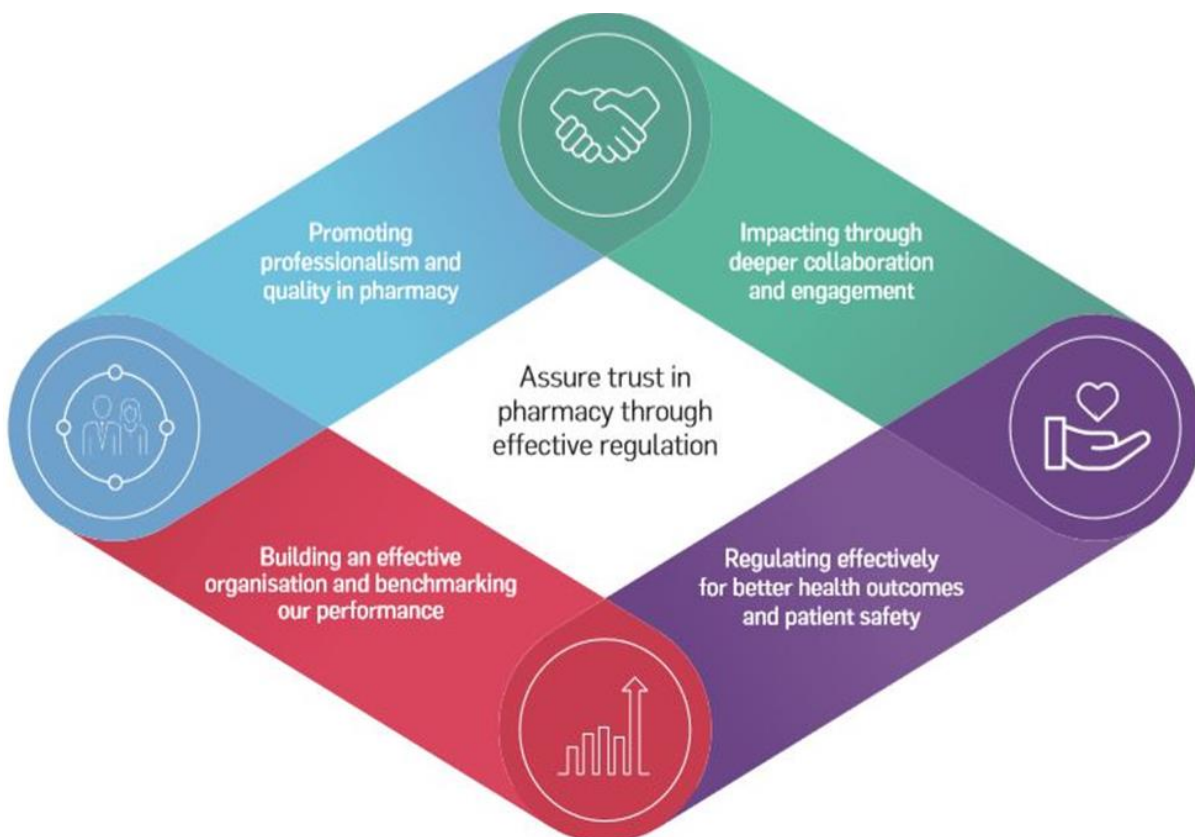


# Report of the Registrar



19<sup>th</sup> September 2019

## Highlights from the Registrar

**Recognition for Excellence:** Subsequent to making our submission for recognition under the EFQM Excellence Model in the week of 17 June, external assessors conducted an assessment visit on 24 and 25 July. Shortly after, we were advised that we had achieved 4-Star Recognition and we were formally presented with our award certificate at an event in PSI House on 12 September. This award marks a significant milestone in the ongoing development of PSI and demonstrates a high level of commitment by all of my colleagues to achieving a high, and externally-validated, level of organisational performance in pursuit of our public-interest mission. I would like to acknowledge the contribution of all involved, particularly the core team, as well as the support of Council over the last three years as we worked to put in place the key measures and improvements to which this award testifies.

