



IRISH
PHARMACY
UNION

The voice of community pharmacy

ANNUAL REPORT OF IPU EXECUTIVE COMMITTEE 2013



2013 AGM IPU & AGM IPU Services Ltd

Friday 26 and Sunday 28 April 2013
(confined to paid up members of the IPU)

Chairman: Mr Rory O'Donnell, President

Agenda

Friday 26 April

- 17.45**
1. Welcome
 2. One minute's silence in memory of pharmacists who died since the 2012 AGM
 3. Minutes of 2012 AGM
 4. **Financial Report and Accounts 2012**
 - a. Adoption of Audited Statement of Accounts
 - b. Appointment of Auditors
 - c. Union Membership Subscriptions
 5. **IPU Services Ltd, AGM**
Minutes of 2012 AGM
Financial Statements 2012
 - a. Adoption of Directors' Report
 - b. Adoption of Audited Statement of Accounts
 - c. Remuneration of Auditors
 6. **Union Secretariat Report**
 7. **Group Reports / Open Forum: Introduction and Update**
 - a. Pharmacy Contractors' Committee Report
 - b. Community Pharmacy Committee Report
 - c. Employee Pharmacists' Committee Report
 - d. Communications Report
 - e. International Pharmacy Matters
 8. **Open Forum**

20.00 End of First Session

Sunday 28 April

- 12.30**
9. **Report on Motions from 2012 AGM**
 10. **2013 AGM Motions** (Page 8 of Report)
 11. **Open Forum**
- 14.00** Closing of Conference by IPU President, Rory O'Donnell.

Message from the President

I have great pleasure in welcoming you to the third annual IPU National Pharmacy Conference in Carton House. This year's conference builds on the successes of the previous two and promises to be an even bigger and better event than before.

As before, we offer an excellent suite of Continuing Education and Business topics, with the opportunity to meet up with colleagues and to catch up on the latest developments in pharmacy. A great amount of credit needs to go to those individuals who put such a wonderful programme of events together.

These continue to be difficult times for our sector and for society in general. The threat of further cuts through FEMPI and the implementation of reference pricing later this year, will significantly test our resolve. With consumer demand remaining subdued, economic uncertainty a constant and business costs remaining high the future for many of us will remain uncertain for the foreseeable future.

An ageing demographic and rising incidences of chronic diseases will increase demands on an already overstretched health service, providing an opportunity for us to position ourselves centrally in the provision of healthcare services to ensure that these services are delivered at the lowest level of complexity.

We support the Government's healthcare strategy 'Future Health: A Strategic Framework for Reform of the Health Service 2012-2015', which sets out a new integrated model of care that treats patients at the lowest level of complexity that is safe, timely, efficient and as close as possible to home. Pharmacists

are ideally placed to play an increased role in healthcare and can deliver additional services such as chronic disease management, health screening, treating minor ailments and medicine use reviews.

The IPU has been extremely active in promoting the sector to all our stakeholders and ensuring that the role of the pharmacist is valued and appreciated. The IPU will continue to engage constructively with Government, other healthcare professionals and with the public to ensure that the potential of our sector is realised and that the future of community pharmacy is secured. We will continue to do everything within our remit to assist the members and ensure that your voice is heard and understood.

We continue to regularly communicate with members through the newsletters, monthly GM, SME text service and Social Media. It is not a one-way process. I would encourage members to get in touch with the IPU and avail of the many great services that are available. From professional and business assistance and training, to the comprehensive Product File, CPD and IPU NET and IPU Academy there are a massive amount of services available for the benefit of members. I would encourage you to avail of these and to also keep us informed of areas of concern that we can address on your behalf.

I would like to take this opportunity to thank Vice-President Kathy Maher, Hon Treasurer John Gleeson and all our hard working committee members who work tirelessly on your behalf. They are ably supported by the dedicated staff in Butterfield House, all of whom remain committed to supporting and assisting all of us. On your behalf, I thank all of them most sincerely for their commitment, dedication and enthusiasm.

Finally, I would like to pay particular thanks to our Secretary General, Séamus Feely, whose dedication and guidance has sustained us all through some of the toughest times our profession has ever faced. I join you in thanking him for his unremitting efforts on behalf of pharmacy, pharmacists and the IPU down the years.

Rory O'Donnell MPSI

The IPU will continue to engage constructively with Government, other healthcare professionals and with the public to ensure that the potential of our sector is realised and that the future of community pharmacy is secured.



Kathy Maher
Vice-President, IPU



John Gleeson
Honorary Treasurer



Rory O'Donnell
President, IPU

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The Financial Statements for the Irish Pharmacy Union and IPU Services Ltd have been circulated to all members of the IPU.

Appendices

I A List of Submissions Made During the Year

All are available on www.ipu.ie.

II Some Key Letters and Responses Received Throughout the Year:

- Financial Emergency Measures in the Public Interest Act 2009 (FEMPI)
- Reference Pricing
- Reductions in the Cost of Medicines
- PSI Matters
- Primary Care Centres
- Pharmacy Vaccination Service
- Benzodiazepines
- PCRS Communications
- Extemporaneous Preparations
- Pradaxa
- ICCPE / Pharmacy Training Grant / Continuing Education
- Driving Licence Photographs
- Other Matters
 - Bankruptcy
 - Switching
 - Directive on Recognition of Professional Qualifications
 - High Tech Medicines
 - National Consumer Agency (NCA) Survey

III A List of Press Releases Issued to the National Media During the Year on Various Matters

IV Letters Published in Newspapers

Executive Committee 2012–2014

President: Rory O'Donnell
Vice-President: Kathy Maher
Honorary Treasurer: John Gleeson

Regional Representatives (8)

Sean Reilly	East
Kathy Maher	North East
Conan Burke	North West
Gerry Guinan	South
Niall Mulligan	South East
Peter McElwee	Midland
Joanne Hynes	West
John Gleeson	Mid West

Community Employee Group (3)

Rebecca Barry
David Carroll
Caitriona O'Riordan

Past President

Darragh O'Loughlin

Co-Options

Ann Marie Horan
John MacNamara

NB: Up to five members may be co-opted by the Executive Committee

Financial Statements

1. Irish Pharmacy Union

Financial Reports and Accounts for Year Ended 31 December 2012

In accordance with the Constitution of the IPU, the Executive Committee submits the audited accounts for consideration by members.

The full details of the Accounts have been circulated to members with the Summary of the 2013 Annual Report of the IPU Executive Committee.

