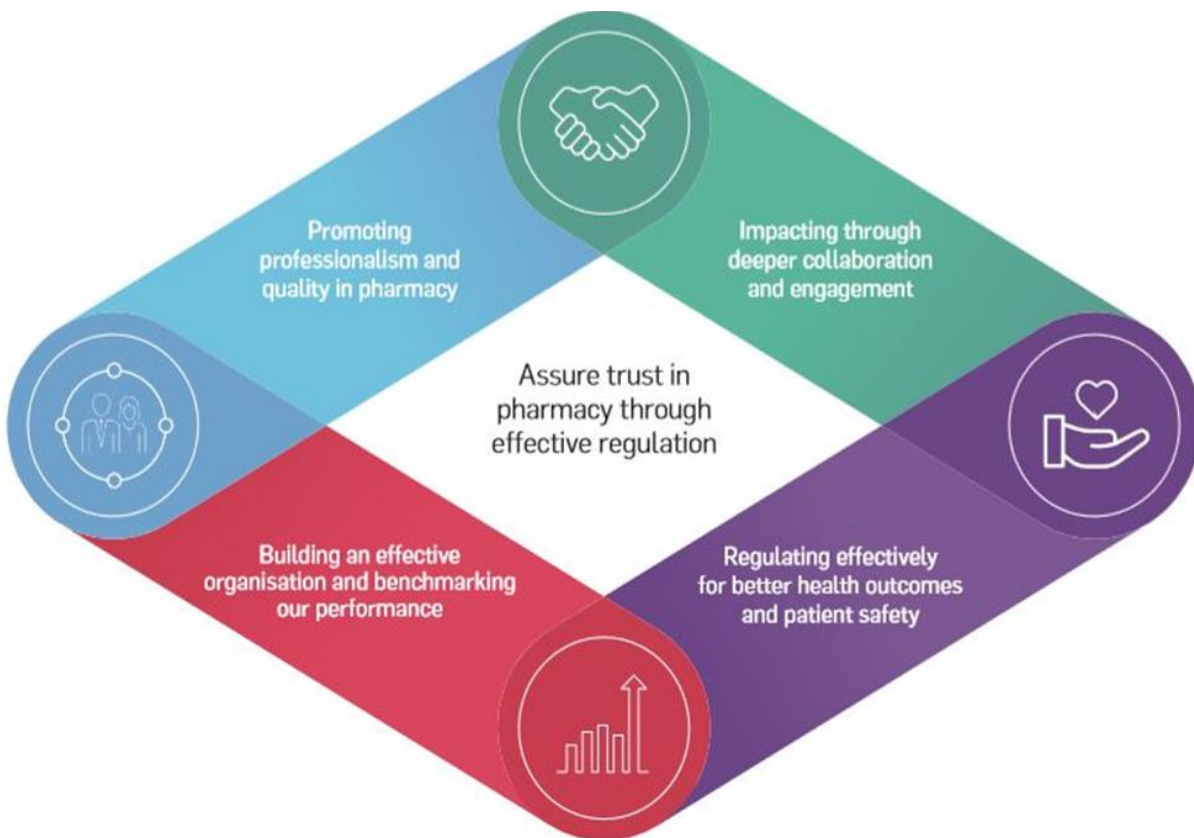


Report of the Registrar



Report to Council Meeting of 4th March 2021

Highlights from the Registrar

Approval of training for administration of COVID-19 vaccines by pharmacists

Extensive work has been undertaken by PSI staff, with the input of an expert panel of pharmacists, to approve training for pharmacists to administer the COVID-19 vaccines. The training developed by the National Immunisation Office (NIO) in respect of the Pfizer BioNtech/Cominarty and the Moderna vaccines was assessed and an approval recommendation made to the Registrar during January. This training was approved on 29 January 2021 as the necessary training for the purposes of Regulation 4F (b) of the Medicinal Products (Prescription and Control of Supply) Regulations (SI 698 of 2020). This training is approved in circumstances where the pharmacist undertaking the NIO training for the vaccinator role, has participated in the most recent influenza vaccination season and has vaccinated patients in the last twelve months, and will be participating in the national COVID-19 vaccination programme to deliver the Comirnaty/ Pfizer BioNtech and the Moderna vaccine, in vaccination centres within the structure of a vaccination team. These pharmacists will also have undergone relevant PSI-accredited training and will be up to date in the recognition and management of anaphylaxis, and in basic life support.

We are currently in the process, again with the support of our expert panel, in approving the NIO training for the AstraZeneca vaccine. This process is currently well-advanced.

