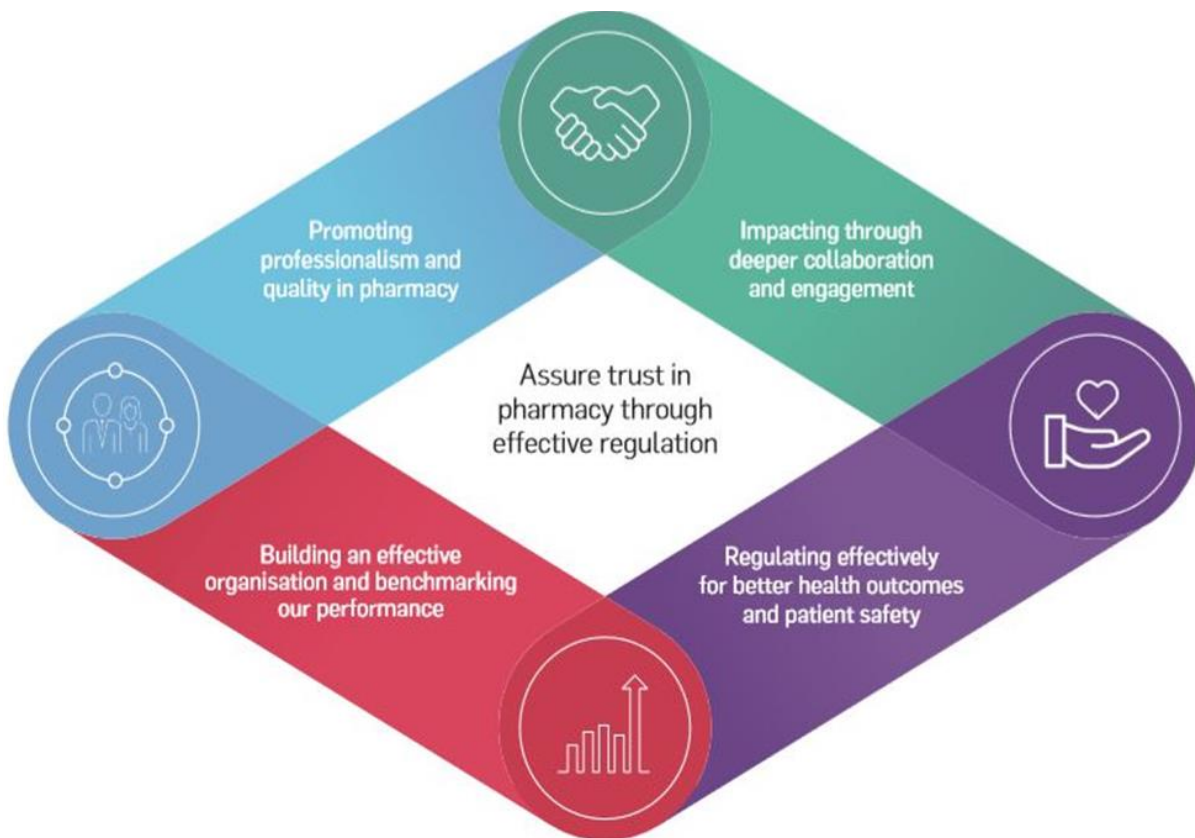


Report of the Registrar



Report to Council Meeting of 10th December 2020

Highlights from the Registrar

- **PSI's Corporate Strategy 2021-2023:** It was agreed by Council at its meeting 8 October 2020 that the draft strategy could be sent for Consultation to the Minister for Health. A detailed and supportive response was received from the Minister on 17 November 2020 and was presented to the Council during the discussion of the Service Plan 2020 at the informal Council Planning meeting 19 November 2020. The Minister's response was incorporated into the draft Strategy. This was reviewed at a meeting of the Council Strategy Sub-Group on 26 November 2020. Various amendments have since been made and the final draft is for consideration by Council at its meeting on 10 December 2020.
- **Service Plan 2021:** The Service Plan has been prepared in the context of the forthcoming new Corporate Strategy. An earlier draft was discussed with the PSI Council at the informal Council Planning meeting 19 November 2020 and also submitted to the Performance & Resources Committee and the Audit & Risk Committee during November. The final version of the Service Plan 2021 is for consideration by Council on 10 December 2020.
- **Preparing for the availability of COVID-19 vaccine:** Together with our Head of Policy, I met with the medicines unit of the DoH in November for initial discussions of policy and legislative considerations to underpin the immunisation programme. I will give a further update on this developing situation at the Council meeting on 10 December.