If the Accounts are approved by the meeting after their presentation, members will be asked to formally adopt the Accounts for the year ended 31 December 2012 and agree the election of Auditors. In this context, the following motions will be put to the meeting:

- a. *"That the Executive Committee Report and Audited Statement of Accounts of the Irish Pharmacy Union for the year ended 31 December 2012 as submitted to this meeting, be and are hereby adopted."*
- b. *"That this meeting agrees to the election of Baker Tilly Ryan Glennon for a further year as Auditors for the IPU and IPU Services Ltd."*

2. IPU Services Limited

Financial Reports and Accounts for Year Ended 31 December 2012

At this Annual General Meeting of IPU Services Ltd, members are asked to consider the Report of the Directors and the Auditors' Report on the Accounts for Year Ended 31 December 2012.

The accounts and financial reports have been circulated to all members.

"That the Directors' Report and Audited Statement of Accounts for the year ended 31 December 2012 as submitted to this meeting, be and are hereby adopted."

Report of the 39th Annual General Meeting of the Irish Pharmacy Union and IPU Services Ltd

Radisson Blu Hotel, Galway
27 & 29 April 2012

Friday 27 April - AGM Motions

Present: The President, Mr Darragh O'Loughlin, and 53 members.

In Attendance: Mr Seamus Feely, Mr Jim Curran, Ms Ciara Enright, Ms Aoife Garrigan, Ms Fiona Hannigan, Mr Darren Kelly, Ms Jill Lyons, Ms Wendy McGlashan, Ms Roisin Molloy, Ms Aoibheann Ni Shuilleabháin and Ms Patrice O'Connor.

Apologies: Apologies were received from seven members.

[A full report of the 2012 AGM is available from the IPU offices.]

1. The President welcomed the attendance to the 39th Annual General Meeting of the Irish Pharmacy Union.

2. On the proposal of the President all present stood in silence in memory of deceased members and their families who had died since the 2011 AGM.

3. Report of 2011 AGM
The report of the 38th Annual General Meeting was taken as read and agreed. The report is available on the members' section of www.ipu.ie. The minutes were proposed by Niall Mulligan, seconded by Roy Hogan and unanimously approved by the meeting.

4. Financial Reports and Accounts 2011

a. Kathy Maher (Honorary Treasurer) presented the Union's Financial Report. The Honorary Treasurer drew members' attention to Page 31 of the Annual Report and proceeded to explain changes in income and expenditure in 2011.

Following the presentation, the following motion approving the accounts was proposed by John McNamara, seconded by Shane Howard and carried unanimously:

"That the Executive Committee Report and Audited Statement of Accounts for the Irish Pharmacy Union for the year ended 31 December 2011 as submitted to this meeting be and are hereby adopted."

b. The following motion was proposed by Paul Fahey, seconded by Ann-Marie Horan and carried:

"That this meeting agrees to the election of Baker Tilly Ryan Glennon for a further year as auditors for the IPU and IPU Services Ltd."

c. As subscriptions have been reduced by 38% over the past two years, the Treasurer informed the meeting that the Executive Committee had agreed not to make any change to the annual subscription payable.

5. IPU Services Ltd AGM

The accounts were presented by the Treasurer and on the proposal of Eoghan Hanly, seconded by John Gleeson, it was resolved:

"That the Directors' Report and Audited Statement of Accounts for the year ended 31 December 2011 as submitted to this meeting, be and are hereby adopted."

This motion was carried.

6. Union Secretariat Report

The IPU Secretariat Report was circulated to members by post and was also available on the members' section of the IPU website, www.ipu.ie, prior to the meeting, as part of the Executive Committee report. The Secretary General, Mr Seamus Feely, introduced the Secretariat report.

7. Group Reports

a. Pharmacy Contractors Committee (PCC) Report

This report was introduced by Mr Morgan Power, Chairman of the Pharmacy Contractors' Committee.

The report was circulated to members in advance of the meeting and a more detailed report was published on the members' section of www.ipu.ie.

b. Community Pharmacy Committee (CPC) Report

This report was presented by Mr Bernard Duggan, Chairman of the Community Pharmacy Committee.

The report was circulated to members in advance of the meeting and a more detailed report was published on the members' section of www.ipu.ie.

c. Community Employee (EPC) Report

This report was delivered by Ms Caitriona O'Riordan, Chairperson of the Employee Pharmacists' Committee.

The report was circulated to members in advance of the meeting and a more detailed report was published on the members' section of www.ipu.ie.

d. Public Relations Report

This report was available on the members' section of www.ipu.ie and was taken as read.

e. International Pharmacy Matters

This report was available on the members' section of www.ipu.ie and was taken as read.

8. Open Forum

This report was available on the members' section of www.ipu.ie and was taken as read.

Sunday 29 April - AGM Motions

- Present:** The President, Mr Darragh O'Loughlin, and 57 members.
- In Attendance:** Mr Seamus Feely, Mr Jim Curran, Ms Aoife Garrigan, Ms Fiona Hannigan, Mr Darren Kelly, Ms Jill Lyons, Ms Wendy McGlashan, Ms Roisin Molloy, Ms Aoibheann Ní Shúilleabháin and Ms Patrice O'Connor.
- Apologies:** Apologies were received from seven members.

9. Report on Motions from 2011 AGM

The report on motions from the 38th Annual General Meeting was taken as read and agreed.

10. 2012 AGM Motions

The 2012 Motions and actions taken on them are on Pages 8 to 9 of this report. All motions were debated and considered by the meeting and then passed.

11. Open Forum

This report was available on the members' section of www.ipu.ie and was taken as read.

The President thanked his colleagues for attending the IPU AGM and reminded them that the Panel Discussion would begin shortly.

The President then closed the 39th Annual General Meeting of the Irish Pharmacy Union.

2012 AGM Motions and Report on Action Taken

The following motions, proposed in accordance with Article 29 of the Constitution, were brought before the 2012 AGM for consideration:

1. Proposed: **Morgan Power**
Seconded: **Brian Walsh**

“That this AGM calls on the Minister to:

- *Reverse the decision to reduce the reimbursable price of fridge items;*
- *Increase the low level dispensing fees currently paid to contractors;*
- *Review the reimbursement price of medicines to pharmacists;*
- *Review the current level of remuneration for new Services; and*
- *Put a proper negotiation system in place to review such matters.”*

Action: The IPU made a submission and a presentation to the FEMPI Review in May 2012 and again in January 2013. The IPU took these opportunities to request a complete review of pharmacy payments.

The IPU highlighted to the Minister and to departmental officials that pharmacies remain highly vulnerable and some have gone into examinership and/or receivership. The IPU called on the Minister to use the reviews to adjust a number of issues, fundamental to the provision of pharmacy services. These include:

- The elimination of the low level dispensing fees
- The reversal of the fridge items decision
- Review of the Reimbursement Price to Pharmacists
- Review the current level of remuneration for new Services;
- Put a proper negotiation system in place to review such matters.

