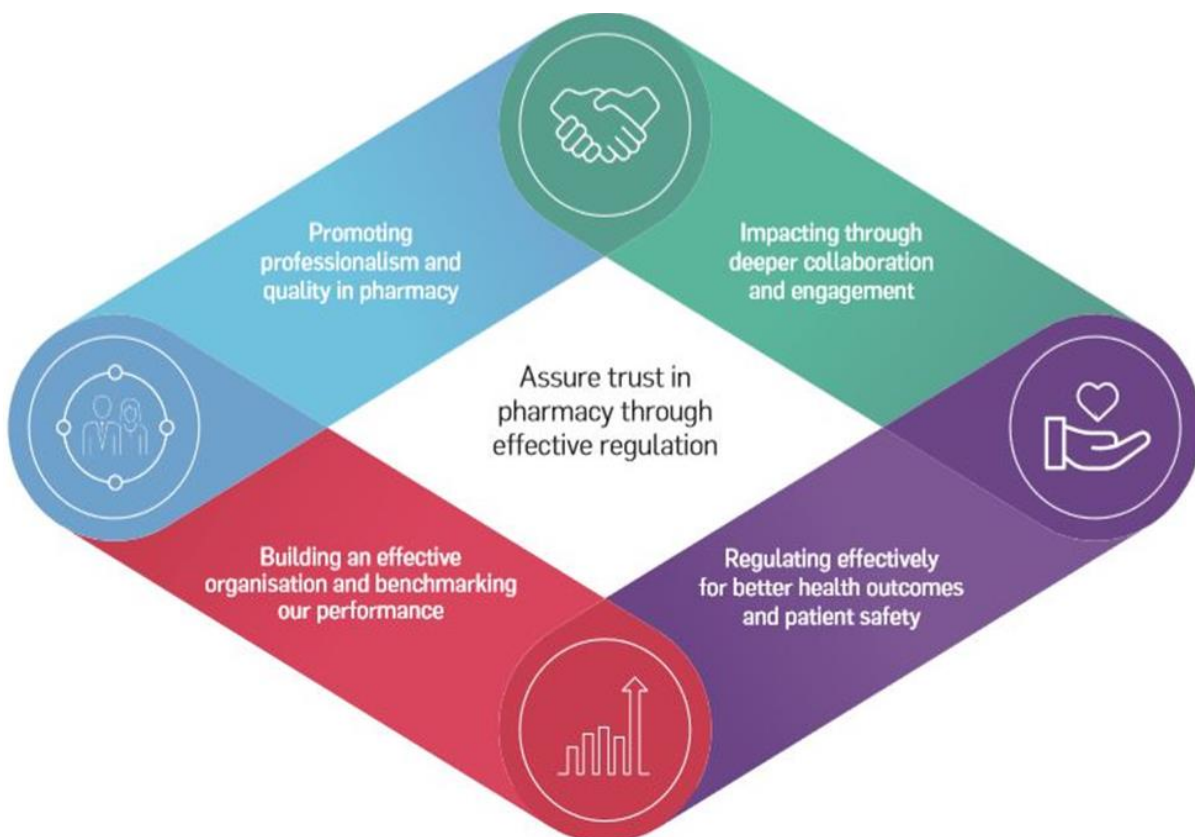


# Report of the Registrar



## Highlights from the Registrar

### **Code of Practice for the Governance of State Bodies: New annex on Gender Balance, Diversity, and Inclusion**

A new annex to the existing Code of Practice for the Governance of State Bodies (2016 version), was published on 10 September 2020. The Annex includes an obligation for the Chairperson of a State body to include progress in promoting equality, diversity and inclusion within the organisation in the annual report to the Minister, as well as a status update on the target to achieve 40% representation of women and of men on State Boards. Also, Departments are to examine Board terms so as to allow for an acceleration towards better gender balance in membership. Board evaluation processes should, from now on, identify issues around gender diversity as a means of enhancing Board effectiveness. Government Departments are also to take steps to inform their respective Minister of the gender balance on a State Boards at the time of making further appointments. The PSI Executive will consider any necessary steps that fall to PSI to take in relation to the new annex and any necessary changes to be made to PSI's Governance Framework.