We are also working closely with the HSE, in conjunction with the Irish Pharmacy Union, to plan for the operationalising of vaccine supply and administration via community pharmacies. Work is also continuing with the HSE in relation to safe governance of Mass Vaccination Centres and ensuring that any pharmacist who is vaccinating the public in an MVC has undertaken all PSI-required training and, if not a currently experienced vaccinator, is properly and safely supported to undertake the full vaccinator role.

The contribution of the expert panel members, and of my PSI colleagues, in all of the foregoing work is greatly appreciated and demonstrates the commitment of PSI, working in partnership with the profession and with other stakeholders, to support the profession's safe involvement in the national vaccination programme.

Governance meeting with the Department of Health

The third governance meeting of 2020 with the Department of Health took place on 8 December 2020, and the agreed minutes from the meeting of 11 November 2020 have been shared with the Council.

Update on managing our external response to Covid-19

The PSI COVID response group continues to meet on a weekly basis. We continue to manage our external response to COVID-19 via a number of ongoing workstreams across the organisation:



- **Roll out of the COVID-19 vaccine programme**

This is a priority area for PSI and work is ongoing on the approval of the NIO training now available for the AstraZeneca vaccine.

The [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) \(No.7\) Regulations 2020 \(S.I. 698 of 2020\)](#) allow a registered pharmacist to supply and administer a COVID-19 vaccine where he/she has received training approved by the PSI. The PSI approved the HSE National Immunisation Office (NIO) COVID-19 vaccination training for the Pfizer/Biontech and Moderna COVID-19 vaccines in January, and work is ongoing to approve the necessary and relevant training for the AstraZeneca vaccine.

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

The **COVID-19 Operational Standards for Pharmacies** have been developed which 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.



From October-December 2020, 16 pharmacies participated in the initial 'use and learn period'. 3 of these were remote virtual visits, 13 were onsite visits. An expression of interest email was issued to superintendent pharmacists seeking volunteers to facilitate further visits in 2021.

Thirty pharmacies responded to participate in the next phase of 'use and learn' visits January-March 2021. Remote virtual visits are currently being developed as part of standards methodology. The visits are arranged on an appointment basis.

- **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 IOP 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. The group recently discussed a noted increase in people presenting in pharmacies either after a positive COVID test, with symptoms or while awaiting test results. As a result, the HSE updated COVID messages to explicitly advise people not to present in pharmacies and to arrange for other to attend on their behalf. The group have also discussed the COVID-19 vaccination for pharmacists and also provision of the vaccines by pharmacists. A subgroup of the forum of the HSE, PSI and IPU has been formed and are meeting to discuss the roll-out to community pharmacy.

- **Rapid Antigen Detection Tests for SARS-CoV-2 in pharmacies**

We are aware that rapid antigen and/or antibody testing services/kits are being offered to the public via some pharmacies, either directly or in association with third parties.

Antigen detection tests are immunoassays that detect the presence or absence of specific antigens on the surface of the virus. Antigen detection tests for SARS-CoV-2 detection carried out at the point of care are known as Rapid Antigen detection tests (RADTs). RADTs need a sample to contain thousands of virus particles per microlitre to produce a positive result and therefore have shown to be less sensitive in detecting SARS-CoV-2 infection so if a person has low amounts of virus in their body, therefore the test can give a false-negative result. This has resulted in concern that these tests are of limited use for widespread testing of the population.

The PSI have been engaging with the HPRA and the HSE to understand the current public health advice on the appropriate use of these tests. HPRA have issued a number of notices [highlighting the limitations of these tests](#) and have emphasised to PSI that these tests are CE marked for diagnostic use and have not been approved for asymptomatic patients. The HSE has recently issued [guidance on antigen tests](#) and have only recommended their use in 2 specific settings acute hospitals and in controlling community outbreaks within vulnerably populations. Validation work by the HSE antigen testing validation group found that the results of tests in in asymptomatic patients fell below the WHO recommended 80% for sensitivity. This matter is also under review by the relevant HSE expert group, the National Near-Patient Testing Group.

It would therefore seem that the while these tests are of use for symptomatic patients or patient with high viral load, current national advice does not recommend these tests for widespread use in the population. This would mean these tests would not be suitable for use in community pharmacy setting. As national advice and policy in relation to COVID-19 is under continuous review and may change, PSI will, before finalising any advice to pharmacies, ensure appropriate engagement with these authorities.

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

Now that HealthMail has been in use for a number of months the HSE, Medical Council and PSI plan issue a communication to prescribers and pharmacists to include some top tips on using HealthMail based on feedback received from practitioners. The three organisations have also reviewed and included some updates in 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’](#). Both of these will be published in the coming weeks.

