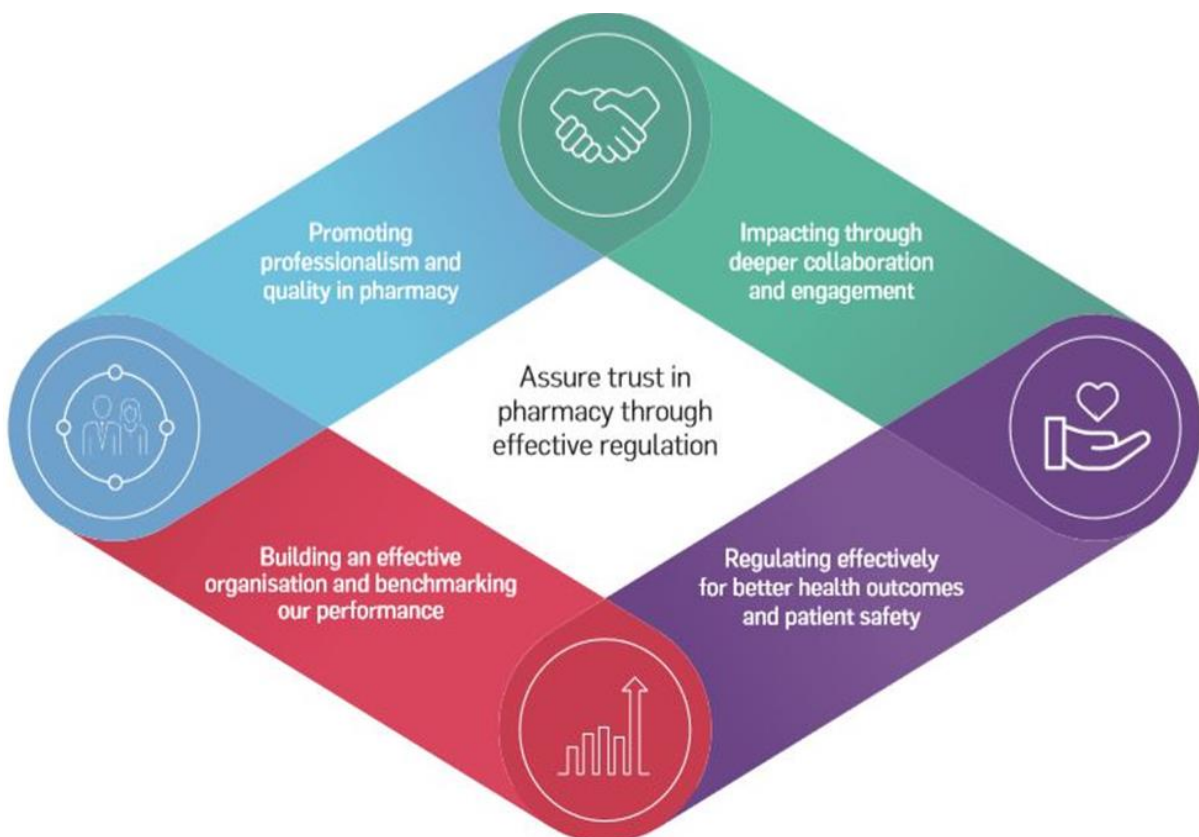


Report of the Registrar



17 May 2018

Highlights from the Registrar

Regional Seminars for Superintendent Pharmacists: The final four of our 11 regional seminars for Superintendent Pharmacists took place Galway, Athlone, Donegal and Sligo in March/April. As with previous seminars, there were lively discussions on a broad range of topics and attendees welcomed the opportunity to meet staff of PSI, share ideas and issues, and were enthusiastic about ongoing engagement on work of mutual interest. I would like to acknowledge the contribution of my colleagues Conor O’Leary and Irene Patterson together with other PSI colleagues to the success of the seminars. The slides which we used at the Seminars are attached as an appendix to this Report. We are collating an overview of the topics raised during the seminars, and the feedback received which will be presented to Council in June. I will make a short presentation on the seminars at the Council meeting on 17 May.

