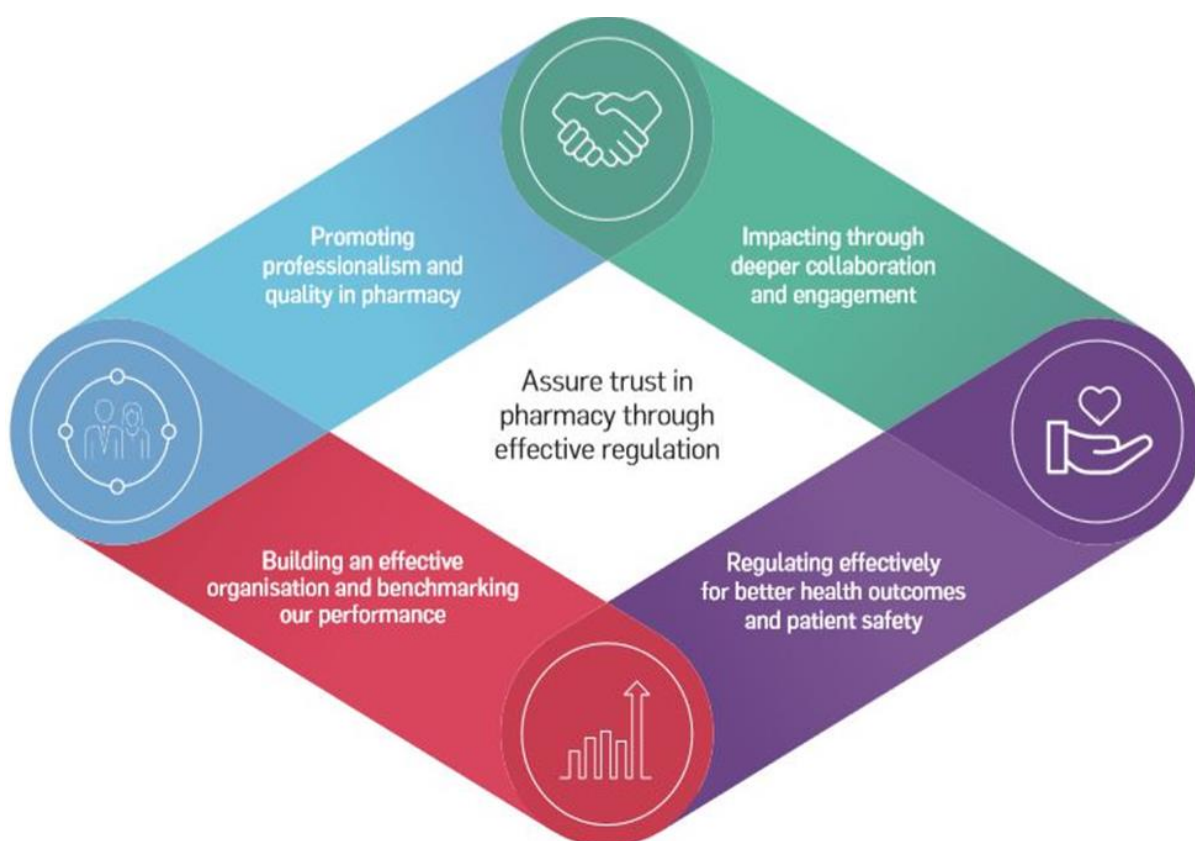


# Report of the Registrar



Report to Council Meeting of 18<sup>th</sup> June 2020

## Highlights from the Registrar

### Managing our response to Covid-19

- As reported at the March and April Council meetings, the PSI Executive has been working on our response to Covid-19, both internally and externally, since the issue began to assume prominence from early-February.
- I am pleased to report to Council that the organisation has responded very well to the many challenges which have arisen during the March to May period.
- I would, again, pay tribute to my colleagues for the dedication, commitment and flexibility shown by all during this unprecedented situation.
- **Internal response:** Since early March, our Business Continuity Planning Group has been working to ensure that the organisation can continue to operate and to discharge its functions in an appropriate manner.
  - This work continues and has now moved into the planning required under the Government's "Return to Work Safely Protocol".
  - In keeping with Government policy, we will continue to work from home, as an organisation, for the foreseeable future.
  - We are working with our facilities company to make all necessary preparations required for PSI House to be safe to use as a workplace. Only minimal and restricted use is currently allowed in PSI House.
- **External response:** As from early March, we put in place a COVID-19 response group to coordinate and manage the key strands of activity arising for PSI during the COVID-19 pandemic.
  - The group met initially on a daily basis which has reduced gradually to a once-weekly meeting as the crisis has continued to abate.
  - The following table summarises the key strands of activity in which we have been involved since the start of the crisis. Updates since the previous Council meeting in April are shown in **RED**.

