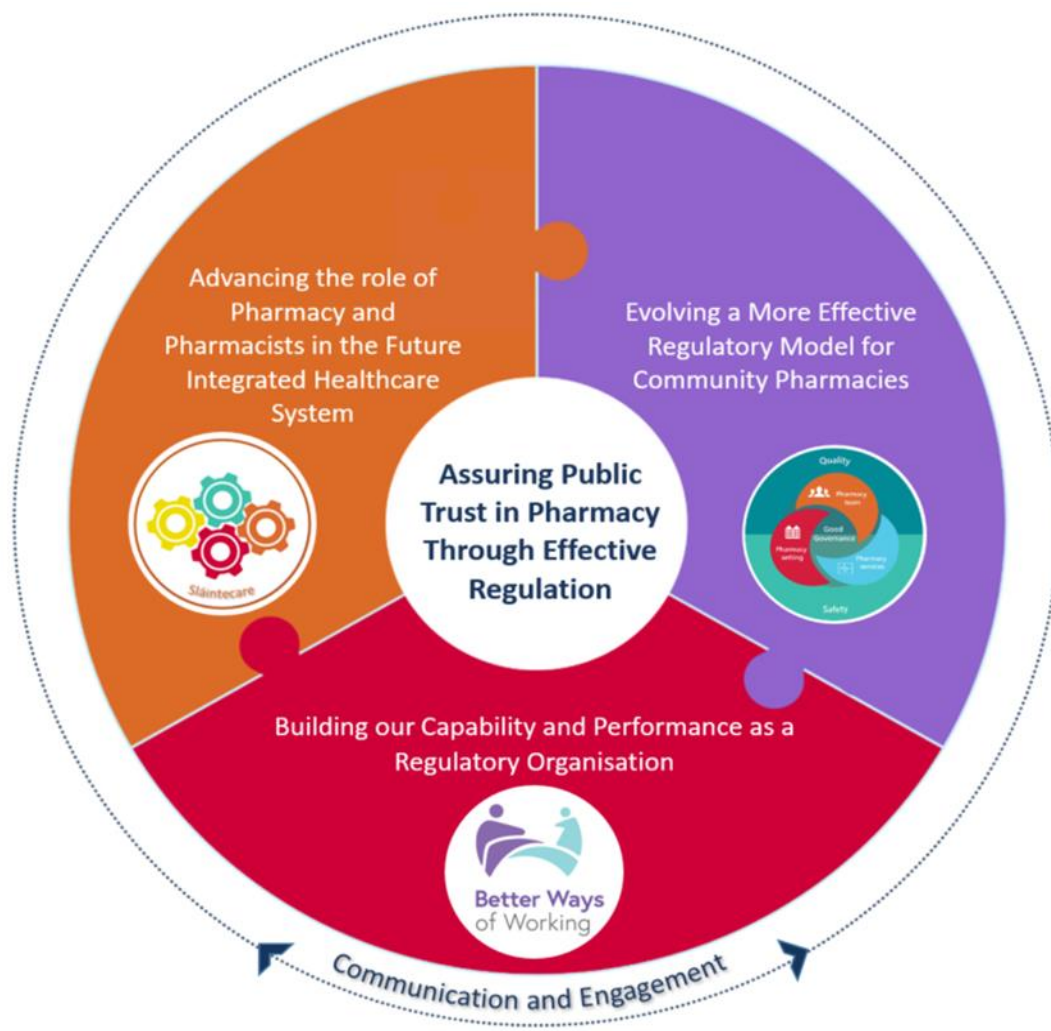


Report of the Registrar

Council Meeting 27th April 2023



Highlights from the Registrar

Emerging Risks to Future Pharmacy Workforce Project

Work on this important strategic project continues to progress. There was a very constructive discussion at the workshop held as part of the 23 March Council Development Day. This focussed on the draft recommendations and actions identified as necessary to help ensure the future sustainability of a patient-facing pharmacist workforce. The third meeting of the Working Group, comprising senior stakeholders from across the health system and pharmacy sector, took place on 4 April. This meeting also focussed on the draft recommendations and actions and, importantly, their associated owners and timelines. The final report has been drafted and is undergoing an iterative review and edit phase between the PSI and Grant Thornton. The next steps are that a draft report will be presented to the Regulatory and Professional Policy Committee, and a dedicated meeting will be held to discuss their feedback in advance of the final report being presented to Council.