- **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 available. The IOP recently hosted a webinar on the COVID-19 vaccines by the Prof Karina Butler Chair of the National Immunisation Advisory Committee (NIAC) and Dr Brian Cleary Chief pharmacist Rotunda hospital and Member of NIAC.



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

- **MPharm Placements:** The PSI has accepted two students on Year 4 placements as part of the integrated MPharm programme for 2021. The students will be due to commence their placements in September 2021.
- **Practice Review:** Further to a review carried out by the IOP on the options for Practice Review in 2021, Council made the decision to cancel Practice Review for 2021 due to the COVID-19 public health emergency. Notification was issued by PSI to pharmacists affected by this decision.
- **Education and Training Rules Amendments:** A short consultation took place from 11th December 2020 to 3rd January 2021 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 for placement (8 months) to be a period of six months in exceptional circumstances. 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 on 21st January 2021. The Rules have since received the Minister's consent.
- **Core Competency Framework (CCF):** Continuing on from the review undertaken in 2020 of the CCF, the PSI is now progressing with a more detailed review in 2021. The PSI has prepared a Terms of Reference for a Project Steering Group and invited participation from a number of key stakeholders to the Group.
- **Review the CPD Model for Pharmacists:** The Education Team at PSI have conducted two workshops with non-pharmacist PSI staff as part of initial scoping activities for the CPD Review Project. It was explored with workshop attendees their understanding of CPD for pharmacists and what it means to them, and to gain their feedback on the CPD system. Pharmacist employees at PSI have also been surveyed to gain initial feedback on the CPD system. The outputs of these activities will be used to inform the next steps of the project, including wider stakeholder engagement exercises.



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

Annual Reporting Process Development

The Education Team at the PSI has developed a revised annual reporting process in consultation with the three Schools of Pharmacy at Trinity College Dublin, the Royal College of Surgeons in Ireland and at University College Cork. Pursuant to Rule 13 of The Pharmaceutical Society of Ireland (Education and Training) Rules 2014, providers must provide an annual report and notify the PSI of material changes in respect of approved degree programmes. Annual reports will highlight how the MPharm continues to align to the accreditation standards and highlight where changes have been made, if any, since the last accreditation visit. An update on any conditions and recommendations approved by Council will also be provided. Annual reports will be provided by the three Schools of Pharmacy in August of each year and will be considered by Council thereafter.

Interprofessional Learning (IPL)

IPL is a key component of the MPharm degree and continues to be delivered despite the necessary restrictions put in place in Higher Education Institutions (HEIs) due to COVID-19. HEI's have developed novel IT solutions to ensure IPL opportunities remain part of the curriculum and that students continue to be provided with these learning opportunities. Representatives of the PSI Education Team met with one of the HEIs in February to understand the innovative methods used. The developments at the HEI have allowed students to work with students and professionals from other health professions as well as patients.

Benchmarking organisation design and change

The Registrar received an inquiry from the Veterinary Council to share information as they were seeking to benchmark organisation design and change in comparable organisations. A representative of the PSI Corporate Governance team has met with a representative of the Veterinary Council in January 2021 for this purpose.



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

- **Falsified Medicines Directive:** In January, the Head of Regulation attended a meeting 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 of Covid-19 and Brexit, the Group has decided that FMD will remain in a use and learn period.
 - A reminder communication regarding FMD will feature in the next PSI newsletter issue.

- **Audit of Retail Pharmacy Businesses in Hospital Settings:**

As part of the PSI Service Plan 2020, the PSI sought further information to complete the review of the regulation of Retail Pharmacy Business (RPB) in hospital pharmacy. The PSI continued its work examining the provisions of the Pharmacy Act 2007 as they apply to hospital pharmacy departments registered under the Act as retail pharmacy businesses (RPB). All 75 registered hospital pharmacy RPBs were invited to participate in a survey which allowed further analysis of the nature of the pharmacy services provided and the extent of their provision. The objective was to bring clarity for all involved as to the precise regulatory remit of the PSI in the hospital pharmacies. To date a total 68 pharmacies have engaged in this audit survey.

- **Commencement of Regulated Professions (Health & Social Care) Amendment Act 2020**
The Regulated Professions (Health & Social Care) (Amendment) Act 2020 (2020 Act), which amends the Pharmacy Act 2007 (2007 Act), was commenced by Ministerial Order under Statutory Instrument No. 54/2021 dated 10th February 2021. Whilst the 2020 Act was signed into law on 14th October 2020, the Statutory Instrument gave 13th February 2021 as the commencement date for the significant majority of the amendments. This means that any changes to the 2007 Act, which includes the operation of some new provisions, will take effect on this date, with a small number of exceptions.