IIOP Contract: I signed the new contract for provision of CPD services, via the IIOP, with the RCSI on 9 May. This represents the culmination of an extensive process of procurement since the summer of 2017 and the contribution of Damhnait Gaughan, Lorraine Horgan, Cora O’Connell and other colleagues over this period deserves commendation.

Lecture on Regulation: I attended a guest lecture at UCD School of Law on 26 April given by Professor Julia Black from the London School of Economics, who is a noted international expert on regulation. I am awaiting the slides from the lecture and will circulate these to Council for interest once received.

IPU Annual Conference – Plenary Session: Dr. Cora Nestor and I were invited to the Plenary Session which took place on Saturday, 28 April. There were two interesting presentations – one from Professor Charles Normand of TCD and one from Thomas E. Menighan from the American Association of Pharmacists. I am distributing both to Council members as an appendix to this Report.

Dr. Cheryl Stokes: Our colleague Cheryl has recently commenced maternity leave from her role. I am sure Council joins me in wishing Cheryl and her family the very best. During Cheryl’s absence, Louise Canavan has been appointed as Acting Head of Corporate Governance and Public Affairs and we wish Louise well in her new role.



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 Registrar and Head of Education and Registration met with both the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) in London on 24 April. Constructive engagement and discussion occurred on a tripartite basis, addressing and exploring the potential implications and issues arising from Brexit with reference to recognition and registration. Some potential options for mitigation of these were explored and it was agreed to develop a set of principles to underpin exploration of possible bilateral arrangements. A further update will be given at Council by Ms. Damhnait Gaughan.
- As part of the ongoing accreditation process for the 5-year MPharm programmes a paper-based review is being undertaken for 2017/2018. The required paper based submissions have been provided by the three schools of pharmacy for review by the accreditation team. The three schools of pharmacy have also submitted annual reports as part of the continuing accreditation of the BPharm programmes.
- In order to advance the development of the profession and increase collaboration with key education stakeholders, two MPharm students have been selected to undergo a placement at the PSI via APPEL. The Professional Development and Learning (PD&L) Unit is liaising with the APPEL office in the context of PSI being a placement provider to ensure a structured programme is in place which adheres to required governance.
- The Irish Institute of Pharmacy (IloP) has reported that the 2017/2018 ePortfolio Review has been completed with submissions received from 1,217 pharmacists. A final report on the process will be provided by the IloP in May. The first Practice Review event took place on 21st and 22nd April with positive engagement and participation reported by the IloP.
- As a continuation of the work that started with the Interprofessional Learning (IPL) Conference in 2015, engagement has begun with key stakeholders to explore the potential development of IPL in the Irish context with a view to holding a bi-annual IPL meeting.
- Following on from discussions at the 11 superintendent seminars which have been held around the country, work has begun on the development of an Accountability

Framework which will set out key requirements for supervising pharmacists and superintendent pharmacists, as well as those responsible for the overall governance of retail pharmacy businesses, for example the senior management and boards of corporate entities. The framework will be based around standards and will be designed to assure the public that professional pharmacy services are being delivered in safe and reliable ways. We intend to collaborate further with pharmacists and pharmacy businesses during the development of this framework.

- The Pharmacy Practice Development (PPD) Department is continuing to review the draft Code of Conduct and has significantly progressed the revised Code, incorporating the feedback received to date from stakeholders, including a strong focus on the exercise of professional judgement. The revised Code will shortly be provided to the PSI Council seeking its feedback. This will take place ahead of broader engagement with stakeholders on the revised Code later in Q2.
- The Head of the PPD Department attended a multi-stakeholder meeting in the HPRA on February 13. This meeting was attended by representatives from the Department of Health, HSE, Epilepsy Ireland and the Organisation for Anti-Convulsant Syndrome (OACS), and addressed the public safety issues and public interest concerns arising from the use of valproate containing medicines during pregnancy. The meeting also aimed to co-ordinate the national response following the then recent recommendations of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC). PRAC recommended that each member state implement a formal national Pregnancy Prevention Programme (PPP) for valproate containing medicines.
- The PSI Registrar and a member of the PPD Department met with two patient representatives on 23 April in order to listen to their concerns regarding valproate-containing medicines and to identify areas where the PSI could assist. The patient representatives were highly complementary of the stance taken by PSI earlier in the year in relation to specifying what patients can expect of pharmacists when being supplied with these medicines.
- Implementation of the Report on Future Pharmacy Practice-Meeting Patients' Needs - : A meeting is scheduled for the end of May with Dr Philip Crowley National Director for Quality Improvement Division and his team to discuss the report's recommendations.
- As discussed at the March meeting, draft Terms of Reference have been circulated as part of Council's papers to establish a working group to consider the future of the IIOP.



