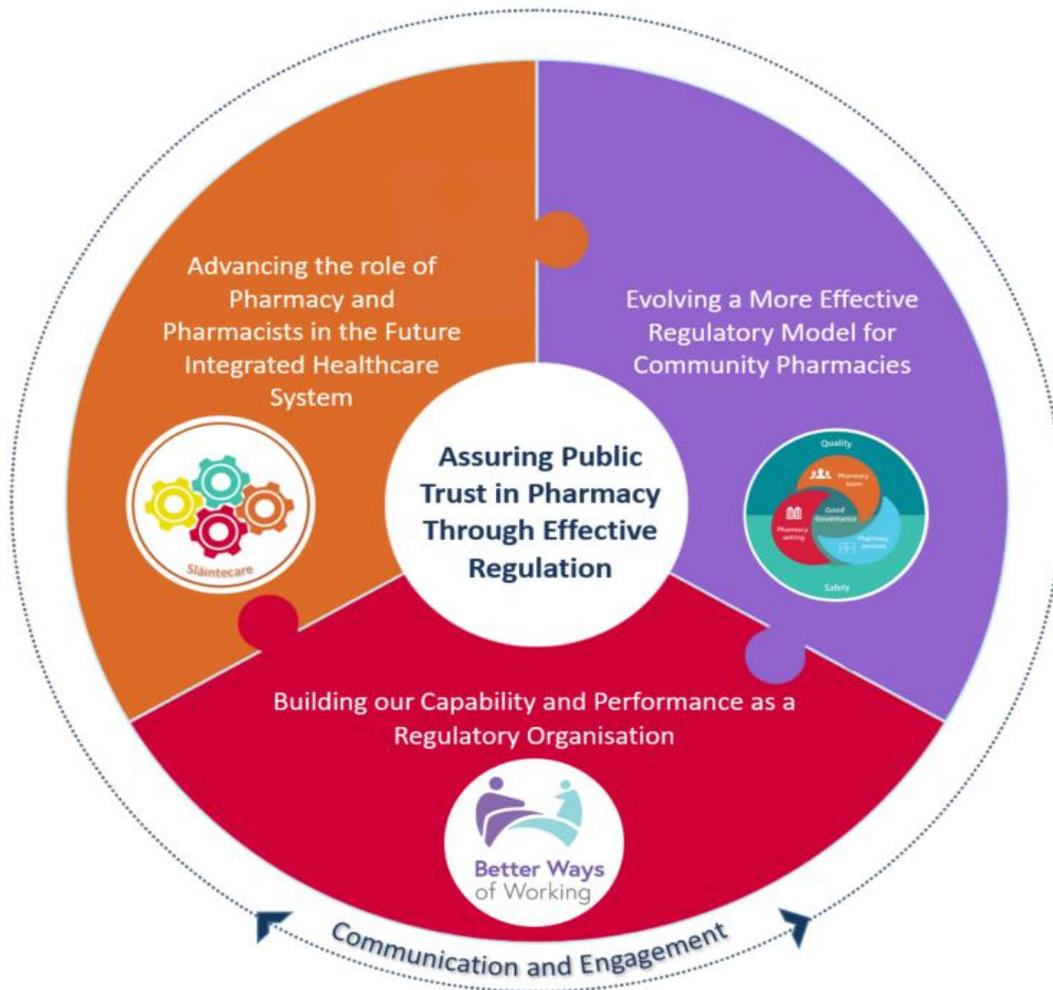




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Registrar



Report to Council Meeting of 16th December 2021

Highlights from the Registrar

Governance Meetings with Department of Health

The third governance meeting with the Department of Health was held on 30 November (one of three scheduled each year). The minutes from the previous meeting of 29 September have been uploaded to Council iPads.

Earlier in November (12th), the President and I were invited to meet the Department to discuss the process of agreeing the Performance Delivery Agreement for 2021. This was a useful discussion, chaired by Mr. Muiris O'Connor, Assistant-Secretary. The President explained the position of Council as regards the regulation of pharmacists and pharmacies and that the Council is committed to carrying forward the objectives outlined in its current Corporate Strategy. The Department explained how it wishes to exercise appropriate oversight of public bodies under its remit, including PSI. It was agreed that the position paper, which is included under Objective 2.1 of the draft Service Plan 2022, would be a helpful step in ensuring common understanding between PSI and the Department as to how PSI believes community pharmacy regulation can operate more effectively in 2022/2023 as well as in the context of potential future regulatory reform.

