of progress on the national eHealth strategy for Ireland and the development of a national ePrescribing system and is keen that progress continues in this area that can contribute to the delivery of improved patient outcomes.

System resilience

Assuring continuity of healthcare and of medicines supply to patients through pharmacies has been of key importance in the national response to the pandemic. However, in our experience, it is evident that a more formal integration of community pharmacy into the healthcare planning system is required and this is something that needs to be considered as part of preparedness for future crises and shocks so that continuity of medicines supply can be fully robust. WHO has also emphasised the importance of strengthening primary care in emergency risk management and building resilient health systems (WHO, 2021). This is another reason to support the full implementation of Sláintecare in order to place patient-centred primary healthcare at the core of the system. Among other necessary steps, we would highlight that more direct and formal communication routes to pharmacists as key frontline workers in the primary care sector are needed.

5. What are the main barriers to achieving these actions, and what could be potential solutions?

As the health system continues to respond to the impact of COVID-19 there remains considerable pressures on the health service from delayed access to treatment and longer waiting lists as well as already increasing chronic disease and an ageing population. This will require significant reform and an even more urgent necessity to move towards greater integration and an expansion of primary care. There needs to be a clear vision for a fully integrated primary care system with pharmacies playing an integral role. Pharmacists are trained in the expertise of medicines management. In the [Future Pharmacy Practice in Ireland: Meeting Patients' Needs report](#) published by PSI in 2016, the value of supplementary prescribing by pharmacists and the documented evidence-base underpinning this, is set out in some detail.

The COVID-19 pandemic has been extremely challenging for healthcare professionals including pharmacists and pharmacy teams. Consideration needs to be given to the impact of the pandemic on the healthcare workforce and the retention of staff in frontline roles.