The PCC met during 2012 to review strategy to ensure that these issues would be dealt with in 2013. The PCC will continue to follow up on these issues.

2. Proposed: **Liam Butler**
Seconded: **Dermot Twomey**

“That this AGM calls on the HSE PCRS to agree to an HSE-IPU Pharmacy Customer Charter which would set out a transparent, equitable and fair process in which the HSE should interact with pharmacy contractors on all queries.”

Action: The IPU met with the HSE as part of the Joint Consultative Group in March 2012. The main issue on this agenda was the establishment of a HSE-IPU Pharmacy Customer Charter to set out a transparent, equitable and fair process in which the HSE should interact with pharmacy contractors on all queries. The IPU continued throughout 2012 to request the HSE to put in place guidelines to ensure that pharmacy contractors were dealt with in a fair and reasonable manner. During 2012 the HSE created a new position of Head of Customer Service in the PCRS. The PCRS Contract Manager and the PCRS Administrator have met with the Head of Customer Service three times since November 2012. The IPU is currently liaising with the HSE on the HSE-IPU Charter along with a review of the HSE Administrative Arrangements to ensure that pharmacy contractors are dealt with in a professional manner.

3. Proposed: **Bernard Duggan**
Seconded: **Daragh Connolly**

“That this AGM calls on the Department of Health and HSE to further expand the role of the community pharmacist by developing a community-pharmacist-led national cardiovascular screening service, which incorporates accredited standards and training for the service and identifies a number of different funding options for provision of the service.”

Action: The IPU joined forces with the Irish Heart Foundation to develop Cardiovascular Risk Assessment Training for Pharmacists. Two courses were delivered in Dublin in October 2012, one in Cork in March 2013 and one more in Dublin in April 2013. A health screening module on IPU NET was launched in January 2013 to assist pharmacists in offering health check services. Guidelines and SOPs are available on the IPU website. Promotional materials were sent to pharmacies in March 2013. The IPU met with VHI in late March to seek reimbursement for pharmacy health screening for their clients.

4. Proposed: **Caitriona O’Riordan**
Seconded: **Sarah Magner**

“That this AGM calls on the Irish Institute of Pharmacy to ensure that, in its role as a management and accreditation body, the funding agreed between the IPU and the Department of Health, as part of the 1996 Community Pharmacy Contractor Agreement, will be ring-fenced within the Institute to fund continuing education initiatives for community pharmacists, who make up the largest portion of the PSI register.”

Action: At the time of going to print, the Irish Institute of Pharmacy had still not been set up. The IPU has written to the Department of Health on several occasions over the past year, asking that funding previously provided to ICCPE be ring-fenced for community pharmacists’ training.

Following the dissolution of ICCPE at the end of 2012, IPU Academy was set up to deliver a Spring Programme. Six topics were delivered in 87 venues around the country. On 19 Mar 2013, 986 pharmacists had booked 4450 courses, 297 new members had signed up to IPU Academy and 56 new members joined the IPU.

We are now in the process of developing an online Learning Management System to support IPU Academy. In the meantime, we have developed an e-learning EHC module which was put in place when ellaOne came onto the Irish market in May 2012. Members were able to access a range of training courses at the 2012 IPU National Pharmacy Conference and feedback was excellent. In addition, we have had at least one CPD article in every edition of the IPU Review in 2012/13.

5. Proposed: **Jack Shanahan**
Seconded: **Sean Reilly**

“That this AGM calls on the HSE PCRS and Department of Health to work with the IPU’s IT Steering Group, initially to ensure a smooth roll out of both generic substitution and reference pricing, and any other issues that require a pharmacy IT change.”

Action: We are in the process of implementing a number of developments to the IPU Product File so that it continues to meet the needs of members and other users and, in particular, to facilitate reference pricing and generic substitution. We have had a number of meetings with the Department in this regard and made a detailed submission, proposing amendments to the legislation. We also had a number of meetings with DoH, PCRS, IMB, and system vendors to discuss the implementation of reference pricing and generic substitution. A number of letters have been written to the DoH and PCRS, outlining our concerns. The IPU has also met with the vendors to go through the changes that have been made to the IPU Product File to facilitate reference pricing and generic substitution.

IPU Secretariat Report

1. Introduction

The past year has been an eventful and demanding year for all of us involved in the pharmacy sector as we grapple with change, continued subdued consumer demand and increased bureaucracy and poor communications from the HSE. Business and regulatory costs remain high including those costs controlled by Government and its agencies. Against this background, it is to the credit of the profession that high quality and efficient services continue to be provided to patients up and down this country. Looking to the next twelve months, while there are some tentative signs of economic recovery, economic growth is unlikely to reach the level necessary to dramatically improve overall economic performance and to lift demand in the domestic economy.

The Executive Committee has overseen the management of the IPU and the work of the three main IPU Committees throughout the past twelve months. The report of activities undertaken by the three main national committees provide you with a flavour of the wide range of activities that we are now involved in on an ongoing basis. This is all made possible by the maintenance of unity in the sector, which has enabled us to develop our activities and services for you and we are grateful for your continued support. It also ensures that we are there for you on an individual basis when you need us.

2. Membership & Pharmacy Ownership (as at 5 March 2013)

(1) Membership of the IPU

Community Proprietors	869	
Industry & Wholesale	7	
Community Employees	1040*	
Hospital	7	
Army, Academic & Admin	3	
Associate Members	7	1933

(2) Number of Community Pharmacies

Pharmacist Owned:

Single shops	756	
Chains	604	1360

Non-Pharmacist Owned:

Single shops		75
Chains	136	211 (1571)

(3) Total Number of Chains (two and over)

	Pharmacist	Non-Pharmacist	
Two pharmacies	114	4	236
Three	39	1	120
Four	10	2	48
Five	6	2	40
Six	6	1	42
Eight	2	1	24
Nine	2		18
Eleven	1	11	
Thirteen	1	13	
Fourteen	1	14	
Fifteen	1	15	
Sixteen	1	16	
Twenty	1	20	
Twenty-Six	1		26
Twenty-Eight	1		28
Sixty Nine	1	69	
	(604)	(136)	(740)

*Notes on Employee Membership

352 are Supervising Pharmacists availing of the free membership for additional pharmacies

122 are Supervising Pharmacists in non-pharmacist owned pharmacies and are covered by the sub paid by the pharmacy.

53 are availing of the free membership.

3. Product File Unit

The IPU Product File is managed by Fiona Hannigan and her team: Ger Gahan, Eilish Barrett and Ciara Browne. As well as supplying price updates and product information for members, they provide the following services and advice:

- Product sourcing
- General queries on the IPU Product File
- GMS pricing issues
- Short Supply and Discontinued Lists

The IPU also provides a Drug Interaction File and information files on drug use in Pregnancy and Breastfeeding, produced by the School of Pharmacy in Trinity College Dublin. These are based on the ATC classification system and are designed to warn pharmacists of the possibility of an interaction.

