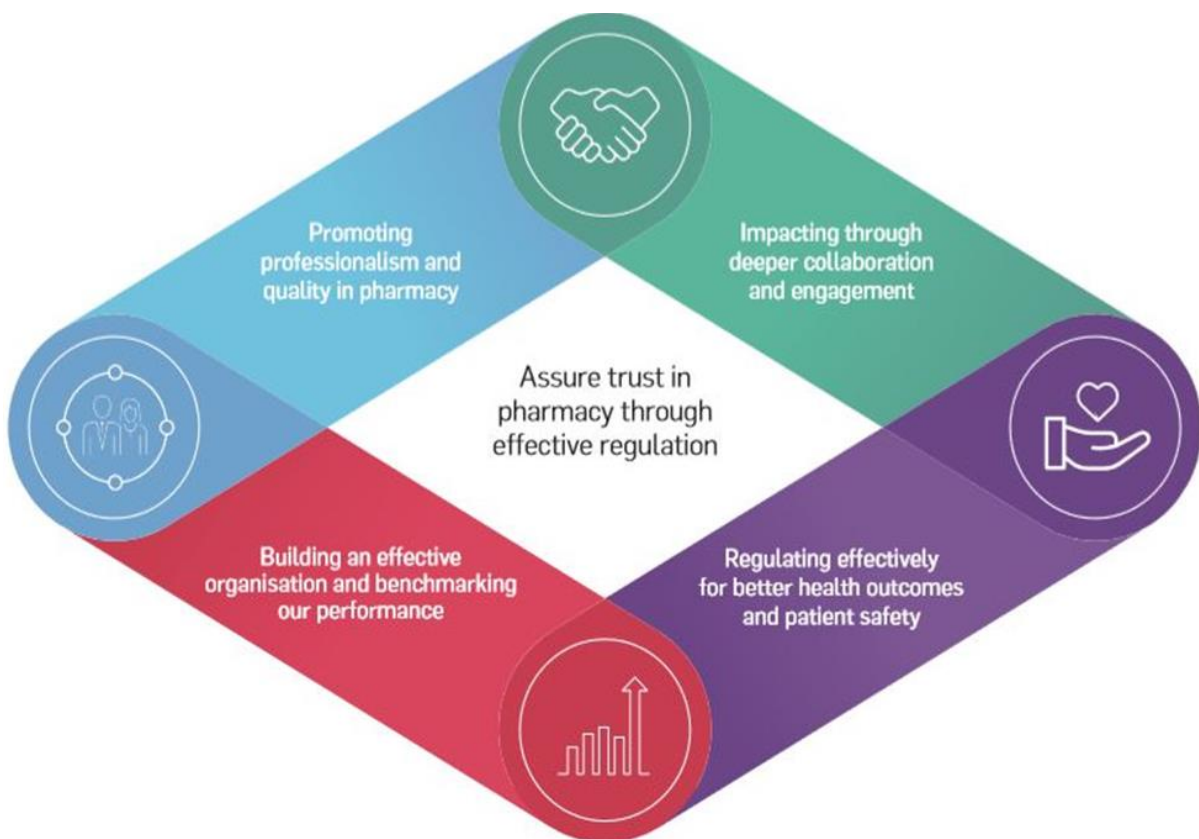


# Report of the Registrar



## Highlights from the Registrar

- The Chairpersons' Forum has met on two occasions since the June Council meeting to progress implementation of the recommendations to restructure the Advisory Committees of Council, following the Council's acceptance of the recommendations in the review conducted by Better Boards. An update on this matter is included on the 20 September Council meeting agenda.
- The Executive have commenced the process of business and budget planning for 2019. A draft Service Plan, and priority actions to advance the implementation of the Corporate Strategy for 2019 and 2020, are scheduled for discussion by Council at the 25 October development and planning day. This day will also include a session with Leslie Cuthbert on decision making and a workshop discussion on the draft revised Code of Conduct for pharmacists.
- The Slaintecare Implementation Strategy was published on 8 August. I have written to the Executive Director responsible for implementation to ensure that she is aware that the PSI's "Future Pharmacy Report" contains recommendations which are relevant to the objectives of Slaintecare.
- Two 4th Year Pharmacy Students, from RCSI and Trinity College, have begun their 4-month experiential learning placement with PSI. These pharmacy students are the first cohort of the new 5-year degree program and PSI is delighted to be an approved Appel training establishment. We have a varied training plan prepared for both students to provide a broad experience of the type of work PSI carries out. The training will also contribute to the core competency behaviours (taken from the Core Competency Framework for Pharmacists) which each student must demonstrate during the 4th year placement.
- We are working closing with CORU in planning our co-hosting of the Healthcare Professionals Crossing Borders (HPCB) Conference on 4 February 2019 in Dublin Castle. This is an event that will bring together those working in regulation and professional recognition/registration from across Europe. The Department of Health has given its support for the event and an attendance in the region of 120 is expected.
- The President, the Registrar and two PSI colleagues will attend the CLEAR Conference in Philadelphia from 25 to 29 September. This is a major annual conference on professional regulation and attracts an audience of regulatory board members and executive staff from agencies across the English-speaking world. PSI will present a workshop at the Conference on the process of developing the revised Code of Conduct.

- Key external meetings attended since the June Council meeting:
  - 12 July – Meeting with Department of Health (DoH) regarding (a) legislative reform, (b) regulation of the retail element of hospital pharmacy and (c) conscientious objection.
  - 31 July – Meeting with DoH regarding our previously-submitted business cases requesting sanction for additional posts.
  - 15 August – Regular four-monthly governance meeting with DoH.