No	Covid-19 - Key Strands of Activity
1	<b>Registration &amp; Education</b> <ul style="list-style-type: none"> <li>• Emergency Restoration Bill                             <ul style="list-style-type: none"> <li>○ The Emergency Measures in the Public Interest (Covid-19) Act 2020 was signed by the President on 27 March 2020. Council approved delegation of functions under this Act to the Registrar on 6 April. New Section 77 Temporary Restoration Route is now fully operational. Almost 300 formerly registered pharmacists were canvassed as potential restoration applicants.</li> <li>○ <b>UPDATE: 38 pharmacists, and one pharmaceutical assistant have been restored via this route to date. Summary of data on additions to the pharmacist register are provided to the DoH on a weekly basis.</b></li> </ul> </li> </ul>

No	Covid-19 - Key Strands of Activity
	<p>The IOP, in collaboration with the PSI, has developed a return to practise resource for the purpose of providing support to those returning to practise.</p> <ul style="list-style-type: none"> <li>• Letter to Minister asking for support to maintain pharmacy students on placements. DoH confirmed support for maintaining placements and APPEL informed.</li> <li>• Revised Rules (SI 377) drafted to reduce 5<sup>th</sup> year placement duration from 8 months to 6 months – before Council on 26 March. UPDATE: The Minister consented to these Rules and the President and Registrar signed them on 24 April 2020</li> <li>• We are examining a route for third country pharmacists to join the register – similar to route approved for Council in context of Brexit. UPDATE: Email sent to targeted stakeholders 28 April 2020. Public consultation on Rules closed 4 May 2020. Over 250 responses were received and themes were identified. The public consultation report and decision is for Council on 18 June.</li> <li>• Amendments to the PSI (Fees) Rules 2014 were drafted to provide for pharmacies to apply for a deferral of fees up to 31 July 2020. Any such deferred fees will not fall due until 30 September 2020. Council approved the Rules for submission to the Minister on Tuesday, 2 June. They are currently with the Minister for his consent.</li> <li>• IOP informed to cancel planned Practice Reviews/information events. Notifications issued. Preparations for practice review scheduled later in the year under discussion.</li> <li>• We continue to carefully review current arrangements for pharmacists who are subject to monitoring due to undertakings given or conditions being in place.</li> <li>• IOP and CPD for COVID-19. PSI is working with the IOP to develop specific CPD resources for pharmacists during COVID-19. A working group with PSI and IOP is being established to ensure early delivery of this resource.</li> </ul>
2	<p><b>Medicinal products legislation</b></p> <ul style="list-style-type: none"> <li>• We have worked with the DoH on amendments to Medicinal Products Regulations relating to prescription and supply requirements relating to the validity of prescriptions and the electronic transfer of prescriptions via Healthmail. Revised Regulations came into effect as from 2 April 2020.</li> <li>• To assist pharmacists and prescribers, the PSI, Medical Council and HSE have published joint guidance setting out the amendments to the legislation for supply of prescription-only medicines during the Covid-19 pandemic. The joint guidance issued on 3 April 2020. We have also developed frequently asked questions and answers on amendments to Medicinal Products Regulations and liaised with HSE PCRS on FAQs for Pharmacy and GP Circulars (14/4/20, 17/4/20)</li> <li>• We continue to work with the DoH on responding to the COVID challenges in relation to medicines including developing a Serious Shortage Protocols (SSPs) framework and further proposed legislative amendments.</li> </ul>