### **Equality, Diversity & Inclusion**

On the topic of diversity and inclusion, the PSI's internal Working Group on Equality, Diversity & Inclusion (EDI) commenced work in September with the publication of the PSI's [EDI Statement](#) on the PSI website. We have also published a PSI EDI Calendar, and launched an EDI learning resource for use by all PSI staff.

### **Managing our response to Covid-19**

We continue to manage our external response to COVID-19 via a number of ongoing workstreams:

- **Vaccination Services Delivered by Pharmacists:**

We have worked with the Department of Health on amendments to Medicinal Products Regulations to enable pharmacies to provide an influenza vaccination service at suitable locations, offsite from retail pharmacy premises. This amendment will help to increase access to the influenza vaccine and will facilitate uptake. As we enter this year's influenza season it is even more important than usual that as many people as possible are vaccinated against influenza, as a resurgence of COVID-19 during the upcoming influenza season could present significant challenges to the delivery of healthcare services. This legislative amendment is expected to be enacted very shortly. We have prepared guidance to support this practice extension which is for consideration by Council at its meeting on 8 October.

- **HSE Community Pharmacy Contingency Planning Forum:**

The PSI continues to participate in the *Community Pharmacy Contingency Planning Forum*, established by the HSE to discuss contingency planning for community pharmacy services in the context of the challenges arising from COVID-19. The Group answers to 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, and co-Lead of COVID-19 public health response. This forum includes stakeholders from the IPU, together with a number of community pharmacists from across Ireland, representatives from HSE divisions (Quality Improvement, Primary Care Reimbursement Service, Community Strategy and Primary Care Strategy), the Department of Health and PSI. The forum continues to provide useful and relevant opportunities for community pharmacists to raise issues relating to COVID-19. Among the issues discussed to date, are; preparing for the seasonal flu vaccination season; the use of the Healthmail facility to transmit prescriptions from GP to pharmacy (see following item); infection prevention and control measures in pharmacies; and the importance of pharmacies being part of promoting confidence among the public in the use of health services. As winter approaches and COVID-19 continues to be a serious threat to public health, we expect our continued participation in the Forum to be an important element in how PSI helps mitigate risk to public health.

- **Electronic Transfer of Prescriptions (Healthmail)**

The Head of Policy met recently with the DoH and HSE on the current use of Healthmail for the electronic transfer of prescriptions during the COVID-19 pandemic. The HSE's Primary Care Reimbursement Service (PCRS) has undertaken a review of how Healthmail is operating between pharmacies and GPs with a view to identifying any improvements or clarifications required. This review included webinars and gathering feedback from both professions. Following the gathering of this feedback, it is now proposed to review and update the '[HSE/PSI/Medical Council Joint Guidance for prescribers and pharmacists on legislation changes to facilitate the safe supply of medicines during the COVID-19 pandemic](#)' with any clarifications required.

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

Following Council approval on 23 July, the **COVID-19 Operational Standards for Pharmacies** were published on 7 August. The Standards aim to provide guidance and support to those in leadership and governance positions in the retail pharmacy sector, in continuing to ensure safe services and a safe environment for patients, public, and staff.

The Standards are being implemented initially through a '**use and learn**' period.

In order to support the implementation of the Standards a communication support pack was sent to all registrants on 26 August which included:



- An introductory video,
- A one-page summary poster (reproduced above), and
- A designated email address for registrants' feedback on the Standards.

Further support will also be provided to registrants by way of a webinar in October. Work has also commenced on developing a **monitoring framework** which will be used to assess the performance of pharmacies against the Standards. The Framework will also be developed collaboratively, under the direction of the ELT Steering group, and in partnership with the COVID-19 Operational Standards Safety Collaborative group (which includes representatives from the IPU, 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).

The most recent meeting of the Safety Collaborative was held on 9 September. It is intended that **initial field-testing** will begin at pharmacy sites on an appointment basis in early October. Our expectation at this point is that we will continue in the use-and-learn stage until the end of 2020.