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

- Two meetings took place with the HPRA on 24 and 25 April. One was our regular liaison meeting between the management teams of both bodies which discussed a range of issues of mutual concern. This is in accordance with the Memorandum of Understanding between the bodies. The second meeting was between communications personnel in both organisations to discuss an idea for a shared public health campaign and to seek to enhance communication between our two organisations. We are each now considering how we might progress together on several issues of public interest and we will update the Council at future meetings.
- The Health Information and Quality Authority (HIQA) is drafting National Infection Prevention and Control Standards for Community Services. HIQA has formed an advisory group to inform the development of the standards and the PSI has contributed to this process. The standards are relevant to community pharmacy practice notwithstanding that the application of standards and the relevance of some features provided will vary in the context of the pharmacy setting. This variation in applicability was specifically raised through the advisory group, and the role of the PSI as the regulator of Retail Pharmacy Businesses was acknowledged.
- PSI has also been invited to nominate a member to the HIQA Advisory Group on ePrescribing. This Group will draw up recommendations to be made to the Minister for Health in respect of electronic prescribing and the electronic transfer of prescriptions in the community setting including governance structure, stakeholder engagement, a standards-based approach, and models for rolling out a national community based ePrescribing solution
- There were two consultations with registrants and others during April and May:
 - a public consultation on new draft Accreditation Standards for CPD Programmes in Pharmacy was carried out for the purposes of streamlining and quality assuring accredited CPD programmes for pharmacists. A public consultation report will be presented to Council on 21 June;

- a survey was also carried out to seek feedback from registrants on the use of the Pharmacy Assessment System to date, as part of the review of the operation of this audit system. Those consultation reports will come to the Council at future meetings.
- Delivery of a new website is a key project for the PSI, commencing with open procurement for a suitable provider this May. The project specifications and tender document have been written and are in final review stage. The PSI will be seeking a company, for the design, development, implementation and hosting of the site, and for maintenance and support services. The website is a key communications channel that should provide an accessible, informative point of reference for all users. In its current state it is limited in its functionality and adaptability, it is not device responsive and there are security concerns with the content management system.
- The Registrar and members of the management team met with the HSE Primary Care Reimbursement Service (PCRS) on 3 May to discuss concerns highlighted in inquiries on the HSE high tech scheme. The meeting also discussed the merits ongoing and broader collaboration between the two organisations in the public interest and it was agreed to explore developing a Memorandum of Understanding between the organisations. Both organisations also discussed the findings of the Future Pharmacy Practice Report as were relevant to the primary care area.
- The Registrar and Head of Policy met with the National Patient Safety Office on 18 April to discuss the implementation of the National Action Plan on Antimicrobial Resistance (iNAP) 2017-2020. PSI is keen to support this important initiative and to understand the next steps for the action plan and what the expectations are as regards input from PSI.



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

- A report has been produced by the Working group on Temporary Absence, which examined matters relating to what constitutes the temporary absence of a registered pharmacist and what may and may not be done by a registered pharmaceutical assistant when acting on behalf of a registered pharmacist in his/her absence. This will be presented to Council in the context of its request last year to re-examine this matter, with further consideration to be given as to what could be covered within the scope of Rules, as provided for under Section 30 (2) of the Act. This matter is for Council's private agenda on 17 May.
- We have commenced a review of the Pharmacy Assessment System to evaluate its implementation to date. The Pharmacy Assessment System was developed as a practical tool to facilitate the supervising pharmacist, superintendent pharmacist and the pharmacy owner, along with their pharmacy team, to critically review and reflect on their pharmacy's practice and identify areas where improvements may be required. This plays an important role in demonstrating a pharmacy team's commitment to continuous quality improvement directed towards ensuring patient safety and quality care. As part of the review, a survey was issued to all pharmacists, pharmaceutical assistants and pharmacies and PSI inspectors will also visit some pharmacies to ask about their use of the Pharmacy Assessment System and to answer questions. The survey feedback and findings from the pharmacy visits will be provided to Council for consideration at its meeting in September 2018.
- The Disciplinary Committees of the PSI (Health Committee and Professional Conduct Committee) received training from a UK expert on the drafting of reports following fitness to practise inquiries. Over the course of each day-long session the Committees were facilitated in critiquing a number of their past reports with a view to increasing quality and consistency in their reports. The feedback received from both sessions was positive. Separately, the Preliminary Proceedings Committee also received training on the topics of bias and good decision-making.