Product File/ITSG Update 2013

■ Reference Pricing/Generic Substitution.

- Consultant engaged to assist in updating IPU Product File
- A number of meetings held with the Implementation Group,
- IMB Webinar held February 2013; twenty interchangeable groups identified and updated on IPU Product File
- Meetings with system vendors held in February 2013 to discuss incorporation of Reference Pricing/Generic Substitution with the IPU Product File
- Standardisation of fields on IPU Product File ongoing
- Work has begun on IPU database changes and user interface to facilitate the introduction of Reference Pricing/Generic Substitution
- No sample data files yet from IMB or HSE PCRS

■ IPU Product File link to IMB Website.

- IPU Product File updated to distinguish PA/PPA/DRP and EU products
- IMB File tested for mapping to IPU Product File
- Queries sent back to IMB
- Sample fields sent to vendors for testing
- Electronic Download of Product File.
- Usernames and password reissued to all users for January 2013
- Consultant engaged to assist with IPU Product File security
- Report produced on IPU Product File security for Executive Committee
- Emails for Helix & Touchstore users to cease from May 2013
- CD's for Touchstore users to cease from April 2013

■ IPU Comms move to broadband.

- Brentech engaged to act on behalf of IPU
- Technical Team set up and a number of teleconferences held
- Forum meeting to be arranged shortly to discuss finalisation of project
- Due to be piloted mid-2013 and live by end of year

■ BNF Warning Codes.

- Map IPU Warning Codes with BNF Warning Codes.
- Modify product file to reflect the new set of codes.
- Codes launched June 2012

4. Administration Unit

The Administration Unit has three staff members: Patrice O'Connor, who works part-time, looks after reception and assists in the day-to-day running of the office; Ciara Enright, who works part-time as the IPU's accountant, is Secretary to the Finance Committee. She maintains books of account and advises members on a range of taxation and accountancy problems. Roisin Molloy is responsible for all aspects of membership and the management of the Secretary General's office.

5. Contractual and other Related Issues

Jill Lyons and Aoife Garrigan deal with a wide range of contractual issues. Jill Lyons is Secretary to the Pharmacy Contractors' Committee (PCC). Jill has played a key role in developing many of the PCC initiatives throughout the year and in the resolution of problems with the Health Service Executive, Primary Care Reimbursement Service and the Department of Health. Throughout 2012 Jill was involved in preparing the submission and the oral presentation to the FEMPI Review. She is also working with the HSE and the Elton John AIDS Foundation on the implementation of the Needle Exchange Programme through Community Pharmacy, and preparing for the implementation of the Reference Pricing and Generic Substitution. Jill also represents the IPU at the PGEU Economic Working Group. Jill and Aoife have spent much of the year liaising with the HSE on the numerous contractual queries that arise. Aoife also deals with remuneration queries, compiling information on raids on pharmacies and collecting information on stolen and forged prescriptions.

IPU Secretariat Report

(continued)

6. Policy and Public Affairs

Jim Curran, as Director of Communications and Strategy, oversees the IPU's internal and external communications and is responsible for developing the IPU's strategy. His responsibilities include promoting the interests of the IPU and the membership through effective communications with members, media, agencies and other parties that influence the sector. He is also responsible for overseeing events, business development and policy research Jim oversaw the introduction of the new strategy statement for the IPU, which will cover the period from 2013-2016. Jim is an editorial associate of the IPU Review and is also Secretary to the Executive Committee. He also represents the IPU on external committees.

7. Media and Communications

Jim Curran oversees this area. Wendy McGlashan is Admin Secretary to the Executive Committee and is responsible for IPU publications, including the production of the IPU Review, IPU News (the weekly e-newsletter) and co-production of the IPU Yearbook.

Aoibheann Ní Shúilleabháin is responsible for organising the annual IPU National Pharmacy Conference. She manages the IPU website and co-ordinates IPU advertising campaigns. She works on the co-ordination of communications activities and assists with national and regional media coverage for the IPU and public opinion research. She is an editorial associate of the IPU Review.

Communications

- **Market Research:** The IPU undertook market research amongst the general public and the results will be presented at the IPU National Pharmacy Conference.
- **Advertising and Public Relations:** The IPU ran advertising campaigns in April and October-December, which included radio ads and in-store materials. The ads aimed

to promote the role of the pharmacist and encouraged people to 'ask your pharmacist first'. Public relations activities, including the issuing of 45 press releases also raised the profile of pharmacists in the media, with interviews on national TV and radio, as well as in regional media, highlighting the role of the pharmacist.

■ **Communications with Members:**

Communications with members continues to improve with the IPU website, IPU News (the weekly e-newsletter) and @ipumail all seeing an increase in uptake from members. In the last year, new services have been launched such as an SMS Service, Members' Forum on the IPU website and a Facebook page. A booklet, *On Your Side and At Your Side*, was also sent to members highlighting the support and services that the IPU provides to members.

- **Publications:** The IPU Review, Yearbook and a weekly e-newsletter are all produced in-house rather than through external contractors for efficiency reasons.

- **Annual Review:** The Annual Review of the sector is part of an ongoing annual series that authoritatively tracks changes in community pharmacy. It is essential research and a reference that enables us, as a representative body, to promote members' interests based on credible facts that are measured consistently over time. The 2011 Review was carried out by Grant Thornton and is available in the members section of the website.

IPU National Pharmacy Conference

The annual IPU National Pharmacy Conference has been a great success since the inaugural event in 2011. Since then, the conference has grown and expanded to facilitate the needs of members. The Conference is a great opportunity for members to come together in an educational and social environment. Over the weekend, pharmacists have the opportunity to build on their Continuing Professional Development (CPD) and receive updates on the work of the IPU at

the AGM. The President's Dinner is also held over the weekend of the Conference. The success of the conference is evident in the growing numbers of pharmacists attending each year.

8. Pharmacy Services

The Director of Pharmacy Services, Pamela Logan, co-ordinates all Professional, IT and Training matters within the IPU. Pamela acts as Secretary to CPC and details of issues covered by this Committee can be found in the CPC report. She works with relevant departments and agencies, both nationally and internationally, to promote the role of the pharmacist. Pamela also represents the IPU at PGEU and FIP. Liz Hoctor is the CPD & IT Manager and has been instrumental in the setting up of IPU Academy to support members in their engagement with continuing professional development. Liz also oversees IPU NET, our online web-based platform designed to support members in the delivery of new pharmacy services.

