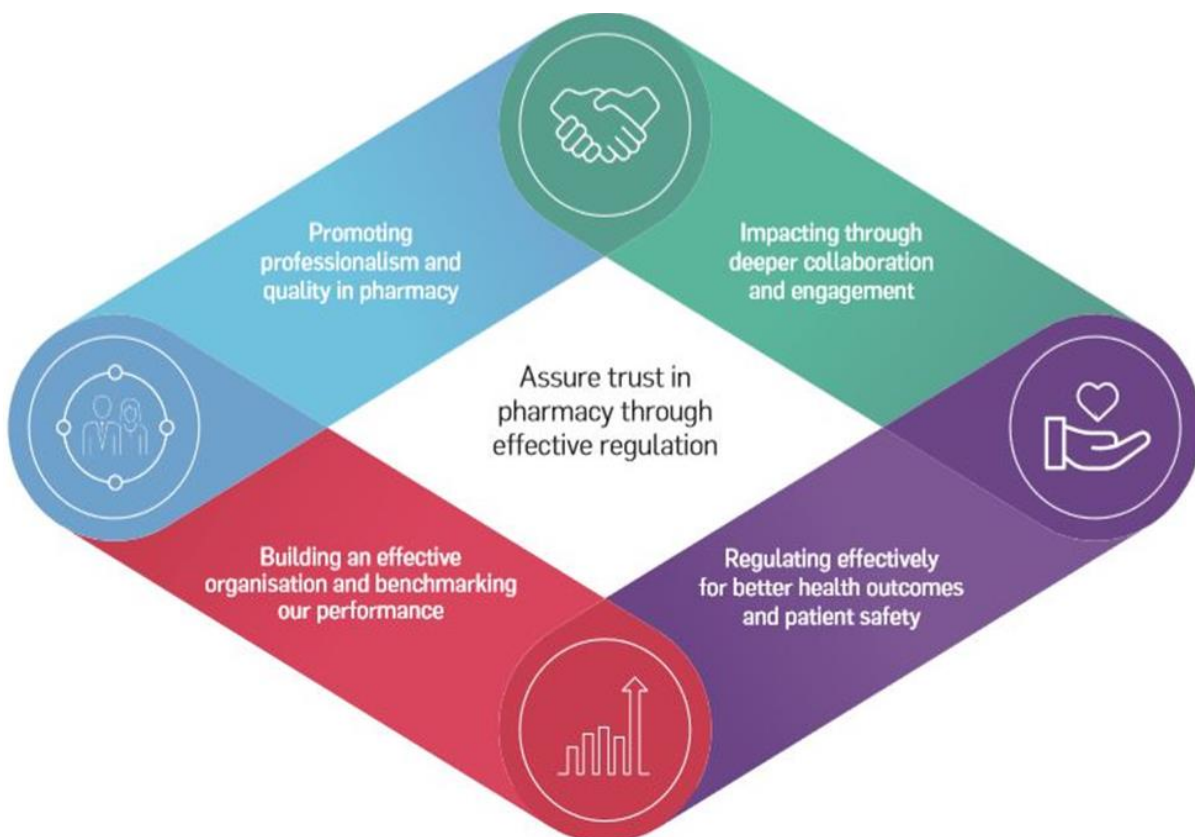


Report of the Registrar



Highlights from the Registrar

Managing our response to Covid-19

- The PSI Executive has been working on our response to Covid-19 since the issue began to assume prominence from early-February.
- As this situation has developed, I have maintained ongoing contact with the President to ensure that she is kept informed of progress and of the key decisions being made.
- **Internal response:** Since 9 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.
 - Since 13 March, most PSI staff have been working from home and as of 19 March, all staff are working from home in accordance with Government direction.
 - Thanks to the ongoing commitment and flexibility of our staff across all grades and functions, we are maintaining continuity of our services to registrants and to the public.
 - As of 23 March, we released two experienced staff members to the Department of Health to assist with work under the National Public Health Emergency Team. One other pharmacist member of staff has also been released to support contact tracing teams.
 - We have not had further requests for staff to be redeployed – the situation remains fluid and may change as the national response to Covid-19 evolves.
 - PSI staff are included as “essential workers” under the Health Act 1947 (Section 31A-Temporary Restrictions) (Covid-19) Regulations 2020 which were recently signed by the Minister.
- **External response:** We established a dedicated Covid-19 Response Group of senior staff on 9 March.
 - This Group, which met daily up to 8 April and every second day since, is the means through which we are coordinating PSI’s external response to this public health emergency.
 - Since my previous report to Council on 26 March, this Group has continued to work intensively in response to this unprecedented crisis. Thanks to the dedication of the people involved, and other colleagues, we have managed to stay up with the pace of the many demands that have arisen.
 - Up to 8 April, we were dealing with multiple issue that were complex, involved potential patient risk, involved multiple stakeholders and required decisions to be made within short timeframes. Since 8 April, the situation has stabilised and the general situation, while still far from the norm, has become more manageable.

- The table below summarises the various issues being dealt with as of 25 March 2020 and is the table circulated to Council at its meeting of 26 March. By way of indicating progress in the interim, I have added **update text in red**. Where new issues have arisen in the meantime, **these are shown in blue**.

