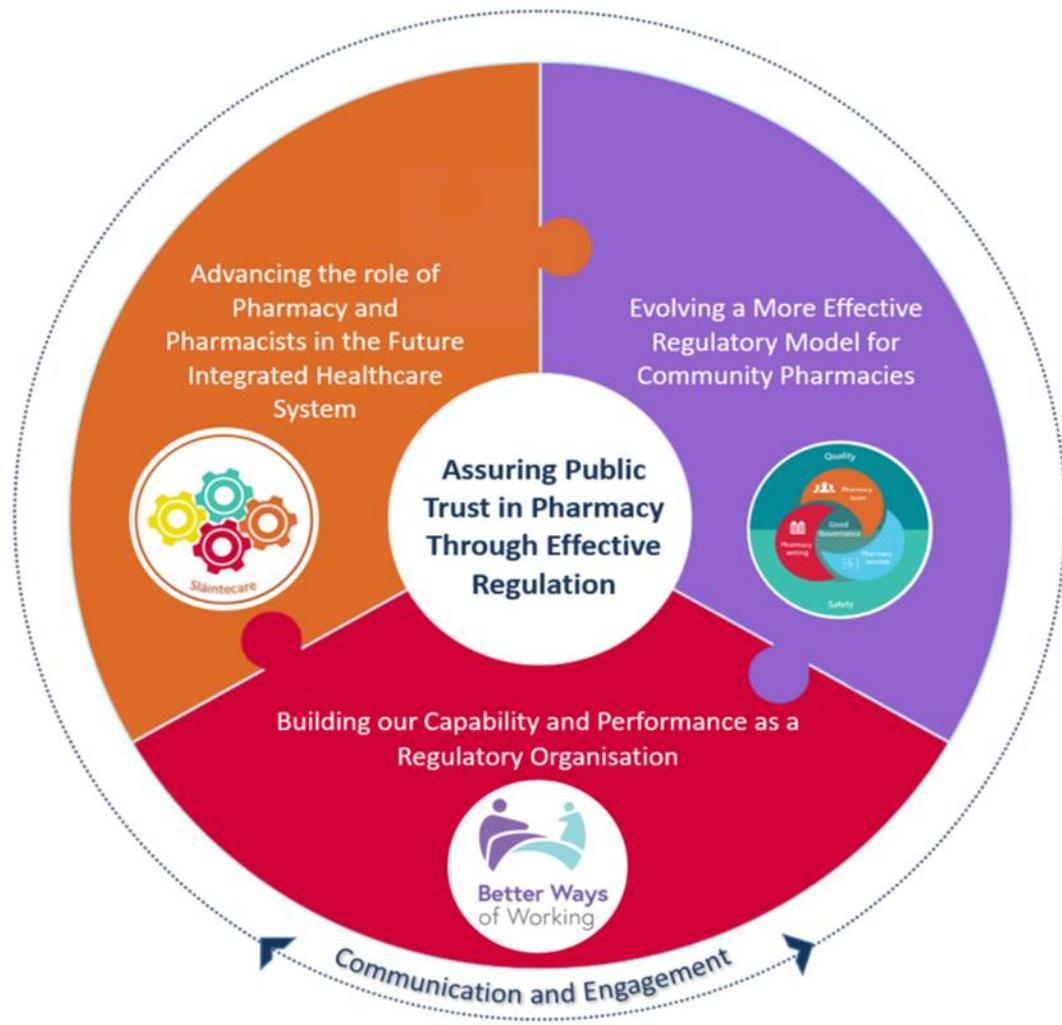


Report of the Registrar

Council Meeting 2nd March 2023



Highlights from the Registrar

Focus Group meetings held with pharmacists in patient-facing roles and MPharm students

Between 25-27 January, we hosted Focus Group meetings with pharmacists and students who were selected following an expression of interest process. The Focus Groups were established in support of the *Emerging Risks to Future Pharmacy Workforce* project. Participants represented five different cohorts within the pharmacy workforce:

- Superintendent pharmacists
- Supervising pharmacists
- Support and locum pharmacists
- Hospital pharmacists
- 4th and 5th year pharmacy students

The meetings were very productive and beneficial in providing context and insights into challenges and opportunities relating to community and hospital pharmacy roles. Outputs from the Focus Groups will be a very important component of the project, providing the voice of the profession, and we appreciate all those who took the time to attend.