Summary of situation to date: At the most recent meeting of the HSE Pharmacy Contingency Planning Forum, the DoH provided an update on the planning underway by government departments and the HSE to prepare for the availability of COVID-19 vaccines. A high-level task force has been established by the Department of an Taoiseach which will decide many of the policy matters involved including the prioritisation of groups for the vaccine. The HSE also has an implementation working group with 9 different work streams identified including logistics, distribution, storage, communications and engagement with the relevant agencies. The DoH emphasised that there are many unknowns at this stage while the vaccines are undergoing regulatory review but that intense planning was underway to prepare for availability of the vaccines and phased roll-out over 2021.

The NIO and the PSI have commenced preliminary initial discussions around the potential practical issues that may arise in the context of vaccine delivery as part of the national planning and implementation framework, once this is elucidated. Items discussed include technical aspects of the various vaccines that may be available, education and training for pharmacists and the potential to access relevant NIO training and procedures when available, risk, risk mitigation strategies and cohesion within the health service. It was agreed that both agencies would have regular contact as more becomes known.

With the current intense media coverage and interest from the public, pharmacists will be an important source of accurate and reliable information for patients on the COVID-19 vaccine. The PSI is participating in a COVID-19 communication group with the DoH and HSE and we have emphasised the importance of the availability of information materials on the vaccines for health professionals. However, it is acknowledged that limited scientific or clinical information is available at this stage on the various vaccines but should become more widely known when a vaccine receives regulatory approval.

Update on managing our external response to Covid-19

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



- **Electronic Transfer of Prescriptions (HealthMail)** The PSI (Head of Policy) met with the DoH, the HSE (PCRS division) and the Medical Council on the current use of HealthMail for the electronic transfer of prescriptions during the COVID-19 pandemic. The PSI, HSE and Medical Council have issued a joint guidance for pharmacists and prescribers on the new provisions brought in during the CoVID-19 pandemic. The group also reviewed the experience to date of the additional provisions in the legislation namely the provision to extend the validity of prescriptions from 6-9months and the extension of the emergency supply provisions. The group agreed that due to the ongoing pandemic no changes to these provisions should be made. However, it is important to highlight to pharmacists and prescribers that these provisions are discretionary and should only be used when in the pharmacists consider in their professional judgement it is necessary to assure the continuity of patient care.

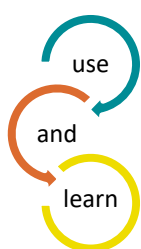
The HSE's Primary Care Reimbursement Service (PCRS) has undertaken a review of how HealthMail is operating between pharmacies and GPs with a view to identifying any improvements or clarifications required. This review included webinars and gathering feedback from both professions. Following the gathering of this feedback, it is now proposed for the HSE, Medical Council and PSI to issue a communication to prescribers and pharmacists to include some top tips on using HealthMail and 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.

The PSI has raised with the DoH in a number of communications that while HealthMail works very well as an **interim solution** and was a key initiative in addressing the pressures brought by the pandemic, HealthMail is not a full e-prescribing integrated solution with all of the required functionality and necessary safeguards inbuilt. The PSI understands that work on a long-term e-prescribing solution is in train but has emphasised the need for this work to be prioritised by DoH and the HSE.

