

PSI Council Bulletin July 2008

Consultation Process on Implementation of Pharmacy Act 2007

- In line with our statutory obligations to inform key stakeholders of the impact of legislative changes, a series of information briefings around the country by the Standards and Practice (S&P) Unit successfully concluded with four meetings in Dublin in the first week of July. In all, 20 briefings were held at locations nationwide, with very high attendance rates, and the feedback from the attending pharmacy owners and supervising pharmacists has been generally positive and encouraging.
- In particular, the Pharmacy Practice Guidance Manual has been extremely well received. Through these meetings, the Guidance Manual has been distributed to all attendees and the final statistics from the Roadshow are currently being compiled and will be circulated on completion.
- All individual pharmacies not represented at the sessions are now being contacted by letter and the Guidance Manual, along with the presentation slides from the briefing sessions and the draft statutory rules for registration of Retail Pharmacy Businesses, are being distributed to these pharmacies.
- The Pharmacy Practice Guidance Manual was launched to the public at a press briefing in Buswell's Hotel, Dublin on 10 July. The PSI was represented at the event by the Registrar and the Chair of the S&P Committee Noeleen Harvey. Damhnait Gaughan from the S&P Unit gave a presentation outlining the content and context of the Guidance Manual, as well as the non-compliance issues raised during the briefing sessions around the country.
- The Guidance Manual is also being distributed to other key stakeholder groups, including patient support and representative organisations and pre-registration pharmacy students.
- The development of statutory rules in advance of commencement of the next phase of the Act is progressing and the development of PSI statutory rules has now advanced to the drafting stage. Once these initial drafts are available, they will be circulated to Council for comment and then will go for public consultation. It is expected that the public consultation will take place at the

end of Aug / early Sept with a view to the Rules being ready for signing by the Minister at the end of Sept. The draft Code of Conduct will also go for public consultation around that time.

Pharmacy Ireland 2020

- The 'next steps' in the Pharmacy Ireland 2020 (PI2020) initiative, following on from the publication of the Interim Report, are being progressed. Submissions will continue to be accepted for the next couple of months, and a number of submissions have been received since the publication of the Interim Report, including one from the Dublin Academic Teaching Hospitals.
- The first in a series of focus group meetings, facilitated by Cathriona Hallahan, took place on 22 July at 18 Shrewsbury Road, and was attended by representatives from a number of patient and consumer support and representative bodies. The turnout and level of engagement at the meeting was very positive, both in terms of contributing to the PI2020 process, but also from the point of view of establishing and building relationships with these key stakeholders. There are a number of further focus group meetings planned for the next couple of months.
- Due to government business, the Minister's planned visit to Scotland to look at pharmacy services over there has been postponed to mid-September. The Office will continue to liaise with Department officials on this matter.

President's Report

- The President and Registrar had a high level meeting with their counterparts in the Pharmaceutical Society of Northern Ireland (PSNI) on 8 July in Belfast. Following on from the signing of a co-operation agreement at last year's Summit, further co-operation and assistance on a number of issues, including formal sharing of learning on regulatory matters, was discussed at the meeting. The President was very pleased with the reception in Belfast and it is planned to hold a further meeting in Dublin later this year. In addition, the PSNI President Raymond Anderson, was invited to attend this year's PSI National Pharmacy Summit.
- The President and Registrar attended a meeting with Minister Harney and senior officials from the Department of Health and Children on 14 July. A number of matters relating to patient safety, as well as the implementation of further provisions of the Pharmacy Act, were discussed.
- The President and Registrar held a brief meeting and photo-call at Leinster House with the Minister for Arts, Sport and Tourism Martin Cullen on 15 July. The President secured the Minister's strong personal support for a bid to bring a future Congress of the International Pharmaceutical Federation (FIP) to Dublin. The annual FIP Congress typically attracts at least

3,000 delegates and would be a significant economic boon to the city. The direct involvement and support of Minister Cullen, as well as the support already expressed by the Minister for Health and her Department, will be vital to the success of the bid.

- The President and Registrar met with the Minister for Agriculture, Fisheries and Food, Brendan Smith on 16 July. A number of long-standing issues relating to veterinary medicines were discussed at the meeting, and the President and Minister agreed that a small working group, involving the PSI and senior department officials, would meet to resolve these issues.
- The President and Registrar met with the President and Secretary General of the IPU on 16 July and the two Presidents congratulated each other on their respective elections. A number of matters of mutual concern, including the next phase of implementation of the Pharmacy Act, were discussed. The President assured the IPU delegation that the PSI would continue to engage in further consultation and information processes with the IPU and its members as the implementation progresses.