Pharmacy involvement in COVID-19 and Influenza vaccination programmes

Since their involvement in June 2021, community pharmacies have administered more than 1.3 million COVID-19 vaccines, representing 10.5% of all vaccines administered since the commencement of the national programme. For the current autumn/winter booster campaign, community pharmacies have administered almost 250,000 doses, which is 25% of all vaccines administered.

As part of the current 'flu vaccination campaign, community pharmacies have provided almost 360,000 vaccines, which is 29% of all vaccines administered nationally.

This significant contribution by pharmacists and their teams represents a shift in how healthcare is delivered across our communities, accelerated by changes introduced due to the COVID-19 pandemic.

Approval of the HSE's National Immunisation Office training module on Comirnaty 3 micrograms/dose (for those aged 6 months to 4 years old)

On 10 February, we concluded our assessment of the National Immunisation Office (NIO) training in respect of **Comirnaty® 3 micrograms/dose (for those aged 6 months to 4 years old)** as training for the purposes of Regulation 4F(b) of the Medicinal Products (Prescription and Control of Supply) Regulations (S.I. No. 698 of 2020) to facilitate pharmacist vaccinators in supplying and administering this vaccine, as part of the COVID-19 national vaccination

implementation plan. This work was supported and enabled with the valuable contributions of an external assessment team, comprising pharmacists with relevant expertise from a variety of settings, to review the training and recommend its approval as appropriate for pharmacists.

Note: the HSE currently have no plans to deliver this vaccine in community pharmacies, with the roll-out of this vaccine being planned for specialist centres and/or Centralised Vaccination Centres (CVCs) only.

Ongoing Regulatory Work Programmes in 2023

Activity	Outputs	Update
A. Development of PSI's next Corporate Strategy	Strategy approved by Council by year-end with a clear focus on the PSI's development and future direction	Proposal for consideration by Council to extend the Corporate Strategy for an additional year.
B. Operationalise the revised Third Country Qualification Recognition (TCQR) route process leading to registration as a pharmacist	Revised route commenced by end Q4	The PSI project team is in the process of implementing the revised route, with the current focus being on establishing an Expert Advisory Group to support the project, conducting the public consultation on the revised PSI Registration Rules, and 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. The new process is expected to be in place in late 2023.
C. Implement the revised Core Competency Framework (CCF) for pharmacists	<ul style="list-style-type: none"> • Roadmap in place for the implementation of the revised CCF by the end of Q1 • Engagement throughout the year with key stakeholders impacted by the revised CCF, including registrants, Schools of Pharmacy (incorporating APPEL), and the Irish 	Engagement has commenced with the IIOB and the Schools of Pharmacy in relation to the implementation of the CCF. The initial focus will be on the implementation of the CCF for CPD purposes.

	Institute of Pharmacy (IIOp)	
<p>D. Revise the Accreditation Standards for CPD Programmes and Courses for Pharmacists and commence the revision of the MPharm Accreditation Standards</p>	<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 	<p>A review of the Accreditation Standards for CPD Programmes and Courses will take place in 2023 and take account of national and international developments and best practice in relation to CPD Accreditation Standards. Work is currently ongoing in relation to identifying the external expertise required to assist with this review.</p>
<p>E. 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 (see D. above) and relevant guidance documents for RPBs to be reviewed in 2023 will be informed by HSE's Antimicrobial stewardship: Guidance for all healthcare settings. 	<p>Our commitment is to work with our stakeholders to help improve knowledge and awareness of antimicrobial resistance (AMR).</p> <p>In February, at the request of HSE-AMRIC (Antimicrobial Resistance and Infection Control) and the Irish Institute of Pharmacy (IIOp), we participated in a RCSI Charter Day in-person session focusing on antimicrobial stewardship. We were delighted to be part of this collaborative forum to help drive this important agenda forward and start the national conversation on empowering pharmacists</p>