Service issues with our new registrant portal

We have experienced some issues with our new registrant portal during November/December. Some of these have caused delay and confusion as registrants have logged-in to the portal in order to complete their continued registration. We very much regret that these issues have arisen, and the inconvenience caused to some registrants. We have worked extensively to identify the root causes of these issues and to put appropriate fixes in place, in conjunction with our technology and payments providers. Also, to provide support and feedback to registrants affected. More information on the current status of these issues will be provided via the BTP Programme Board at the Council meeting on 16 December (see also page 10 of this Report).

Meetings and external engagements since previous Report

13 October	Association of Chief Executives of State Bodies: Seminar on diversity at work
14 October	Public Services Conference 2021
27 October	RCSI: Guest lecture on leadership within the pharmacy profession
4 November	Meeting to brief DoH on the case for reform of the Pharmacy Act
9 November	Stakeholder meeting with IPU
11 November	IPA Governance Forum: Periodic Critical Reviews
12 November	Meeting with DoH regarding performance delivery agreement
30 November	Periodic governance meeting with DoH
1 December	Meeting with DoH to discuss FMD compliance in pharmacies
9 December	Meeting with APPEL Board (Heads of the three Schools of Pharmacy)

And finally...

This is my final Report to Council in my role as Registrar, having presented over thirty Reports since September 2016. Looking back, it is gratifying to see how each one has given me the opportunity to report on progress by PSI in relation to the ambitious programme of strategic change and development which we, Council and Executive, have been committed to over that time. Despite challenges along the way, COVID-19 and others, we have made significant progress towards building PSI as an effective and forward-looking regulator which is dedicated to, and highly capable of, both serving the public interest and protecting the public.

Personally, I have greatly enjoyed my time working with my fellow PSI colleagues. I have learned so much from each person and I will be bringing all of this good and positive experience with me to my next role. I will definitely miss the close working relationships which have been built up since 2016 and I wish all of my colleagues the very best in their future personal and working lives.

Likewise, I have learned a lot from working with the various Council members I have met along the way, and, in particular, from the four Presidents with whom I have worked. Each, in their different ways, has demonstrated deep commitment to the PSI mission while also exemplifying the best values and traditions of the pharmacy profession.

As I leave PSI, I feel very proud of my association with pharmacy and pharmacists. I hope the profession, supported and regulated by PSI, prospers professionally and takes its proper place as an essential part of our future healthcare system in Ireland – one where patient needs and interests always lie at the heart of everybody's concerns.

Update on managing our response to COVID-19

COVID-19 vaccination programme

The booster programme for COVID-19 vaccination is currently well underway pharmacies moving through the age cohorts in line with NIAC advice. The PSI continues to participate in the weekly meetings of the HSE's vaccination programme subgroup, which has been meeting weekly since January this year to coordinate the safe roll-out of the vaccination service in community pharmacies.

A total of **426,099** vaccines have been administered to date via community pharmacies. The below table gives the breakdown of the age profile of the people attending pharmacies for vaccines. At the moment there are approximately 30,000 doses been given weekly in pharmacies with first time doses still presenting.

Age-Range	Vaccinations
a. < 12	64
b. 12-15	48734
c. 16-19	50275
d. 20-29	145143
e. 30-39	74496
f. 40-49	22522
g. 50-59	38045
h. 60-69	38061
i. 70-79	7180
j. 80-89	1335
k. 90+	244
	426099

The vaccine subgroup will also be moving to consider what preparations are necessary for implementation of the recent NIAC advice on vaccinating children aged 5-11years. Among other matters, there will be a need to discuss the development of training by National Immunisation Office (NIO), updating the HSE operational guidance for COVID vaccinations in Pharmacy, as well as further amendments to the medicinal products legislation.