9. Training & HR Department

Susan McManus, Training and HR Manager, organises and co-ordinates a selection of training courses for pharmacy staff. Janice Burke assists Susan in this department. 123 Pharmacy Technicians' graduated in March 2013. There are 210 students at present partaking in Year 1 and 162 students in Year 2 of the course. In addition, 151 students completed the MCA Course in 2012 in Dublin, Limerick, Kilkenny, Cork, Galway, Tullamore, Tralee, and Waterford. 63 students completed the Interact course and 15 completed the Interact Plus course. The FÁS Pharmacy Sales Traineeship course was administered in Baldoyle, Dublin and Douglas, Cork; and to Senior Colleges in Dun Laoghaire, Dublin; Monaghan Institute; Limerick College of Further Education; and St John's College, Cork. Susan also acts as Secretary to the Employee Pharmacists' Committee, co-produces the

IPU Yearbook and Diary and Wall-Planner and advises members on Human Resource issues.

The Training Department in conjunction with the Business Development Department rolled out the Diploma in Leadership and Management in February 2013. This is a highly interactive course spanning over 24 months, utilising various teaching methods, including classroom workshops, on-the-job projects, individual and group exercises, case study work groups, learner forums and individual presentations. The 'face-to-face' element of this course will be delivered by Susan Madden, RTCL, in Butterfield House. Also hosted in Butterfield House were two Employment Seminars in February and March 2013, covering Employment Legislation and NERA inspections.

10. Business Services

The Business Development Manager, Darren Kelly, is responsible for business services and advice to members. In 2012 "Strategies for Growth" business training was held around the country to help members understand their business and maximise their profits. A new fully accredited Diploma in Leadership & Management was launched in February 2013. This course was developed to help pharmacy owners, managers and supervisors could gain the knowledge required to help them manage their pharmacies. A number of affinity schemes have been negotiated for members on a range of products and services and details can be found on www.ipu.ie. Members are kept up-to-date with current legislation through notices in the IPU Review, Yearbook, E-Newsletter and General Memoranda. Members can contact the Business Department for advice and information on the Business Helpline 01 406 1558. Darren operates the IPU Retail Review Consultancy Service, which is available to members at a discounted rate. Darren will come to your pharmacy for a full day retail review, develop a plan and implement the plan over the course of the day. The feedback from members who have availed of this service has been very positive. Details of this service can be found on www.ipu.ie and in the IPU Review.

Darren also oversees the general maintenance and upkeep of Butterfield House.

The IPU VAT scheme received full Revenue approval from 1 September 2012 and has been well received by members and accountants.

11. External Consultants

Gordon MRM (PR Consultants); Coolamber (IT Consultants); John Behan (Industrial Relations Advisor) and Sean McHugh (Industrial Relations Advisor); provide advice and support to the IPU as requested on an ongoing basis. Leaf Environmental has been retained as consultants to the IPU on matters regarding environmental and waste management issues.

12. Main Committee Meetings

The number of committee meetings was:

	'12	'11	'10	'09
• Executive Committee	7	6	6	9
• Community Pharmacy Committee	4	5	5	6
• Pharmacy Contractors' Committee	6	5	8	8
• Finance Sub-Committee	6	7	7	7
• All Committee Meetings	1	0	0	3
• Employee Pharmacists' Committee	4	4	4	3

13. IPU Publications

The following are sent to members, on a regular basis:

- IPU Review
- IPU Weekly E-Newsletter
- General Memoranda
- Price Index List Updates
- IPU Product File by email and on Disk and CD
- Yearbook & Diary
- Wall Planner
- Quarterly Business Trends Surveys
- Training Course Updates
- Employee Pharmacists' Committee Newsletter
- Reap the Rewards of IPU Membership

14. Pensions and Insurance

AIC (Corporate) Ltd, Pharmacy Insurance Ireland and Liberty Asset Management provide insurance and pension services for members.

IPU Secretariat Report

(continued)

15. Submissions

The following submissions were made during the year. All are available on www.ipu.ie > Publications & Submissions.

2012

- **FEMPI Review 5**
- DoH - May 2012
- **Pharmacovigilance Regulations**
- DoH - July 2012
- **Rapid Discharge Planning**
- HSE - Sep 2012
- **National Integrated Care Guidance**
- HSE - Sep 2012
- **Pre-Budget 2013 Submission**
- Departments of Finance & Public Reform
- Oct 2012

2013

- **FEMPI Review**
- DoH - Jan 2013
- **Medicines Shortages and ULMs Consultation**
- DoH - Jan 2013
- **Standardising Patient Discharge Summary Information**
- HIQA - Jan 2013
- **Alex White Briefing**
- Mar 2013
- **Falsified Medicines Regulations**
- DoH - Mar 2013

16. IPU Review

The IPU Review is produced in-house by Jim Curran, Wendy McGlashan and Aoibheann Ní Shúilleabháin.

17. Conclusion

As this is my last year as Secretary General, I would like to thank each and every member of the IPU for your support and participation in the work of the IPU and most especially for your support to me personally over the years. I would like in particular to thank all the Presidents that I have had the pleasure of working with during my twelve years with the IPU. Their commitment never ceased to amaze me and was always a source of encouragement and inspiration. Finally, to my work colleagues, a big "thank you" for delivering so much to our members through your commitment and dedication and I always enjoyed basking in your achievements. I have no doubt that the IPU will continue to evolve and change and go from strength to strength in the years ahead.

Seamus Feely,
Secretary General



Seamus Feely
Secretary General, IPU

Pharmacy Contractors' Committee (PCC) Report 2012-2013

The Pharmacy Contractors' Committee took office in February 2012. Morgan Power was elected as Chairman and Brian Walsh as Vice-Chairman. The Committee has met six times since last year's AGM. The Committee has met six times since the beginning of the year. There has also been a sub-PCC meeting and one All Committee meeting since the last AGM.

Over the past year the PCC's energies have been focused on preparing for two reviews under the Financial Emergency Measures in the Public Interest Act 2009 (FEMPI), the implementation of the Reference Pricing and Generic Substitution, dealing with the decisions of the HSE PCRS along with many other urgent issues which have arisen during the year.

The main items on the Committee's agenda since the last AGM:

Department of Health (DoH) Matters:

- Preparing the Submission and Oral Presentation in the context of the Review carried out under the FEMPI Act in May 2012 and again in December 2012;
- Communicating with members and gathering information from them in advance of the FEMPI Act reviews;
- Communicating with members in the aftermath of the FEMPI Act review in May 2012;
- Monitoring the implementation of the Prescription Levy;
- Preparing for the introduction of Reference Pricing and Generic Substitution;
- Meetings with Ministers; and
- The impact of the reductions in the reimbursement price of fridge items.