- **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 meets fortnightly and 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 and the IIOP together with a number of community pharmacists from across Ireland, representatives from HSE (Quality Improvement, Primary Care Reimbursement Service, Community Strategy and

Primary Care Strategy divisions), the Department of Health and PSI. The forum continues to provide useful and relevant opportunities for community pharmacists to raise current issues relating to COVID-19. Among the issues discussed to date, are the seasonal flu vaccination; the use of the HealthMail facility to transmit prescriptions from GP to pharmacy (see above item); infection prevention and control measures in pharmacies and relevant public health advice. The group has also worked to put in place access to mental health supports for pharmacists via a service provided by the HSE. The timeframe for access to these mental health supports was recently extended by the HSE and PSI will communicate this to all pharmacists in an upcoming communication.

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

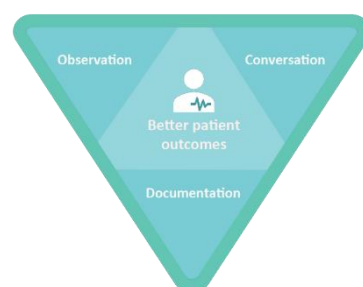


The **COVID-19 Operational Standards for Pharmacies** are currently in a ‘**use and learn**’ period. This is a flexible period which we expect will continue until early 2021. During this period, the PSI will be engaging with and visiting pharmacies to gather feedback on the use of the Standards in practice and how they are being used to support safety and quality in pharmacies.

Initial field-testing has begun at pharmacies. The visits were arranged on an appointment basis. To date, 9 visits have been conducted; 3 virtual and 6 physical visits, with additional visits planned before the end of the year. We plan on extending the next phase of visits in the New Year. As such, an expression of interest email will issue to superintendent pharmacists seeking volunteers to facilitate further field-testing in early 2021.

During the visits we are triangulating 3 types of supporting evidence of implementation of the Standards:

1. **Observing** premises and practices. We do make it clear that we are not assessing the individual performance/competence of pharmacists or other pharmacy staff.
2. Having **conversations** with those in governance roles and their teams.
3. Looking at relevant **documentation**.



To further support the implementation of the Standards, the PSI hosted our first webinar on the COVID-19 Operational Standards for Pharmacies:

‘Supporting safety and leadership in pharmacies during COVID-19’ on 18 November.

Over 360 people attended the webinar, during which, two Superintendent Pharmacists shared their insights and learnings on using the Standards in practice.

- **COVID-19 Information Hub:** At the request of the PSI, the IOP 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. This is updated on a continuous

basis as new information is made available including looking at what information on COVID vaccines can be made available for pharmacists.

- **Website review and Communication:** We are currently reviewing and updating the COVID-19 section of the PSI website and propose to circulate a further communication to pharmacists with links to information on the COVID-19 vaccine and the available mental health supports from the HSE and updates from HPSC.



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

- **Student placements:** To date, our two 4th year pharmacy students undertaking their experiential placements at PSI, have been involved in significant projects across different departments in the PSI to gain experience in relation to our varying functions and work areas. Both have integrated very well virtually with their PSI colleagues and will complete their 16-week placement with the PSI on 18 December. Their contribution and fresh attitudes are a welcome addition to the process of ongoing development and change in PSI.
- **Core Competency Framework:** The Core Competency Framework was reviewed this year and Council adopted the report and recommendations therein at its meeting on 8 October 2020. The Core Competency Framework remains unchanged at present and PSI will explore and consult with stakeholders on the possible introduction of a Core Competency Framework that allows pharmacists to demonstrate different levels of competence; -the applicability of the Core Competency Framework to all pharmacist roles; the inclusion, use and purpose of the behaviours in the Core Competency Framework; and the findings of the benchmarking exercise undertaken. On-going review of the Core Competency Framework will continue in 2021, in consultation with our various stakeholders
- **Integrated MPharm:** In September 2015, the first cohort of students undertaking the new integrated MPharm commenced their training . This year, on successful completion of the five-year programme, the first graduates of this programme joined the Register of Pharmacists. The integrated MPharm involves the integration and dispersal of practice placements for students throughout the five years (rather than solely during the final year) and facilitates placements of varying durations in the three main areas of pharmacy practice; community, hospital and industry.



