



AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Report of the Registrar

Agenda Item D

22nd March 2018

Report of the Office of the Registrar

Key updates

- As part of our ongoing work under the Corporate Strategy (and our 2018 Service Plan) to promote adoption of the recommendations of the Future Pharmacy Practice Report by key stakeholders, Dr. Cora Nestor and I presented on the recommendations to the Director-General of the HSE and the National Leadership Team on 16 January. Our presentation was very well received and we had some useful discussion as to how the recommendations might be carried forward by the HSE as part of its various strands of activity, particularly within the primary care domain. On foot of this meeting, we are now engaging with the key National Directors in relation to specific recommendations and how these can be adopted and their implementation in practice advanced.
- Further to our strategic objective to prepare for the implications of Brexit, I and colleagues will be meeting the CEOs of the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland (PSNI) in London on 24 April. Separately, but on a related note, members of the PSI management team will meet our PSNI colleagues in Belfast on 7 May.
- I met the CEO of the PSNI on 29 January to sign the MOU as approved by Council in December 2017. Arising from this, there is a proposal before Council on 22 March to agree to establish observer status for members of both respective Councils at each other's public meetings.
- Since the December Council meeting, we issued two important press releases in conjunction with communication to the profession and to retail pharmacy businesses:
 - On 29 January, and on foot of guidance issued by the Health Products Regulatory Authority, we issued a regulatory notice advising the profession that food intolerance testing should not be provided in pharmacies. We also issued a press release to advise the public of the PSI position.
 - On 22 February, we issued instructions to the profession (which was a reiteration of previously-issued communication) in relation to the supply of medicines containing valproate. This was on foot of recent safety recommendations from the European Medicines Agency. We also issued a press release to inform the public as to what they can expect from pharmacies in relation to these medicines and making clear, in the light of the known risks, that PSI wants to hear of any circumstance where defined supply procedures are not being followed. We continue to work with other statutory bodies and patient representatives on measures to further mitigate these risks.
- We are undertaking a series of 11 regional seminars for Superintendent Pharmacists as part of our work to explain the purpose and intent of our new Corporate Strategy. We are also taking the opportunity to explore with attendees how outcome-based standards might be used to support and recognise good governance, safety and professionalism in retail pharmacy businesses. As of 22 March, we will have completed seven seminars – four in the Dublin region as well as Limerick, Cork and Kilkenny. The seminars are going very well and feedback is positive and supportive of further engagement.

- Our Corporate Strategy was published on 15 February and I would like to express my thanks to our Communications Team for the superb work on its design and printing. Likewise for the 2017 Annual Report which is before Council for approval on 22 March.
- In furtherance of the objective in our 2018 Service Plan to explore how behavioural economics could support more effective pharmacy regulation, I attended a one-day course on this topic with Professor Liam Delaney on 16 February. A number of PSI colleagues have also attended this course.

Key meetings & presentations

- 11 January – Met Chair and one of the acting Chairs of the PPC.
- 16 January – Presented on recommendations from Future Pharmacy Practice Report to HSE Director-General and Leadership Team.
- 29 January – Met CEO of Pharmaceutical Society of Northern Ireland to sign Memorandum of Understanding.
- 6 & 7 March – Two seminars with Superintendent Pharmacists in PSI House.
- 7 March – Quarterly business meeting with IPU.
- 12, 13, 14 March – Seminars with Superintendent Pharmacists in Limerick, Cork and Kilkenny.
- 15 March – Four-monthly governance meeting with Department of Health.
- 20 & 21 March – Two seminars with Superintendent Pharmacists in Dublin.

Report of the Operations Department

Key Administration and Finance Updates

Finance:

- Year-end reconciliations finalised and management accounts prepared in preparation for the on-site visit of the external auditors.
- Financial statements for the year end 31st December 2017 prepared and then audited by the new external auditors, JPA Brenson Lawlor.
- Department of Health funding for IIOIP reviewed and audited by JPA Brenson Lawlor,
- Independent review and verification of the adequacy of the Superannuation Fund liability provision in the financial statements and the amount held on deposit to meet this liability as at the 31st December 2017 carried out by Anne Brady McQuillans DFK
- PSI funds reinvested in line with the agreed actions of the Investment Group meeting of 1st March.
- Comprehensive review of risk register to update it in line with the updated risk management policy and guidelines.

Procurement:

- Annual procurement plan developed for 2018
- Evaluation concluded on the ICT Penetration test and contract awarded with successful tenderer.
- Procurement for new IIOIP contract progressing with clarification and negotiation with preferred provider ongoing.
- ITT for governance review of Council sub-structures issued by way of mini-tender. Closing date 12th March 2018.
- ITT for replacement Notebooks tender issued utilising 'OGP Framework Agreement for the Provision of Desktop and Notebook Computers and Associated Services' with closing date 5th March. Evaluation to take place week of 19th March.
- ITT in development for new PSI website.

Facilities:

- Full PAT testing undertaken. PAT (portable appliance testing) is the testing of any and all portable equipment so that employers are able to ascertain whether or not the portable equipment (including cables and plugs) is safe and without risk on the day of the test, to persons coming into direct or indirect contact with any live part of the equipment.
- Remedial work on the fire safety doors undertaken.
- Health and safety risk assessment conducted in December 2017 by external consultants.