Health Service Executive (HSE) Matters:

- The implementation of the Needle Exchange Programme with the HSE and Elton John AIDS Foundation;
- Participating in the Joint Consultative Group with the HSE;
- Ensuring the continued operation of the Incomplete Claims Protocol with the HSE;
- Monitoring the claiming and payment for Pradaxa and Xarelto;

- Monitoring the withdrawal from the GMS of Glucosamine, Orlistat, Omega-3 and Gluten-free products;
- Monitoring all Community Drugs Schemes and all pharmacy payments;
- Liaising with the HSE and DoH to resolve issues around the Community Pharmacy Contractors' Contract;
- Ongoing HSE PCRS Administration issues; and
- Working with individual members in resolving problems with payments.

Monitoring the Cost of Medicines:

- Monitoring the reduction in the cost of medicines in 2012;
- Strongly making the case to the Department for sufficient notice of any change in the price of medicines;
- Advising members on the reductions.

Department of Health (DoH) Matters:

FEMPI Legislation

The PCC prepared submissions and presentations for the FEMPI Review in May 2012 and December 2012/January 2013. The PCC liaised with Grant Thornton in the collation of figures for these submissions and put forward the best possible case to the Minister. The PCC communicated all developments to the membership in a timely and straightforward manner. There was no further reductions announced in May 2012, which was a success for pharmacists. The PCC has managed to protect key 'red line' issues – current dispensing fees, mark-up, and the reimbursement price of non-drug items to date.

However, there continues to be a loss on fridge medicines. The PCC requested that the Minister and the HSE put in place a

system to compensate pharmacists for any loss they experience when dispensing fridge items. The PCC will continue to put forward the pharmacist's case to the Minister at every opportunity.

The PCC has communicated extensively with members and has sought information as part of the Annual Review of the Sector. Members' input is vital in making our case and the PCC thanks all members who have participated in this year's survey.

The PCC will meet with their Senior Counsel, Michael Collins, shortly to discuss the FEMPI appeal and the possibility of initiating a further legal challenge in light of any further FEMPI reductions.

Prescription Levy

The Minister has indicated that he is not in a position to abolish the prescription levy because of the economic situation. The PCC wrote to the Minister requesting amendments to the legislation to exclude certain cohorts of patients and this is something that we will continue to pursue, especially in light of the increase in 2013.

Reference Pricing

The PCC has been advocating for the introduction of generic substitution since 2003. The PCC has more recently sought to influence the manner in which generic substitution might be introduced in light of the Government's commitment to introduce legislation for the implementation of generic substitution and reference pricing. The PCC has made the case that generic substitution should be introduced in advance of reference pricing.

The Health (Pricing and Supply of Medical Goods) Bill 2012 was published last summer. The IPU met with the Department of Health and HSE on numerous occasions to discuss the legislation.

Pharmacy Contractors' Committee (PCC) Report 2012-2013

(continued)

The PCC will continue to follow up on this matter to ensure that we receive adequate notice of any change and influence the manner in which the new legislation is implemented. Equally, we will continue to make the case that any reference price must not jeopardise continuity of supply or further undermine the viability of pharmacy businesses.

Meeting with the Minister

There was a meeting with Minister Roisin Shortall, Minister of State at the Department of Health in early 2012.

HSE Matters

Withdrawal of Reimbursement of Certain Products

The HSE announced the withdrawal of reimbursement for Glucosamine, Orlistat and Omega-3 Triglycerides and gluten-free foods from all Community Drugs Schemes.

The announcement was effective from 1 September, despite the HSE not officially notifying the IPU until Monday 3 September. The PCC requested and was granted, a grace period of three days up until Tuesday 4 September. This was welcomed by members as the HSE paid for the claims processed during the initial few days of the announcement.

This decision was due to the deficit in the HSE finances and, therefore, there was nothing that could be done to stop or delay it. It is expected that there will be further changes to oral nutritional supplements and other medicines in the coming weeks and months and the PCC will continue to monitor this situation.

Pradaxa and Xarelto

There have been a number of restrictions around the reimbursement of Pradaxa and Xarelto since 2011. The HSE issued circulars to GPs, Hospitals and Pharmacists in July 2012 clarifying reimbursement for Pradaxa and Xarelto as a second line therapy where warfarin may not be appropriate for the patient. Reimbursement for the pharmacist is only guaranteed where the patient has a properly filled out prescription and

a letter of approval from the HSE. The onus is on the prescriber, not the pharmacist, to fill out and send off the application form. The PCC had liaised with the HSE in advance of the circular being issued and the HSE had made a number of changes to the final draft of the circular based on suggestions from the IPU.

Due to the persistence of the PCC all Pradaxa claims previously outstanding, dating back to November 2011, were paid in 2012. The PCC continues to monitor payments for these medicines.

Roll-out of the NEX Programme

Throughout 2012 the PCC worked with the HSE and the Elton John AIDS Foundation on the Needle Exchange Programme. There are now over 75 pharmacies participating in the programme with more coming on-stream over the next few months. Due to the arguments put forward by the PCC, the fee paid to pharmacists for needle exchange is €5 and not part of the sliding scale of fees (€5, €4.50 and €3.50). The PCC is providing support to pharmacists participating in the programme through regular contact. There is also a specific area on the IPU forum for comments and feedback on the programme. A National Pharmacy Co-ordinator for outside the Eastern Area was appointed in late 2011. In late 2012 two Pharmacy Liaison Workers were appointed. This was a very successful outcome from the IPU's perspective as it provides pharmacies with further back-up and support.

The extension of the Incomplete Claims Protocol

The IPU negotiated the Incomplete Claims Protocol, which ensures that pharmacists get paid for all medicines dispensed in good faith to medical card patients. This protocol continues to be monitored by the IPU and HSE at the Joint Consultative Group (JCG). The PCC also managed to negotiate for the extension of this Protocol into 2013. This was a very successful outcome to a long running problem for members.

Advising members on their PCRS Claims

The IPU regularly issues advice and tips for members on how to go about checking their claims and minimising rejected claims. The IPU has recently put together a *Pharmacy Claims Checklist*, which is available on the IPU website and which gives helpful tips to members to save them time and money.

Adherence to Pharmacy Contract

The PCC continued to monitor the HSE/DoH adherence to conditions of Pharmacy Contract and followed up on a number of individual member's queries throughout 2012.

Liaising with the HSE

The PCC met with the HSE as part of the JCG twice since the last AGM. In addition, while working on the implementation of the needle exchange programme, there were numerous meetings with HSE and DoH officials. Overall, there is good interaction between both sides and our aim is to continue to have a constructive relationship with the HSE and the DoH.