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

A table showing the current position as to each of the eight priority projects on the 2020 Service Plan is being circulated to Council members separately. In summary, the table shows that four are progressing and four are deferred for consideration as part of our work on PSI's next 3-year Corporate Strategy. We also added a ninth priority project on the COVID-19 Operational Standards (mentioned earlier) which is also progressing as per plan.

Our 2020 Service Plan also contained 12 continuous improvement objectives. The status of each of these is summarised below.

CONTINUOUS IMPROVEMENT PROJECTS FOR 2020	Current Status
Patient safety objective 1: Examine how PSI can contribute to reducing the overuse of benzodiazepine medicines	Continue - Patient info leaflet & poster developed with Medical Council-led stakeholder group
Patient safety objective 2: Assure the safe supply of medicines from pharmacies into residential care settings	Assess for Service Plan 2021 in light of resource availability
Redesign and update the PSI Website	Include in Service Plan 2021
Operationalise the PSI Regulatory Risk Statement	Include in Service Plan 2021
Review the Core Competency Framework for Pharmacists	Complete

EFQM – Embed the discipline and approaches underpinning Excellence throughout PSI	Include in Service Plan 2021
Manage Brexit impacts and revise PSI's third country qualification route	Ongoing and for Service Plan 2021
Complete the review of the regulation of the retail pharmacy business (RPB) element of hospital pharmacy departments	Plan to further advance during 2020
Develop methodology to underpin how PSI will regulate for quality and safety in retail pharmacies	Partly being advanced under new priority Operational Standards Project
Engage with the pharmacy profession around the revised Code of Conduct and professionalism	Plan to advance further during 2020 & next Strategy
Complete the review of the PSI Council's "Guide to Sanctioning"	Complete
Fully implement PSI's HR Strategy 2018-2020	Ongoing and for Service Plan 2021

### Pharmacy Benevolent Fund – Update

Since the July 23 Council meeting, we have implemented two measures arising from discussion of this topic at the Council:

1. Text is now included in the Registration Notification letter that issues to each pharmacist who newly joins the PSI Register alerting them to the charitable work of the Benevolent Fund.
2. A notification appears as part of the online acknowledgement page when a pharmacist completes his or her annual continued registration - see screenshot below.

Signed \_\_\_\_\_  
Date: \_\_\_\_\_

The reference to your application is PT [Click here to print this acknowledgement](#)

Thank you for submitting your application for Continued Registration. Your details have been transferred to the PSI Registration Unit.

Your new certificate of registration will be issued upon successful processing of your application.

The Pharmacy Benevolent Fund CLG is a registered charity with its main object being:  
"the relief of poverty by giving financial assistance to persons in need who are or have been engaged in or associated with the pharmaceutical profession and to the spouses, widows, widowers, children and other dependents of such persons who themselves are in need (and also to any other persons in the State who may be considered to be in need of financial assistance.)"

Further details as to the Fund's purpose, finances and activities are available on [www.pbf.ie](http://www.pbf.ie). The Fund welcomes donations to support its charitable purpose via the donate online button on its website

[Site Map](#)



## 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

- **Guidance to support pharmacies in providing safe influenza vaccination services offsite from the pharmacy premises:**

Pharmacists have been authorised to supply and administer the influenza vaccine on retail pharmacy premises since 2011. We have been notified by the Department of Health of its intent to amend relevant legislation in the coming weeks to permit pharmacists to supply and administer the influenza vaccine at suitable and appropriate locations, offsite from the retail pharmacy premises. Due to the impact of COVID-19 there will be additional pressures on our healthcare service this winter, increasing and access to the influenza vaccine is a high priority in order to protect the public, especially the most vulnerable, and to help mitigate the impact on the health services as the pandemic continues to evolve.

We have prepared guidance to support pharmacy owners, superintendent pharmacists and supervising pharmacists to plan and carry out this type of service safely, and to the same high standard currently provided within the retail pharmacy premises. This guidance is on the Council meeting agenda for approval. This imminent practice extension along with other key information and guidance to safely provide an influenza vaccination service was highlighted to all registrants in a recent PSI newsletter.