**Business transformation:** This process will now commence at an operational following successful conclusion of the detailed and careful procurement process (for discussion by Council on its private agenda on 19 September). I want to pay tribute to the team of PSI colleagues who have worked intensively on this project over the last 18 months. Their focus on the objective and careful attention to detail has been exemplary. Also, thanks go to the external people who have worked with us on the procurement evaluation and as part of the oversight process.

**Service Planning for 2020:** The ELT has commenced the process of developing the Service Plan for 2020. An initial planning workshop was held for managers on 28 August. Further work will be done prior to a discussion with Council at the Development & Planning Day on 24 October. Our Business Transformation will be a major component of the 2020 Service Plan as will work on developing a new Corporate Strategy for the three-year period 2021 to 2023. There will be limited scope for new projects in 2020 other than those which Council agrees to be critical priorities.

**Judicial Review proceedings:** On 15 July, PSI submitted its Statement of Opposition and supporting affidavit in these proceedings. The matter is next before the High Court for mention on 7 October.

### **Key external meetings and events attended since the 20 June Council meeting:**

10 July: I attended a meeting of the Health and Social Care Regulators' Forum.

16 July: Together with our Head of Policy, I attended a meeting with the National Patient Safety Office (Department of Health) to discuss a number of issues including the forthcoming Patient Safety Bill.

25 July: I attended a further meeting of a group of CEOs of regulatory bodies who are interested in working together on the design and implementation of risk-based regulation. A further meeting will take place later in October. We are hoping to cooperate in hosting a seminar in Dublin Castle in November with a number of speakers, including Professor Malcolm Sparrow from Harvard University.

8 August: I attended a meeting at the Medical Council, together with various other stakeholders, to discuss the issue of benzodiazepine supply in Ireland. It was agreed by all present that a further meeting should follow given the significance of this issue for public health and the consensus that there needs to be action to reduce the potential for harm to be caused by these particular medicines.

2 September: Together with the President and our Head of Professional Development & Learning, we hosted a meeting at PSI House with the President and the CEO of the Pharmaceutical Society of Northern Ireland.

10 September: Together with our Head of Governance & Public Affairs, I attended a Brexit stakeholder meeting with the Minister for Health at the Department of Health focussed on preparedness in relation to medicines supply post-Brexit. We updated the Minister and those present on PSI's preparations for Brexit and assured the Minister that PSI is supporting the key public health messaging regarding the importance of there being no stockpiling of medicines.

11 September: Together with our Head of Governance & Public Affairs, I attended our regular Governance Meeting with the Department of Health. The minutes of the previous meeting of 6 June have been uploaded to Council iPads for information, as will the agreed minutes of future meetings.



## 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

- **ePortfolio Review:** A total of 1,382 pharmacists, selected for ePortfolio Review for 2019/2020 period, have been notified of their selection by email from the PSI on 23 July 2019. Pharmacists, who have been selected for ePortfolio review and feel that they have reason to be exempt may make an application to the PSI in accordance with the PSI Extenuating Circumstances Policy.
- **5-year integrated MPharm 4<sup>th</sup> year placements in PSI:** The PSI recently welcomed two Year 4 pharmacy students for their experiential learning placements from 2 September 2019. The students will undertake the 4 months' experience across various departments of the PSI as part of their MPharm qualification. The students are from two of the Schools of Pharmacy and were selected from a pool of student applicants earlier this year.
- **Expression of Interest:** The PSI issued an open public invitation for expressions of interest from suitably qualified individuals to be included in a panel of experts from which nominations to accreditation teams for the review and evaluation of the national pharmacy training programmes (MPharm) would be made. The expression of interest process was open over the month of August 2019. A high level of interest was expressed, with over 40 applications received from experts nationally and internationally. The outcome, to appoint accreditation teams, is an agenda item for the September meeting.
- **Launch and Rollout of the Code of Conduct for Pharmacists:** The launch of the Code is to take place on the 25<sup>th</sup> September 2019 at an event in the Irish Architectural Archive (IAA), 45 Merrion Square, Dublin 2. The revised Code, with a cover letter from the President and Registrar, was posted to all pharmacists at the beginning of September. Engagement roadshows are to begin on the evening of 25<sup>th</sup> September 2019. The dates and locations of all roadshows are shown below - members of Council are very welcome to attend any of these events.