Approval of the HSE's National Immunisation Office (NIO) training modules on adapted COVID-19 vaccine, Comirnaty® Original/Omicron BA. 4-5 10 micrograms (For those aged 5-11 Years).

On 24 March, the Registrar approved the NIO training in respect of **Comirnaty® Original/Omicron BA. 4-5 10 micrograms (For those aged 5-11 Years)**, as training for the purposes of Regulation 4F(b) of the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.7) Regulations 2020 (S.I. No. 698 of 2020) to facilitate pharmacist vaccinators in supplying and administering this vaccine, as part of the COVID-19 national vaccination and implementation plan.

This approval did not require the convening of an expert assessment panel, further to a new risk-based approach to the assessment of NIO training modules on COVID-19 vaccines that we introduced on 21 March. Our risk-based approach and assessment, guided by our principles of regulatory risk, focus on whether the NIO training module(s) relates to a new COVID-19 vaccine or an adapted COVID-19 vaccine product. Consideration is also given as to the intended patient cohort for the vaccine, i.e., adults or children. A risk-based decision support tool has been developed to underpin the risk assessment process.

It should be noted that under the revised approval process, the Registrar reserves the right to convene an expert assessment panel to assess any new or revised NIO training modules in relation to COVID-19 vaccines as and when deemed necessary.

Governance Meeting with Department of Health (DoH) Officials

On 29 March, members of the ELT (Executive Leadership Team) met with officials from the DoH for the first governance meeting of 2023. Topics under discussion at the meeting included progress in relation to the Service Plan 2023, the extension of the Corporate Strategy by an additional year, outstanding sanction from DoH regarding increases approved by Council to PSI staffing levels, Third Country Qualification Recognition (TCQR) Route, Corporate Risk Register, Falsified Medicines Directive, pharmacy workforce challenges and expansion of services provided by pharmacists.

The approved Minutes from the meeting, which took place in September 2022, are available on Council iPads.

Ongoing Regulatory Work Programmes in 2023

Activity	Outputs	Update
Implement the revised Core Competency Framework (CCF) for pharmacists.	<ul style="list-style-type: none"> A roadmap is in place in place for the implementation of the revised CCF for pharmacists in 2023. 	Engagement with the Irish Institute of Pharmacy (IIOP) and the Schools of Pharmacy regarding the implementation of the CCF has continued. An implementation plan has been agreed upon with the IIOP focusing on the implementation of the CCF for CPD purposes and is now being actioned. A meeting with the Schools of Pharmacy will take place on 26 April.
Revise the Accreditation Standards for CPD Programmes and Courses for Pharmacists and commence the revision of the MPharm Accreditation Standards.	<ul style="list-style-type: none"> Accreditation Standards for CPD Programmes and Courses for Pharmacists reviewed and approved by Council by Q4 Project plan in place for MPharm Accreditation Standards review and inputs identified by Q4 	A review of the Accreditation Standards for CPD Programmes and Courses has commenced. The review will take account of national and international developments and best practice in relation to CPD Accreditation Standards. Terms of Reference for a Working Group (who will assist with the review) have been approved by the Executive Leadership team.
Operationalise our Regulatory Risk Statement as a key tool in managing incoming information, intelligence, and strategic learning to help identify and respond to risks to patient safety and/or serious concerns as to the quality of community pharmacy services.	<ul style="list-style-type: none"> New risk reporting mechanisms developed and operating by year-end. Continued development of the joined-up approach to identifying and addressing regulatory risk. 	The review of the operation of the Regulatory Risk Analysis and Response Group was completed, and the report of the review was considered by ELT. The recommended follow-up actions for 2023 were approved by ELT.