This information included the [Guidance on the Provision of an Influenza Vaccination Service for Children aged 6 months and older](#), published in July 2020, and the [Practical Guidance when Providing a Pharmacy Vaccination Service during the COVID-19 pandemic](#), published in August 2020.

- **ePortfolio Review:**

The selection for the 2020/2021 ePortfolio Review was made at the end of July, and selected pharmacists were notified via email on 24 July 2020. Pharmacists, who have been selected for ePortfolio review and feel that they have reason to be exempt may make an application to the PSI in accordance with the PSI Extenuating Circumstances

Policy. Applications were recently reviewed by the Registrar and deferral was granted in cases which met the policy criteria.

- **Professional Registration Exam (PRE): NPIP:**

The final sitting of the PRE under the NPIP was held on 26<sup>th</sup> August 2020. Twelve students sat this exam.

- **Professional Registration Exam (PRE): MPharm:**

The first sitting of the PRE for the MPharm was held on 26<sup>th</sup> September 2020. This exam was held virtually.

- **5-year integrated MPharm - 4<sup>th</sup> year placements in PSI:**

The PSI recently welcomed two, Year 4, pharmacy students for their experiential learning placements from 31 August 2020. The students will undertake the 4 months' experience, mainly remotely, across various departments of the PSI as part of their MPharm qualification. The students are from two of the Schools of Pharmacy and were selected from a pool of student applicants earlier this year.

- **Irish Institute of Pharmacy:**

The PSI has commenced engagement with stakeholders including Department of Health, the HSE Medicines Management Programmes, and the HSE Patient Safety Programme, to plan CPD programmes for pharmacists as part of the Workplan 2021 for the Irish Institute of Pharmacy.





## 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

- **COVID-19 Information Hub:**

At the request of the PSI, the IIOP developed a single source of up-to-date and comprehensive information on COVID-19. This ensures that pharmacists have access to a tool to facilitate their ongoing CPD needs in this area, helping to facilitate safe practice on behalf of patients.

- **QQI Event:**

Members of the Education Team attended an event organised by the Quality and Qualifications Ireland (QQI) on 9 July 2020 entitled '*Finding Common Ground: QA Processes – Reporting and Adapting to Virtual Environments*'. Our Education Standards Officer made a presentation at this meeting on the PSI's Accreditation Process. The purpose of this event was to share experience, challenges and good practice in reporting on validation and accreditation processes with QQI and other professional, statutory and regulatory bodies.

- **CPD Executives Meeting:**

The Education Manager attended a virtual meeting of CPD Executives on 5 August 2020. The Group was set up to share learning and experience of CPD, including the use of eLearning platforms and CPD compliance policies. At this meeting, a presentation was made by the Head of Professional Development at Chartered Accountants Ireland providing information on their experience since the COVID-19 crisis including the results of a survey they did on CPD with members of Chartered Accountants Ireland.

- **COVID-19 Operational Standards:**

As part of our COVID-19 Operational Standards programme, we developed a number of resources including an introductory video and a poster. These are available on the PSI website and were sent to registrants by email.



- **Benzodiazepine multi-stakeholder group:**

The PSI Head of Policy attended a meeting in September 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 stakeholder group which includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP, is focussed on developing strategies to address the overprescribing of benzodiazepines.

As part of its work, it has 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 or pharmacist. The materials have been initially circulated electronically by the HSE with a view to receiving feedback from practitioners and providing further communication on the resources from the stakeholder group and hard copies in the coming months.

The Group also discussed a standardised prescription format for all controlled drugs and had initial discussions on improvements to the controlled drug legislation.

- **Other matters**

- Members of the Regulation Department met with representatives from the IPU, the Department of Health and the managing director of Pharmsmart, for a demonstration of an electronic Controlled Drugs Register product, called CDsmart on 10 September.
- We marked World Patient Safety day on the 17 September, and World Pharmacist Day on the 25 September via the PSI Twitter account.



## 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

- **Sanctions Guidance:**

The updated PSI Sanctions Guidance came into effect on 1 September 2020 and is published on the [PSI website](#).