Legal Advice / Cases

The FEMPI Appeal is being pursued by the PCC as mentioned above. The Mullally Case is awaiting a decision from the Hickey Case in relation Supreme Court appeal. The IPU liaises with solicitors from Beauchamps and Mason Hayes & Curran on all these cases to ensure that PCC Committee decisions are implemented and result in the best outcome for members, where possible.

Monitoring the Cost of Medicines

Reductions to the Cost of Medicines

There were two significant reductions in the price of medicines during 2012 under IPHA and APMI agreements with the HSE/Department. The PCC sought a deferral on each implementation date by at least one month. This was not granted because of the current state of the public finances. However, we were given more notice of the reductions on the APMI medicines and members were given an opportunity to reduce their stock accordingly. The IPU communicated to members to warn them of the need to reduce stock levels in order to minimise the loss in stock value as a consequence of the current consultations between the DoH and IPHA on medicine prices.

Conclusion

This is a summary of some of the major issues dealt with throughout the year. However, officials of the IPU intervened in many other matters on a daily basis, including individual issues for members.

The PCC is actively working with the HSE on members' behalf. Progress can be slow and discussions take time. There are often difficult issues to resolve but, at all times, the PCC continues to pursue issues on behalf of members until, ultimately, a resolution is found.

**Morgan Power,
Chairman, PCC**

Community Pharmacy Committee (CPC) Report 2012-2013

The Community Pharmacy Committee (CPC) is chaired by Bernard Duggan with Daragh Connolly as Vice-Chairman. CPC's mission statement is *CPC – working to serve and support community pharmacists in their practices and to promote and expand their role as pharmacists by continually developing professional, ethical, business and technological ideals and standards.*

The CPC is split into three sub-groups:

■ **Professional Development Steering Group**

Mary Barry, Louise Begley, Anna Kelly, John McLaughlin, Ultan Molloy, Sarah Magner, Niamh Murphy.

■ **Business Steering Group**

Roy Hogan, Daragh Connolly, Elizabeth Lang, Michael Tierney, Aidan Walsh.

■ **IT Steering Group**

Stephen Nolan, Rory O'Donnell, Jack Shanahan. Sean Reilly (Executive) and Michael Walsh (PCC) have also been co-opted onto the ITSG.

CPC has met four times since the April 2012 AGM (May, September, November 2012 and February 2013). In March 2012, the Committee met to agree on a strategy for 2012-2014. The objectives identified in the strategy are outlined below with a brief summary of activities undertaken to meet these objectives.

Professional Issues

Promote the role of the pharmacist in Government and HSE strategy

We have had a number of meetings with the Department of Health in the past year to discuss a variety of issues such as reference pricing and generic substitution, medicines shortages, self-care, switching and benzodiazepines. We have also met health spokespersons from all parties on a number of occasions to discuss similar issues. Submissions were made on Medicines Shortages and Unlicensed Medicines in January 2013 and on Patient Discharge in January 2013.

Work with DoH, IMB, IPHA, PGEU, EMA and patient groups to further improve accessibility of medicines through switches from POM to Pharmacist-only or by other appropriate means

The IPU and IPHA co-hosted the launch of a Self-Care Framework for Ireland in September 2012. The Framework promotes the idea that patients should be encouraged to take responsibility for their own care, with assistance from healthcare professionals, and advocates that the range of medicines available to patients should be expanded through switching from prescription to non-prescription status. The IPU attended the AESGP conference in Dublin in Jan 2013 which focused on switching. The IMB set up a Consultation Panel to review the classification of medicines, following a public consultation in July 2011; the IPU presented to the Panel in Feb 2013.

Develop a health screening role for pharmacists to incorporate training, standards for pharmacy service and funding options

The IPU joined forces with the Irish Heart Foundation to develop Cardiovascular Risk Assessment Training for Pharmacists. Two courses were delivered in Dublin in October 2012, one in Cork in March 2013 and one in Dublin in April 2013. A health screening module on IPU NET was launched in January 2013 to assist pharmacists in offering health check services. Guidelines and SOPs are available on the IPU website. Promotional materials were sent to pharmacies in March 2013.

Pursue the implementation of Medicine Use Reviews in community pharmacy

We used the opportunity in our submission to the Department, on the Health (Pricing and Supply of Medical Goods) Bill, to call for Medicine Use Reviews and a New Medicines Service to be introduced. The purpose of these initiatives is to improve compliance, reduce leakage to secondary care and reduce wastage of medicines. These services were also highlighted in a briefing note to Minister Alex White in March 2013.

Extend the pharmacy vaccination service to include other vaccines and high tech injectables

Vaccination cohorts were extended in 2012/13 to all at-risk groups. In September/October 2012, 600 pharmacists attended refresher training and 200 completed ab initio training. The number of pharmacies vaccinating in 2012/13 increased by 69% to 817 and the number of vaccinations doubled to 18,358. According to IPU NET statistics, 27% of people vaccinated in pharmacy had never been vaccinated before and 80% of those were in an at-risk group.

Members were surveyed in Feb 2013 for feedback on the vaccination service. We met with the PSI in February 2013 to advocate for online refresher vaccination training, reduced number of Anapens and inclusion of pneumonia and Hepatitis B vaccinations.

The IPU has met with a number of pharma companies to discuss developing a high tech injecting training service whereby pharmacists would train their patients in self-injecting high tech medicines.

Assist members in dealing with PSI/HSE/IMB/DoA inspections and Fitness to Practise issues

We have assisted a significant number of members in dealing with complaints made to the PSI or investigations instigated following PSI inspections and helped members prepare for FTP hearings and District Court appearances. The Inspections Checklist has been updated and we have developed a template to assist members in responding to their inspection report. A Self-Audit Tool on IPU NET was launched in Feb 2013. The IPU wrote to the PSI in February 2013 requesting that notice be given for inspections. We have also produced a range of SOP templates which members can download from the IPU website and personalise for their pharmacy.

Lobby for amendments to the Pharmacy Act 2007

We have called for amendments to how FTP is processed in the Health (Pricing and Supply of Medical Goods) Bill and for removal of bankruptcy from registration requirements as part of the Personal Insolvency Bill. The IPU also wrote to the Minister for Health in October 2012 requesting a reduction in PSI fees.

Liaise with DoH and IMB on the transposition of EU Directives (Falsified Medicines, Pharmacovigilance, and Patients' Rights) into Irish legislation

We made a detailed submission to the Department of Health on the legislation to transpose the Pharmacovigilance Directive. This legislation, which was passed in July 2012, clarifies the process for reporting ADRs to the IMB. We also made a submission in March 2013 on legislation to transpose the Falsified Medicines Directive.

Work with PSI on FIP 2013

Darragh O'Loughlin represents the IPU on the Local Host Committee for FIP 2013, which will be held in Dublin from 31 August to 5 September next year. We hope to see many Irish pharmacists in attendance at this prestigious conference and indeed presenting on their work as community pharmacists.