No	Covid-19 - Key Strands of Activity
3	<p><b>Pharmacy Contingency Planning</b></p> <ul style="list-style-type: none"> <li>We have worked with HSE as regards contingency planning for pharmacies <ul style="list-style-type: none"> <li>HSE Contingency Business Planning advice</li> <li>HSE contingency planning for methadone patients</li> <li>HSE FAQs on measures to reduce administrative burden</li> <li>Response to HSE Contingency (Phase 2) Planning for Community Pharmacies</li> </ul> </li> <li>We published updated contingency planning guidance jointly with HSE.  <a href="#">PSI and HSE Joint Guidance on Business Continuity Planning for Community Pharmacies During the COVID-19 Pandemic</a> (version 2)  <b>UPDATE: This was issued as joint PSI/HSE Guidance on 24 April 2020.</b> </li> <li>As part of contingency planning, PSI wrote to DoH on 28 March highlighting the need for priority infection testing for pharmacists. As of 1 April, this was introduced.</li> <li>We wrote to DoH on 28 March highlighting the need for a multi-stakeholder contingency planning forum to be put in place to ensure continuity of community pharmacy services. The HSE forum on pharmacy contingency planning is now established. The first meeting took place on 22 March, and weekly thereafter.  <b>UPDATE: It was decided at its meeting on 3 June that future Forum meetings will be held on a fortnightly basis with an agenda that focuses more on strategic and policy issues in relation to community pharmacy and primary care.</b> </li> <li>We have followed-up with some individual pharmacies as regards actions they are taking which may not be in accordance with HPSC guidance.</li> </ul>
4	<p><b>Development of PSI operational standards on pharmacy and COVID-19</b></p> <ul style="list-style-type: none"> <li><b>PSI is developing operational standards to apply to pharmacies during COVID-19. These standards will describe the outcomes which PSI expects from pharmacies in terms of their continued delivery of safe services and a safe environment for patients, public and their staff in the continued presence of Covid-19. The standards are drafted under Regulation 4(1)(b) and 14 of the RPB Regulations. The Standards will encompass four domains: governance, pharmacy staff, pharmacy setting and pharmacy services. A monitoring programme will also be developed in tandem with the development of the operational standards. An internal steering group is guiding the development of the Standards. A safety collaborative has also been formed with key stakeholders, including practising pharmacists. We are aiming to publish the Standards by 31 July (these will come to Council for approval, via the RPP Committee, on 23 July.).</b></li> <li><b>We are working with HPSC in the context of the Covid-19 Operational Standards to ensure that the correct and appropriate infection prevention and control measures are reflected in the standards</b></li> </ul> <p><b>Reducing infection transmission</b></p> <ul style="list-style-type: none"> <li>We have worked with HSE/HPSC to ensure that guidance for pharmacies is relevant and is communicated to the profession. The following guidance has been circulated to date: <ul style="list-style-type: none"> <li>HPSC guidance on public health measures</li> <li>HPSC updated poster for delay phase-circulated to pharmacies</li> <li>PPE Guidance</li> </ul> </li> </ul>

No	Covid-19 - Key Strands of Activity
	<ul style="list-style-type: none"> <li>○ HPSC guidance for Health Care workers</li> <li>○ <b>HPSC guidance on the use of masks by health care workers (22 April 2020)</b></li> </ul>
5	<p><b>Preparing for vaccinations in pharmacy</b></p> <ul style="list-style-type: none"> <li>• <b>An expert review by Dr Nicola Tyers was commissioned on the feasibility of the delivery of vaccination training remotely due to COVID-19 restrictions. Following this expert input and recommendation, the Registrar has approved this mode of delivery and the IOP are working with training providers to provide training in an online format for the upcoming influenza season.</b></li> <li>• <b>Two separate addenda to PSI guidance on vaccinations service have been developed; one for managing vaccinations in pharmacies during the COVID-19 pandemic and the second for Influenza Vaccination Services for Children from 6 months old.</b></li> </ul>
6	<p><b>Covid-19 and medicines</b></p> <ul style="list-style-type: none"> <li>• We have worked with HSE and HPRA to ensure updated and correct information re information on COVID-19 and medicines is available to pharmacists including circulation of the below; <ul style="list-style-type: none"> <li>○ HSE statement Re anti-inflammatories and anti-hypertensive medicines</li> <li>○ HPRA statement Re anti-inflammatories and anti-hypertensive medicines</li> <li>○ EMA statement re anti-inflammatories</li> <li>○ HSE info on your medicines</li> <li>○ HSE letter on shortage of Co-Amoxiclav</li> <li>○ HSE letter on requests for antivirals for COVID-19</li> <li>○ <b>We worked with HPRA regarding changes in procedures to Batch Specific Requests during COVID-19. We shared the HPRA's update as part of our email communication update on 16 May</b></li> </ul> </li> <li>• The PSI and the HSE have published on 30 March joint guidance to support patients, volunteers and pharmacists with the safe delivery of medicines at this time. <a href="#"><u>Home delivery of medicines by public servants and volunteers during the COVID-19 pandemic</u></a>. Email communication issued to public/patient advocacy groups.</li> <li>• <b>Falsified Medicines Directive requirements. While scanning rates fell during the acute phase of the COVID crisis, we are working closely with the IMVO to increase scanning rates again and will develop communications to remind pharmacies of the scanning requirements and the need to achieve compliance with these.</b></li> </ul> <p><b>Covid-19 testing kits</b> We worked with HPRA to ensure advice was issued on finger-prick testing for Covid-19</p> <p><b>Covid-19 Research Projects</b></p> <ul style="list-style-type: none"> <li>• We have been invited to participate in two HRB-funded rapid research projects – one from TCD and one from RCSI. We await news on whether these have been successful in being awarded funding. <b>UPDATE: Funding was not approved for these particular projects.</b></li> </ul>
7	<b>Governance &amp; Organisational Issues</b>