		<p>to deliver antimicrobial stewardship.</p> <p>We also attended an online Westminster Health Forum policy conference which discussed the “Next steps for tackling antimicrobial resistance”. Some of the key areas for discussion included: combatting antimicrobial resistance in the UK, supporting AMR research and innovation and the role of international collaboration in tackling AMR.</p>
<p>F. 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</p>	<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. 	<p>Review currently being carried out on the operation of the Regulatory Risk Analysis and Response Group following its first year of operation in 2022.</p>

Communication and Stakeholder Engagement Updates

Overview of meetings attended by the Registrar and PSI staff	
January-March (Bi-weekly meetings)	National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group: this group meets to discuss the ongoing roll-out of the COVID-19 and influenza vaccination programmes in community pharmacy. It is chaired by the HSE and includes representatives from the IPU as well as the PSI.
January	In early January, we met with a number of third-level institutions as they prepared to submit applications for a new School of Pharmacy following a call from the Higher Education Authority.
11 January	We were invited to the launch of the Strategic Plan 2022-27 by the School of Pharmacy and Pharmaceutical Sciences at Trinity College Dublin.
25-27 January	The Focus Groups established as part of the <i>Emerging Risks to Future Pharmacy Workforce</i> project were hosted in PSI House – five meetings were held across three days
26 January	In March 2020, the Committee of Ministers of the Council of Europe adopted a new Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services. We attended a webinar to explain the content and added value of the Resolution, share examples of how pharmaceutical care activities can be implemented in daily practice in community and hospital pharmacy settings, provide insights about interprofessional cooperation in pharmaceutical care, and give an overview of the implementation of pharmaceutical care in some Council of Europe member states.
26 January	We attended the Practitioner Health Matters Programme Strategy Workshop.
30 January	We attended a National Near-Patient Testing (NPT) Consultative Group meeting.
February	The National ePrescribing Project held early stakeholder engagements in January and February. The project team met virtually with patients, prescribers and pharmacy representatives to understand how ePrescribing might meet their needs and to identify potential gaps, drivers and barriers to ePrescribing across these three key groups to help inform the immediate and longer-term plans for the project. As

	part of this engagement, PSI attended three of the pharmacist stakeholder engagement sessions.
Between January and February	At the request of the Department of Health, we reviewed and provided feedback on two statutory instruments, which were drafted to amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to provide for changes to the COVID-19 vaccination programme.
20 February	We attended an event hosted by Quality and Qualifications Ireland (QQI) for professional and regulatory bodies, which discussed developments in relation to the assessment of learners, academic integrity, and joint accreditation process between professional and regulatory bodies and higher education institutions (HEIs).
22 February	Meeting with the Irish Pharmaceutical Healthcare Association (IPHA).
27 February	Attendance and presentation at the Boots Ireland Supervising Pharmacist (SVP) Day.

Recent communication/engagement with our registrants:

- Emails focused on the following topics were sent to PSI registrants: Appropriate supervision and responsibilities for pharmacy students (26 January) and Medicines Availability Update (13 January). Both emails had input from relevant external stakeholders.
- Notice of the nomination period for the appointment of pharmacists to the PSI Council has been published (22 February) with an email sent to all on the Register of Pharmacists.

Recent communication/collaboration with other regulatory and public authorities and other external communication:

- We issued a [press release on 1 February](#) welcoming the Higher Education Authority's (HEA) establishment of an expert advisory panel in relation to increasing capacity in higher education for pharmacy. We are participating in the panel, represented by Dr. Nicola Tyres, which is assessing applications to expand existing courses or develop new courses.
- We are running a public consultation on the proposed amendments to the PSI (Registration) Rules to facilitate changes we wish to make for a new Third Country

Qualification Recognition (TCQR) route. This consultation is open to all who wish to provide their feedback.

- We are engaging with the Medical Council in relation to matters of mutual concern and patient safety, which have been raised by members of the PSI Council regarding pharmacist interventions in relation to prescriptions. A meeting has been scheduled with the Medical Council on 28 February to explore the issues as part of a collaborative approach.

Public consultations and other submissions:

HIQA's public consultation on Draft National Standards for Information Management in Health and Social Care.