To date in 2021, there have been 14 statutory instruments drafted to introduce amendments to the Medicinal Products Prescription and Control of Supply Regulations to provide for the COVID vaccination programme. PSI continues to assist DoH in the review of these draft regulations.

HSE Community Pharmacy Planning Forum:

The HSE has re-established the Community Pharmacy Planning Forum. The group is now chaired by Pat Healy, National Director, HSE. It has been agreed that the group will meet monthly with new terms of reference. These provide for ongoing engagement and consultation with the pharmacy sector to support consideration of the strategic direction for the future development of community pharmacy services in line with Sláintecare. The forum will also provide a process for ongoing strategic planning

required for the future of community pharmacy in the longer term and also in the context of the ongoing COVID-19 Public Health Emergency. This forum includes stakeholders from the IPU and the IIOIP 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.



Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System

Key updates

Student placement: To date, our 4th year pharmacy student undertaking her 16-week experiential learning placement at PSI, has had the opportunity to be involved in significant projects across our different teams to gain experience in relation to our functions and responsibilities. For example, presentations on protected disclosures were made to all PSI staff as well as to the Audit & Risk Committee. As with last year, this interaction has been done online, but a big effort has been made to ensure inclusion and involvement in all aspects of the organisation and this has worked well. The placement will finish on 16 December, and, as always, the contribution, positive attitude and approach of pharmacy students to our work are very welcome.

Communication and Engagement Update

Staff from Strategic Policy and Communications met with HIQA standards team as part of their public consultation of the Draft Overarching National Standards for the Care and Support of Children using Health and Social Care Services.

The PSI President and the Head of Strategic Policy and Communications attended the Medical Council stakeholder group on strategies to reduce the overprescribing of benzodiazepines.

The Head of Governance and the Head of Strategic Policy and Communications also met with the HPRA with a view to updating the MoU between the two organisations.

The Head of Community Pharmacy Assurance and the Head of Strategic Policy and Communications met with representatives of the Irish Pharmacy Union.

PSI have been invited to participate in a DoH and HSE Working Group that has been established on Preventing Paracetamol-Related Intentional Drug Overdose. The overall aim of this Working Group (WG) is to collaborate on actions to prevent paracetamol-related intentional drug overdose. The working group is set up under the DoH group on *Connecting for Life, Ireland's National Strategy to Reduce Suicide (2015-2024)*. The HSE lead from the group is to meet with PSI to discuss promoting awareness of the legislation and risk minimisation measures aimed at limiting access to paracetamol and sharing and optimising educational materials and disseminating research findings in relation to paracetamol-related overdose.

The PSI was pleased to be part of the exhibitor zone at the APPEL Future of PharmacIE online event in October, for which our current 4th year pharmacy student did a large amount of the work. One of our PSI pharmacist colleagues was also a panellist for one of the career discussions. In November, the Head of Strategic Policy and Communication presented to the master's degree students in Hospital Pharmacy in TCD. The Professional Standards team, along with our current pharmacy student, also continued their regular engagement through the three Schools of Pharmacy by presenting to first year students, introducing the PSI and our regulatory role.

The President and the Registrar have each contributed short end-of-year articles to the pharmacy publications, the Irish Pharmacist and the Irish Pharmacy News. A press release will issue following the public Council meeting on 16 December, regarding the resignation of the Registrar and the appointment of the interim Registrar, and notice will appear on our own digital platforms.

Over the course of the year, in the region of twenty media queries have been dealt with, as well as supporting our Fitness to Practise colleagues where journalists attend public inquiries (online).



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive:

The PSI continues to participate in 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). The Safety Features Oversight Group, following consultation with all relevant stakeholders, has now agreed a plan for ending ‘use and learn’ on a phased basis, concluding at the end of Q1 2022.

In preparation for the end of use and learn in Ireland, the PSI has held recent meetings with the Irish Medicines Verification Organisation (IMVO) who are responsible for maintaining the national repository, the HPRA and the DoH.