No	Covid-19 - Key Strands of Activity
	<ul style="list-style-type: none"> <li>Put in place the arrangements for the virtual Council meeting on 26 March. Four urgent decisions subsequently made by email by Council – for recording at Council meeting of 23 April 2020.</li> <li>We have responded to requests for temporary transfer of PSI people externally to contribute to the national response. <b>UPDATE: One of our temporary transferees will return on 29 June.</b></li> <li>We are working internally to keep PSI staff informed of developments and of public policy on sick leave, special leave and redeployments.</li> <li>We are reviewing the Covid-19 impact on 2020 Service Plan. <b>UPDATE: A revised Plan is for discussion by Council on 18 June.</b></li> </ul>
8	<b>PSI External Communications</b> <ul style="list-style-type: none"> <li>We issued a joint statement to registrants from the President and Registrar on 12 March.</li> <li>The Registrar issued a statement on how we will regulate in the current emergency on 19 March.</li> <li><b>UPDATE: A further message issued to registrants from the PSI President and Registrar on 24 April</b></li> <li><b>The recommencing of receiving and progressing complaints through formal statutory complaints process was communicated to the profession on 22 May.</b></li> <li>We have issued 20 regular emails to registrants summarising resources and information from trusted public authorities - March 6<sup>th</sup>, 12<sup>th</sup>, 13<sup>th</sup>, 15<sup>th</sup>, 16<sup>th</sup>, 17<sup>th</sup>, 21<sup>st</sup>, 27<sup>th</sup>, 28<sup>th</sup>, 30<sup>th</sup>, April - 1<sup>st</sup>, 3<sup>rd</sup>, 10<sup>th</sup>, <b>22<sup>nd</sup>, 24<sup>th</sup></b>, May – <b>1<sup>st</sup>, 16<sup>th</sup>, 22<sup>nd</sup>, 29<sup>th</sup></b></li> <li>We redesigned our Covid-19 webpages to make them more user-friendly.</li> </ul>
9	<b>Query Management</b> <ul style="list-style-type: none"> <li>We are managing incoming Covid-19 related queries from registrants and the public.</li> <li>To date PSI has received <b>236</b> queries with <b>219</b> responses.</li> <li>FAQs have been published on some commonly occurring queries.</li> </ul>

### Service Plan 2020 - Impact of Covid-19

As reported at the 23 April Council meeting, the Executive has been keeping the 2020 Service Plan objectives under review in order to determine the impact of the Covid-19 crisis on the Plan. The current assessment is set out in the following two tables showing, respectively, each of the 8 Priority Projects and each of the 12 Continuous Improvement Projects, categorised as:

**A – Continue**                      **B – Continue if possible**                      **C – Defer**

Now that the pressure of responding to the crisis has abated, the Executive will work to develop a revised Plan with revised timeframes, budgets, etc. to bring before Council at the 23 July meeting.

Assuming no return to Covid-19 crisis conditions during the Autumn/Winter, we are cautiously optimistic that important elements of this year's Plan can still be delivered.

<b>TABLE 1 – PRIORITY PROJECTS FOR 2020</b>	<b>Status as at 11 June 2020</b>
Deliver the year one objectives of our Business Transformation Programme	Continue
Implement an organisational and people development programme to underpin transformation	Continue [revised timeframe]
Advance reform of the Pharmacy Act	Defer
Assess emerging risks to the continued availability of a professional pharmacy workforce within community pharmacy in Ireland	Continue [In Context of Next Strategy]
Publish Governance & Accountability Standards for Retail Pharmacy Businesses	Continue if possible [subject to new priority Operational Standards project]
Develop the Future Funding Strategy for PSI	Continue [In Context of Next Strategy]
Review the CPD Model for pharmacists	Continue [In Context of Next Strategy]
Develop the PSI's next 3-year Corporate Strategy	Continue
<b>NEW Develop Covid-19 Operational Standards for Retail Pharmacies</b>	<b>Priority Covid-19 Response Project</b>

<b>TABLE 2 – CONTINUOUS IMPROVEMENT PROJECTS FOR 2020</b>	<b>Status as at 11 June 2020</b>
Patient safety objective 1: Examine how PSI can contribute to reducing the overuse of benzodiazepine medicines	Continue - Patient info leaflet & poster developed
Patient safety objective 2: Assure the safe supply of medicines from pharmacies into residential care settings	Defer
Redesign and update the PSI Website	Continue if possible
Operationalise the PSI Regulatory Risk Statement	Defer [but resource may become available in late Autumn to advance this]
Review the Core Competency Framework for Pharmacists	Continue [revised timeframe]
EFQM – Embed the discipline and approaches underpinning Excellence throughout PSI	Continue
Manage Brexit impacts and revise PSI's third country qualification route	Continue
Complete the review of the regulation of the retail pharmacy business (RPB) element of hospital pharmacy departments	Defer [but resource may become available in late Autumn to advance this]
Develop methodology to underpin how PSI will regulate for quality and safety in retail pharmacies	Partly continued under new priority Operational Standards Project
Engage with the pharmacy profession around the revised Code of Conduct and professionalism	Continue if possible, via webinars, etc. in Autumn/Winter
Complete the review of the PSI Council's "Guide to Sanctioning"	Continue [For approval by Council on 18 June]
Fully implement PSI's HR Strategy 2018-2020	Continue





## Promoting professionalism and quality in pharmacy

We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.