Stakeholder Engagement and Key Meetings

- Sustainable Energy Authority of Ireland (SEAI) annual Public Sector Energy Efficiency Conference in UCD – participation by Head of Operations on 17 January 2018

Key ICT Updates

- Business Continuity Plan deployment for severe snow and Storm Emma ensuring limited business disruption on 1-2 March 2018.
- The ICT Penetration test is ongoing, with a completion date of end March 2018.
- External validation the PSI's new ICT security policies has been completed. Draft policies will be issued for staff consultation by end March.

Key meetings

- ICT Officer attended Certified Information Systems Security Professional (CISSP) training course with New Horizons in January.

Key Human Resources Updates

Strategic Workforce Planning:

- Significant work undertaken on development of business cases for posts approved by Council at 21 September 2017 meeting for submission to the Department of Health for sanction.

Recruitment Activities:

- Open recruitment has commenced for the position of Pharmacy Inspector, Inspection & Enforcement Unit, Regulation Department (permanent post).
- Recruitment has commenced for temporary agency staff to the position of Accounts Assistant, Administration & Finance Unit, for a period of 3 months.
- Open recruitment commencing for 2-year fixed-term contract career-break replacement post of Finance and Support Services Manager.

Learning and Development Activities:

- Mandatory manual handling awareness training was delivered by ESA Consultants to staff on 13 December 2017.
- Conclusion of joint PSI-CORU leadership development delivered by IPA for Grades 6-8/HEO-AP levels

Stakeholder Engagement and Key Meetings

- Head of Operations participation in Registration and Continuing Practice Committee meeting of the Irish Medical Council on 11 January 2018.

Report of the Pharmacy Practice Development Department

Key Updates

PPD Staff Update

Róisín Cunniffe and Irene Patterson have returned to the PPD department after maternity leave, and Avril Ryan and Mary Mockler will be leaving after providing great assistance to the department.

Dispensing Zantac Syrup to Minors

An email was sent to all pharmacists reminding them to be extra vigilant in the dispensing of Zantac Syrup 75mg/5ml for children. Pharmacists were urged to review a previously published learning involving dispensing Zantac Syrup 75mg/5ml to an infant, and take all precautions necessary to ensure a similar incident does not happen in their pharmacy.

Food intolerance testing not appropriate in pharmacies

The HPRA's Medical Devices Information Notice on Food Intolerance Testing published in January 2018 was highlighted in Issue 1 of the PSI newsletter. In light of this, PSI have advised superintendent pharmacists and pharmacy owners that offering food intolerance testing in pharmacies, to diagnose food intolerance, is not appropriate.

Stakeholder Engagement and Key Meetings

Department staff attended the following meetings and conferences on behalf of the PSI:

- Tobacco partners meetings
- PSI/HPRA teleconference meeting
- HPRA stakeholder meetings
- HPRA multi-stakeholder meeting
- Meeting focussed on the Memorandum of Understanding (MOU) with Pharmaceutical Society of Northern Ireland (PSNI)
- High Tech Hub meeting Primary Care Reimbursement Services (PCRS)

Other

- Self Care Talk, Royal College of Physicians Ireland (RCPI)
- Workshop on open disclosure with HSE
- Workshop on sharing best practice to enhance patient safety by optimising public awareness on falsified medicines
- Workshop with HSE on Liberating Structures

- Meeting with Renault-Nissan consulting
- Meeting with HSE on eHealth update
- Meeting with IPU executive

Statistics:

In 2017 there were a total of 455 queries. To date for 2018, there have been 77 practice queries received. We are working on options to support pharmacists who have queries relevant to the functions of PSI while also ensuring that the resources deployed to queries do not negatively impact on our other functions.

Report of the Education and Registration Department

Key Education Updates

- The APPEL student matching system for the statutory 4-month placements went live on 7 March 2018.
- Four-month placements will take place from September to December 2018 as the students enter their 4th year of the MPharm programme.
- Contract negotiations are in final stages as part of a procurement process for a service provider for the IIOp
- The first Practice Review Event will be held on 21st and 22nd April 2018. 72 pharmacists are scheduled to participate in the first review.

Stakeholder Engagement and Key Meetings (Education)

- The Quarterly Strategy meeting was held with the IIOp on 20 December 2017.
- An IIOp Operations meeting was held with the IIOp on 14 February 2018.
- Contact has issued to a range of health professional regulators with a view to holding a meeting on Inter-Professional Learning and Education
- PSI proposes to host two pharmacists visiting from the Pharmacy Board Malaysia and one candidate from the National Pharmacy Council in Rwanda (funded via the Pharmabridge program) from June 11th – June 19th.
- Members of the unit attended Advanced FOI training on 12 March.
- Staff member participated in EFQM workshop 31/1/18.

Key Registration Updates

- Two EU/TCQR Registration meetings have been held to date in 2018.
- To date in 2018, one alert has been issued under the Internal Market Information System to other EU Competent Authorities responsible for the implementation of the provisions of the Professional Qualifications Directive as it pertains to pharmacists.
- Two EPCs for establishment of service have been processed to date in 2018 (new European route of entry to recognition and registration). Currently, there are no applications in process.
- The 2017 Continued Registration project has been completed, with 4600 applications for continued registration for pharmacists, and 315 applications for continued registration for pharmaceutical assistants processed between October and December 2017. The percentage of applications for this period that utilised the online application systems was 95%.
- The next Equivalence Examination to be conducted under the TCQR process is scheduled to be held in UCC on the 28th and 29th March.