No	Covid-19 - Key Strands of Activity
1	<p>Registration & Education</p> <ul style="list-style-type: none"> • Emergency restoration Bill <ul style="list-style-type: none"> ○ Significant PSI input to this Bill, due to be enacted this weekend, providing for a Covid-19 route to restoration to the register of pharmacists and pharmaceutical assistants. ○ Provides for HCPs to practice medicine under the direction of a medical practitioner ○ Delegation of functions under this new Act to the Registrar will be required next week. ○ UPDATE: 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. Twenty-six pharmacists restored via this route to date. Almost 300 formerly registered pharmacists were canvassed as potential restoration applicants. • Further emergency provisions may be required via sections 7 & 8 of the Pharmacy Act • Revised Rules (SI 377) drafted to reduce 5th year placement duration from 8 months to 6 months – before Council on 26 March. UPDATE: These Rules are with the Minister for consent which is expected shortly. • IOP informed to cancel planned Practice Reviews/information events. UPDATE: Notifications issued. • Letter to Minister asking for support to maintain pharmacy students on placements. UPDATE: DoH confirmed support for maintaining placements and APPEL informed. • We are planning to canvass non-patient facing pharmacists as regards moving to patient facing roles recognising that there are risk issues involved. • We are examining a route for third country pharmacists to join the register – similar to route approved for Council in context of Brexit. UPDATE: Rules approved by Council and with Minister for consent – DoH has requested these be time-limited. • We are carefully reviewing current arrangements for pharmacists who are subject to monitoring due to undertakings given or conditions being in place.
2	<p>Medicinal products legislation</p> <ul style="list-style-type: none"> • We have worked with the DoH on amendments to Medicinal Products Regulations relating to prescription and supply requirements. UPDATE: Revised Regulations came into effect as from 2 April 2020. • We are developing Joint Guidance with Medical Council and HSE. UPDATE: The joint guidance issued on 3 April 2020. • We are contributing to DoH work on Serious Shortage Protocols (SSPs) and legislative amendments. •
3	<p>Pharmacy Contingency Planning</p> <ul style="list-style-type: none"> • We have worked with HSE as regards contingency planning for pharmacies