  - 28 August - Registrar and Education Manager addressed this year’s intake of pharmacy graduates (the final planned intake) who are commencing the National Pharmacy Internship Programme at the RCSI.



## 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

- The Minister for Health, Simon Harris, has provided written approval for the Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business to be published, as required under Regulation 14 of the Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). These were updated in light of changes in legislation. The guidelines are now available on the PSI website for downloading and incorporating into the Pharmacy Practice Guidance Folder. The profession was informed of the publication of these guidelines in Issue 2 of the PSI newsletter.
- The PSI assisted colleagues in the HPRA in raising awareness of the pharmacy-level recall of several medicines containing the active ingredient valsartan (used to treat blood pressure and heart conditions) during July. An EU wide recall was initiated when the impurity NDMA was identified as part of the manufacturing process at certain manufacturing sites. Several emails were sent by the PSI, on behalf of the HPRA, to all registrants, notifying them of the information available on the HPRA's website about the products and batches affected, and what actions to take.
- The HPRA has recently included a group of Salbutamol 100mcg pressurised metered-dose inhalers on the List of Interchangeable Medicines. As this is the first group of inhalers to be deemed interchangeable, important practice and patient matters were highlighted to all pharmacists in Issue 2 of the newsletter. Pharmacists were reminded of the importance of counselling patients on an inhaler technique, and most importantly when there is a change to the product supplied, as this could differ between inhaler devices on the interchangeable list.
- Issue 3 of the PSI newsletter highlighted changes being made to the Summary of Product Characteristics (SmPC) and patient leaflets (PL) for oral methotrexate following a recent review of the available literature at EU level. These are being updated to better reflect current knowledge and requirements for risk minimisation for patients using methotrexate, which is a known teratogen and contraindicated in pregnancy and lactation. Pharmacists were reminded that they must counsel both women of child-bearing age, and men when supplying methotrexate regarding pregnancy prevention, and all patients should be advised to read the information printed on the PL in order to be informed about their medicine.

- Approximately 1,400 pharmacists have been called by the PSI for ePortfolio Review for 2018/2019. Applications for initial extenuating circumstances closed on 24 August 2018 and all applications have now been reviewed by the Registrar.
- A Workshop on Education Remediation was held on 28 June 2018 at PSI House with regard to the development of guidelines to support an education remediation process for pharmacists. Several pharmacists with previous mentorship experience and/or experience in disciplinary processes were invited to the workshop to gain their insight to support guideline development.