The commenced amendments mostly relate to new and/or amended grounds for complaints against pharmacists and pharmacy owners, enhanced powers in relation to the exchange of information between other regulators in Ireland and abroad, the entitlement of registrants to now apply to the High Court to have any sanctions against them involving admonishment or censure cancelled, broader obligations in relation to the publication of sanctions and information following disciplinary hearings and clarification of the route by which third country applicants can apply to have their qualifications to practise as pharmacists recognised. There are also some administrative changes to the exercise of some of the PSI's statutory functions, additional information regarding PSI functions, and additional powers are conferred on the Council to make statutory rules in relation to specific matters.

Those amendments not yet being commenced until either later in the year or next year are few, and relate to changes which also affect other stakeholders such as an Garda Síochána and in respect of which further consultation is required. Other sections of the Act which have been deferred for commencement relate to changes to the registration process for pharmacists and pharmacy owners. This is because the PSI is at an advanced stage of the design and roll out of a new digital registration process which will streamline the process for registrants, and it is necessary to ensure that the system reflects the requirements of the new legislation before it is finalised.

The commencement of the amended legislation will result in some operational changes internally for the PSI and which we have almost completed. The website is also in the process of being updated to reflect any changes where relevant and communications with stakeholders will be undertaken, as appropriate. The amendments will require Council policy development, in the short to medium term, to underpin and support the making of statutory rules in specific areas, as appropriate.

The PSI very much welcomes this reforming legislation which will help contribute to more effective regulation in a landscape which has evolved both commercially as well as in terms of patient safety since the Pharmacy Act was first introduced in 2007. We also acknowledge the commitment of colleagues in the Department of Health to steering this complex piece of legislation through the legislative process.



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 Project (BTP) update:**

Work continues in earnest on the Business Transformation Project, with the focus since last Council meeting on closing off the final requirements for Phase 1 of the project (which is delivering our new digital system for registration, including registrant portal and the new public register). There have also been robust and comprehensive Data Validation activities being undertaken which are still ongoing to ensure the accuracy and completeness of data migrated from existing to new systems. Steering Group for the project and the PM are working closely with Codec to define a suitable and realistic launch date for this phase. Meanwhile, focus is being given to the people change aspects of the project, in recognition that a large-scale project of this nature requires careful consideration and planning in relation to the impact it will have on staff. We are working with the team at BearingPoint on this, and internal engagement with PSI staff is ongoing in the form of weekly 'clinics' that provide demos of the new system, and a forum for questions and feedback to be addressed.

- **Organisation Development Project (ODP) update**

The Organisation Development Project has completed Phase 1, 'Mobilisation' and Phase 2 'Current State Analysis' and Phase 3 'Future Organisation Structure' has commenced. The activities include assessing organisation design options and elaboration of a future target operating model. A Manager Forum is being established and PSI managers will be supported by BearingPoint in guiding their Teams through the change process. The Change Champion Network (8 PSI staff members) continues to have bi-monthly training sessions by BearingPoint to become change facilitators. Finally, a Coaching Programme for the PSI Executive Leadership Team is planned, that will focus on both core leadership competencies aligned to the public service competency framework and specific actions to support the delivery of the PSI Corporate Strategy and the ODP Implementation Plan. Updates to staff have been provided through remote working channels, Team Briefs and on 'Clinics' with Units, and engagement continues to be encouraged through various channels. The final deliverable of the Phase is the future Target Operating Model for the PSI.

- **Public Sector Innovation Fund**

In February, the PSI applied to The Public Service Innovation Fund 2021. This is a competitive fund that aims to support innovative ideas from across public service organisations. Projects must have a strong focus on outcomes, impact, scalability, transferability and learning within the Public Service. The PSI proposal seeks to develop an app that will assist pharmacists in navigating the training requirements for the delivery of COVID- 19 vaccinations, and to support all other vaccinations and emergency medicines training. The app would provide a simplified and intuitive interface for pharmacists to identify the user’s specific training needs, based on past training and experience. It is hoped the solution will provide a better user experience for pharmacists, reduce PSI query management time, facilitate uptake of training in vaccinations and emergency medicines, and thereby deliver on the public health agenda of improved access to these services, and in particular the National COVID-19 Vaccination Strategy. The submission aligns with PSI’s commitment to maximising the use of digital channels and driving efficiency and effectiveness as part of our Digital First Policy Statement.