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

- **Presentation to Pharmacy Students:** On 11th, 18th and 20th November 2020, the PSI presented virtually to 1st year MPharm students in RCSI, TCD and UCC on the role of the PSI.
- **QQI Event:** Members of the Education Team attended an event organised by the Quality and Qualifications Ireland (QQI) on 6 November 2020 entitled 'Finding Common Ground: COVID-19 Reflections'. The purpose of this event was to focus on participants' reflections in respect of the sectoral response to the COVID-19 pandemic and related issues, including assessment and placements.
- **Rebranding:** A PSI brand refresh project was undertaken in late 2017 to include an updated PSI logo and PSI templates. The roll out of the updated PSI logo was to coincide with the redevelopment of the PSI website. As PSI registration certificates are being updated to include the new PSI logo and colours to coincide with the launch of the new registration system in early 2021, it has been decided to roll out the new PSI logo on the PSI website and documents before commencement of the website redevelopment project. Work is currently underway on this project and it is expected to have the rebranding on the website completed by year end.
- **Governance meeting with DOH:** The second governance meeting of the year with the Department of Health took place 11 November 2020, and the agreed minutes from the meeting 29 June 2020 have been shared with the Council.





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

- **Registration Rules amendment:** The Minister has given his consent, and signed amending Registration Rules, the purpose of which are to amend the current Third Country Qualification Route process in the context of an evidence base for equivalence of qualification, the timelines and administrative process in handling an application from an individual holding a UK qualification, to assure that all such applications will be managed in as timely a process as possible, and in line with current EU Route timelines.
- **Falsified Medicines Directive:** The Head of Regulation and the Head of Policy attended a number of meetings of the National Safety Features Oversight Group comprising 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).
 - Because of the challenges that the Covid-19 situation and Brexit may bring over the next 2-3 months, the Group has decided that FMD will remain in a use and learn phase into 2021.
 - To date, the PSI has contacted 28 Retail Pharmacy Businesses (RPB) regarding FMD registration issues.
 - On 23rd November, the PSI issued an email to 353 RPBs whose FMD scanning activity wasn't detected on the IMVO repository system during selected dates, with an inclusive survey to better understand issues surrounding FMD non-compliance, to be completed by 9th December.
 - To date (3/12/20) Over 50 RPBs have contacted the IMVO, 112 have completed survey responses, 100 have contacted the PSI directly.
 - A national collaborative communication regarding FMD will be issued by all involved groups. This will feature in the PSI December newsletter issue.
- **Audit of Retail Pharmacy Businesses in Hospital Settings:** The PSI continue to review the regulation of RPB in hospital setting as part of the PSI Service Plan 2020. Part 2 of the audit conducted in 2018/2019, concluded that the nature and level of services provided by pharmacies in hospitals varied considerably under the provisions of the Act.

From this, further clarification was sought to better understand pharmacy services and the extent of their provision in hospitals. In October, seven RPB's in hospitals engaged in

a pilot study to understand the provision of pharmacy services. Following this the PSI issued a further survey to all hospital pharmacies with a return deadline of 18th December. To date (03/12/20), there are 7 responses, with additional 5 hospitals corresponding with the PSI.

- **Fitness to Practice Inquiries and “remote” hearings”**

- **Designation of the PSI as a “State body” in order to conduct remote hearings:**

The impact of Covid 19 has delayed the hearing of Fitness to Practice Inquiries before our Disciplinary Committees, in that to run them in the traditional face to face way is contrary to Government guidelines. Indeed, the Courts Services, and other bodies holding similar legal hearings have faced similar challenges. In response to this, the Civil Law and Criminal Law (Miscellaneous Provision) Act 2020 was enacted to provide for, amongst other matters, the holding of remote hearings and meetings by State bodies under Part 5 of the Act, in circumstances where the Minister had “designated” those State bodies in order to avail of the provisions in the Act. The relevant sections of the Act were commenced on the 20th August 2020. As of 19 November 2020, Orders were made by the Minister designating PSI as a “State body” so as to be able to conduct remote meetings (including Council meetings) and hearings.