The Registrar wrote to all superintendent pharmacists in November to remind them of their legal and professional requirement under this EU legislation to verify the safety features on the packaging of medicinal products by scanning and decommissioning each medicine that they dispense to patients. The data from the Irish Medicines Verification System shows that the current decommissioning rate in Ireland is low and inconsistent by comparison with other EU States. The Registrar has directed all superintendent pharmacists to review the practices in their pharmacies in relation to FMD to ensure full and consistent compliance with the requirements of this EU legislation and prepare for the end of use and learn in 2022. The PSI also reviewed and updated the information available to pharmacists on FMD on the PSI website.

The PSI continues to engage with retail pharmacy businesses (RPB) to “engage, explain and encourage” compliance during the ‘use and learn’ period. We also use this engagement to explore broader issues as to how the overall FMD approach from Europe is working within Irish pharmacies and with the systems they use in their day-to-day work. Such issues are reported back to the National Safety Features Oversight Group.

As part of encouraging registrants with FMD compliance during the use and learn period, the PSI has contacted Retail Pharmacy Businesses (RPB) regarding FMD scanning activity during a week period in both October 2021 and November 2021.

Improper conduct by students of pharmacy in pharmacies

Arising from concerning information and evidence which has come to the attention of PSI during 2021, the Council asked that the Registrar write to the Heads of the three Schools of Pharmacy to alert them to these issues and to ask that they take all steps open to them to ensure that students are clear as to the expectations around conduct and compliance with pharmacy and medicines law while working and/or present in pharmacies. Each of the Schools has confirmed that they have addressed this issue on foot of the PSI letter and that students are clear as to what they should do if they feel compromised in any placement or working situation. We will stay in touch with the Schools on this issue.

COVID-19 Operational Standards for Pharmacies:

We continue to conduct exploratory COVID-19 Operational Standards visits through an extended “use and learn” process which will conclude at the end of 2021. Work continues on the training of PSI’s Quality Assessors in the conduct of standards visits and our other inspection functions.

Engagement meetings

The Head of Community Pharmacy Assurance met with the HSE Clinical Lead for ePharmacy to discuss matters and issues pertaining to the development of an ePharmacy system.

The Head of Community Pharmacy Assurance and colleagues also met with the Department of Agriculture and the Marine and received a briefing on the National Veterinary Prescription System (NVPS) which is being rolled out in conjunction with the introduction of the new EU Veterinary Medicinal Products (VMP) and Medicated Feed Regulation which will apply from 28 January 2022.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Strategic HR Update:

- **Workforce planning and recruitment:**

The following positions were filled since the last Registrar's Report:

- Regulatory Executive (Permanent)
- Quality and Safety Manager (Permanent)
- Customer Relations and Registration Lead (Permanent)
- Professional Standards Manager (Fixed-term - Career break backfill)

We have three ongoing competitions (Business Support Services Assistant, Regulatory Solicitor and Acting Head of Practitioner Assurance) and one position for which sanction was received (Senior Pharmacist) which will be commenced shortly. Business cases for four replacement posts are currently with the Department of Health for sanction, including the post of Registrar/Chief Officer.

- **Business continuity and blended working:** The introduction of a pilot of blended working arrangements at PSI has been postponed to 2022, in line with recent Government public health advice regarding working from where possible.

Business Transformation Programme (BTP) Update:

Phase 1 of the BTP's digital transformation project – the new online system for registration – was launched on 27 September. To date, 83% of all registrants – pharmacists, pharmaceutical assistants and pharmacies – have activated their profile, i.e., they have signed into the new portal, irrespective of date of expiry of their certificates of registration.

Registrants have been applying for first time registration and for continued registration using the new online portal, since that date. The large majority of all registrants, and applicant registrants, have moved seamlessly through our new system. As might be expected with any new online system, we have also encountered some issues that came to light during November, which is our busiest period in any year for continued registrations. These issues had not been apparent during our 'hypercare'

period in October. The issues experienced by some of our registrants range from activation of profiles (with the main issue stemming from a single email address being attached to multiple entities/persons) through to some card payment issues (this latter issue, in part, resulting from communication between the registration portal, PSI's payment gateway provider, and our technology partner, Codec).

We have been working with our third-party providers to resolve these issues and we expect a resolution of key functionality issues before year-end. PSI has also been engaging directly with any impacted registrants and has reassured applicants for continued registration, who may be experiencing some technical difficulties, that late fee penalties are being waived for them.