Meetings

- A bi-lateral meeting between the PSI and IMB was held on 16 June to discuss matters of mutual concern. Enhanced co-operation on a number of medicine and patient safety issues was agreed at the meeting, and a Memorandum of Understanding between the two regulators is currently being drafted, led by Dr Cheryl Stokes from the PSI and Mr John Lynch, Director of Compliance at the IMB.
- A subsequent meeting was held between Dr Cheryl Stokes and Kate O'Flaherty from the PSI with Dr Joan Gilvarry, Director of Human Medicines at the IMB and colleagues, to progress co-operation on matters relating to communication and patient safety. As a result of this meeting, reciprocal links on the two bodies' respective websites have been established.
- At a meeting of the Regulator's Forum of CEOs of health regulators on 24 June, attended by the Registrar, a number of working parties were established to enhance co-operation between the various healthcare regulatory bodies. A number of PSI staff have been nominated to the various working parties, which will be led by CEOs of the regulators, and which will cover Public Consultation, Patient & Lay Involvement, Codes of Conduct and Inspection and Accreditation. The PSI Registrar will lead the Inspection and Accreditation working party. The Regulators Forum is also to discuss Protective Disclosure and associated matters with the Department of Health and Children. The PSI will host the next Regulators Forum meeting in September.
- PSI Head of Legal Affairs, Marita Kinsella, attended a meeting of the Health Professionals Crossing Borders (HPCB) initiative in the Hague on 30 June, which was hosted by the Dutch Ministry of Health. The purpose of the meeting was to consider and commence

implementation of the regulatory actions set out in the HPCB Portugal Agreement. Over 60 delegates from 19 European countries attended the meeting. The main outcomes of the meeting were as follows: (a) while there is a diverse approach to regulation in Europe, the regulation of qualifications should go hand in hand with continued performance enhancement and assurance of current competence; (b) a consistent approach to assessment and registration of non-EEA graduates is needed across Europe.

- The Chair of the Professional Development & Learning Committee, Dr. Paul Gallagher, and the Head of Education & Registration, Lorraine Horgan, attended the European Association of Faculties of Pharmacy – 2008 Annual Conference in Lille, 12-14 June. The conference theme this year was ‘New issues in Pharmacy Education’ and presentations included an overview of the impact of the Bologna process on the sectoral professions, innovative approaches to patient care and pharmaceutical care delivery and an overview of practitioner development pathways.
- Dr Gallagher and Lorraine Horgan also attended the *Professional lifelong learning - Critical perspectives on CPD* conference at the University of Leeds on 24 June. The PSI’s Head of Education & Registration Lorraine Horgan presented a paper entitled ‘*Re-imaging CPD within the emerging paradigm of learning*’ which is based on her ongoing doctoral research. (See <http://www.leeds.ac.uk/medicine/meu/lifelong08/index.html> for further information.)
- Chair of Chairs, Cathriona Hallahan organised a briefing for PSI staff and Council members, in particular the Committee Chairs, at the National Productivity Centre (NPC) on 19 June. The session at the NPC included a briefing on the importance of factors such as management capability, ICT use and innovation in maximising productivity and improving organisation performance. Those who attended the session felt it was very beneficial and thought-provoking and thanks are extended to Cathriona for organising the session.

Registration Matters

- A Tutor Pharmacist Course was held at the Institute of Public Administration on 4-5 June and was attended by 12 pharmacists.
- 2007/08 Pre-Registration Training Year: The second pre-registration year assessment was held on 7 June at the RCSI. 143 students sat the assessment and all candidates were successful.
- 2008/09 Pre-Registration Training Year: 164 applications had been received by the PSI as at 23 June 2008 from pharmacy graduates wishing to undertake the 2008/09 practical training year. Figures provided by the Schools of Pharmacy in late June indicate that there are no more than 11 of the eligible graduates who have still to secure a training placement.
- Registration of pharmacies: All owners who had so far failed to return Statement of Return forms were contacted with final reminders in early July, and all have given an undertaking to have these

forms returned to the PSI week beginning 14 July 2008. There are currently (as of 24 July) a total of 5 (five) SORs outstanding. This situation is unacceptable at this stage of the year and the Registrar will brief Council further on this issue at the October meeting. The total number of pharmacies notified to the PSI as of 30th June, 2008 was 1657 (1586 community pharmacies and 71 hospital pharmacies). From January 1st to June 30th, 2008, 21 new community pharmacies have been notified and fully registered with the PSI and a further 12 pharmacy openings, notified in 2008, are currently pending. The total number of transfers of pharmacy ownership notified to the PSI from January to June 2008, was 14 at June 30th.

- Registration of pharmacists: The total number of registered pharmacists as at 4 July 2008 was 4,625 (compared with 4,504 at 31 December 2007).

Reviews of pharmacy education and accreditation

- With the contractual arrangements underpinning this project close to finalisation, invitations have been issued to a number of people to participate in the Project Steering Group with a view to holding its first meeting with the team from Aston University week beginning 28 July. The purpose of this group is to monitor progress of the project and to ensure compliance with the stated objectives on behalf of the PSI. A high-level Policy Steering Committee will also be established to oversee the projects and give guidance to the reviewers from a more general policy perspective. The policy committee will be comprised of many of the stakeholders involved in pharmacy education and training in Ireland. The review of the pre-registration training year will form part of the initial work package with self-completion questionnaires and focus groups to be carried out over the coming months.