### Key updates

- **ePortfolio Review:** The PSI received the outcomes report for ePortfolio Review 2019/2020 in May 2020 from the Executive Director of the Irish Institute of Pharmacy (IloP). The IloP undertook the review in line with the IloP ePortfolio Review Policy as approved by PSI Council on 21 June 2018, and according to the IloP 2019/20 ePortfolio Review Standards. A total of 1,352 pharmacists were invited to submit an extract of their ePortfolio for review in January 2020. Over 97% achieved an outcome of 'Standard Met'.
- **Professional Registration Exam (PRE):** The holding of the final sitting of the PRE under the NPIP was postponed in May and all relevant candidates were notified. This exam has been rescheduled for the second half of August, the exact date to be confirmed. The planned rescheduling of the PRE remains subject to the ongoing COVID-19 pandemic and the public health advice provided by the government. Both PSI and RCSI have updated the relevant candidates of the rescheduling.
- **Operational Standards for Retail Pharmacy Businesses in times of COVID-19:** The development of draft Operational Standards for Retail Pharmacy Businesses in times of Covid has begun. The aim of the standards is to provide clear indicators of safe, high quality patient-centred care and good governance within pharmacies during the Covid-19 pandemic. Work on the standards is cross-departmental and under the direction of an internal ELT Steering Group. The first pre-consultation meeting of our safety collaboration group (which includes representatives from the IPU and community pharmacies, the HSE, the HSE's Antimicrobial Resistance and Infection Control Group (AMRIC), as well as the PSI President, Registrar and the Chair of the RPP Committee) was held on 26 May via video conference. A second meeting was held on 10 June. Development of a quality assessment framework which will underpin monitoring of these standards began on 3 June.



- **Guidance on the Provision of an Influenza Vaccination Service for Children aged 6 months and older:** The purpose of this guidance is to assist pharmacy owners, superintendent pharmacists and supervising pharmacists who wish to expand their influenza vaccination service to include young children for the 2020/2021 'flu season. This guidance will be included as an addendum to the PSI's current Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses, which sets out the legal and professional requirements which need to be fulfilled in order to safely provide a vaccination service. This guidance is on Council Agenda for approval.
- **Practical Guidance when Providing a Pharmacy Vaccination Service during the COVID-19 pandemic:** This document aims to provide practical guidance to support pharmacy owners, superintendent pharmacists and supervising pharmacists in adapting vaccination services to help reduce the risk of transmission of COVID-19 and to protect patients and pharmacy staff. This guidance is on Council Agenda for approval.

## Impacting through collaboration and engagement



We will deepen our engagement and communication with stakeholders to ensure our work is making an impact and that we are focused on the key outcome areas.

### Key updates

- **Memorandum of Understanding:** The PSI has engaged with Sport Ireland, the authority responsible for the development of sport in Ireland including high performance and anti-doping, to develop a draft Memorandum of Understanding to promote and govern inter-agency cooperation and mutual assistance. The MoU has the approval of the Minister for Transport, Tourism and Sport under the Sport Ireland Act, 2015 and is before Council on 18 June for approval.
- **Benzodiazepine multi-stakeholder group:** The Head of Policy attended a meeting in May of the Medical Council Stakeholder group regarding overprescribing of Benzodiazepines (in keeping with one of our continuous improvement projects under our 2020 Service Plan). This is a wide stakeholder group including the Medical Council, HSE, HPRA, DoH, PSI and ICGP that is focussed on developing strategies to address the overprescribing of benzodiazepines. As part of the work, all the stakeholders involved have developed a patient information leaflet on 'insomnia and anxiety medicines' and posters for GP surgeries and pharmacies highlighting the concerns with long term use of these medicines and encouraging patients to discuss reducing the use of these medicines with their Doctor, Pharmacist or Nurse. The materials will be circulated electronically by the HSE on a trial basis over the summer months with a view to receiving feedback from practitioners and providing hard copies in the autumn.
- **HSE Community Pharmacy Contingency Planning Forum:** The PSI continues to participate in the HSE's Community Pharmacy Contingency Planning Group which has been established by the HSE to discuss contingency planning for community pharmacy services in the context of ongoing COVID-19 challenges and changes. This forum involves a wide group of stakeholders from the IPU, together with a number of community pharmacists from across Ireland, a number of HSE divisions (Quality Improvement, Primary Care Reimbursement Service, Community Strategy and Primary Care Strategy), the Department of Health and PSI. The forum provides a valuable opportunity for community pharmacists to raise issues relating to COVID-19 which are arising in practice and allows for discussions on planning for a 'new normal' in the short to medium term in community pharmacies. Among the issues discussed to date are the use of Healthmail, infection