- **Inspection & Compliance Activity:**

The PSI is continuing to carry out inspection and investigation activity on a risk basis, as required, and in line with Government advice. Several virtual inspections of pharmacies have been carried out during the pandemic.

- The I&E unit are using other methods to ensure compliance including, self-declarations, phone calls with registrants, and requests for photo, video and documentary evidence. We are also developing new assessment methods such as use of Microsoft forms for compliance surveys.

- As part of the Section 71 process, the Registrar can make a number of decisions when considering a report under Section 71(1)(d) of the Act, including that the Registrar may request that a pharmacist attend a meeting with the Head of Regulation to discuss the findings of the report and the responses submitted. These meetings are being held virtually during the pandemic, where possible, to facilitate pharmacist's attendance, and progress inspection and compliance matters.

- **Falsified Medicines Directive (FMD):**

The National Safety Features Oversight Group continues to monitor progress of the implementation of the EU Falsified Medicines Directive. This group comprises of the Irish Medicines Verification Organisation (IMVO), the Department of Health, the Health Products Regulatory Authority (HPRA), the PSI, the HSE and the Private Hospitals Association (PHA). The Safety Features Oversight Group has met in recent months and is now looking at a new timetable for ending the current use and learn period. The PSI is working closely with the IMVO to increase scanning rates and will contact pharmacies that have not been scanning in recent months to understand the challenges they have encountered and with a view to increasing scanning and compliance rates.



## 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:**

Budget spend continues to track as expected as phase 1 of this Programme nears 60% completion.

Deployment for phase 1 has been deferred to mid-January 2021 as several factors, including COVID-19, resourcing constraints, overlap with a spike in continued registration activities, combined to make an early Q4 2020 deployment date unfeasible.

- **Organisation Development Project:**

PSI is preparing the Organisation Development Project. After the mini tender that was conducted in the first half of 2020, the contract was awarded to BearingPoint 23 July 2020, and the contract is currently being progressed. We are also in discussion with BearingPoint about project mobilisation and commencement.

- **PSI's draft Corporate strategy 2021-2023**

A public consultation on the draft strategy opened on 30 July 2020 and closed on 21 August 2020. PSI registrants were notified by email, and the public were notified on the PSI website and Twitter. Over 200 stakeholders received targeted emails. At close of the consultation period, 157 responses had been received.

- **Business Continuity Planning and Remote Working:**

The PSI implemented a comprehensive set of measures in accordance with the Government's Return to Work Safety Protocol to ensure staff working in PSI House or travelling for PSI business are operating in a safe environment. All protocols are set out in the PSI's COVID-19 Response Plan which was issued to staff on 14 August. A Visitors' Handbook is available for all third-party visitors and issued in prior to accessing PSI House.

Since 18th August, up to seven staff can access PSI House on a daily basis, for essential work. Depending on the level of restrictions as directed by Government, the plan is to increase the number to 13 staff, accessing PSI House on a daily basis.

A staff survey administered in July revealed that staff were satisfied overall with their experience of working from home (7.4 out of 10 on average), with very strong satisfaction about the support staff receive from their managers, and the access to information about PSI's Business Continuity Planning. Pulse surveys will be organised every two months to monitor staff engagement and one has just closed end September.

- **Cybersecurity monitoring:**

All security systems continue to function as planned. Our Microsoft Admin centre and our Aurora reports show that the system perimeters are monitored and protected. Online training for PSI staff on how to create secure passwords was completed in September and all users were forced to change their passwords. Additional measures will be introduced in Q4 2020.

The PSI uses an industry leader for our security awareness training platform. This system enables online cyber security training on a monthly basis for all our staff. There is also recurring phishing simulations run for all staff. The results of these are reviewed with a cyber security expert to plan adjustments to the training programme. This programme is backed up by a fortnightly presentation to all staff by our ICT team on the current scams, as well as weekly hints and tips.

- **Staffing and Recruitment:**

Four recruitment campaigns are currently open (Temporary Legal Affairs Manager, Registrant and Customer Relations Manager, Regulatory Project Pharmacist and Finance and Support Services Executive).