Stakeholder Engagement and Key Meetings (Registration)

- Staff members are participating in the organisation's meetings on the EFQM Excellence Model
- Staff members have completed Survey Monkey training
- Staff member attended meeting in DoH regarding Brexit.
- Staff member participated in TA working group meeting 15/1/18.
- Staff member participated in meeting with CEO PSNI 29/1/18
- Staff member participated in EFQM workshop 31/1/18.
- Staff member attended MDP registration workshop event – Dishonesty 2/2/18.
- A member of the unit attended Advanced FOI training on 12 March.
- Head of Dept participated in meeting on behalf of the President with HPMP, NOSP and other regulators.
- Head of Dept attended CORU registration committee meeting 14/3/18.

Report of the Regulation Department

Key Inspection and Enforcement Updates

- An I&E Committee meeting was held on the 27 February 2018. The next meeting is provisionally scheduled for the 22 May 2018.
- A permanent role in the I&E unit for a Pharmacy Inspector was advertised and interviews have been held.
- The 2017 Continued Registration project has been completed, with 1,349 applications for continued registration processed between October and December 2017.
- An article on the 2017 Non-Compliance trends will be published in upcoming newsletter.

Inspection Policy Project:

- The I&E unit issued documentation to all pharmacies for the completion of the third cycle of the Pharmacy Assessment System.
- The I&E unit continues to issue monthly reminders to all pharmacies, including links to resources available to assist pharmacists in completing the Pharmacy Assessment System.
- The I&E unit is commencing a review of the Pharmacy Assessment System. This review will include a survey of pharmacists to gather feedback on their experiences using the Pharmacy Assessment System.
- The unit also plan to conduct visits to pharmacies to verify that the Pharmacy Assessment System is being used continuously and to gather feedback on how pharmacists find using it.
- The results of the survey and visits will form part of the review of the Pharmacy Assessment System which will be presented to Council later this year.

Key Statistics:

- There are currently (*as of the 12 March 2018*):
 - 1,928 registered retail pharmacy businesses
 - 51 retail pharmacy businesses registered on Part A of the Internet Supply List.
 - 80 other retailers registered on Part B of the Internet Supply List.
- To date in 2018 (*correct as of 12 March 2018*):
 - There have been 25 retail pharmacy businesses registered, and 28 pharmacies removed from the Register.
 - There have been 93 changes of superintendent and/or supervising pharmacists.
 - There have been 17 registration inspections conducted in accordance with Section 19 of the Pharmacy Act 2007.
 - There have been 32 pharmacy inspections conducted in accordance with Section 67 of the Pharmacy Act 2007.
 - One new investigation has commenced in 2018. 30 investigations are on-going from previous years into serious matters which were brought to the attention of the PSI.

- There have been 7 concerns referred to the I&E Unit by the Legal Affairs Unit, other external bodies and members of the public. All concerns are reviewed and assessed by the unit and may be referred for further investigation or other action.

Stakeholder Engagement and Key Meetings:

- Members of the unit attended 2 CLEAR webinar conferences entitled “Nudging, Judging and De-Sludging: How Behavioural Sciences Can Be Applied to Compliance in the Regulatory Sector” on 24 January and “Law & Order: The Intersection of Criminal Justice and Professional Regulation” on 07 February.
- Members of the unit attended an eHealth with the HSE meeting 12 February.
- A member of the unit met with the HPRA in relation to medicines shortages on 16 January.
- A member of the unit attended a meeting with the HSE on High Tech medicines on 30 January.
- A member of the unit attended Behavioural Economics training on 16 February.
- Members of the unit met with the HSE inspectorate on 08 March.
- A member of the unit attended Advanced FOI training on 12 March.
- A member of the unit is attending EDQM training on Medicrime, 22 and 23 March.

Key Legal Affairs Updates

Key Legal Affairs and Fitness to Practise Updates

- A new procedure has been introduced whereby each member of a Disciplinary Committee (either Health or Professional Conduct Committee) receive a written update setting out Council's decision on sanction following a Council meeting. Currently, a Disciplinary Committee will make a recommendation to Council on the issue of sanction. In light of this, it is important for the relevant Disciplinary Committee to be aware of Council's ultimate decision on sanction.
- The Registrar held a meeting with the Chair and one of the Acting Chairs of the Preliminary Proceedings Committee on 11 January.
- A callover of the Health and Professional Conduct Committee, which was due to be held on 28 February but had to be cancelled due to Storm Emma, was re-scheduled for 15 March on which date an update was provided to the relevant Chair and Committee on the Inquiry caseload.
- Since the last Council meeting two new members joined the Professional Conduct Committee. Both members, who were drawn from the Panel which was formed following the Expression of Interest for Disciplinary Committee Members, received induction training from the Manager of Legal Affairs and are ready to participate in hearings before the PCC.
- Training on report writing has been organised for the Professional Conduct Committee and Health Committee and will take place on 9 and 13 April respectively. Training has also been organised for the Preliminary Proceedings Committee on 12 April (half-day) and 23 April (full-day).
- Following constructive discussions with the Audit Committee in the final quarter of 2017, it was agreed that the Registrar would report on the length of time Fitness to Practise cases take to get to hearing (on the basis of a KPI of two years). For Quarter 1 of 2018, the concluded cases from 2017 have been reviewed (see below). Going forward, each quarter a report will be provided regarding any cases concluded in that quarter:
 - 2017 – 60% of cases were concluded in under 2 years and 90% of cases were concluded in under three years. The remaining cases (which related to one inquiry) took longer than 3 years due to an on-going criminal case which was happening in parallel to the FTP case.