No	Covid-19 - Key Strands of Activity
	<ul style="list-style-type: none"> ○ HSE Contingency Business Planning advice ○ HSE contingency planning for methadone patients ○ HSE FAQs on measures to reduce administrative burden ○ Response to HSE Contingency (Phase 2) Planning for Community Pharmacies ○ Access for community pharmacists to priority testing for Covid-19 infection • UPDATE: We are finalising updated contingency planning guidance with HSE and this will be issued as joint PSI/HSE Guidance shortly. We also wrote to DoH on 28 March highlighting the need for priority infection testing for pharmacists. As of 1 April, this was introduced. • 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. This is now being established and the first meeting takes place on 22 March, and weekly thereafter. • We have followed-up with some individual pharmacies as regards actions they are taking which may not be in accordance with HPSC guidance. •
4	<p>Reducing infection transmission</p> <ul style="list-style-type: none"> • We have worked with HSE/HPSC to ensure that guidance for pharmacies is relevant and communicated: <ul style="list-style-type: none"> ○ HPSC guidance on public health measures ○ HPSC updated poster for delay phase-circulated to pharmacies ○ PPE Guidance ○ HPSC guidance for Health Care workers ○ Update: We have regularly communicated on these issues to the profession. <p>Covid-19 testing kits</p> <ul style="list-style-type: none"> • We worked with HPRA to ensure advice was issued on finger-prick testing for Covid-19.
5	<p>Covid-19 and medicines</p> <ul style="list-style-type: none"> • We have worked with HSE re information on medicines <ul style="list-style-type: none"> ○ HSE statement Re anti-inflammatories and anti-hypertensive medicines ○ HPRA statement Re anti-inflammatories and anti-hypertensive medicines ○ EMA statement re anti-inflammatories ○ HSE info on your medicines ○ HSE letter on shortage of Co-Amoxiclav ○ HSE letter on requests for antivirals for COVID-19 ○ Guidance on delivery of medicines to people cocooning. UPDATE: We published PSI/HSE Joint Guidance on Home Delivery of Medicines on 30 March. Email communication issued to public/patient advocacy groups. <p>Covid-19 Research Projects</p> <ul style="list-style-type: none"> • 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.
6	Governance & Organisational Issues

No	Covid-19 - Key Strands of Activity
	<ul style="list-style-type: none"> Put in place the arrangements for the virtual Council meeting on 26 March. Update: Four urgent decisions subsequently made by email by Council – for recording at Council meeting of 23 April 2020. We have responded to requests for temporary transfer of PSI people externally We are working internally to keep PSI staff informed of developments and of public policy on sick leave, special leave and redeployments. We are reviewing the Covid-19 impact on 2020 Service Plan. UPDATE: See following section of this Report for further details.
7	PSI External Communications <ul style="list-style-type: none"> We issued a joint statement to registrants from the President and Registrar on 12 March. I issued a statement on how we will regulate in the current emergency on 19 March. We have issued regular emails to registrants summarising resources and information from trusted public authorities - March 6th, 12th, 13th, 15th, 16th, 17th, 21st, 27th, 28th, 30th, April - 1st, 3rd, 10th We redesigned our Covid-19 webpages to make them more user-friendly.
8	Query Management <ul style="list-style-type: none"> We are managing incoming queries from registrants and the public. Query log shows 82 queries received; 38 closed, UPDATE: now 172 and 141 respectively. FAQs have been published on some commonly occurring queries.

Service Plan 2020 - Impact of Covid-19

The Executive reviewed the 2020 Service Plan objectives on 2 April with a view to determining what impact the Covid-19 crisis is having on the Plan.

Based on the then known situation, each of the 8 Priority Projects and each of the 12 Continuous Improvement Projects were categorised, on a preliminary basis, as:

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

The results are shown in the following table.

Important: This assessment will be reviewed again on 30 April in the light of current and now expected circumstances.

TABLE 1 – PRIORITY PROJECTS FOR 2020	
Deliver the year one objectives of our Business Transformation Programme	Continue

TABLE 1 – PRIORITY PROJECTS FOR 2020	
Implement an organisational and people development programme to underpin transformation	Continue
Advance reform of the Pharmacy Act	Defer
Assess emerging risks to the continued availability of a professional pharmacy workforce within community pharmacy in Ireland	Defer
Publish Governance & Accountability Standards for Retail Pharmacy Businesses	Continue if possible
Develop the Future Funding Strategy for PSI	Defer
Review the CPD Model for pharmacists	Defer
Develop the PSI's next 3-year Corporate Strategy	Continue if possible