## 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

- A nominee from the PSI Executive participated in the HIQA Advisory Group on ePrescribing. The Group reviewed and advised on HIQA's Draft Recommendations for the National, Community-based ePrescribing Programme, following the public consultation. In keeping with our functions in relation to the control and supply of medicines by pharmacists and pharmacies, PSI submitted substantial comments to the review. The recommendations will be submitted by HIQA to the Minister for Health.
- The PSI also made a detailed submission to the recent HIQA public consultations on a Draft Standard on Information Requirements for Community-based ePrescribing.
- Two members of staff, from the Pharmacy Practice Development (PPD) Department and Education Unit, and the PSI President and Vice President, attended the FIP (International Pharmaceutical Federation) Conference 2018 in Glasgow in early September. This is a useful engagement for the PSI to maintain an updated view of practice, education and training, medicines and health system developments that is useful to the PSI's own work.
- The Head the PPD Department gave a presentation on 'Pharmacy Professionalism and Ethics' on behalf of PSI as part of the Orientation Day to first year pharmacy students at Trinity College Dublin.
- A member of the PPD Department gave a presentation at the College of Psychiatrists of Ireland CPD event. The presentation raised awareness of common issues pharmacists encounter with incomplete controlled drugs prescriptions and raised awareness of the Medical Council and PSI joint guidance on controlled drugs for doctors and pharmacists published last October.
- Two members of the FTPLA unit attended a Fitness to Practise Forum with representatives from Healthcare and non-Healthcare Regulators with a view to shared learning and exploration of efficiencies to be gained through collaboration amongst the bodies.
- Two members of the Education Unit attended the HSE Practice Education Conference held on 26 July at RCSI. The theme of the conference was 'Making practice education work for you: Interprofessional perspective'. The Conference brought a range of health professionals together to share learning, concepts and experiences of practice education. The conference was relevant to the PSI's role as the accreditor of the MPharm programme

for pharmacist training, and in the context of its own role as an accredited APPEL training establishment.

- We continue to work on building our profile on social media, endeavouring to tweet on relevant topics several times per week, and post to LinkedIn circa once per week. We have 440 followers on Twitter, an increase of 75% since the March Council meeting, and 196 followers on LinkedIn, an increase of 32% since the March Council meeting. From January to August, our Twitter posts have so far received 119,235 impressions\*, with an average of 494 impressions per day. The average engagement rate with our tweets is 1.1%. Our LinkedIn posts have received 16,568 impressions\*, an average click through rate of 3.9% and an average engagement rate of 4.8%. (\* Impressions refer to the number of times that a tweet or post is displayed/shown to someone on their timeline, or in search results.).
- As in 2017, the PSI will take a stand at the Department of Health-led National Patient Safety Conference in Dublin Castle in mid-October as an opportunity to engage with those working in healthcare, regulation and policy, and to discuss and share our recent work – particularly on the Code of Conduct and the Future Pharmacy Practice recommendations.



## 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

- The Registrar and the Head of Policy met with senior officials of the Department of Health on 12 July to discuss legislative reform. We had a very positive discussion as to the rationale for, and potential benefits arising from, reform. As a result of the discussions, we will assist the DoH officials in developing a policy proposal for submission to the DoH Policy Committee later in the Autumn.
- The project to review the operation of the Pharmacy Assessment System has been completed. Recommendations arising from the review are included on the 20 September Council meeting agenda for decision.
- Following the June Council meeting, where Council approved a project for a standards-based approach to governance and accountability for retail pharmacy businesses, we are in the process of establishing a Standards Advisory Group. This group will provide practical guidance and expertise during the development of the standards. We have had very helpful engagement with HIQA about the good-practice methodology to be used in the standards development process.
- The Head of Policy and Head of Regulation are engaged with the DoH and a multi-stakeholder group on the introduction of the EU delegated regulation to introduce safety features on medicines under the EU Falsified Medicines Directive. PSI executive have also met with the Irish Medicines Verification Organisation (IMVO) which is tasked with introducing the regulations in Ireland. The IMVO is completing the pilot of the scheme in community pharmacies and the PSI will continue to work closely with all stakeholders as this Directive is introduced across the EU.
- Meetings have been held between the out-going and in-coming Chairs of the Professional Conduct Committee (PCC) and Preliminary Proceedings Committee during which the out-going Chairs discussed their experience of being on the relevant disciplinary committees over several years.
- Training focused on the development of effective chairing skills was provided to the Chairs of the Disciplinary Committees (Preliminary Proceedings Committee, Professional Conduct Committee and Health Committee) on 19 July 2018.