|                     |   |
|---------------------|---|
| <b>Dublin City</b>  | 25 <sup>th</sup> and 26 <sup>th</sup> September |
| <b>North Dublin</b> | 1 October                                       |
| <b>Galway</b>       | 2 October                                       |
| <b>Cork</b>         | 8 October                                       |

|                 |            |
|-----------------|------------|
| <b>Limerick</b> | 9 October  |
| <b>Athlone</b>  | 10 October |

In tandem with hosting these events, members of the PPD and Communications Departments are developing a suite of resources, (including a short video, FAQ tools and an ethical decision-making framework) to support the launch and ongoing understanding and use of the Code. This information will be available with the Code as part of a dedicated page on the PSI website and will form part of the materials used in the continuing roll out of the Code. Further initiatives relating to the Code will be undertaken as part of Service Plan 2020.

- **Governance and Accountability Standards:** The first draft of the Standards has been completed and discussed at the most-recent Standards Advisory Group meeting, held on the 25<sup>th</sup> June. An internal group including members of the Executive Leadership Team is examining the current draft standards and the next iteration will be reviewed at the fourth Standards Advisory Group meeting, scheduled for 22<sup>nd</sup> October 2019.
- **National Patient Safety Conference:** The PSI will again this year be taking a stand at the National Patient Safety conference on 13<sup>th</sup> November 2019, where general information on the PSI will be provided, as well as information on our Regulatory Risk Statement and the updated Code of Conduct. A poster will also be presented on the development of the PSI's Regulatory Risk Statement.
- **High Tech Scheme:** The PSI had a meeting with the HSE to discuss relevant developments in the application of the High Tech Scheme by the HSE. As part of this meeting, required changes to the guidance on [Good Dispensing Practice – High Tech Scheme](#) were discussed as well as other relevant practice issues in this area.
- **Supply of Zantac Liquid to Paediatric Patients:** As part of ongoing activities to mitigate risk in dispensing of this particular medicine, a meeting between PSI and HPRA took place on the 22<sup>nd</sup> July 2019. This meeting discussed the issues surrounding dispensing of Zantac Liquid to paediatric patients. This engagement is in addition to a range of measures undertaken by PSI over the past 12 months, including communication with each of the three Schools of Pharmacy and with the Irish Medication Safety Network (IMSN) as well as publishing [Learnings from Fitness to Practise on Zantac dispensing](#) on the PSI website and newsletter. The PSI intends to engage with specialist prescribers in the near future, to discuss this matter further and explore supplementary mitigation actions that may be taken.
- **Influenza Season 2019/20:** PSI staff met with staff from the National Immunisation Office, the Department of Health and the IPU on the 1<sup>st</sup> August 2019, to discuss HSE plans

for the forthcoming 'flu season and the provision of 'flu vaccines through community pharmacies.

- **Irish Institute of Pharmacy:** The PSI has commenced engagement with stakeholders including IIOP, DoH, HSE Medicines Management Programmes, Acute Hospitals Drugs Management Programme to prioritise and plan for CPD programmes for pharmacists as part of the Workplan 2020 for the Irish Institute of Pharmacy.



## 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

- **CLEAR Annual Education Conference:** Further to the Education Unit's work on interprofessional learning, PSI has been invited, with CORU, to deliver a workshop session at the CLEAR Annual Educational Conference, Minneapolis, on Interprofessional Education Standards for Contemporary Health Delivery. The session will be delivered in conjunction with the Australian Pharmacy Council and the Australian Psychology Accreditation Council.
- **Accreditation Standards for the National Pharmacy Programmes:** A public consultation process on the draft Accreditation Standards for the national pharmacy programmes (MPharm) was held over the month of July. The Education Unit has also held meetings with the Heads of Schools at each of the higher education institutions to gain their input and opinions on the development of the PSI's draft Accreditation Policy to govern the procedures and processes for accreditation of pharmacy programmes. Accreditation policy and standards are agenda items for the September meeting.
- **National Patient Safety Office:** The Registrar and Head of Policy met with the National Patient Safety Office on 16th July to discuss the General scheme of the Patient Safety Bill 2018 which provides for mandatory open disclosure and notifiable patient safety incidents and also the implementation of the National Action Plan on Antimicrobial Resistance 2017-2020.
- **FIP Annual Conference:** PSI has been invited to present at the FIP annual conference at the end of September. The Head of Policy will present on the Report on Future Pharmacy Practice-Meeting Patients' Needs at the session titled *Realising pharmacy's potential: Putting successful plans in place*. Head of Policy will also attend a new FIP Forum of Pharmacy Professional Regulators during the conference.
- **National Data Infrastructure (NDI) Champions' Group:** The PSI's Open Data Officer attended a meeting of the National Data Infrastructure (NDI) Champions' Group, at the Department of the Taoiseach on the 2<sup>nd</sup> of September, to receive an update on workstreams linked to the NDI project from the Central Statistics Office Statistical System Co-ordination Directorate.