Key Meetings

Preliminary Proceedings Committee (PPC):

- The PPC met on 11 January and considered five cases, one of which was referred to the Professional Conduct Committee. A second meeting was held on 22 February and five cases were considered, one of which was referred to the Professional Conduct Committee.

Professional Conduct Committee (PCC):

- Since the Council meeting on 8 December 2017, three Inquiries were held before the PCC on 4, 13 and 18 December 2017 and also 5 February 2018.

Health Committee:

- Since the last Council meeting on 8 December 2017, two Inquiries were held before the Health Committee on 7, 8 and 11 December 2017.
- Finally, one confirmation hearing relating to a health inquiry, took place before the President of the High Court on 28 January 2018, on which date he approved the Council's decision in terms of sanction.

Report from the Corporate Governance and Public Affairs Unit

Corporate Governance Updates:

Corporate Governance:

In line with the Code of Practice for the Governance of State Bodies we have agreed a Performance Delivery Agreement and Oversight Agreement with the Department of Health (Appendix 1). The Oversight Agreement is a dynamic document insofar as it should be reviewed annually and updated as required. The Performance Delivery Agreement should be reviewed at one formal meeting per year between senior Department officials and representatives of the Council and management of the PSI to strengthen the relationship between the two organisations.

We have commenced work on the governance review of Council sub-structures. We initially tried to procure the work through the Framework Agreement, which was put in place as part of the tender for the governance review, which was already established with CIPFA, but unfortunately CIPFA were not in a position to carry out the work within the timelines required and did not submit a tender. We therefore had to initiate a separate tender process, which has delayed the commencement of the project. The closing date for tender submissions was 12 March and evaluation of tenders received took place on 14 March.

Risk Management:

Work is ongoing to implement the updated risk management policy and guidelines. A workshop was held with staff of the Operations Department to review risk statements and ensure the controls were effective in addressing the risks identified. Workshops will be rolled out for all Departments in the coming weeks to ensure risk management is further embedded in the organisation and facilitate more efficient reporting at Departmental level.

Internal Audit:

The Internal Auditors reviewed the area of Data Protection, Records Management and Freedom of Information and met with the Audit and Risk Committee to present their findings (further information provided in the Report from the Audit and Risk Committee). The next internal audit will be in the area of HR.

PSI Corporate Strategy 2018 – 2020:

The Strategy was officially published on 15 February and a press release issued. It is available on the PSI website and was circulated by email to all PSI registrants and other subscribers via the newsletter, as well as by email to other stakeholders.

The fundamental objectives of the Corporate Strategy are being highlighted as part of the ongoing seminars for superintendent pharmacists during March and April. An interview with the Registrar highlighting some of the key objectives of the Strategy will also be published in Irish Pharmacy News in March.

Data Protection:

Work is ongoing to prepare the PSI for the upcoming General Data Protection Regulation (GDPR). We have rolled out Privacy Engine to all PSI staff, which is software to assist us in conducting a gap analysis to ensure our compliance with GDPR. PrivacyEngine will enable us to maintain training logs,

data processing activity logs, including details of data breaches, and subject access requests, linking them to a data risk register, from which alerts and instructions will be generated by the PSI's Data Protection Officer and issued via email to members of staff to complete actions to address any risk identified. Information contained within PrivacyEngine will provide an audit trail for the Data Protection Commissioner, if we are asked to provide evidence of how we manage our data risks, or data breaches, should they occur. Workshops with Departments will be held over the coming weeks to complement the work carried out to day and to probe and challenge our current processes.

Records Management:

We have developed a records management policy and guideline, which has been considered by the PSI's Information Governance Group and is currently under consideration by the SMT. An audit of records kept by the PSI has been conducted and we are on track for having an updated retention schedule in place by May.

Freedom of Information:

We organised FOI decision maker training for PSI staff and three members of the Department attended the training, which was procured through an OGP Framework.

We have received one FOI request since January.

Key Public Affairs Updates

PSI Newsletter & Updates:

- We issued the first newsletter of the year on 15 February. It contained information on the PSI's new Corporate Strategy and this years' Service Plan, a reminder about a recent communication on food intolerance testing, medicine safety reminders and an awareness article about the new General Data Protection Regulations coming into force in May.
- The February issue of the newsletter had an open rate of 43% with a click to open rate of 27%. The December issue, following the last Council meeting of 2017, had an open rate of 55% with a click to open rate of 29%. These statistics are correct as of 12 March 2018. (Comparison statistics for newsletter engagement were provided at the December 2017 meeting, appended to the Registrar's Report)
- We have communicated recently on two important public health matters. In both instances we issued a public statement and communicated directly with pharmacists.
 - 22 February – clear direction was given to pharmacists to provide adequate patient information and resources to women of childbearing age who are taking valproate containing medicines. This follows new recommendations from the European Medicines Agency and concern about reported failure to provide relevant information to women where there is potential for serious harm to be caused by the drug in-utero.
 - 29 January – a regulatory notice was sent to all registered pharmacists and pharmacy owners advising that they should not offer food intolerance testing services to diagnose food intolerance. This followed clarity on the matter in a Medical Devices Information Notice from the Health Products Regulatory Authority (HPRA). It advises that there is no single test available to diagnose food intolerance and states that any test which claims to indicate an intolerance to food is of little clinical validity.

See PSI news and events for further information on both of these matters.