<p>Advance our actions to contribute to Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025 (known as iNAP2) to address antimicrobial resistance (AMR) and help advance Ireland's response to AMR by improving awareness and knowledge of AMR amongst the pharmacy profession, including pharmacy students, to ensure that it is an integral part of the delivery of pharmacy services.</p>	<ul style="list-style-type: none"> • Participation of pharmacists in continuing professional development (CPD) and education on AMR, infection prevention and control (IPC) and antimicrobial stewardship (AMS) encouraged by the promotion of resources and increased awareness of the importance of these areas for practice. • Accreditation standards review and relevant guidance documents for RPBs (Retail Pharmacy Business) to be reviewed in 2023 will be informed by HSE's Antimicrobial stewardship: Guidance for all healthcare settings. 	<p>In our March newsletter, we included a designated section on antimicrobial stewardship (AMS) entitled "Empowering pharmacists to deliver antimicrobial stewardship." In this newsletter, we took the opportunity to raise awareness about the Pharmacist Antimicrobial Stewardship Network (PAMS-net) and how pharmacists can join and use the network, which aims to support pharmacists across all sectors to work towards the common goal of promoting responsible use of antimicrobials in all patients and limiting the emergence of antimicrobial resistance.</p> <p>We also signposted to HSE information, tools, and resources on AMS and Antibiotic Prescribing.</p>
<p>Operationalise the revised Third Country Qualification Recognition (TCQR) route process leading to registration as a pharmacist.</p>	<ul style="list-style-type: none"> • Revised route commenced by end Q4 	<p>The PSI project team is in the process of implementing the revised TCQR route, with the current focus being on developing the examination component of the new process and on designing a new approach to the adaptation placement system which will see placements managed for the applicants on behalf of the PSI, through a quality assured process. On 19 April, the project team met with a panel of experts to recommend the content and structure of exams under the revised route.</p> <p>An Advisory Group was convened to ensure the robustness of the new TCQR route so that potential risks can be identified and managed. The first</p>

		<p>meeting of the Advisory Group took place on 31 March, at which initial feedback was received from the Group on the five stages of the revised process.</p> <p>A public consultation took place between 24 February – 19 March 2023 on proposed Rules to amend the PSI (Registration) Rules 2008, as amended. The amendments would allow the PSI to implement the revised TCQR approach.</p>
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Communication and Stakeholder Engagement Updates

Overview of meetings attended by the Registrar and PSI staff	
March-April (Bi-weekly meetings)	National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group: Discussions at these meetings focus on the ongoing roll-out of the national COVID-19 vaccination programme in community pharmacy, with attention now turning to the Spring COVID-19 Booster Vaccine Campaign.
1 March	We attended the Medical Council stakeholder group meeting to discuss strategies to address overprescribing of controlled drugs. This stakeholder group includes representatives from the Medical Council, HSE, HPRA (Health Products Regulatory Authority), Department of Health, the PSI and ICGP (Irish College of General Practitioners).
3 March	Meeting with the HPRA to discuss Medicines Shortages Framework.
9 March	We attended the National Healthcare Quality Reporting System (NHQRS) Strategic Planning Workshop at the National Patient Safety Office.
13 March	Meeting with the IPU (Irish Pharmacy Union) to have a collaborative discussion on pharmacy practice matters.
14 March	Meeting with the Department of Health regarding the Reform of the Pharmacy Act.
15 March	We met with the GCP/PV inspector at the HPRA to have an initial discussion on pharmacy aspects relating to Decentralised Clinical Trials.
16 March	We met with the Inspector of Mental Health Services regarding the Independent Review of the provision of Child and Adolescent Mental Health Services (CAMHS) in the State to determine whether any matters of relevance to the exercise of PSI's statutory duties have arisen in the course of the review.
28 March	We attended the quarterly Safety Features Oversight Group at the IMVO office to discuss FMD compliance and the impact of Brexit on FMD.
29 March	We met with officials from the Department of Health (DoH) for the first Governance Meeting of 2023.
29 March	We met with the HSE and IPU to discuss future developments proposed for the Pharmavax system, which is used to record the administration of publicly funded vaccines within community pharmacy.
29 March	PSI representative attended the Sodium Valproate Stakeholder group, which was established by the Department of Health to address concerns about sodium valproate.

29 March	We met with Fieldfisher to discuss updates in professional regulation over the past year.
30 March	We attended a cross-border meeting on controlled drugs and issues regarding prescribing and supply facilitated by the Care Quality Commission.
30 March 2023	PSI staff attended a meeting of the Preventing Paracetamol-Related Intentional Drug Overdose Working Group.
30 March 2023	We met with officials from the Department of Health and the IPU to discuss matters concerning pharmacist workforce shortages and solutions.
4 April 2023	The third meeting of the Working Group established as part of the Emerging Risks to the Future Pharmacy Workforce Project was held at PSI House.
12 April 2023	We met with CORU to advise on the use of open data.