- **National Clinical Guideline Development:** The PSI continued to contribute to the HSE Identification, Diagnosis and Treatment of Tobacco Addiction - Clinical Practice Guideline Development Group. This group forms part of the [HSE Tobacco Free Ireland Programme Implementation Plan 2018-2021](#).
- **Presentation to Pharmacy Students:** The PSI provided a presentation at Trinity College to 1st Year pharmacy students as part of their induction week, which gave information on the role of the PSI and Professional Ethics.





## 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

- **Falsified Medicines Directive (FMD)** safety feature requirements came into effect on 9<sup>th</sup> February 2019. Since then the system in Ireland has been in a ‘use and learn’ phase to ensure the continuity of safe supply of medicines to patients while all parties gained a better understanding of the new system.
  - Almost 11.3 million scans of packs of medicines have taken place in Irish pharmacies, hospitals and wholesalers since February and the number of scans is growing weekly.
  - Barcode data for over 180 million packs has been uploaded to the national system by manufacturers. The number of packs bearing 2D barcodes in pharmacies will increase as these packs work their way through the supply chain.
  - Analysis of alerts continues across Europe and initiatives have been taken to reduce the number of alerts. These initiatives are taking effect and the rate of alerts vs scans continues to fall and now stands at 3.5% (down from a high of 20%).
  - The National Safety Features Oversight Group comprising the IMVO, the Department of Health, the Health Products Regulatory Authority (HPRA), the PSI, the HSE and the Private Hospitals Association (PHA) has been closely monitoring progress since the go live date on 9<sup>th</sup> February. Taking all factors into account, the group has decided that the use and learn period will be further extended to allow additional time for the system to stabilise and to ensure that everyone is ready when it becomes mandatory to investigate and close out all alerts before supplying the packs. The use and learn period will end on a phased basis, and a detailed plan as to how this will be done, including dates, will be published at the end of September.
  - This was communicated to all pharmacists and pharmacies on 2<sup>nd</sup> September.
- **Regulatory Risk Statement:** In October 2018, work commenced on the development of a Regulatory Risk Policy Statement, which would set out in clear terms how the PSI defines regulatory risk. Based on this definition, a framework would then be described which shows how PSI identifies, analyses and responds to regulatory risk across all our areas of responsibility. The Regulatory Risk Statement encompasses the full spectrum of regulatory responsibilities held by the PSI, to include the regulation of the education of pharmacists, engagement with CPD, compliance by the pharmacy profession with its Code of Conduct and the ongoing regulation of retail pharmacy businesses in the interests of public safety and quality. The aim of the statement is to help ensure PSI is taking all requisite actions to prevent harm to patients by making pharmacy a safer environment, through effective risk-

based regulation. The Regulatory Risk Statement was reviewed and approved by the Regulatory and Professional Policy Committee on the 5<sup>th</sup> September 2019, with a recommendation that the policy is presented to Council for consideration on the 19<sup>th</sup> September.