Media and PQs:

- We have issued three press releases to date this year. As above, in regard to statements about valproate and food intolerance testing, and to mark publication of the Corporate Strategy 2018-2020.
- There was press and social media interest and coverage of both PSI statements on valproate and food intolerance testing with articles appearing in most of the daily news and weekend papers. The Corporate Strategy has been covered in all of the recent pharmacy press publications, along with notice of the superintendent pharmacist seminars.
- We have dealt with nine media queries so far this year on a broad variety of topics. Articles have been updated again on Council members' iPads in the folder under General Information\Media Coverage.

Social Media

- As you will be aware the PSI began to use Twitter (@PSIRegulator) and LinkedIn (PSI–The Pharmacy Regulator) in October last year and we are continuing to work on building our profile on both of these platforms. We endeavour to tweet on relevant topics several times per week, and post to LinkedIn circa once per week with content relevant to that platform. We are incorporating use of social media in planning all of our communications and events, and by way of supporting public health campaigns.
- We have 250 followers on Twitter, which is up by 50 in the past month, and 148 followers so far on LinkedIn.
- In 2018 to date, our Twitter posts have so far received 32,000 impressions*, with an average of 455 impressions per day. The average engagement rate with our tweets is 1.6%. In the past month, there has been most engagement with tweets of general interest: our directive that patients must receive adequate information about their valproate medicine; our support of the Alzheimer Society's 'Denim 4 Dementia Day'; and launch of our new Corporate Strategy.
- Our LinkedIn posts have received 6,374 impressions*, an average click through rate of 3.5% and an average engagement rate of 4.1%.

* Impressions refer to the number of times that a tweet or post is displayed/shown to someone on their timeline, or in search results.

PSI Website

The website had an overall 21% increase in sessions, a 17% increase in users and a 24% increase in unique page views in 2017, compared to 2016. We endeavour to keep the website under review and to make regular updates. We have been working recently on improving the Search Engine Optimisation (SEO) of the website making it more straightforward for people to find information about, or held by, the PSI through Google searches.

Events and Publications

The communications function has been supporting the Pharmacy Practice Development team and the Registrar with the administration and roll-out of the seminars for superintendent pharmacists across 11 locations during March and April. All superintendent pharmacists and Council members were emailed with an invitation to attend one of the seminars and provided with

access to the PSI's Corporate Strategy 2018-2020. The Registrar will provide an up-to-date overview of those seminars at the March meeting.

Stakeholder Engagement and Key Meetings

- Two department members attended a social media conference in January for public bodies and the charitable sector.
- The PSI renewed its membership of the Institute of Public Administration's (IPA) Governance Forum. Since the last public Council meeting, one member of Council, attended a talk on; Board Effectiveness Reviews – People, Process, Culture and Performance Considerations; and one Audit and Risk Committee member attended a presentation on; Audit Committees - Key Features of an Effective Committee. A member the department attended a round table discussion on Key Governance Topics for 2018, hosted at the IPA.
- A member of the department attended the; Delivering Accountability under the General Data Protection Regulation (GDPR), conference on January 23rd 2018, held in Dublin Castle.
- We have made use of two CLEAR webinars with useful regulatory application: (1) "Nudging, Judging and De-Sludging: How Behavioural Sciences Can Be Applied to Compliance in the Regulatory Sector and (2) Effective Public Engagement: two regulators share the whys, hows and lessons learned on setting up a consumer/public advisory group.
- Three members of the Department attended Advanced FOI training on 12 March.
- Three members of the Department attended a three day workshop on implementation of the Service Plan and Corporate Strategy.
- The Registrar and Head of Corporate Governance and Public Affairs met with officials from the Department of Health on 15 March for the first governance meeting of 2018.
- Louise and Conor have joined up with the HSE's 'Liberating Structures' (LS) working group, a group that seeks to apply the LS model of facilitation and workshop techniques to promote wide staff and stakeholder input, in different ways, to problem solve and quality improve in the healthcare and other work environments.

Appendix 1

Performance Delivery Agreement agreed between Minister for Health/Department of Health and the Pharmaceutical Society of Ireland.

1. Introduction:

This agreement was reached between the Pharmaceutical Society of Ireland (PSI) and the Medicines, Controlled Drugs and Pharmacy Legislation Unit of the Department of Health in accordance with the requirements of the Code of Practice for the Governance of State Bodies published in 2016.

Department of Health

The Department of Health's role is to develop and implement policy in relation to the regulation of pharmacists and pharmacies, including in the development of pharmacy education and training policy and the professional role of the pharmacist in the healthcare system.

Pharmaceutical Society of Ireland

The PSI, is an independent statutory body established under the Act, and is the pharmacy regulator in Ireland.

The principal function of the PSI is to regulate the profession and practice of pharmacy having regard to the need to protect, maintain and promote the health, safety and wellbeing of the public.

The PSI has responsibility for regulating the professional practice of circa 5,600 pharmacists, 380 pharmaceutical assistants and 1,900 pharmacies.

The Act sets out the principal functions and duties of the PSI. The principal areas of responsibility of the PSI include:

- Statutory registration of pharmacists, pharmaceutical assistants and pharmacies;
- Accreditation of educational programmes for the pharmacy profession at different levels, and standards for continued professional development and training;
- Quality assurance of standards, and the development of pharmacy practice;
- Inspection of pharmacies and enforcement of medicines and pharmacy legislation, including the taking of prosecutions;
- Receiving complaints about pharmacists and pharmacies, operating the statutory fitness-to-practise processes and imposing sanctions on pharmacists.