Recent communication/engagement with our registrants:

- A [statement on self-service locker services and controlled drugs safes and registers](#) for pharmacies and compliance with current legislation was sent to all registrants and for the particular attention of superintendent pharmacists and pharmacy owners (5 April).
- An email was sent to registered pharmacists outlining the candidates and election processes for the election of pharmacists to the Council, as well as social media reminders.
- As part of the ongoing workforce project, an email was sent to a group of registered pharmacists who have no primary area of practice listed with their registration to request that they consider updating this detail to improve the accuracy of the data available on the register (24 March).

Recent communication/collaboration with other regulatory and public authorities:

- In March, we attended a collaborative workshop between the Department of Health, the International Society for Quality in Health Care (ISQua) and the Health Service Executive (HSE) to support the implementation of the HSE's Patient Safety Strategy 2019 – 2024. It included presentations and workshops by clinicians and academics leading in the field of patient safety.
- In relation to our engagement with the Medical Council on matters of mutual concern and patient safety regarding pharmacist interventions regarding prescriptions, joint correspondence to be sent to the Department of Health is currently being drafted and reviewed.

Other external communication:

- Issue 1 of the [PSI Newsletter](#) for 2023 was sent to registrants and subscribers in mid-March.
- The PSI receives and responds to media queries on a frequent basis. The PSI was contacted by Prime Time for its programme (11 April) focused on the use and regulation of over-the-counter codeine medicines. The PSI provided a written statement to the programme.
- We also provided information to the Department of Health for response to a set of parliamentary questions raised about the codeine guidance and the PSI's regulatory role and responsibilities.

Public consultations and other submissions:

- **National Patient Voice Partner PVP (Patient Voice Partners) Policy**

In March, we provided feedback, through an online survey, to the Department of Health's Public Consultation on the draft Patient Voice Partner (PVP) Policy. The purpose of the policy is to ensure patient participation is embedded in health policy and service development, that PVPs (Patient Voice Partners) are recognised and valued for their contribution, to support the implementation of Sláintecare and as part of the Department's Strategic Priority 3, to promote initiatives for patient engagement by the National Patient Safety Office.

- **Department of Education- Minimum Training Requirements under Directive 2005/36/EC**

In April, we provided some initial comments and observations to the Department of Further and Higher Education, Research, Innovation and Science on proposed updates to the minimum training requirements for pharmacists as part of the work being undertaken at EU Commission level by the Group of Coordinators for the Professional Qualifications Directive, namely Directive 2005/36/EC.



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

Key updates

Emerging Risks to Future Pharmacy Workforce

As we enter the latter stages of the project, the focus is on developing a draft report that combines the outputs of the various project deliverables. Central to the report will be the presentation of evidence-based recommendations and actions that are necessary to address risks to the future sustainability of the pharmacist workforce. This work between the PSI project team and Steering Group, and the project delivery team in Grant Thornton, is being undertaken with engagement and consultation with the Working Group established as part of the project and the RPP committee. This is to ensure that the report delivers on the agreed scope and that appropriate owners and timelines are assigned to actions. Council will be presented with the draft report at its June meeting, pending approval by RPP.

Review of the Continuing Professional Development (CPD) Model for Pharmacists

Work continues on the review of the CPD model for pharmacists, with independent external support from Mazars. A presentation on work conducted to date, emergent findings and the next steps in the project were delivered by Mazars to the Regulatory and Professional Policy (RPP) Committee at its meeting on 13 April. Work will continue over the coming weeks on this project with a view to presenting a draft report to Council at its June meeting.

Developing a CPD Model for Pharmaceutical Assistants

Work on the project that aims to propose a continuing professional development (CPD) model for pharmaceutical assistants has continued. Mazars, who are providing external support on this project, provided an update to the Regulatory and Professional Policy (RPP) Committee at its meeting on 13 April 2023 on progress made to date. A report is expected to be presented to Council at its June meeting.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive

The National Safety Features Oversight Group met on 28 March 2023, and the following issues were discussed.

- Alert rates are decreasing weekly, with week 11 recording an alert-to-scan ratio: of 0.09%, but consistently improving to the region of 0.05%. The overall alert-to-scan ratio across Europe is 0.17% (week 8 starting on 20 February 2023).
- Unlicensed medicines accounted for 12% of alerts, repeated decommissioning at the same location accounted for 6% of alerts and borrowings (decommissioned at multiple locations) accounted for 16% of alerts. The breakdown of alerts for pharmacies in February 2023; 50% of pharmacies did not receive any alerts, whilst the 90% of pharmacies received 3 alerts or less during the month.
- The Irish Medicines Verification Organisation noted that most pharmacies engaged with resolving alerts, but there were a number of alerts outstanding.
- Decommissioning rates have declined from a peak of 70.8% in December 2022 to 61.3% in week 12 (Monday, 20 March 2023). The IMVO will provide assistance to pharmacies that are verifying but not decommissioning.