- **TrialView – Software to support remote hearings:** In the meantime, PSI has continued to explore ways of conducting hearings either fully remotely or in a hybrid fashion where some evidence would be given in person, and some remotely. The audio-visual equipment and sound system in the Council room was upgraded to make provision for hybrid inquiries to take place. Various software tools and platforms were evaluated to facilitate this. We also consulted with other Regulators who were experiencing similar challenges and also looked at what the Courts Service was doing. The conclusion was that at least for the moment, given the ever-changing landscape around Covid-19 restrictions, it would be better to plan for hearings on a fully remote basis, and a software platform called TrialView was identified as the most suitable operator over which to try and do this. Following significant engagement and consultation with both internal and external stakeholders around the use of TrialView as a platform, we are now in a position to proceed to engage TrialView to conduct its first fully remote hearing in a Fitness to Practice matter around mid-December. It is proposed to contract TrialView for the provision of a single licence for a single hearing on a trial basis at first, and to use the experience on a “lessons learned” basis before considering potentially negotiating a longer term solution to cover say, a 12 month period. Full training and support will be provided by PSI and/or TrialView to all end users including Disciplinary Committee members. A training session for Disciplinary Committee Members took place on 4th December 2020.

- **Regulated Professions (Health & Social Care) Amendment Act 2020:** Council has already had a briefing on this new legislation which amends the Pharmacy Act 2007. Work is underway within the PSI to prepare for the implementation of the new functions and powers once the new Act is commenced. Commencement of three sections will take place in June 2021 and late 2022, in order to facilitate the substantial preparation required by PSI. It is intended to deliver training to the PPC, Professional Conduct and Health Committees around the amendments in January 2021.



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

- **Sustainability at the PSI:** To raise awareness among our staff of our individual and organisational impact on the environment and ways we can alter our behaviour to minimise this impact, the PSI's Workplace Safety & Environmental Sustainability Committee, with the assistance of our pharmacy students on placement, organised a series of events as part of Global Climate Change Action Week at the PSI, from 19-23 October 2020.
- **Board Evaluation:** PSI engaged Lionheart to undertake the yearly effectiveness review of the PSI Council in line with corporate governance best practice. The review was conducted during October 2020 through an online questionnaire and the report findings were presented to the Council at the Planning and Development day on 22 October 2020. A report was delivered by Lionheart to the executive and shared with the Council, and an action plan based on the report recommendations has been presented to the President.
- **Organisation Development Project:** The Organisation Development Project has completed Phase 1, 'Mobilisation', and Phase 2 'Current State Analysis' has commenced. The activities include analysis and engagement with staff using surveys and remote working tools. Also, a Change Champion Network is currently being set up comprising of up to 8 PSI staff members that will be trained and guided by BearingPoint to become change facilitators.
- **Freedom of Information:** Four PSI staff have been trained as FOI decision makers and 3 of these have been delegated the function as decision maker by the Registrar under the Freedom of Information Act 2014.
- **Workforce planning update:** Six appointments following open recruitment competitions have been made since the October Council meeting (Legal Affairs Manager (maternity leave cover), Registrant and Customer Relations Manager, Project Pharmacist roles x 2 (following the establishment of a panel for fixed-term Senior Pharmacist grade roles), Finance and Support Services Executive and Business Support Officer). Two competitions are currently open (ICT Manager and Regulatory Risk Coordinator) and more roles will be opening in Q1 2021 subject to progress being made with the DOH sanction process.

- **Business continuity, remote working and staff wellbeing update:**

Pulse Surveys administered every two months are showing a stable rating of experience of working from home of around 8 out of 10. The next survey will be administered in early December.

Small numbers of staff are accessing PSI House on a regular basis and COVID-19 related measures have been strengthened during Level 5 restrictions.

In November and December, several initiatives from the HR Office and the Wellbeing Group were focused on fostering and maintaining relationships between colleagues.

- **Cybersecurity update:**

All security systems continue to function as planned. Our Microsoft Admin centre and our firewall reports show that the system perimeters are monitored and protected.