The PSI is governed by a 21-member Council established under Section 10 of the Act with a non-pharmacist majority. Nine pharmacist members of the Council are elected by the profession and all members of the Council are appointed by the Minister for Health.

2. Corporate Governance:

The legislative framework through which the PSI operates is the Pharmacy Act 2007 and the regulations made under it. The PSI is obliged to comply with the Code of Practice for the Governance of State Bodies and has documented the areas of non-compliance and partial compliance within the oversight agreement between the PSI and the Department of Health. The PSI is seeking clarity from the Department of Finance regarding the applicability of the Public Spending Code to the PSI.

3. Objectives of the Agreement:

The objective of this Agreement is to ensure that the work of the PSI is aligned with the Department's strategic objectives, taking into account the statutory functions of the PSI. The PSI's strategic goals are closely linked to two of the Department of Health's five strategic objectives.

- Objective 2: Ensure the delivery of high quality and safe health and social care.
- Objective 4: Promote effective and efficient management of the health services

The PSI has documented its key priorities and objectives in its Corporate Strategy 2018-2020 and in its annual Service Plans <http://www.thepsi.ie/tns/Publications/Publications.aspx>. The PSI considered the Department's Statement of Strategy in the development of its Corporate Strategy and following feedback from the Department the Corporate Strategy was approved by the Council of the PSI in December 2017.

The PSI's strategic goals (2018-2020) are:

Promote professionalism and quality in pharmacy (linked to objectives 2 and 4).

Impact through deeper collaboration and engagement with stakeholders (linked to objectives 2 and 4).

Regulate effectively for better health outcomes and patient safety (linked to objectives 2 and 4).

Build an effective organisation and benchmark performance (linked to objectives 2 and 4).

4. Mutual Commitments: Pharmaceutical Society of Ireland

The PSI has documented its commitments in its Corporate Strategy 2018-2020 and in its annual Service Plans which support the implementation of the Corporate Strategy.

Department of Health

The Department's role is to develop and implement policy in relation to the regulation of pharmacists and pharmacies including the development of pharmacy education and training policy and the professional role of the pharmacist in the healthcare system.

The Department is also responsible for ensuring that the PSI performs its statutory functions under the Pharmacy Act 2007 and other relevant legislation and that it is resourced to perform these

functions. The Department ensures that the statutory body meets all the best practice governance, transparency and accountability requirements.

The Department's role also includes ensuring that the legislative framework in place is fit for purpose and meets the changing needs of the sector.

The Department performs its role by holding three governance meetings with the PSI annually, by processing appointments to the Council and all staff related requests in a timely manner and by managing the drawdown of the Irish Institute of Pharmacy (IIOF) funding. The PSI reports on progress on the agreed Annual Work Programme and the use of the €600,000 of Exchequer funding received from the Department as part-funding for the work of the IIOF. Funding is allocated to the PSI following agreement on a work programme by the HSE and the Department. The Department prioritises good working relationships with the PSI Executive and provides whatever support and assistance is required to assist the PSI in achieving its statutory functions.

The Pharmacy Act 2007 includes the following:

- Minister may assign new functions to the PSI;
- Minister appoints Council members and has powers to remove Council members;
- Appointments, remuneration and allowances, terms and conditions and superannuation are subject to the Minister's approval;
- Fees levied by the PSI are subject to the Minister's approval;
- Power to borrow is subject to the Minister's approval;
- Minister's consent is required for the Code of Conduct for pharmacists;
- Annual Report and Accounts must be submitted to the Minister no later than 3 months after end of financial year;
- PSI provides an annual service plan and corporate strategy.

5. Inputs: The following Resources are available to the PSI.

PSI funding

The PSI is funded by a fees system which is approved by the Minister for Health. In 2017 total income from fees was €6,629,301.

The PSI is also in receipt of €600,000 exchequer funding as part-funding for the work of the IIOF.

PSI Staffing

The PSI currently employs 42 staff.

The PSI has indicated that it will be submitting a detailed staffing proposal outlining their staffing requirements up to and including 2020.

The PSI's Annual Report and Financial Statements provide additional information and are available on the PSI website: <http://www.thepsi.ie/tns/Publications/Publications.aspx>

6. Performance/Service Levels and Performance Measurement:

Section One –High Level Goals and Objectives

In the PSI's Corporate Strategy, high level goals and objectives that are aligned with the Department of Health's remit with regard to patient safety include the following:

- The PSI will partner with relevant statutory agencies within the health system to support them in adopting the recommendations of the Future Pharmacy Practice Report¹. This includes removing regulatory barriers to necessary innovation in pharmacy practice and utilising our knowledge and research findings to inform policy development and support legislative changes relating to pharmacy and healthcare reform into the future. (Timeline 2018-2020)
- Designing, through collaboration with pharmacists and other stakeholders, new types of standards (incorporating learnings from complaints and fitness to practice reports) which will support practitioners who are committed to best professional practice and the delivery of best outcomes for the public. (Timeline 2018-2020)
- Engaging with our educational partners and other healthcare regulators to ensure that pharmacists' education standards and any new practice standards, including our Core Competency Framework, evolve in line with changing needs of the public and the expanding role of pharmacy. This includes encouraging a greater focus on interprofessional learning within undergraduate and postgraduate education as a proven way of ensuring that patients benefit from integrated care and better health outcomes. (Timeline 2018-2020)
- Managing and supporting the challenges arising from the Brexit process, as they relate to the PSI's remit, including the recognition of UK-gained qualifications, free movement considerations in the context of availability of pharmacist manpower, and practical patient issues including medicine availability and the facilitation of cross-border healthcare. (Timeline 2018-2020)
- Reviewing whether governance and management structures within retail pharmacy businesses are working to protect the public, and defining, with stakeholders, the high standards of leadership and accountability that must be practised by those holding key governance positions. This accountability framework will apply to supervising and superintendent pharmacists as well as those responsible for the overall governance of pharmacy businesses, e.g., the senior management and the boards of corporate entities. (Timeline 2018-2020)
- Engaging with stakeholders in a strategic review of the future of the Irish Institute of Pharmacy to ensure that its longer-term mission is clear and that its structure, governance and financing is on a secure and stable footing. (Timeline 2018-2019)
- Publishing an updated Code of Conduct for pharmacists and engaging with the profession to highlight the ethical expectations of the Code and to ensure its guiding principles form the basis on which pharmacy is practised into the future. (Timeline 2018)
- Communicating widely and working extensively with stakeholders – the Department of Health, government agencies, regulators and our registrants – to promote mutual learning,

¹ Pharmaceutical Society of Ireland. Future Pharmacy Practice in Ireland - Meeting Patients' Needs. 2016. Available at: <http://bit.ly/FuturePharmacyPSI>

to co-design regulatory improvements and to exchange information that informs both our work and wider health policy development. (Timeline 2018-2020)

- Recognising that the current Pharmacy Act was passed in 2007, the PSI will work with the Department of Health and other stakeholders in the pharmacy sector to advance a regulatory reform programme across the primary and secondary legislation. This will include proposals to streamline requirements which create regulatory burden without addressing safety and to replace these with provisions which will support the PSI in taking a risk-led approach to the regulation of pharmacists and pharmacy businesses. (Timeline 2018-2020)
- Developing outcomes-based, responsive, targeted and proportionate regulatory approaches which are designed to assess the true quality of pharmacy practice and services and which assure the public that these services can be trusted. This includes developing the PSI's Pharmacy Assessment System further as a positive driver for quality improvement within pharmacy businesses. (Timeline 2018-2020)
- Reviewing how effective the PSI's current approaches are in identifying and responding to key safety issues and facilitating the development of new and inclusive safety collaboratives to address these areas of risk. (Timeline 2019-2020)

Section Two – Key Outputs

Key outcomes relating to the implementation of the objectives outlined above include:

- The potential contribution of pharmacy practice is informed through our research and knowledge and valued by policy makers and commissioners of services as a key enabler of better health outcomes for the public.
- Change and innovation within pharmacy services is facilitated by the PSI through new initiatives in standards development.
- Education, training and CPD processes are in place that are effectively contributing to, and underpinning, good professional practice and ongoing learning.
- Changes relating to the PSI's functions that arise out of the Brexit process are managed so as to minimise the impact on pharmacy services in Ireland.
- A revised Code of Conduct is published with its key changes and intent clearly communicated to all registrants.
- Pharmacies demonstrate good governance and are delivering care and services that are reliable, safe and effective.
- There is increased public awareness and understanding of the PSI's role and of how the pharmacy regulatory system in Ireland protects the public, assures trust and supports professionalism.
- The PSI is a force for positive change and for collaboration and learning within the pharmacy sector as well as being seen as an efficient regulator which operates to high standards of openness and accountability.
- A programme of reform is commenced to address changes to the PSI's primary and secondary legislation, to allow for more meaningful regulation that is focussed on patient outcomes and key risk areas.
- The regulatory model is recognised as being effective, proportionate, streamlined and one which assesses key outcome areas which underpin trust in pharmacy.
- Robust and streamlined registration and fitness processes are in operation, which ensure registered pharmacists and pharmacies are safe and that timely action is taken to address deficits.
- Pharmacies are experiencing the benefits of risk-based pharmacy regulation that is up-to-date, transparent, highlights outcomes achievement and targets those who consistently fail to meet clear standards of quality and performance.
- Better information is available to the public and to pharmacies about the standard of pharmacy services in Ireland and there is greater assurance as to the safety and reliability of those services.

7. Potential Risk Factors

The risks to achieving the high-level goals and objectives are documented in the Principal Risks and Uncertainties section of the PSI's Annual Reports <http://www.thepsi.ie/tns/Publications/Publications.aspx>

8. Performance Management

(See section 6)

9. Flexibility and Amendment of Targets

If due to unforeseen circumstances it becomes necessary to alter the contents of this agreement and/or the timelines, the Department will engage with the PSI to agree amended targets.

10. Monitoring Arrangements

This Agreement will be a standing item on the agenda of the governance meetings between the Department and the PSI.

The PSI's Annual Report to the Minister will reference this performance delivery agreement

11. Duration and Signatories to the Agreement

This agreement covers the period January 2018 to December 2020 (3 years)

Eugene Lennon
Principal Officer
Medicines, Controlled Drugs and Pharmacy Legislation Unit

Date

Niall Byrne
Registrar and Chief Officer
Pharmaceutical Society of Ireland

Date

Oversight agreement between the Department of Health and the Pharmaceutical Society of Ireland (PSI).

This agreement defines the terms of the relationship between the PSI with the Minister for Health/Department of Health.

Section One-Legal Framework:

Please provide information on the legal framework of the State Body:

The [Pharmacy Act 2007 \(the Act\)](#) is the establishing legislation of the Pharmaceutical Society of Ireland.