- Draft Terms of Reference have been circulated as part of Council's papers with a view to establishing a working group to consider regulatory reform.
- The Registrar and Head of Policy met with the DoH National Patient Safety Office on 18 April in relation to the Patient Safety (Licensing) Bill and what form of regulation of hospital pharmacies would be most effective under the proposed structure. This Bill is designed to introduce for the first time licensing of hospitals in Ireland. An update on progress to date in examining the remit of PSI in relation to hospital pharmacy will be provided to Council on 17 May.
- The PSI has also been invited by the Patient Safety Office to meet as regards possible participation on the *WHO 3rd global safety challenge: Medication without Harm* as part of a broader discussion exploring how Ireland can contribute to this important initiative. A meeting is scheduled to initiate this work at the end of the May.



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

- A suite of business cases was submitted to the Department of Health in March along with the Comprehensive Resourcing Review Report incorporating the Strategic Workforce Plan for the period 2018-2020. Feedback from the Department on the business case submissions is awaited.
- Recruitment: Recent activity includes-
 - Open recruitment and selection process to fill the vacant permanent post of Pharmacy Inspector, Inspection and Enforcement Unit, completed with Ms. Orla Carroll appointed.
 - An internal recruitment and selection competition to backfill the post of Head of Corporate Governance and Public Affairs for a period of maternity leave was undertaken. Ms. Louise Canavan has been appointed in an acting capacity to the role to cover during Dr. Cheryl Stokes' period of maternity leave.
 - Interviews for 2-year fixed-term contract (career-break) post of Finance and Support Services Manager have taken place and the appointment process is in progress.
- A workshop on the review to date of sub-Council structures will take place prior to the meeting on 17 May, with Better Boards. To date, an extensive review of delegations, governance documentation and agendas and minutes of both Council and Committee meetings has been undertaken. The consultants have met individually with the Chairs of each Advisory Committee and with the President and Vice-President, and subsequently met this group together on two occasions. There has also been a workshop with the PSI's management team and a meeting with the Registrar. Discussions have included the delegation of functions, clarity of decision-making channels, authority and roles, terms of reference, workload, effectiveness and achieving strategic results, as well as ideas for improving or reforming the existing committee structure.
- The process to appoint a new Internal Auditor has commenced using the Office of Government Procurement (OGP) framework for appointing financial and audit services. In line with their Terms of Reference, the Audit and Risk Committee agreed that, Graham

Knowles will sit on the panel to evaluate the tenders, and appointment of the successful tenderer will be brought to Council for approval at the 21 June meeting. Crowleys DFK is currently providing internal audit services and that contract ends on 21 July 2018.