prevention and control in pharmacies and the need to promote confidence among the public in the use of health services. The Forum is also helping to build understanding between the Forum members as to the need for change and improvement in how community pharmacy operates within the broader health system into the medium and longer term. The forum initially met once weekly and now meets fortnightly. The Group sits under the Office of the Chief Clinical Officer (CCO) in the HSE and is chaired by Dr Philip Crowley, HSE National Director for the Quality Improvement team and Co-Lead COVID-19 Public Health response.

- **Return to Practice Resource:** The PSI in conjunction with the IIOP developed a return to practise resource to provide support to pharmacists who are returning to the PSI Register under COVID-19 section 77 temporary registration. Governance arrangements around the maintenance of the resource were put in place between the IIOP and PSI to ensure the information provided through this resource remains up-to-date and current at all times.
- **CPD Executives Meeting:** The Education Manager attended a virtual meeting of CPD Executives on 2 April 2020. The Group was set up to share learning and experience of CPD, including the use of eLearning platforms and CPD compliance policies. The Group membership comprises representatives from the Royal Institute of Architects in Ireland, Society of Chartered Surveyors Ireland, Society of Actuaries in Ireland, Engineers Ireland and The Institute of Banking. The main focus of the meeting was to share information on each organisation's response to the COVID-19 crisis and share any learnings or tips with each other.



## Regulating effectively for better health outcomes and patient safety

We will regulate in ways that are proportionate, effective and risk-based, with a focus on the key areas relevant to patient health and safety.

### Key updates

- **Complaints and Disciplinary Processes:** The PSI temporarily suspended the processing of complaints and scheduling of inquiries effective from 19 March 2020 in light of the evolving COVID-19 situation at that time. Our processes recommenced on 22 May 2020, after nine weeks. This action was taken in the interests of all parties, both complainants and those who are subject to complaint. Over the next few months we remain committed to ensuring a fair approach for all parties involved and to balancing proportionate regulation with our duty to ensure public safety.

The Preliminary Proceedings Committee will hold its next meeting scheduled for 25 June virtually using Microsoft Teams.

It is anticipated that the next inquiry to be heard before the Professional Conduct Committee will be held virtually. We are engaging with all relevant parties to confirm their ability to participate remotely and to ensure that all procedural requirements can be satisfied.

- **Registration Rules Amendments:** A short consultation took place between 28 April and 4 May 2020 on proposed changes to the existing statutory rules which set out requirements for first time recognition and registration for applicants who first qualified in a Third Country. The proposed amendment to the Rules would provide limited flexibility around consideration of all third country qualifications presented for assessment. Specifically, the changes proposed would facilitate qualified third country applicants to join the Pharmacist Register without being required to undertake an Equivalence Examination and the Professional Registration Examination, as is now the case. Strict requirements, processes and procedures would apply to any such consideration. This was done as a part of current initiatives to meet potential and real challenges arising in the context of the COVID-19 emergency and will be linked to the duration of the emergency. The amended Rules and consultation report are on Council Agenda for consideration.
- **Fees Rules Amendments:** A proposed amendment to the Pharmaceutical Society of Ireland (Fees) Rules 2014 was issued for public consultation between 21 and 26 May. In order to help mitigate any immediate cash flow issues at individual pharmacy level, the

proposed amendment to the Pharmaceutical Society of Ireland (Fees) Rules 2014 permits the granting of a temporary deferral of continued registration fees which are due to be paid by registered pharmacies, for a specified period of time, in the context of the Covid-19 public health emergency. Pharmacies may apply for a deferment of fees due to be paid up to 31 July 2020 and any deferred fees will fall due for payment at 30 September 2020. The draft Rules and public consultation report are on Council Agenda for consideration and decision.

- **Falsified Medicines Directive (FMD):** The National Safety Features Oversight Group has been closely monitoring progress of the implementation of the EU Falsified Medicines Directive during the COVID-19 pandemic. This group has met a number of times in recent months and comprises of the Irish Medicines Verification Organisation (IMVO), the Department of Health, the Health Products Regulatory Authority (HPRA), the Pharmaceutical Society of Ireland (PSI), the Health Service Executive (HSE) and the Private Hospitals Association (PHA). The Safety Features Oversight Group has agreed that the proposed ending of the 'use and learn' period would be paused during the acute phase of the crisis. The group are now relooking at a new timetable for ending the use and learn period. While scanning rates fell during the acute phase of the COVID crisis, there is evidence that these rates are now recovering, and the PSI is working closely with the IMVO to increase scanning rates again and will develop communications to remind pharmacies on the scanning requirements.