Section Two-Environment in which body operates:

Commercial Body Non-commercial Body Regulatory Body *

Section Three-Purpose and Responsibilities of the State Body:

The PSI, is an independent statutory body established under the Act, and is the pharmacy regulator in Ireland.

The principal function of the PSI is to regulate the profession and practice of pharmacy having regard to the need to protect, maintain and promote the health, safety and wellbeing of the public.

The PSI has responsibility for regulating the professional practice of circa 5,600 pharmacists, 380 pharmaceutical assistants and 1,900 pharmacies.

The Act sets out the principal functions and duties of the PSI. The principal areas of responsibility of the PSI include:

- Statutory registration of pharmacists, pharmaceutical assistants and pharmacies;
- Accreditation of educational programmes for the pharmacy profession at different levels, and standards for continued professional development and training;
- Quality assurance of standards, and the development of pharmacy practice;
- Inspection of pharmacies and enforcement of medicines and pharmacy legislation, including the taking of prosecutions;
- Receiving complaints about pharmacists and pharmacies, operating the statutory fitness-to-practise processes and imposing sanctions on pharmacists.

The PSI is governed by a 21-member Council established under Section 10 of the Act with a non-pharmacist majority. Nine pharmacist members of the Council are elected by the profession and all members of the Council are appointed by the Minister for Health.

Section Four-the State Body should outline here the level of compliance with the Code:

In August 2017 the PSI carried out a review of compliance with the Code of Practice for the Governance of State Bodies. Areas of non-compliance and partial compliance are outlined below:

Non-Compliance:

Section 1.4 Reporting Requirements under the Business and Financial Reporting Requirements

(ix) Pension Liabilities: The standard conventions setting out how public service superannuation liabilities are reflected should be followed in all cases.

PSI Explanation: FRS 102 is not being applied pending confirmation from the Department of Health on the funding mechanism for 'The Pharmaceutical Society of Ireland Scheme 2016'. PSI has fully communicated in this regard with the Department. In our 2016 Annual Report and Financial Statements we disclosed as part of the Report from the President that we were not in compliance in relation to the pension liability, which was also disclosed in the Financial Statements.

Partial Compliance:

Section 1 Role of the Board

1.9 Expenditure and Performance: *Decision on major items of expenditure should be aligned with medium to long-term strategies so as to ensure that such expenditure is focused on clearly defined objectives and outcomes. A performance measurement system should be put in place to assess the effectiveness/outcome of such expenditure and this should be reported to the Board.*

PSI Explanation The PSI has in place a Corporate Procurement plan, which will inform the development of a value for money (VFM) strategy, which will form a key component of the PSI's Corporate Strategy 2018-2020. The VFM strategy will ensure that expenditure is aligned with the PSI's strategic objectives, both medium and long term, and its outcomes assessed against key performance indicators, and financial targets.

Section Five – details of the Performance Delivery Agreement - See Appendix D p.67 of the Code

The Performance Delivery Agreement is for a period of three years from the date of signing. The Signatories of the Agreement should be the PSI Registrar/Chief Officer and the Principal Officer, Department's Medicines, Controlled Drugs and Pharmacy Legislation Unit.

Section Six – Arrangements for oversight, monitoring and reporting on conformity with the oversight agreement including those actions and areas of expenditure where prior sanction from the Department of Health and/or Department of Public, Expenditure and Reform is required.

*Three governance meetings yearly. Annual return submitted in relation to compliance with the Code of Practice for the Governance of State Bodies.

Returns made by PSI are as follows per National HR

Disability Returns: The Department of Health is obliged to collect and report data on the number and proportion of employees with disabilities in the organisation each year. Each public body under the aegis of the Department, the Pharmaceutical Society of Ireland included, are required to complete a Statutory Report forms issued by the National Disability Authority each year also. The NDA submit the returns to the National HR Unit and in turn we send out to all agencies under our remit. This report consists of a Part A which is a Narrative Statement outlining measures taken in order to achieve the statutory minimum of 3% of employees with disabilities in their organisation and a Part B which is an excel spread sheet showing their statistics ie: total number of employees, total number of employees with a disability etc.

Quarterly returns: Each quarter DPER sends a template spread sheet through the National HR unit to be issued to all non-commercial state agencies, PSI included.

The numbers requested are: Actual number of employees, estimated year end number, number of pensioners and number of planned pensioners.

Misc returns: DPER also request miscellaneous returns in relation to staffing terms and conditions on an ad hoc basis.

Irish Institute of Pharmacy

The PSI reports on progress on the agreed Annual Work Programme and the use of the €600,000 of Exchequer funding received from the Department as part-funding for the work of the IIOF. Funding is allocated to the PSI following agreement on a work programme by the HSE and the Department. There are agreed criteria between the Department and the PSI for the drawdown of funding and the PSI has procedures in place for the submission of invoices etc. which are generated for the IIOF by the RCSI (which is the contracted body). The PSI also submits separate annual audited accounts to the Department accounting for the use of the €600k, or the amount actually drawn down in the year. A letter of allocation for each year is issued by the Department and funding is approved only on the basis of the agreed work programme.

Signed: _____ **Principal Officer** **Date:** _____

Line Unit: _____

Signed: _____ **Registrar/Chief Officer** **Date:** _____

Note: Any bodies having derogation from provisions of the Code of Practice for the Governance of State Bodies should have such explanatory notes written into their oversight agreements. Reasons for exemptions should be clearly explained in the oversight agreement.