- All PSI staff have undergone online data protection training. Further online training will continue in May to increase awareness and highlight the additional compliance requirements under the General Data Protection Regulation. A review of all data processing activities has been carried out, and we are currently updating all our data protection and record retention policies.
- Appointments were made to the PSI's new Workplace Safety and Environmental Sustainability Committee, expanding the role of a Safety Committee, which is a statutory requirement, to encompass our responsibilities towards protecting the environment, including energy awareness. A series of events and initiatives were developed and rolled out in the week of 23 April to launch the new Committee and raise our awareness of environmental sustainability matters.
- We have updated a policy for Council and Committee members on media and online engagement - available on Council iPads. This is an update to reflect the PSI's changed online presence, a reminder about the appropriate spokespeople for the organisation and the importance of cohesive messaging from PSI. This policy should be read in conjunction with the Code of Conduct for Council and Committee Members.
- In preparation for the organisational business process review, the Head of Operations attended a Department of Public Expenditure and Reform showcase of business process automation and its potential for innovation in public service delivery.
- Members of the PD&L Unit attended the first of a series of EFQM (*European Foundation for Quality Management*) online seminars in relation to leadership and employee empowerment. PSI engagement with the EFQM framework (*a non-prescriptive business excellence framework for organizational management*) is intended to build an effective organisation, benchmarked for excellence and designed to ensure PSI is as fit as possible to deliver on the Council strategy.
- Major review and development of new Information Security Policies being finalised for staff consultation. Project plan developed for roll-out in Q2, including all changes to ICT systems and procedures. The annual IT systems penetration test is being finalised, with the report pending in May.

Appendix 1 –Statistical Summary

Fitness to Practise: Concerns information as at 27 April 2018				
No of new concerns received since last Council meeting	Total concerns received to date in 2018	No of concerns open	No of concerns considered since last Council meeting	Outcome of concerns considered:
8	49	11	28	13/28: Closed 15/28: Referred to other Depts. for consideration/further action

Complaints: Screening Committee (PPC) Information as at 27 April 2018				
No of new complaints received since last Council meeting	Total complaints received to date in 2018	Total no of complaints open	No of complaints where decision made by PPC since last Council meeting	Outcome of complaints considered by the PPC
5	18	21*	5	<ul style="list-style-type: none"> 4/5: No further action 1/5: Further action - Referred to Conduct committee

*The number of complaints open can exceed the number received in 2018 as there are a number of complaints from 2017 which are being processed also.

Complaints being prepared for Inquiry/Mediation as at 27 April 2018				
No of new complaints referred for Inquiry since last Council meeting	Total open complaints being investigated/prepared for Inquiry	No of Complaints being investigated/prepared for the Professional Conduct Committee	No of Complaints being investigated/prepared for Health Committee	No of Complaints at Mediation
1	12	11	1	0

Post Inquiry Complaints awaiting sanction/High Court confirmation hearing			
Complaints being processed after Inquiry	No of complaints for noting/sanction before Council	No of Complaints at High Court Sanction	*KPI
5	4	1	4/5 Inquiries: KPI met

*KPI = 2 years from when the complaint was received to when to the date the inquiry commenced.

Investigation		
No of investigations open	No of investigations initiated since the last Council meeting	No of investigations closed since the last Council meeting
30	0	0

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses as on 27/04/2018	1929
Number of Retail Pharmacy Businesses Registered since 1/1/2018	42
Number of Retail Pharmacy Businesses Cancelled since 1/1/2018	42
Number of Changes in Supervising and Superintendent Pharmacists since 1/1/2018	167

Inspection (1/1/2018 to 25/04/2018)	
Number of Registration- related Inspections (Section 19)	29
Number of pharmacy inspections (Section 67)	57

Internet Supply	
Number of Pharmacies on Part A, as on 27/04/2018	44
Number of Non-Pharmacies on Part B, as on 27/04/2018	80

Appendix 2 Income and Expenditure Overview

Income and Expenditure 31st March 2018 - Summary Period: 31st March 2018

	<u>2017 Budget</u>	<u>YTD Budget</u>	<u>Period Budget as % of Annual Budget</u>	<u>YTD Actual</u>	<u>YTD Variance</u>	<u>YTD Variance %</u>	<u>Remaining Budget</u>
	<u>€'000</u>	<u>€'000</u>		<u>€'000</u>	<u>€'000</u>		<u>€'000</u>
Total Income	7,550	1,845	24%	1,810	(35)	-2%	5,740
Total Operating Expenses	8,217	1,803	22%	1,613	189	11%	6,604
Net Operating Surplus	(667)	42	-6%	197	155	370%	(864)
Projects Funded From Reserves							
APPEL	199	44	22%	45	(1)	✓	154
Code of Conduct	36	1	3%	-	1	100% ✓	36
Business Transformation Office	104	-		-	-		104
Adjusted Surplus/(Deficit) for the Year	(329)	87	0%	242	155	0%	570