The group discussed how the Windsor framework would impact alert rates and medicines supplies in Ireland. FMD will cease to apply in Northern Ireland as their National Medicines Verification Systems will be disconnected from European Medicines Verification Organisation. It will be some time before the full impact of the Windsor Framework will be understood.

Sodium valproate stakeholder group

The Department of Health has invited the PSI to the sodium valproate stakeholder group to discuss actions taken to date to ensure adoption of the European Medicines Agency (EMA) pharmacovigilance risk assessment committee recommended valproate pregnancy prevention programme in practice and oversee the implementation of actions identified if necessary.

Supervising pharmacist vacancies

The PSI continues to liaise with superintendent pharmacists and pharmacy owners on the issues of supervising pharmacist vacancies. We have invited a number of superintendent and pharmacy owners who are in the escalation process to PSI House to discuss the challenges regarding supervising pharmacist recruitment. The PSI values the insights and information provided by those who have contributed to date.

Advance Reform of the Pharmacy Act project

In March, we met with the Department of Health to agree on the next steps in the project approach. It was agreed that PSI would proceed with commissioning an evidence review to examine reform of the regulation of pharmacies in the first instance. This evidence review will inform the development of evidence-based policy proposals for reforming the Act in this area.

It was also agreed that an Advisory Group would be established, the membership of which will include the Department, to provide expert advice and guidance on the evidence review process and the development of evidence-based policy proposals for the reform of the regulation of pharmacies in Ireland.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Strategic HR Matters

- **Strategic Workforce Planning**

The Programme Delivery and Innovation Manager and HR and People Development Officer roles have now been filled. We currently have two live campaigns, a 3.5-year fixed-term contract Quality Assessor position, which is now at interview stage, and a permanent Programme Delivery and Innovation Analyst position, which is about to be advertised.

The Department of Health has also sanctioned the Head of Strategic Policy, Research and Communication for a 2-year career-break backfill on a full-time basis. At the end of March, PSI also received sanction for 4 Quality Assessor (Engineer III grade) posts to deliver as part of our Quality and Safety Team. We plan to advertise these posts in Q2. These sanctioned posts include three new posts for the PSI, the business cases for which were submitted to the Department in 2022. Eight new posts remain to be considered by the Department for sanction, which were previously approved by the PSI Council, with 4 priority posts pending approval.

- **Blended Working Policy roll-out**

PSI is now in the final stages of rolling out our blended working policy which we anticipate will be complete by 30 April 2023. Applications from all employees were made for blended working arrangements. A full review of the blended working policy and arrangements will be carried out in October 2023.

- **Business Transformation Programme (BTP) Update**

PSI continues to work closely with Codec to complete Phase 1.1. of the BTP. There have been a number of discussions between the CEOs of both organisations in order to ensure the successful delivery of Phase 1.1. Codec has committed to deliver Phase 1.1 by the end of June (behind schedule); and as per agreed scope and budget. Phase 1.1 will join up the public Register with outcomes from the complaints process; and will extend the Register to include what is termed the 'Internet Supply List.' PSI is currently finalising requirements for improving the experience for members of the public interacting with the regulator (Phase 2 Complaints, Concerns and Queries), and this is an area of focus for our digital transformation journey through 2023.

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

Service/Goods to be Procured	Current Status
Website Re-Design Development, Hosting and Support services	Following the completion of the direct market engagement, an evaluation panel meeting was convened on 12 April with clarifications now to be progressed in advance of finalising a recommendation to the Registrar on a supplier.
Procurement Consultancy Services	Outcome letters have been issued following the evaluation panel meeting on 17 February that was supported by the OGP (OGP drawdown competition closed on 9 December 2022). Draft contract in preparation for winning tenderer.
Pension Administration Services	Following the closing of the OGP Framework drawdown competition on 8 February 2023, the evaluation panel meeting was convened on 17 April, supported by the OGP. Outcome in the process of being finalised in advance of making a recommendation to the Registrar.
Third Country Qualification Recognition – Equivalence Exam (for existing TCQR route)	Documentation is being finalised in advance of publication on eTenders in the coming days.