- **Hospital Pharmacy Questionnaire:** Seventy hospital pharmacies responded to a questionnaire on the extent and nature of the services provided via each of these RPBs. The data is currently being compiled and assessed.
- **Disciplinary Committees:** Two training sessions for the Disciplinary Committees were run since the last Council meeting. The first was for the Health Committee and Conduct Committee which was held on 19 June. The second was for the Preliminary Proceedings Committee and was held on 27 June.
- **Guide to Sanctioning:** The Guide to Sanctioning is currently under review with a view to updating the current Guide. The matter was considered by the Regulatory & Professional Policy Committee at their meeting on 5 September. Further work will now follow based on helpful feedback received.
- **Legislative Reform:** The PSI previously met with the DoH on 11th June to discuss the outline and rationale for reform of the Pharmacy Act. At the most-recent governance meeting on 11 September, it was agreed that PSI should proceed to scope out the proposed project under three strands; governance, regulation of pharmacies, regulation of pharmacists. A paper will be submitted to the Department with a further meeting on this to follow with PSI by year end.
- **Preparing for Brexit** – In the context of preparing for the imminent departure of the UK from the European Union, PSI, as a public body under the aegis of the Department of Health, has been working to ensure that appropriate preparations are in place to mitigate against any potential challenges arising which are within its remit, ability and function to address and mitigate, including recognition of qualifications. These preparatory actions encompass a spectrum of activities ranging from continued engagement with our UK/NI counterparts, continued engagement and activities within the health sector in Ireland and review of our regulatory mechanisms in respect of recognition to ensure that processes are proportionate, effective and risk-based, and take account of our remit in patient protection and safety.



## 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

- In line with good governance principles, including the Code of Practice for the Governance of State Bodies, Council members completed an independently-conducted self-assessment of its performance and operation during the summer period, with a report made available to Council members for consideration at its September meeting.
- Following the implementation of the reformed Advisory Committee structure from January 2019, it was agreed by Council to assess the operation and effectiveness of the Committees and their terms of reference before year end 2019. That discussion will be facilitated at the Council's Development and Planning Day in October.
- ICT Security:
  - Roll-out of the PSI ICT Security User Manual for staff is now complete with 2-part authentication to be put in place before end of October. In conjunction with the new security policies, mandatory online ICT security user awareness training has been established for all staff (initial training plus annual refresher training). Simulated phishing attacks have been carried out to measure baseline level and will continue to be administered.
  - A new ICT Security User Manual is in development for Council and Committee members to complete the PSI's information security management system (ISMS). This ISMS, which is mapped to ISO 27001, is a framework of policies and procedures that includes all legal, physical and technical controls involved in the PSI's information risk management processes. The principles of this risk management and assurance framework will be discussed with Council at its October development session.
- Recruitment for the following sanctioned posts is as follows:
  - Education Standards Officer commenced on 8 July
  - Business Analyst commenced on 12 August
  - Business Transformation Project Manager – start-date of 7 October confirmed
  - Regulatory Project Pharmacists (maternity leave cover posts x 2) commenced on 4 September
- The Business Transformation Programme procurement process is almost complete. A recommendation regarding a 'preferred bidder' is being brought to Council today.

Internal preparations are in train, i.e., planning, communication, resource allocation etc. to ensure the PSI is ready to commence delivery of the programme in October 2019.

- A proposal to invest in organisational development support to underpin transformation will be brought to Council at its 19 December meeting.
- The General Pharmaceutical Council in the UK kindly demonstrated their online pharmacist registration portal to the PSI in July. The demonstration outlined the potential benefits to the PSI with regards to the online experience - something which is a key deliverable under our Business Transformation Programme.

- Update on current procurement activity for contract values in excess of €25K:

| Services / Goods to be procured        | Current Status   |
|--|--|
| <b>Digital Transformation Services</b> | Competitive Dialogue process utilised - The Invitation to Tender process has now concluded and a recommendation from the Registrar will be put to the Council for approval. CONCLUDING |
| <b>Merchant Services</b>               | OGP Framework drawdown - process has concluded, new contract in place, technology tested and operating with the PSI now realising the benefit in the reduced fees. COMPLETE            |
| <b>PCs/ Laptops/Tablet devices</b>     | OGP Framework drawdown - procurement stage concluded and contract in place with new laptop deployment in train. COMPLETE   |
| <b>Specialist Surveyors</b>            | Restricted Procedure utilised – Pre-Qualification Questionnaire phase completed. ITT to be published in September 2019.  |
| <b>Facilities Management</b>           | PQQ phase completed and ITT phase currently in progress. Closing date for tender responses is 30 September 2019.   |
| <b>Website Development &amp; Build</b> | Restricted Procedure to be utilised on eTenders with the Pre-Qualifying Questionnaire in preparation for publication in September.   |