TABLE 2 – CONTINUOUS IMPROVEMENT PROJECTS FOR 2020	
Patient safety objective 1: Examine how PSI can contribute to reducing the overuse of benzodiazepine medicines	Defer
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
Review the Core Competency Framework for Pharmacists	Continue
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
Develop methodology to underpin how PSI will regulate for quality and safety in retail pharmacies	Continue if possible
Engage with the pharmacy profession around the revised Code of Conduct and professionalism	Defer
Complete the review of the PSI Council's "Guide to Sanctioning"	Continue if possible
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

- **Accreditation:** The PSI conducted three accreditation visits at the Schools of Pharmacy in Royal College of Surgeons in Ireland (RCSI) (March 2020), Trinity College Dublin and University College Cork (February 2020). The reports of the accreditation teams will be considered by Council at its June 2020 Council meeting.
- **MPharm Placements:** The PSI has accepted two students on Year 4 placements as part of the integrated MPharm programme for 2020. The students will be due to commence their placements in September 2020.
- **Practice Review:** The first Practice Review events for 2020 scheduled for 25th and 26th April were cancelled due to the COVID-19 public health emergency. Notifications to this effect were circulated by the PSI and IIOP.
- **Professional Registration Exam (PRE):** The holding of the final sitting of the PRE under the NPIP, which was scheduled for 8th May, has been postponed in the context of the current Covid-19 pandemic. This was notified to relevant candidates following detailed consideration. While it is not possible at present to confirm the date at which it will rescheduled, both the PSI and the RCSI are committed to scheduling it at the earliest opportunity, subject to how the Covid-19 situation develops.
- **Guidance for prescribers and pharmacists on legislation changes to facilitate the safe supply of medicines during the COVID-19 pandemic:** On 3 April, the Minister for Health Simon Harris signed amending regulations to facilitate how prescription-only medicines, including controlled drugs, can be supplied to patients by pharmacists during the COVID-19 pandemic to ensure continued care and treatment for patients. The changes amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) and the Misuse of Drugs Regulations 2017 (as amended). To assist pharmacists and prescribers in utilising these amendments in their day to day practice, the PSI, in collaboration with the Medical Council and HSE, has published joint guidance setting out the relevant amendments to the legislation. This is available in the COVID-19 section on the PSI website.
- **FAQs:** Following some queries that were raised with the PSI in the week following the amendments to the prescription regulations, we have published a small number of [FAQs](#)

on our website for additional information about these emergency measures. We will continue to monitor queries that are received and provide any further information or resources for pharmacists as needed in the dedicated Covid-19 section on our website.

- **Guide on the home delivery of medicines by public servants and volunteers during the COVID-19 pandemic:** During the current public health emergency, there is greatly increased need for medicines to be delivered to patients, particularly the more vulnerable members of our communities who are cocooning at home. There is a significant national community effort organised to facilitate those deliveries, which may be provided by staff of public bodies, local authorities, An Post, An Garda Síochána, pharmacy staff members and/or voluntary organisations or groups. The PSI and the HSE have published joint guidance to support patients, volunteers and pharmacists with the safe delivery of medicines at this time. The PSI made the guidance available to PSI registrants, and to patient and public advocacy organisations for the benefit of their respective members/patient cohorts and volunteers.