## Building an effective organisation and benchmarking our performance

We will build an agile and high-performing organisation, capable of delivering on our mission and have our performance independently assessed.

### Key updates

- **Business Continuity and Working from Home:**

- **Business continuity and ongoing re-integration**

All PSI staff are working from home since the 19<sup>th</sup> of March. All critical functions are operating remotely, with the exception of our fieldwork activity which remains suspended, but planning is taking place with a view to it being re-activated on a risk-led basis.

Activities which had been suspended, i.e. recruitment and disciplinary processes, are recommencing using technology to replace physical face-to-face interactions.

PSI House open from 08h-15h00 to allow essential access by staff on a one-by-one basis.

Planning in train to allow small teams to resume office-based work from Monday, 31<sup>st</sup> of August. This is in keeping with DPER direction to public service employers issued end May to continue with remote working throughout all stages of the 'Reopening Ireland' Government roadmap, and beyond, for all employees that can do so.

- **Government Return to Work Safely Protocol:** Work is ongoing to meet the requirements set out in the Protocol issued by Government on the 8<sup>th</sup> of May. A 'worker representative', as required under the Protocol, was appointed by the ELT following a call for Expressions of Interest from staff.

The BCP activity and return to PSI House planning is being coordinated by the COVID-19 Incident Response and Recovery Team, a working group has been set up to develop the COVID-19 Response Plan as required under the Protocol and has commenced its work and the Safety and Sustainability Committee is providing oversight of the health and safety related elements of this work.

- **Working from Home Policy:** Positive feedback from staff since the start of the working from home arrangements in terms of team and management support, IT infrastructure and support, and communication of information about the

organisational response. Survey administered to staff end May and report and response in development.

Additional work is in train to increase awareness about the importance of ergonomics and measures to support staff wellbeing and resilience. We continue to meet as an organisation each week via MS Teams to help ensure all staff feel included in the life of PSI even while we all work remotely.

- **Staffing and Recruitment:**

- Recruitment has recommenced and our first online recruitment competition closed in early June (Solicitor role) with virtual interviewing taking place on the 5<sup>th</sup> of June
- Three permanent Quality Assessor – Pharmacy Services roles were filled from a panel at end of April

- **Strategy Development 2021-2023:** Since the April meeting of the Council, there has been significant re-engagement on development of the next Corporate Strategy based on agreed revised timelines and approach, with the intent to deliver a Strategy for approval at the end of year Council meeting. The Council Strategy Subgroup and the management team have each met online, and the Council had an online Strategy session on 4 June. The approach acknowledges that the PSI has already set a strategic direction in a number of areas that remain relevant, that some planned activities for 2020 will be further extended into 2021, and that the PSI will need to consider in its strategic planning the impact and requirements presented by the Covid-19 public health crisis. Consideration is being given to several emerging themes that will require the PSI's attention in the coming years. It is planned to seek approval for public consultation on a draft Strategy document at the July Council meeting and to engage with a variety of stakeholders, as best as possible, over the summer and autumn period.

- **Business Transformation Programme:**

A good response was received to the request for tender from an OGP framework for external expertise and support to facilitate organisation development to deliver on the Business Transformation Programme. This organisation development strand runs in parallel with the process and technology improvements the Business Transformation Programme will deliver.

Budget spend continues to track as expected at the halfway stage of Phase 1 of this Programme. To note, Phase 1 will deliver all aspects of qualification recognition and registration for individuals; all aspects of registration for pharmacies; and will support the management of related registration processes. The programme remains on track to deliver phase 1 in October 2020.



- **Council iPad replacement project:** The Performance & Resources Committee is piloting the alternative to using an iPad to receive documents. This will be using a PSI Microsoft Account to log on to access the documents.

There are 3 phases to the pilot:

- Phase 1: set up accounts and use them for emails to and from PSI. This phase is complete.
  - Phase 2: use this account for document dissemination and iPad as backup. This phase was planned to be completed in April but has been moved to August due to the impact of COVID-19. Documentation for P&R Committee meeting in August and the Council meetings in July and September will be issued via both the PSI Office 365 email account and via the iPads.
  - Phase 3: trial the use of the PSI Microsoft account only, without iPads, for the P&R Committee members for P&R Committee and for Council meetings. This is due to be completed by end October.
  - Following the pilot and evaluation, a full rollout to the Council is envisaged by the end of the year.
- **Update on current procurement activity for contract values in excess of €25K:**

Services / Goods to be procured	Current Status
IT Support and Hosting	The standstill period has now concluded following notification of tender outcome to bidders. This procurement is now moving to contract exchange stage.
Provision of Organisation Development Services, including Organisational Design, Implementation and Change Management Support Services	This Office of Government Procurement (OGP) Framework mini-tender competition closed on 18 May. Following a good response, this is now at the evaluation stage.
Website Redevelopment & Build	The Invitation to Tender phase of this competition has been paused until Q4 2020 in light of the current public health emergency and staff resources.