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (figures as of 17 April 2023)

For the purposes of this appendix, please note that references to '*last report date*' refers to the Registrar's Report submitted for the Council meeting on 2 March 2023.

Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)

Total new complaints received year to date	23
New complaints received since last report date	12
Total open, active complaints*	45
Complaints considered by PPC since last report date **	7

* This figure may include complaints received prior to 2023 which are still being processed

**These complaints were heard at 1 meeting. 42% of these complaints met the KPI of the PPC decision within six months from the date of receipt of complaint to the date of the final PPC decision.

Fitness to Practise (as of 17 April 2023)

Inquiries

Total concluded year to date *	5
Heard since last report **	3
Complaints being investigated/prepared for hearing	39

* 1 of which was opened but adjourned until Q1 2023 and involved a registrant out of the jurisdiction, which delayed the scheduling. 40% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry.

**all took place before the PCC (Professional Conduct Committee)

Mediation

Total referrals to mediation since last report	1
Total referrals pending mediation	1
Held year to date	0

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard since last report*	0
Heard year to date*	4
Sanction hearings/undertakings being prepared for Council *	8

*per registrant

High Court Sanction Confirmation Hearings

Heard year to date	1
Cases being prepared for High Court confirmation	0

Appeals

Heard year to date	0
Cases being prepared for High Court appeal	0
Judgment awaited	1

Call-Overs and Other Applications Before Committees of Inquiry

Callovers heard year to date:	
1. Professional Conduct Committee	1. 1
2. Health Committee	2. 1
Held since last report date.	
1. Professional Conduct Committee	1. 1
2. Health Committee	2. 1

The next PCC and HC Callovers are scheduled for 13 June 2023

Interim Suspension Applications

Applications heard by Council year to date	0
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Prosecution

Cases being prepared for District Court Prosecution	1
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Professional Registration (figures as of 18 April 2023)

Route/ Application Type	Applications Received 2023 to date	Applications in Process (including applications received in previous years)
Third Country Qualification Recognition (TCQR) – excluding UK	52	267
Route/Application Type		Registrations/ Actions Completed 2023
National Route		3
EU Route		43
Non-National Route (Third Country) – UK only		21
Non-National Route (Third Country) (excl. UK)		12
European Professional Card – Establishment of Service (Qualification Recognition)		2
European Professional Card – Temporary & Occasional Provision of Service		0
Voluntary Cancellations from Register		40
Involuntary Cancellations from Register		15
Restorations to Register following Voluntary Cancellation		4
Restorations to Register following Involuntary Cancellation		2
Certificates of Current Professional Status issued		23
IMI Alerts (Internal Market Information) issued by PSI		2

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses (as of 14 April 2023)	
Number of Registered Retail Pharmacy Businesses	1986
Retail Pharmacy Business Openings by Type	New Openings: 9 New Openings (Change of Ownership): 17 New Openings (Permanent Relocation): 0
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations (Closure): 3 Voluntary Cancellations (Permanent Relocations): 0 Voluntary Cancellations (Changes of Ownership): 17 Involuntary Cancellations: 1
Number of Changes in Supervising and Superintendent Pharmacists. (Numbers as of 12 April 2023)	Supervising pharmacist changes: 166 Superintendent Pharmacist changes: 23

Internet Supply Figures as of 18 April 2023	
Number of Pharmacies on Part A	176
Number of Non-Pharmacies on Part B	156

Regulation of Retail Pharmacy Businesses (figures as of 12 April 2023)

Pharmacy Inspections 2023		PSI 2023 Service Plan Pharmacy Inspection Key Performance Indicator (KPI)
Total number of on-site Pharmacy Inspections Visits to date.	37	160
Total number of registration-related Virtual Inspections to date.	8	20
Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date.	2	0

Concerns

Total new concerns received year to date	49
New concerns received since last report date	27
Concerns reviewed since last report date	26
Open concerns	14

Investigation Activity 2023 (Part 7 of the Pharmacy Act / Inspection & Enforcement)		
No. of investigations open	No. of investigations initiated since the last Council meeting	No. of investigations closed since the last Council meeting
16	2	0
Investigation Activity 2023 (Section 67) – e.g., <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i>		5