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

- **Communication and Engagement during COVID-19:** In response to the ongoing pandemic, we have sought to provide frequent, supportive and informative messages for registrants and public through regular emails and with regular updates in a dedicated section of our website and through social media channels. Since early March, we have issued 13 email updates to registrants with good engagement and feedback by way of response. As well as relevant regulatory information about how we are working, we have shared guidance and advice, and reiterated important public health information and resources emanating from a variety of trusted public health authorities with which we continue to work closely. We have noted increased followers on Twitter and LinkedIn throughout this period, and we have increased our social media output.
- **Education and Training Rules Amendments:** A short consultation took place at the end of March on proposed changes to the existing statutory rules which set out the education and training requirements for the five-year integrated Master's degree in pharmacy (MPharm). This was opened for public feedback and issued to a targeted group of stakeholders. The PSI proposed an amendment to the Rules that will reduce the legislative requirement (8 months) for placement to be a period of six months in exceptional circumstances and within the period of eight consecutive months provided for in the higher education institutions' calendar. The amendment would apply to students who commenced their fifth-year placement prior to 1 March 2020. This was done as a part of current initiatives to meet potential and real challenges arising in the context of the COVID-19 emergency for individual students. The PSI Council considered the Rules and consultation report and a decision on this, and other measures, was taken by the Council by email on 6 April. The Rules have been submitted to the Minister for consideration and consent.
- **IPL Working Group:** The Interprofessional Learning (IPL) Working Group held its first meeting in 2020 on 14th February. At this meeting, the Group was joined by representatives from the HEVAS (Healthcare Educator Values and Activities) study who provided an overview and update of the work completed to date in relation to the HEVAS study. This study is aimed to establish the shared values and key activities relevant, applicable and useful to all healthcare professionals

- **Core Competency Framework (CCF):** As part of the review of the CCF, a targeted consultation was carried out at the end of February 2020. The feedback received from this consultation will be used to inform consideration of the review of the CCF.



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

- **Section 77 Temporary Restoration Process:** The Emergency Measures in the Public Interest (Covid-19) Act 2020 introduced responsive emergency provisions, including a mechanism to quickly restore health professionals to Statutory Registers. In line with these measures, a new temporary restoration route has been introduced to the Pharmacy Act, referred to as a Section 77 registration. This enables former PSI registrants, including pharmacists and pharmaceutical assistants, who either voluntarily withdrew from the register or were removed due to non-payment of registration fees, to have their registration restored. This process is now operational. All such registrations will cease on 31 July 2020 unless this date is extended by Ministerial Order.



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 Transformation Programme:** The PSI Executive Leadership Team has reaffirmed the importance of this programme in light of resourcing demands associated with the current public health emergency and has prioritised the continued delivery of this objective as part of the 2020 Service Plan, based on our assessment of current demands on PSI resources

Budget spend is tracking as expected and the iterative approach to the system development within Phase One is progressing well. Changes to UAT timeframes, resource allocations and other workstreams have been presented to the Programme's governance structures (Steering Group and Programme Board) as the current public health emergency evolves. The intent remains to deliver the first phase of this programme in October 2020, notwithstanding that the challenges to this timeframe have significantly increased. These challenges are being closely monitored.

- **Business Continuity and Working from Home**
 - **ICT Remote Working and Cyber Security:** The PSI had all the technical functionality in place for remote working during 2019. Microsoft Teams basic training was completed in Q1 2020 as part of our digital development of all staff in readiness for our digital transformation. As part of our business continuity planning, a full personnel remote working test was carried out on 12th of March, which involved all staff working from home on that day. The only functionality that required additional IT input was Sage Cloud and this was completed with a combination of the ICT team, the IT support service provider for our network and Sage. All users have full functionality and access to all data remotely.

All security systems continue to function. Security specifically for working from home includes fully encrypted laptops, a Virtual Private Network and Multi Factor Authentication for connection to PSI applications and data. In addition to this we continue to test and train everyone on our Security Awareness Training Platform.

- **Working from Home Policy:** An emergency working from home policy to address the public health emergency – the 'COVID-19: Exceptional Circumstances Affecting Attendance at Work Policy' was developed and issued to all staff on Friday 13th March

to allow for all staff to work from home and to align with DPER directions to all public service employers. An evidence-based resource pack was developed and disseminated to staff and managers to support them in adapting to the new working environment.

- **Staffing/HR /Recruitment Updates: Five recruitment competitions for permanent roles** were closed since the last update to Council: ICT Support Administrator, Head of Policy, Quality Assessor – Pharmacy Services, Front Desk and Support Services Administrator and HR Lead.
All other recruitment activities are suspended due to the current public health emergency. This will be kept under review.
- **Equality, Diversity and Inclusion Working Group:** Appointments to this new working group were made by ELT in February 2020 following a call for Expressions of Interest from staff. The Group held its first meeting remotely on the 24th of March. The purpose of this group is to advise the Executive Leadership Team (ELT) on PSI policy, process and governance with regard to equality, diversity, and inclusion and to promote a culture of equality, diversity and inclusion across the PSI, and in our engagement with our stakeholders, so that the PSI becomes a model of best practice.