We are pro-actively monitoring the helpline and info@psi.ie email address to respond to queries as quickly as possible, with on average, 90% of all queries being resolved within a 48-hour period. PSI resources are mobilised to ensure that queries are being dealt with efficiently and, where required, technical fixes escalated to our technology partner, Codec. Also, that registrants understand that we sincerely regret the inconvenience caused by these issues.

PSI continues to encourage feedback on our new system from users. Feedback has been received on areas for improvement and areas that have worked well. Approximately 25% of feedback survey respondents have completed their business (mostly continued registration applications) via smartphone devices. This was not previously available as an option and this aspect of our new portal development is an example of how our new technology can streamline registrant interactions with PSI.

Organisation Development Project (ODP) Update:

We continue to implement the agreed ODP changes during this Phase 5 of the project, overseen by the Executive Leadership Team (ELT) as the Steering Group and with the addition of a Coordination Group, which meets weekly. The risk register for the project remains under review, along with a benefits realisation register.

The implementation plan for this phase, comprising three workstreams: 1) Governance and Communications, 2) Change the Way we Work and 3) Develop our People, remains in progress, though there has been some delay in meeting our commitments this quarter of the year due to competing priorities, including staff commitment to managing delivery of the new registration system, and the continued requirement due to COVID-19 to work away from each other and the office has also had some impact. Under workstream 2) the initial focus is on establishing the Programme Delivery function and implement the new matrix-structured functions. In support of those functions, two roles have been filled: a Programme Delivery Manager on an 8-month assignment (Programme Delivery) and a Customer Relations and Registration Lead on a permanent contract (Matrix implementation). Under workstream 3), the work related to the organisation wide Skills and Competencies Assessment Analysis and Development Plan (learning and development – L&D-plan) continues. A first organisation-wide L&D intervention took place between October and December 2021. The training was tailored to 4

different cohorts of staff and was focussed on ‘People management in a hybrid working environment’ or ‘Adapting to a hybrid working environment’, depending on the groups. The coaching programme for the ELT is completing in December. The work on an Internal Communication Strategy continues with cross-organisation input.

The second ODP staff sentiment poll was completed in November. This has been presented across the organisation together with comparative findings from the first poll in June. In line with the review of the last quarter (a Stage Gate review), we are mindful of continuing to provide frequent updates to all staff, to supporting and enhancing the wider management group, and to ensuring that consideration is given to sequencing of activities alongside other work that must continue, and in a remote working environment.

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

<u>Services / Goods to be Procured</u>	<u>Current Status</u>
Website Re-Design Development, Hosting and Support Services	Tender process complete. Contract completion in progress.
Merchant Acquiring Services and Payment Gateway Services	OGP Single Supplier Frameworks (Direct Drawdown) process with Notification to Activate Services Forms (NASF) submitted to suppliers on 29th October
Legal Services	Closing date for tenders to be received: 8th December. Tender evaluation meeting scheduled for 17th December.
Stenography and transcription services	COMPLETE. Services to be accessed through OGP framework. The Notification to Activate Services Form (NASF) issued.
Public Affairs and Communication Advisors	COMPLETE. Contract commenced 21st October.
External Auditors	OGP Framework Tender process complete. Awaiting Council approval at 16th December meeting before OGP issues the outcome letters.
Notebook Computers and Associated Services	OGP Framework. Notification to Activate Goods Form (NAGF) with existing supplier (Datapac) complete. Available to commence equipment purchases.

Appendix 1 –Statistical Summary

Fitness to Practise

For the purposes of this appendix, please note that references to 'last report date' refers to the Registrar's Report dated 7 October 2021.

Fitness to Practise (FTP) Concerns

Total new concerns received year to date	114
New concerns received since last report date	12
Concerns reviewed since last report date	20
Open concerns	5

Fitness to Practise Complaints for Screening Committee (PPC)

Total new complaints received year to date	78
New complaints received since last report date	19
Total open active complaints*	54
Complaints considered by PPC remotely since last report date **	7

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

**89% of which met the KPI of the PPC decision being made within six months from the date of receipt of complaint to the date of the final PPC decision.