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 5 June 2020)

Please note that effective from 19 March 2020 and in light of the evolving COVID-19 situation, at that time the PSI temporarily suspended the processing of complaints and scheduling of Inquiries. Our processes recommenced on 22 May 2020. This report captures the statistics during the suspension of these processes.

For the purposes of this appendix, please note that references to '*last report date*' refers to 20 April 2020.

### Fitness to Practise Concerns

Total concerns received in 2020	95
New concerns received since last report date	32
New concerns received since 9 March 2020*	62
Concerns reviewed since last report date	38
Open concerns FTP	14

\*Emergence of COVID-19 pandemic in Ireland.

### Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2020	23
New complaints received since last report date	3
New complaints received since 9 March 2020	9
Open complaints	28*
Complaints considered by PPC since last report date	0**

\* This figure may include complaints received prior to 2020 which are still being processed

\*\* PPC meetings were temporarily suspended as part of our regulatory response to the COVID-19 pandemic. The next meeting is scheduled for 25 June 2020.

### Inquiries

Heard year to date 2020	6*
Inquiries opened to date but adjourned / not completed	0
Heard since last report	0
Cases being investigated/prepared for hearing	25**

\* Inquiries were temporarily suspended as part of our regulatory response to the COVID-19 pandemic. We are currently in the process of recommencing our investigation and Inquiry processes.

\*\* (20 – PCC & 5 - Health Committee)

### Mediation

Total referrals to mediation 2020	2
Held in 2020	0
Held since last report date	0

### Sanction Hearings/ Undertakings/Dismissals before Council\*

Heard year to date 2020	2
Sanction hearings/undertakings being prepared for Council	6

\* This is reported on a per respondent basis.

### High Court Sanction Confirmation Hearings\*

Heard year to date 2020	1
Cases being prepared for High Court confirmation	0

\* This figure is reported on a per respondent basis.

### Call-Overs and Other Applications Before Committees of Inquiry

Callovers heard year to date 2020	1
Since last report date	0
Section 44 Applications (Withdrawals) since last report date	0

### Prosecutions

Heard year to date 2020	0
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### Suspension Applications

Heard year to date 2020	0
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### Professional Registration (figures as at 04/06/2020)

#### Pharmacists

- 1 alert has been issued to date this year under the Internal Market Information system to other EU Competent Authorities responsible for the implementation of the provisions of the Professional Qualifications Directive as it pertains to pharmacists.
- 2 EPCs for establishment of service have been received to date in 2020 (new European route of entry to recognition and registration). Both have been approved.
- 14 Certificates of Current Professional Status have been issued to date.
- 11 Pharmacist Restoration applications in accordance with S.61 have been processed to date.
- 41 Voluntary Cancellation applications and 14 Involuntary Cancellations have been processed since 1<sup>st</sup> January 2020.
- 2 EU/TCQR Registration meetings held to date this year. March, April and May meetings cancelled in light of Covid-19 outbreak

- 13 Third Country Qualification Recognition (TCQR) applications received to date this year, with an additional 90 applications in process.
- 1 TCQR registration application processed to date this year.
- 63 EU recognition/registration applications processed to date this year.
- 3 National route applications processed to date this year.

**No. of New Registration, and Restoration Applications, Including Section-77 Restorations, in the context of the COVID-19 Period - 9 March 2020 to 4 June 2020**

No. of new registration applications received.	Registered	In-process
	37	11

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
	7	0

No of S.77 Registrations Applications Received	Registered	In Process
	37	2

**Professional Registration (figures as at 05 June 2020)**

**Regulation of Retail Pharmacy Businesses**

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,954
Number of Retail Pharmacy Businesses Registered in 2020	43
Number of Retail Pharmacy Businesses Cancelled in 2020	45
Number of Changes in Supervising and Superintendent Pharmacists in 2020	216

Internet Supply	
Number of Pharmacies on Part A	91
Number of Non-Pharmacies on Part B	83

<b>Inspection Activity 2020</b>	
Total number of Inspections	35
Number of Registration-related Inspections	11
Number of pharmacy inspections	24
<ul style="list-style-type: none"> <li>- Risk-based Inspections</li> <li>- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)</li> </ul>	23 1

<b>Investigation Activity (Part 7 / Inspection &amp; Enforcement)</b>		
No. of investigations open	No. of investigations initiated since the last Council meeting	No. of investigations closed since the last Council meeting
15	0	0
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		2