ICT project progress report

- The ICT project, led by Tony Reilly, has practically completed the development of the public online register of pharmacists in accordance with the legislation, and this is expected to go 'live' during August.
- The system for the registration of retail pharmacy businesses is being developed and is planned for completion in September.
- Facilities to enable pharmacists and pharmacies to update their information and pay their renewal fees over the Internet are also being developed and will be available later this year.
- The next priority is to progress the linking of the various databases of registration, complaints, inspection systems to facilitate tracking of pharmacists and pharmacies between units in the PSI.
- The data clean-up in relation to the dates of birth of pharmacist registrants is almost complete, which will allow an accurate age profiling of registrants to be carried out.

Governance Matters

- Dr Cheryl Stokes is progressing the development of a Corporate Governance Framework for the PSI, in conjunction with the IPA. This framework includes reviewing the current Committee structure, performing a risk assessment and risk register, in conjunction with the internal auditors, and a review of the management and effectiveness of Council meetings.
- PricewaterhouseCoopers have been awarded the tender to undertake the development of processes and procedures within the PSI, and the process mapping project began on 3 July. This will involve the preparation of process and procedures documentation for a number of function areas and the devising of a high level road map for the development of ICT systems to underpin these processes. The project is expected to take three months to complete.
- The 2008 Service Plan implementation is on target and many Committee and project groups will continue to work and meeting during the holiday month of August.

PSI in the media

- The election of the President was widely covered in pharmacy media, as well as local media in the South-East.
- An interview with the President was published in the Irish Medical Times (25.07.08) under the headline 'Pharmacy watchdog gets more bite'. An interview with the President for the Irish Times Health Supplement is expected to be published shortly.
- The launch of the Pharmacy Practice Guidance Manual was widely covered by national and local media, including (to date) the Irish Independent, Irish Examiner, Irish Daily Mirror. The Registrar was interviewed by local radio MWR in Mayo following the launch.
- The following letter from PSI Registrar Dr Ambrose McLoughlin was published in the Pharmaceutical Journal (the official journal of the Royal Pharmaceutical Society of Great Britain), issue 5 July 2008, regarding the clarification of an incorrect interpretation of the Pharmacy Act 2007 reported in an earlier issue of the PJ.

Clarification on Irish Pharmacy Act 2007 and language competency

In a debate on English language competency requirements for pharmacist registration (*PJ*, 14 June, p.732), it was incorrectly stated that Irish Pharmacy Act 2007 allowed the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, to "test registrants' linguistic competence before they could practise in any way that entailed dealing directly with the public".

Section 14 of the Pharmacy Act 2007 sets out the procedures and criteria which apply to pharmacists seeking to be registered in Ireland, both on the first occasion and annually thereafter. The Act does not provide for the blanket language-testing of all European Economic Area registrants. Instead, it requires EEA nationals who lack the linguistic competence necessary to be a registered pharmacist in Ireland to give an undertaking to acquire the necessary competence, and where an EEA national gives this undertaking, the PSI has the power to impose a condition on their registration mandating that they acquire the necessary linguistic competence. In addition, in the draft Regulations governing pharmacy premises and practice standards which

are in development by the Irish Department of Health and Children at present, the PSI understands that an obligation will be placed on pharmacy owners and superintendent pharmacists to be satisfied that all pharmacists and other staff employed or engaged have the necessary language skills.

It is therefore the responsibility of all parties, i.e. the PSI as regulator, the pharmacist seeking to be registered, the pharmacy owner and employer, and the superintendent pharmacist, to ensure that pharmacists have the language competence necessary to provide safe and effective care to patients. It is the PSI's view that this is in line with the obligations of the Professional Qualifications Directive, which requires that EEA pharmacists benefiting from the recognition of their pharmacist qualifications shall have a knowledge of the languages necessary for practising as a pharmacist in Ireland.

- The decision to tender for estate agents to advise on the disposal of the assets was reported in the Irish Times and the Irish Medical Times.

Next Meetings

- The next scheduled Council meeting will be held on Tuesday, 7 October in NUI Galway. As part of the consultative process following the Pharmacy Act, there will be a two guest speaker to address Council and invited guests, as at earlier meetings this year. These will be Professor Keith Wilson, Head of the School of Pharmacy at Aston University, and Dr Mary Keys of NUI Galway Law Faculty, who is also a public representative appointment to the Mental Health Commission.
- The annual National Pharmacy Summit will be held on Tuesday 4 November in the Royal Hospital Kilmainham, Dublin. The Minister for Health and Children has been invited and indicated she was happy to accept the invitation. It is expected that official receipt of the new PSI Seal will be marked by a ceremony at the Summit with the Minister. Further details of the day's agenda will be in the next Bulletin.