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 6 September 2019)

#### Concerns

|  |     |
|--|-----|
| Total concerns received in 2019                            | 102 |
| New concerns received since last report date (7 June 2019) | 44  |
| Concerns reviewed since last report date (7 June 2019)     | 59  |
| Open concerns  | 15  |

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

|   |      |
|---|------|
| Total complaints received in 2019                                 | 55   |
| New complaints received since last report date (7 June 2019)      | 19   |
| Open complaints   | 39*  |
| Complaints considered by PPC since last report date (7 June 2019) | 24** |

\* This figure may include complaints received prior to 2019 which are still being processed

\*\* 92% 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                                     | 7*  |
| Inquiries opened to date but adjourned / not completed | 2   |
| Heard since last report (7 June 2019)                  | 3   |
| Cases being investigated/prepared for hearing          | 25* |

\* 85% of which met KPI for the Inquiry to be held within 2 years from when the complaint was received.

\*\* (21 – PCC & 4 - Health Committee)

#### Mediation

|  |   |
|--|---|
| Heard year to date                         | 1 |
| Heard since last report date (7 June 2019) | 0 |
| Cases being prepared for mediation         | 2 |

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

|   |     |
|---|-----|
| Heard year to date: sanction hearings                     | 7** |
| Sanction hearings/undertakings being prepared for Council | 4   |

\* This is reported on a per respondent basis.

\*\* One of these cases involved an Inquiry which was held in 2018.

### High Court Sanction Confirmation Hearings\*

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

\* This figure is reported on a per respondent basis.

### Call-Overs and Other Applications Before Committees of Inquiry

|                                       |   |
|---------------------------------------|---|
| Callovers heard year to date          | 3 |
| Since last report (7 June 2019)       | 1 |
| Section 44 Applications (Withdrawals) | 1 |

### Prosecutions

|                          |    |
|--------------------------|----|
| Disposed of year to date | 1* |
|--------------------------|----|

\* Proceeding were commenced in 2018 however the case was withdrawn by Registrar at the District Court on foot of action taken by pharmacist Defendant in February 2019.

### Suspension Applications

|                    |   |
|--------------------|---|
| Heard year to date | 0 |
|--------------------|---|

### Professional Registration (figures as at 6 September 2019)

- 1 alert has been issued to date this year 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.
- 12 EPCs for establishment of service have been received (new European route of entry to recognition and registration) – 11 EPCs have been granted, and 1 is in process.
- 45 Certificates of Current Professional Status have been issued to date.
- 19 Restoration applications have been processed to date.
- 81 Voluntary Cancellation applications and 19 Involuntary Cancellations have been processed since 1<sup>st</sup> January 2019.
- 8 EU/TCQR Registration meetings held to date this year.
- 19 Third Country Qualification Recognition applications received to date this year, with an additional 51 applications in process.
- 3 TCQR registration application processed to date this year.
- 122 EU recognition/registration applications processed to date this year.
- 6 National route applications processed to date this year

## Regulation of Retail Pharmacy Businesses

| <b>Registration of Retail Pharmacy Businesses (as at 6 September 2019)</b> |       |
|--|-------|
| Number of Registered Retail Pharmacy Businesses                            | 1,952 |
| Number of Retail Pharmacy Businesses Registered in 2019                    | 177   |
| Number of Retail Pharmacy Businesses Cancelled in 2019                     | 170   |
| Number of Changes in Supervising and Superintendent Pharmacists in 2019    | 439   |

| <b>Internet Supply (as at 6 September 2019)</b> |    |
|---|----|
| Number of Pharmacies on Part A                  | 50 |
| Number of Non-Pharmacies on Part B              | 79 |

| <b>Inspection Activity 2019 (year to date, as at 6 September 2019)</b>                                |     |
|---|-----|
| Total number of Inspections   | 169 |
| Number of Registration-related Inspections  | 83  |
| Number of pharmacy inspections  | 76  |
| - Systems   | 3   |
| - Risk-based Inspections  | 58  |
| - Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) | 15  |

| <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 |
| 21   | 2   | 1  |
| Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i> |   | 3  |