Inquiries (as at 9 December 2021)

Total heard (all remotely) year to date*	12 (totalling 24 Inquiry days)
Heard remotely since last report	6
Complaints being investigated/prepared for hearing	37

10 inquiries took place before the Professional Conduct Committee & 2 inquiries took place before the Health Committee. 1/12 inquiries is adjourned and is to be completed. The 12 inquiries involve 15 Respondents.

Mediation (as at 9 December 2021)

Total complaints referred to mediation year to date	4
Mediations held year to date	2

Sanction Hearings/ Undertakings/Dismissals/Applications before Council* (as at 9 December 2021)

Heard year to date*	10*
Sanction hearings/undertakings being prepared for Council	3

* Some of these matters have come before the Council on more than one date. Some of these matters involved more than one respondent.

High Court Sanction Confirmation Hearings (as at 9 December 2021)

Heard year to date	2
Cases being prepared for High Court confirmation	0

Appeals (as at 9 December 2021)

Heard year to date	1
Cases being appealed following fitness to practise inquiry	0

*The Appeal was heard on 29 November and 8 December. Judgement has been reserved and is awaited.

Call-Overs and Other Applications Before Committees of Inquiry (as at 9 December 2021)

Scheduled Callovers heard year to date:	
(a) Professional Conduct Committee	(a) 4
(b) Health Committee	(b) 3
Held since last report date	(a) 2
(a) Professional Conduct Committee	(b) 1
(b) Health Committee	

Interim Suspension Applications (as at 9 December 2021)

Applications heard by Council year to date	2
Applications heard by the High Court year to date	1

This involved two Respondents.

Prosecution (as at 9 December 2021)

Cases being prepared for District Court Prosecution	1
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Professional Registration (figures as of 06 December 2021)

- 2 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.
- 2 EPC applications for the temporary & occasional provision of service have been received to date in 2021, one of which has been approved while the 2nd one was not a valid application.
- 7 EPCs for establishment of service have been received to date in 2021 (new European route of entry to recognition and registration). 3 completed, 1 in progress, 1 withdrawn and 2 refused.
- 1 EPC application has to date been received and approved for establishment of service in host country (Malta).
- 45 Certificates of Current Professional Status have been issued since 1st January 2021.
- 17 Pharmacist Restoration applications in accordance with S.61 have been processed since 1st January 2021.
- 138 Voluntary Cancellation applications and 53 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.
- 44 Third Country Qualification Recognition (Non-EU/EEA qualified other than UK qualified) applications received to date this year, with 128 applications in total in process.
- 63 TCQR (both UK qualified and outside of UK) registration applications processed to date this year.
- 32 EU recognition/registration applications processed to date this year.
- 144 National route applications processed to date this year.

Pharmacists

No. of New Registration, and Restoration Applications, Including Section-77 Restorations, in the context of the COVID-19 pandemic - 9 March 2020 to 06 December 2021.

No. of new registration applications received which are recorded on applications record db.	Registered	In-process -EU/TCQR (UK qualified)
-	530	16

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
-	37	2

No of S.77 Registrations Applications Received	Registered	In-process
	40	1

Regulation of Retail Pharmacy Businesses (figures as of 08 December 2021)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses @ 08 December 2021	1985
Number of Retail Pharmacy Businesses Registered in 2021 @ 08 December 2021	20 New Openings; 10 Permanent Relocations ; 77 Changes of Ownership Total = 107
Number of Retail Pharmacy Businesses Cancelled in 2021 @ 08 December 2021	Voluntary Cancellations – 9 Closure; 10 Permanent Relocations; 77 Changes of Ownership Total = 96
Number of Changes in Supervising and Superintendent Pharmacists in 2021	524

Internet Supply	
Number of Pharmacies on Part A	201
Number of Non-Pharmacies on Part B	158

Visits to assess against COVID-19 Standards (YTD)	
Total Pharmacy Visits	29
Onsite visits	4
Virtual visits	25

Inspection Activity 2021	
Total number of Inspections	28
Number of Registration-related Inspections	4
Number of pharmacy inspections	19
- Risk-based Inspections	4
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	1

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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
18	2	1
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		7