In January 2023, we provided a submission to HIQA's public consultation on the Draft National Standards for Information Management in Health and Social Care. The standards were developed to promote a more strategic approach to information management across the health and social care system. The scope of the standards extends to all organisations that collect, use and share health and social care information. Improvements to the quality of health and social care information will contribute to the delivery of safe and reliable care.

Medical Council's Public Consultation on draft new Professional Competence Rules and Guidelines.

In February, PSI provided a submission to the Medical Council's Public Consultation on the Draft Maintenance of Professional Competence Rules and accompanying Guidelines. The purpose of the consultation was to obtain feedback on the revised Rules and Guidelines.

Organisation for Economic Cooperation and Development (OECD) Product Market Regulation Questionnaire

In February, at the request of the Department of Finance, we completed an Organisation for Economic Cooperation and Development (OECD) Product Market Regulation Questionnaire on Retail Trade in relation to the retail sale of prescription and non-prescription medicines. The OECD's Product Market Regulation (PMR) indicators measure the regulatory barriers to firm entry and competition and are an important set of indicators in assessing on a cross-country basis the competition-friendly nature of a country's regulatory framework. The PMR indicators are updated every 5 years.



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

Key updates

Emerging Risks to Future Pharmacy Workforce

Work is progressing at pace on this key strategic project for the PSI. Grant Thornton is assisting the project team with project delivery. The following are the main updates since December 2022:

- **Literature Review:** A draft literature review has been developed, which provides an overview of the current landscape relating to sectoral workforce planning and identifies the approaches, models, and strategies for managing sectoral workforce planning in patient-facing pharmacy roles in comparator countries.
- **The Workforce Survey** was published on 23 November until 15 December 2022, and a series of email notifications and reminders were sent to all registered pharmacists. It was also highlighted via our social media channels. APPEL (the Affiliation for Pharmacy Practice Experiential Learning – the shared services consortium of the three pharmacy schools) forwarded a message on behalf of the PSI to all fifth-year pharmacy students. We engaged with the IPU, HPAI and PIER, requesting that they disseminate the survey among their members. There were 1,272 responses to the survey, of which 1,240 were pharmacists (18% response rate), and 32 were fifth-year pharmacy students (17% response rate). A survey analysis report has been drafted for review and feedback.
- Two meetings of the **Working Group** comprising stakeholders from the Department of Health, HSE, academia, pharmacy representative organisations, the IIOF and a practising pharmacist have been hosted in PSI House (8 December and 8 February). At the last meeting, we presented and discussed key themes emerging from the evidence gathered to date. The next meeting is in March and will focus on proposed recommendations to address the future pharmacy workforce needs.
- Five **Focus Group** meetings were held in PSI House in January with pharmacists from a range of patient-facing roles, as well as pharmacy students in 4th and 5th year.

- The **Regulatory and Professional Policy Committee** was provided with an update on the project methodology and outputs from the various deliverables at its meeting on 16 February, followed by discussion and questions.
- There will be a facilitated session with **Council** on the project's progress and draft outputs at the development day on 23 March.
- The draft **Workforce Intelligence Report** will be presented to RPP and Council at their respective meetings in April 2023.

Developing a CPD Model for Pharmaceutical Assistants

In 2022, in response to a statutory change due to be commenced in 2023, we commenced a project with the aim of proposing a continuing professional development (CPD) model for pharmaceutical assistants. Following a procurement process, we appointed Mazars to assist with this project. Engagement meetings with relevant stakeholders have taken place, and research of relevant national and international CPD models has commenced.

Review of the CPD Model for Pharmacists

The review of the CPD model for pharmacists is being carried out using independent, external support from Mazars. The first stage of the review is well advanced, with significant stakeholder engagement being carried out by Mazars in recent weeks with both national and international stakeholders and experts in this area. A report will be drafted taking into consideration the outcome and recommendations from all stages of the review. We expect to present a draft report to Council at its June meeting.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive (FMD)

The National Safety Features Oversight Group met on 19 January 2023. The European Medicines Verification Organisation is now reporting on a quarterly basis. Pharmacists and their teams have achieved an overall compliance rate of approximately 62% for Q3 and Q4 2022, peaking at 70.8% at week 50 (week beginning 12 December 2022). This peak represented 1.92 million products successfully decommissioned. For the same week, Ireland's overall alert rate was 0.05%. The end-user alert rate is consistently between 0.04- 0.06%.