All remote devices were patched with the latest version of Windows 10 in November, next update due in May 2021. Regular online staff training continues to maintain staff awareness of potential for cyber-attacks to occur.

- **Business Transformation Project (BTP) update:**

Budget spend continues to track as expected as Phase 1 of this Programme nears 70% completion. The PSI website has been updated to include a BTP page – see [PSI Quality Development - Business Transformation Programme -PSI \(thepsi.ie\)](#) – and this will be developed further closer to Phase 1 ‘Go-Live’. A communications plan has also been agreed in advance of Go-Live.

User Experience testing on the EU route of qualification recognition and registration was conducted with a small number of volunteer registrant testers end November.

Due to staffing changes on both the PSI and the Codec project teams, the BTP Steering Group is considering the schedule for deployment for Phase 1 which will now likely be end Q1 2021. The final deployment date decision will be taken imminently by the Steering Group. In addition to the project team changes, other factors, including COVID-19, resourcing constraints, overlap with a spike in continued registration activities, have combined to impact on an earlier deployment date. Despite these setbacks, the BTP is making good progress and the project is on track to deliver substantial improvements for the organisation.

- **Procurement activity update 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. Evaluation in train following the Invitation to Tender phase.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 2 December 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 28 September 2020.

Fitness to Practise (FTP) Concerns

Total concerns received year to date	178
New concerns received since last report date	36
Concerns reviewed since last report date	33
Open concerns with FTP	22

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received year to date	44
New complaints received since last report date	10
Open complaints	21*
Complaints considered by PPC remotely** since last report date	11

* 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	39**

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

** (34 – 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"> This was held remotely*. This complaint could not be resolved by mediation and was referred back to the Preliminary Proceedings Committee for referral to a Committee of Inquiry. 	1

*Held over Microsoft Teams.

Sanction Hearings/ Undertakings/Dismissals before Council*

Heard year to date	8
Sanction hearings/undertakings being prepared for Council	0

* This is reported on a per respondent basis.

High Court Sanction Confirmation Hearings*

Heard year to date	4
Privacy application heard before the High Court year to date	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	4
Held remotely* since last report date	2

* Held over Microsoft Teams.

Prosecutions

Heard year to date 2020	0
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Interim Suspension Applications

Heard by Council year to date	2
Heard by High Court* year to date	1

* This figure is reported on a per respondent basis.

Professional Registration (figures as at 30/11/2020)

Pharmacists

- 5 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.
- 12 EPCs for establishment of service have been received to date in 2020, 8 have been processed and 4 are in process (new European route of entry to recognition and registration)
- 40 Certificates of Current Professional Status have been issued to date.
- 21 Pharmacist Restoration applications in accordance with S.61 have been processed to date.
- 84 Voluntary Cancellation applications and 14 Involuntary Cancellations have been processed since 1st 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

- 36 Third Country Qualification Recognition (TCQR) applications received to date this year, with 107 applications in process.
- 4 TCQR registration application processed to date this year.
- 140 EU recognition/registration applications processed to date this year.
- 156 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 30 November 2020.

No. of new registration applications received.	Registered	In-process
268	271 (23 of which were in process prior to 09/03/2020)	20

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
20	16	2 (2 withdrawn)

No of S.77 Registrations Applications Received	Registered	In Process
42	41*	0

*1 x S77 applicant since voluntary cancelled their registration

Regulation of Retail Pharmacy Businesses (figures as at 01 December 2020)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,965
Number of Retail Pharmacy Businesses Registered in 2020	87
Number of Retail Pharmacy Businesses Cancelled in 2020	78
Number of Changes in Supervising and Superintendent Pharmacists in 2020	492

Internet Supply	
Number of Pharmacies on Part A	120
Number of Non-Pharmacies on Part B	81

Visits to assess against COVID-19 Standards	
Total Pharmacy Visits	9
Onsite visits	6
Virtual visits	3

Inspection Activity 2020	
Total number of Inspections	40
Number of Registration-related Inspections	12
Number of pharmacy inspections	
- Risk-based Inspections	27
- 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
13	1	5
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		10