Four more campaigns are scheduled to run in October and November.

All recruitment is done online with interviews conducted on MS Teams.

- The print and post contract have been renewed with flexibility to end the agreement in 2021 post deployment of REGIE, the new registration management system.

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

Services / Goods to be procured	Current Status
The provision of penetration testing, vulnerability scanning, forensic discovery and related ICT services	Restricted Procedure in train with Pre-Qualification Questionnaire stage published on eTenders and due to close on 30.09.2020. ITT stage to follow with shortlist from PQQ stage.
Provision of Organisation Development Services, including Organisational Design, Implementation and Change Management Support Services	This OGP-run competition is at the contract exchange stage, with BearingPoint having been awarded the contract
Website Redevelopment & Build	The Invitation to Tender phase of this competition has been paused until end 2020 in light of the current public health emergency and staff resources.

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 28 September 2020)

Please note that the complaint & inquiry processes were suspended from 19 March to 22 May 2020 due to the COVID-19 public health emergency.

For the purposes of this appendix, please note that references to '*last report date*' refers to 5 June 2020.

#### Fitness to Practise (FTP) Concerns

Total concerns received year to date	142
New concerns received since last report date	47
Concerns reviewed since last report date	43
Open concerns with FTP	9

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

Total complaints received year to date	34
New complaints received since last report date	11
Open complaints	31*
Complaints considered by PPC remotely** since last report date	18

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

\*\* Held over Microsoft Teams.

#### Inquiries

Heard year to date	6*
Heard since last report	0
Cases being investigated/prepared for hearing	31**

\* This figure includes one Inquiry which was commenced in 2019 and concluded in January 2020.

\*\* (26 – Professional Conduct Committee & 5 - Health Committee)

#### Mediation

Total referrals to mediation year to date	2
Consent withdrawn – referred to Committee of Inquiry	1
Held year to date <ul style="list-style-type: none"> <li>This was held remotely* since last report date. This complaint could not be resolved by mediation and has been referred back to the Preliminary Proceedings Committee for referral to a Committee of Inquiry.</li> </ul>	1

\*Held over Microsoft Teams.

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

Heard year to date	7
Sanction hearings/undertakings being prepared for Council	1

\* This is reported on a per respondent basis.

### High Court Sanction Confirmation Hearings\*

Heard year to date	3
Cases being prepared for High Court confirmation	1

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

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

Callovers heard year to date	2
Held remotely* since last report date	1

\* Held over Microsoft Teams.

### Prosecutions

Heard year to date 2020	0
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### Interim Suspension Applications

Heard by High Court* year to date	1
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\* This figure is reported on a per respondent basis.

### Professional Registration (figures as at 24/09/2020)

#### Pharmacists

- 3 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.
- 5 EPCs for establishment of service have been received and processed to date in 2020 (new European route of entry to recognition and registration)
- 33 Certificates of Current Professional Status have been issued to date.
- 14 Pharmacist Restoration applications in accordance with S.61 have been processed to date.
- 65 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. Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of Covid-19 outbreak
- 22 Third Country Qualification Recognition (TCQR) applications received to date this year, with 100 applications in process.
- 2 TCQR registration application processed to date this year.
- 98 EU recognition/registration applications processed to date this year.
- 6 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 28 September 2020**

No. of new registration applications received.	Registered	In-process
77	56	20 in process/1 withdrawn

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
12	11	1

No of S.77 Registrations Applications Received	Registered	In Process
41	41	0

**Professional Registration (figures as at 28 September 2020)**

**Regulation of Retail Pharmacy Businesses**

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,963
Number of Retail Pharmacy Businesses Registered in 2020	70
Number of Retail Pharmacy Businesses Cancelled in 2020	63
Number of Changes in Supervising and Superintendent Pharmacists in 2020	362

Internet Supply	
Number of Pharmacies on Part A	106
Number of Non-Pharmacies on Part B	81

Inspection Activity 2020	
Total number of Inspections	35

Number of Registration-related Inspections	11
Number of pharmacy inspections	24
- Risk-based Inspections	23
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	1

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