Overall, pharmacists and their teams continue on an upward trajectory regarding compliance.

National stakeholders meeting on medicines shortage

On the 12, 19 and 26 January 2023, we attended a meeting of the Medicines Criticality Assessment Group to review the current issues related to medicines shortages, particularly antibiotics and those medicines used to treat winter illnesses such as cough medicines, steroids and nebulisers. Following that meeting, PSI provided an update to all pharmacists and pharmacy owners on the availability of medicines and highlighted pharmacists' important role in supporting patients, including ensuring the ongoing appropriate, rational and safe use of medicines.

PSI representatives from the Quality and Safety team attended a meeting held by the Department of Health on 20 January 2023. The PSI provided an update on the Registrar's correspondence issued to registrants on 13 January 2023.

Codeine specialist surveyor survey

A specialist surveyor (mystery shopper) exercise was conducted across a sample of pharmacies in September and October 2022 to assess compliance with PSI's Guidance on the Safe Supply of Non-prescription Codeine Products to the Public. All pharmacies visited will be contacted by the PSI in early March, informing them if a medicinal product was supplied in line with the Guidance of the PSI.

Advance Reform of the Pharmacy Act project

Following the submission of the PSI position paper to the Department of Health in June 2022 on the need for reform of the Pharmacy Act, which outlines why significant legislative reform is needed and the challenges PSI experiences with using the Act in practice, further discussions on this important matter are scheduled with the Department in early March 2023.

The PSI Council identified the reform of the Pharmacy Act 2007 as a key priority in its Corporate Strategy (2021–2023), and PSI is committed to working with the Department to determine the best way to advance the reform of the Pharmacy Act 2007 in the interests of patients and the public.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Strategic HR Matters

Workforce Planning and Recruitment

We currently have the following campaigns open for competition:

- HR and People Development Officer (HEO grade – replacement post)
- Programme Delivery and Innovation Manager (APO grade – new permanent post)
- Quality Assessor – Pharmacy Services (Engineer II grade – FTC backfill and creation of a panel for future temporary and permanent positions)

We will be running the following campaigns in Q1 2023:

- Programme Delivery and Innovation Analyst (HEO grade – new permanent post)
- Head of Strategic Policy and Communication

Sanction remains outstanding from the Department for a Quality Assessor II – Pharmacy Services post.

Following the prioritisation request from the Department in relation to the 11 new posts approved by Council in 2021, a detailed submission to support 7 priority posts was submitted to the Department of Health towards the end of 2022. Discussions with the Department remain ongoing in respect of those posts. The remaining 4 posts will be advanced later in 2023.

Blended Working Policy roll-out

As part of the roll-out of our Blended Working Policy through the Office for Government Procurement, PSI commissioned the services of an organisation to deliver the required ergonomic and desk-screen assessments. These virtual assessments for all PSI staff home workstation set-ups have been taking place throughout February, with almost 80% of those assessments now complete. Recommendations from these assessments, which include items of equipment to be purchased by PSI, will now be progressed.

The application process is also now in train, and we have asked for all applications to be submitted by 3 March with a view to the policy being fully rolled out by the end of Q2 2023.

Consideration of reviewing and revising our ways of working to reflect the blended working model will be advanced over the course of 2023.

HRIS implementation and 'go-live.'

Our new HRIS went live on 20 February 2023. Our software vendor – Cloudtech – facilitated end-user training before the system went live. The training was carried out in two separate sessions, one for end-users and the other for line managers.

Business Transformation Project (BTP) Update

Phase 1.1 of the BTP was not delivered by the target delivery date of 17/02/2023; this was due to poor product quality (a high number of bugs) identified as part of an initial review by the BTP team during user acceptance testing. We await a response from Codec regarding corrective actions before a revised deployment date is proposed. As this is the second delay in the delivery of Phase 1.1 due to product quality issues, this matter is being escalated for discussion between the CEOs of both organisations.