- **Strategic HR updates:**

Work has commenced on the new HR Strategy 2021-2023 which is proceeding with the current working title of ‘Shaping our Future - Towards Better Ways of Working’. This strategic objective is at the planning and concept development phase with external facilitation to be commissioned to further evolve and develop this initial concept with management and staff.

Meanwhile, on the recruitment front, the role of ICT Manager was filled on a permanent basis in January 2021 and there are two competitions currently in train, Regulatory Risk Coordinator and Regulatory Executive.

- **Freedom of Information Act 2014**

The yearly statistics for 2020 on Freedom of Information Requests was provided to the Department of Health for inclusion in the yearly report to the Office of the Information Commissioner. In 2020, the PSI received 8 requests under the Freedom of Information Act 2014 and one Internal Review was conducted. The PSI publishes an FOI disclosure log that summarises requests made to us and our decisions.

- **Procurement activity update for contract values in excess of €25k:**

Services / Goods to be Procured	Current Status
Merchant Acquiring Services and Payment Gateway Services	Initial queries submitted to the Office of Government Procurement with a view to proceeding with a Single Supplier Framework: Direct Drawdown.
Website Re-Design Development, Hosting and Support Services	Restricted Procedure in progress. Invitation to Tender document being finalised for shortlisted suppliers.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 19 February 2021)

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 2 December 2020.

Fitness to Practise (FTP) Concerns

Total concerns received year to date	33
New concerns received since last report date	39
Concerns reviewed since last report date	33
Open concerns with FTP	10

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received year to date	13
New complaints received since last report date	15
Open complaints	30*
Complaints considered by PPC remotely** since last report date	5***

* This figure may include complaints received prior to 2021 which are still being processed

** Held over Microsoft Teams

*** 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 remotely* year to date	2
Heard remotely since last report	3**
Cases being investigated/prepared for hearing	35***

* Held using a software platform called TrialView

**This figure involves 5 respondents

**(31 – Professional Conduct Committee & 4 - Health Committee)

Mediation

Total referrals to mediation year to date	0
Held year to date	0

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard year to date	0
Sanction hearings/undertakings being prepared for Council	4
Section 44 Applications (Withdrawal of Professional Conduct Committee Complaint) being prepared for Council	1

* This is reported on a per respondent basis.

High Court Sanction Confirmation Hearings*

Heard year to date	0
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

Section 44 Applications* (Withdrawal of Professional Conduct Committee Complaint)	1
Callovers heard year to date	0
Held since last report date	0

* Held using a software platform called TrialView

Professional Registration (figures as at 24.02.2021)

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.
- 0 EPCs for establishment of service have been received to date in 2021, 0 have been processed and 0 are in process (new European route of entry to recognition and registration)
- 8 Certificates of Current Professional Status have been issued since 1st January 2021.
- 3 Pharmacist Restoration applications in accordance with S.61 have been processed since 1st January 2021.
- 42 Voluntary Cancellation applications and 0 Involuntary Cancellations have been processed since 1st January 2021.
- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of Covid-19 outbreak.
- 8 Third Country Qualification Recognition (TCQR) applications received to date this year, with 118 applications in total in process.
- 6 TCQR registration application processed to date this year.
- 4 EU recognition/registration applications processed to date this year.
- 1 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 24 February 2021.

No. of new registration applications received which are recorded on db.	Registered	In-process
295	302 (23 of which were in process prior to 09/03/2020)	11 in process/1 withdrawn/ 2 to be resubmitted via correct route

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
25	23	2

No of S.77 Registrations Applications Received	Registered	In Process
51	43 (7 have since restored to the Register under S.61 and 1 has since voluntarily cancelled)	1

Regulation of Retail Pharmacy Businesses (figures as at 25 February 2021)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1970
Number of Retail Pharmacy Businesses Registered in 2021	12 – 2 (New); 3 (Relocations) & 7 (Changes of Ownership)
Number of Retail Pharmacy Businesses Cancelled in 2021	10 – 0 (Voluntary Cancellations); 3 (Relocations); 7 (Changes of Ownership)
Number of Changes in Supervising and Superintendent Pharmacists in 2021	62

Internet Supply	
Number of Pharmacies on Part A	132
Number of Non-Pharmacies on Part B	79

Visits to assess against COVID-19 Standards	
Total Pharmacy Visits	20
Onsite visits	13
Virtual visits	7

Inspection Activity 2021	
Total number of Inspections	0
Number of Registration-related Inspections	0
Number of Self-Declarations processed	21
Number of pharmacy inspections	
- Risk-based Inspections	0
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	0

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
12	0	2
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		0