- The Preliminary Proceedings Committee has completed a review of the Committee's procedures and have approved an updated version.
- Training will be provided to all members of the Disciplinary Committees on GDPR and the new Data Protection Acts 1988-2018 on 25 September 2018.
- PSI Authorised Officers (Pharmacy Inspectors) conducted two investigations, in June and in August, in collaboration with An Garda Síochána and the Health Products Regulatory Agency (HPRA). Both have resulted in urgent suspension applications to the High Court.
- Members of the Inspection & Enforcement Unit met representatives of the Department of Agriculture in June to discuss how the online sale of human medicines is regulated and how internet supply of veterinary medicines could be reformed by that Department.



## 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

- The Registrar and Head of Operations met with the Department of Health on 31 July to discuss the business cases for new posts that were submitted in March to the Department by the PSI along with the Comprehensive Resourcing Review Report for 2018-2020. A decision is awaited from the Department of Health and ongoing contact is being maintained on this important matter.
- The Business Transformation Office was established over the Summer with the appointment of a Business Transformation Project Initiation Manager on a three-month temporary agency assignment. This assignment is critical to allow the PSI to progress the delivery of the first year of the 2018-2020 Corporate Strategy through our 2018 Service Plan commitments.
- HR Development Project Manager has been appointed on a nine-month temporary agency assignment in September. Part of this assignment includes the development of a HR Strategy for the PSI. This will allow us to focus on ensuring that our Corporate Strategy 2018-2020 can be fully supported by an effective HR Strategy. This assignment will also deliver a new programme of employee engagement to build on the important work already established and to move the PSI forward as an organisation that can meet the EFQM definition of an organisation that can ‘meet or exceed the needs and expectations of their people’. This assignment will also allow the organisation to support its people through the business transformation change process in a supportive capacity.
- The external open recruitment campaign for temporary Regulatory Project Pharmacists (x 2), to join the Regulation Department (9-month maternity leave cover) is close to conclusion. Posts will plan, coordinate and deliver on the following key strategic activities which the PSI is committed pursuing as part of its 2018 Service Plan:
  - Develop a risk assessment framework of retail pharmacies to assist with the effective deployment of regulatory resources together with an associated implementation plan and pilot of new framework.
  - Design the PSI’s programme of themed inspections in key areas of pharmacy practice and develop and implement the associated piloting of this approach as part of the PSI’s compliance activities.

- As part of PSI’s ongoing health and safety developments, further training programmes were delivered to staff on Fire Awareness/ Fire Warden Training, VDU Assessor Training and Health & Safety Committee Representative Training.
- Other training initiatives include:
  - As part of ongoing training of frontline staff, members of the Inspection & Enforcement Unit met with representatives of the Residential Tenancies Board in August to discuss investigation processes and training.
  - In preparation for the continued registration period, in-house Customer Service training was completed by relevant staff members on 21 August.
  - One staff member of the Education team attended a two-day EFQM Qualified Assessor Training in Belfast in August.
- September is the Irish Heart Foundation’s (IHF) ‘Heart Month’. To promote the ‘Heart Month’ campaign, the Workplace Wellbeing Group partnered with IHF to provide an on-site nurse-led Health Check Programme on 4 September for PSI staff.
- Following receipt of the final report on PSI’s IT Security Assessment conducted by Ward Solutions, the majority of critical/high risks and recommendations have been resolved, including the two critical risks. Once the last outstanding risk has been resolved Ward Solutions will carry out a re-test in October.
- Several key changes to the continued registration online and hardcopy forms have been implemented in advance of the main continued registration period in November/December. A key change included updates to the data protection statement.
- Update on ongoing and upcoming high value tenders (generally >€25k services contracts) as per PSI’s Procurement Policy and 2018 Service Plan and budget:

<b>Service/goods to be procured</b>	<b>September Status Update</b>
Procurement external expertise and administrative support services	Procurement concluded using an OGP framework with contract awarded to Greenville Procurement Partners Ltd
Framework Agreement for the provision of Print Services for Bulk Printing and Mailing of Continued Registration Documents and Retail Pharmacy Business Duty Register	Request for Tender published on eTenders on 31 August and closing on 19 September 2018.

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 7 September 2018)

#### Fitness to Practise Concerns

Total concerns received in 2018	96
New concerns received since last report date	30
Open concerns	14*
Concerns reviewed since last report date	35

\* This figure may include concerns received prior to 2018 which are still under review

#### Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2018	34
New complaints received since last report date	13
Open complaints	29*
Complaints considered by PPC since last report date:	15**

\* This figure may include complaints received prior to 2018 which are still being processed

\*\* 73% 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 year to date	5*
Heard since last report	1 **
Cases being investigated/prepared for hearing	14 ***

\* (4 – PCC & 1 - Health Committee). This figure may include inquiries which were commenced in 2017 but concluded in 2018 and which may relate to multiple complaints and/or respondents

\*\* (PCC). Inquiry KPI timeline met i.e. inquiry held within two years from when the complaint was received

\*\*\* (13 – PCC & 1 - Health Committee)

#### Mediation

Heard year to date	0
Heard since last report	0
Cases being prepared for mediation	1

#### Sanction Hearings/ Undertakings/Dismissals before Council\*

Heard year to date	10
Cases being prepared for Council Meeting on 20 September	2

\* This figure is reported on a per respondent basis

## High Court Sanction Confirmation Hearings\*

Heard year to date	4
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\* This figure is reported on a per respondent basis

## Suspension Applications

Two applications have been made to the High Court year to date

## Appeal

One Appeal is currently underway before the High Court

Insert Pharmacist and Pharmaceutical Assistant activity:

New Registrations by route

Cancelled

Restored

<b>Registration of Retail Pharmacy Businesses</b>	
Number of Registered Retail Pharmacy Businesses as of 07/09/2018	1936
Number of Retail Pharmacy Businesses Registered since 1/1/2018	78
Number of Retail Pharmacy Businesses Cancelled since 1/1/2018	71
Number of Changes in Supervising and Superintendent Pharmacists since 1/1/2018	337

<b>Internet Supply (as of 07/09/2018)</b>	
Number of Pharmacies on Part A	48
Number of Non-Pharmacies on Part B	82

<b>Investigation Activity (Part 7 / Inspection &amp; Enforcement)</b>		
No of investigations open	No of investigations initiated since the last Council meeting	No of investigations closed since the last Council meeting
26	4	2
Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits – (01/01/2018 to 07/09/2018)</i>		32

<b>Inspection Activity (1/1/2018 to 07/09/2018)</b>	
Number of Registration-related Inspections (Section 19)	74
Number of pharmacy inspections (Section 67)	96
<ul style="list-style-type: none"> <li>- 79 Inspections – including 21 risk-based inspections, 8 joint inspections with the HSE and 50 systems / routine inspections</li> <li>- 10 Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)</li> </ul>	

- 7 Thematic Inspections – including 6 Flu vaccination inspections and 1 Internet Supply inspection	
Number of pharmacy assessment system review visits, including a review of the pharmacy’s awareness of the updated patient safety information for Valproate-containing medicines	101

<b>Registration of Persons</b>	
Number of Registered Pharmacists as at 13 September 2018	6,071
Number of Registered Pharmaceutical Assistants as at 13 September 2018	335
Number of Registered Druggists as at 13 September 2018	1

<b>Internal Market System</b>	
Number of Alerts issued as at 13 September 2018	5
Number of European Professional Cards issued - host	8
Number of European Professional Cards issued - home	0