- **Update on current procurement activity for contract values in excess of €25K:**

Services / Goods to be procured	Current Status
IT Support and Hosting	The Performance and Resources Committee is undertaking a written process issued on the 3 rd of April to consider a Recommendation of the Registrar on the outcome of this tender process which closed on 26.02.2020. The deadline for conclusion of the P&R Committee written process is 24 April 2020.
Provision of Organisation Development Services, including Organisational Design, Implementation and Change Management Support Services	The Supplementary Request for Tender for Framework Agreement for drawdown from an Office of Government Procurement (OGP) Framework (mini-tender) was published by the OGP on 8 April. Deadline for receipt of tender responses is 18 May 2020.
Specialist Surveyors	This competition is now at the contract agreement stage and has concluded.
Website Redevelopment & Build	The Invitation to Tender documentation to successful applicants from the first phase of this procedure is being considered at present as is timeframe for this competition in light of the current public health emergency and staff resources.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 20 April 2020)

Please note that effective from 19 March 2020 and in light of the evolving COVID-19 situation, the PSI temporarily suspended the processing of complaints and scheduling of Inquiries. This report captures the statistics prior to and during the suspension of these processes.

For the purposes of this appendix, please note that references to 'last report date' refers to 31 January 2020.

Fitness to Practise Concerns

Total concerns received in 2020	63
New concerns received since last report date	48
New concerns received since 9 March 2020	30
Concerns reviewed since last report date	42
Open concerns FTP	12

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2020	20
New complaints received since last report date	18
New complaints received since 9 March 2020	6
Open complaints	25*
Complaints considered by PPC since last report date	4**

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

** 100% of which met KPI of PPC decision being made within six months i.e. from when the complaint was received to when the PPC made a final decision

Inquiries

Heard year to date 2020	6*
Inquiries opened to date but adjourned / not completed	0
Heard since last report	3
Cases being investigated/prepared for hearing	25**

* 5/6 Inquiries met KPI for the Inquiry to be held within 2 years from when the complaint was received. A number of these matters concluded by way of an undertaking at a Callover.

** (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	0
Cases being prepared for High Court confirmation	1

* 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	1
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 21 April 2020)

Pharmacists

- 0 alerts have 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.
- 1 EPC for establishment of service has been received to date in 2020 (new European route of entry to recognition and registration) and is in process
- 11 Certificates of Current Professional Status have been issued to date.
- 11 Pharmacist Restoration applications in accordance with S.61 have been processed to date.
- 39 Voluntary Cancellation applications and 14 Involuntary Cancellations have been processed since 1st January 2020.
- 2 EU/TCQR Registration meetings held to date this year. March meeting cancelled in light of Covid-19 outbreak
- 10 Third Country Qualification Recognition (TCQR) applications received to date this year, with an additional 88 applications in process.

- 1 TCQR registration application processed to date this year.
- 51 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 21 April 2020

No. of new registration applications received.	Registered	In-process
15	10	5

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

No of S.77 Registrations Applications Received	Registered	In Process
29	27	2

Professional Registration (figures as at 15 April 2020)
Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,955
Number of Retail Pharmacy Businesses Registered in 2020	33
Number of Retail Pharmacy Businesses Cancelled in 2020	34
Number of Changes in Supervising and Superintendent Pharmacists in 2020	143

Internet Supply	
Number of Pharmacies on Part A	70
Number of Non-Pharmacies on Part B	82

Inspection Activity 2020	
Total number of Inspections	33
Number of Registration-related Inspections	11
Number of pharmacy inspections	22
<ul style="list-style-type: none"> - Risk-based Inspections - Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) 	<div style="text-align: right;">21</div> <div style="text-align: right;">1</div>

Investigation Activity (Part 7 / Inspection & Enforcement)		
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