Separately the PSI continues to work on improving the experience for members of the public and registrants interacting with the regulator and continues to be an area of focus for our digital transformation journey through 2023.

Digital skills development

As part of our digital transformation programme within the BTP and the roll-out of our new operating model, we are progressing in 2023 with the development of a series of targeted digital training courses for all staff. A full series of courses, based on the outputs of an organisation-wide skills needs analysis, will be commissioned shortly.

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	The direct market engagement was completed. An evaluation panel is convening to make a recommendation to the Registrar on a supplier.
Procurement Consultancy Services	The OGP Framework drawdown competition closed on 9 December 2022. The evaluation panel met on 17 February 2023. Outcome letters are to be circulated.
Pension Administration Services	The OGP Framework drawdown competition closed on 8 February 2023. An evaluation panel is being convened to make a recommendation on a supplier.
Third Country Qualification Recognition – Equivalence Exam (for existing TCQR route)	Documentation in development prior to publication.

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (figures as of 23 February 2023)

For the purposes of this appendix, please note that references to 'last report date' refers to the Interim Registrar's Report submitted for the Council meeting on 15 December 2022

Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)

Total new complaints received year to date	11
New complaints received since last report date	12
Total open, active complaints*	44
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 a complaint to the date of the final PPC decision.

Fitness to Practise

Inquiries

Total concluded year to date *	2
Heard since last report **	2
Complaints being investigated/prepared for hearing	35

* 1 of which was opened but adjourned until Q1 2023 and involved a registrant out of the jurisdiction, which delayed the scheduling. 100% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry.

** 1 took place before the PCC & 1 took place before HC

Mediation

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

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard since last report*	6
Heard year to date*	4
Sanction hearings/undertakings being prepared for Council *	4

*per registrant

High Court Sanction Confirmation Hearings

Heard year to date	0
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:	
(a). Professional Conduct Committee	a. 0
(b). Health Committee	b. 0
Held since last report date:	
(a). Professional Conduct Committee	a. 0
(b). Health Committee	b. 0

The next PCC and HC Callovers are scheduled for 15 March 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 23 February 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	19	247
Route/Application Type	Registrations/ Actions Completed 2023	
National Route	2	
EU Route	26	
Non-National Route (Third Country) – UK only	11	
Non-National Route (Third Country) (excl. UK)	2	
European Professional Card – Establishment of Service (Qualification Recognition)	0	
European Professional Card – Temporary & Occasional Provision of Service	2	
Voluntary Cancellations from Register	32	
Involuntary Cancellations from Register	1	
Restorations to Register following Voluntary Cancellation	2	
Restorations to Register following Involuntary Cancellation	1	
Certificates of Current Professional Status issued	10	
IMI Alerts (Internal Market Information) issued by PSI	1	

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses – numbers as at 31/01/2023	
Number of Registered Retail Pharmacy Businesses	1986
Retail Pharmacy Business Openings by Type	New Openings: 5 New Openings (Change of Ownership): 10 New Openings (Permanent Relocation): 0
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations (Closure): 0 Voluntary Cancellations (Permanent Relocations): 0 Voluntary Cancellations (Changes of Ownership): 10
Number of Changes in Supervising and Superintendent Pharmacists (numbers as at 22/02/2023)	117

Internet Supply Figures as of 22/02/2023	
Number of Pharmacies on Part A	177
Number of Non-Pharmacies on Part B	157

Regulation of Retail Pharmacy Businesses (figures as of 23/02/2023)

Pharmacy Inspections 2023		PSI 2023 Service Plan Pharmacy Inspection Key Performance Indicator (KPI)
Total number of on-site Pharmacy Inspections Visits to date.	15	160
Total number of registration-related Virtual Inspections to date.	2	20
Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date.	0	0

Concerns

Total new concerns received year to date	24
New concerns received since last report date	32
Concerns reviewed since last report date	35
Open concerns	7

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
14	5	4
Investigation Activity 2023 (Section 67) – e.g. <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i>		3