CE/CPD

Develop an IPU CE/CPD platform, IPU Academy, to deliver CE to members and to assist them in self-monitoring of their CPD: online programmes/e-learning; distance learning/download; face-to-face (including on-line pre-learning). By June 2012, develop two x e-learning courses (one to be EHC), two x distance learning courses and two x business courses

Following the dissolution of ICCPE at the end of 2012, IPU Academy was set up to deliver a Spring Programme. Six topics were delivered in

87 venues around the country. The programme was a great success with record attendances and excellent feedback.

We are now in the process of developing an online Learning Management System to support IPU Academy. Members were able to access a range of training courses at the 2012 IPU National Pharmacy Conference and feedback was excellent. In addition, we have had at least one CPD article in every edition of the IPU Review in 2012/13.

Build relationships with Pharma, Schools of Pharmacy, Irish Institute of Pharmacy, patient groups, etc. to assist in the provision of CE/CPD

The IPU has collaborated with GSK and the Asthma Society in providing face-to-face inhaler technique training around the country. We are also working with Pfizer on a diabetes project, both North and South of the border, to produce research to be presented at FIP 2013. We collaborated with the Irish Heart Foundation to produce face-to-face training for pharmacists on Health Checks and this was delivered on two dates in Dublin in October 2012, once in Cork in March 2013 and one more time in Dublin in April 2013. The IPU is now liaising with UCC to produce evidence-based studies using information from IPU NET which we intend to present at FIP 2013.

IT Issues

Maintain the IPU Product File as the number one file on the Irish market; Progress with updating the IPU Product File to facilitate reference pricing and generic substitution; Protect the security of the IPU Product File; Progress with links to the IMB website to facilitate access to SPCs and PILs; Scope out an alternative source for a Drug Interactions File for the IPU Product File

We are in the process of implementing a number of developments to the IPU Product File so that

it continues to meet the needs of members and other users and, in particular, to facilitate reference pricing and generic substitution. Live download of the IPU Product File has now been implemented and new BNF warnings have been incorporated. The IPU Product File will soon have direct links to the IMB website to facilitate access to SPCs and PILs. We will continue to make members aware that the IPU Product File is prepared by pharmacists for pharmacists with no other objective than to facilitate the operation of their business and it is part of the IPU members' offering.

Work with DoH/PCRS on the roll out of reference pricing and generic substitution

We had a number of meetings with the Department in this regard and made a detailed submission, proposing amendments to the legislation. We also had a number of meetings with DoH, PCRS, IMB, and system vendors to discuss the implementation of reference pricing and generic substitution. A number of letters were written to DoH and PCRS, outlining our concerns. The IPU also met with the vendors to go through the changes that have been made to the IPU Product File to facilitate reference pricing and generic substitution.

Work with HIQA on the eHealth Standards Advisory Group (eSAG) to develop eHealth Interoperability Standards

Jack Shanahan, Chairman of the IT Steering Group, represents the IPU on this prestigious advisory group. One main objective of the group is to facilitate implementation of electronic prescriptions. Jack will speak on this topic at the IPU National Pharmacy Conference 2013.

Work with wholesalers and vendors to test and roll out the Pharmacy Broadband Ordering System

We are working with the dispensary system vendors and frontline wholesalers to develop a broadband-based ordering system for pharmacies. The specification has been written and the system developed and tested. Pilot

Community Pharmacy Committee (CPC) Report 2012-2013

(continued)

testing commenced in March 2013 and it is intended to have a full roll-out by end 2013.

Liaise with IPHA on medicines authentication for Ireland, UK and Malta as part of the Falsified Medicines Directive

The Falsified Medicines Directive lays out the principles for an EU-wide medicines authentication system, to prevent counterfeit medicines entering the supply chain. We are working with IPHA and our colleagues in the UK to develop a regional hub to facilitate authentication in Irish and UK pharmacies. The system must be implemented by 2017 but significant work will be required between now and then.

Work with the Business Steering Group to facilitate members in setting up their own websites

The IPU and Pfizer have joined forces to provide a tool to assist members in setting up a pharmacy website. Further information on Mylocalpharmacy.ie can be found in the business section of our website.

IPU NET

IPU NET was launched at our National Conference in 2012. We now have modules in place for EHC, vaccination, diabetes, asthma, health screening and self-audit. 558 pharmacies and 644 pharmacists were registered on IPU NET by March 2013.

Data collected on EHC shows that 86% of EHC consultations take place within 24 hours of unprotected sexual intercourse (UPSI), with 39% taking place within 12 hours of UPSI. Women aged 18 to 24 account for 40% of the consultations and women aged 25 to 30 account for a further 24% of consultations. 60% of women indicated that they were not using any form of contraception at time of consultation. Of those who were using contraception, barrier contraception was used by 60% of women with 38% using oral contraception. 19% of women accessing EHC through community pharmacy possessed a medical card, entitling them to free GP care and prescription medicines.

Data collected on vaccination showed that 27% of people vaccinated in pharmacy in 2012/13 had never been vaccinated before and 80% of those were in an at-risk group.

Develop a roadmap for dispensary system development of all systems, led by a Steering Group of users of all three dispensary systems

The IPU now has a minority shareholding in Touchstore. The purpose of this venture is to influence development of dispensary IT systems, which has fallen behind other jurisdictions in recent years. We will be working on this area over the coming months. Our hope is that all vendors will provide the best possible system at a reasonable price.

Business Issues

The Business Steering Group has met three times since the April 2012 AGM to discuss a range of issues that would assist members in running their businesses.

Business Policy – provide input into national policies affecting small businesses through Chambers Ireland, National Retail Industry Alliance and National Consumer Agency, e.g. rates, rent reviews, retail planning, budgets

Through our membership of Chambers Ireland and National Retail Industry Alliance we have pushed for changes with regard to rates and rent reviews. Roy Hogan, Chairperson of the CPC Business Steering Group, is the IPU nominated member on the Chambers Ireland Ratepayers and Local Government Policy Council.

We also prepared a report on *Planning Implications for Retail Pharmacy Businesses* which was sent to the Minister for the Environment and all the local council planning departments, outlining our concerns and recommendations for changes to the Retail Planning Guidelines regarding out of town developments. As a consequence, pharmacies in out of town developments are discouraged in planning guidelines.

We are also involved in the National Strategic Retail Forum with An Garda Síochána and other retailers. This Forum is working to ensure that a Crime Prevention and Reduction approach is adopted in dealing with the issue of shoplifting. It also recognises the need to foster and sustain, at a Strategic level, positive communication channels between An Garda Síochána and the retail community.

We wrote to the Minister of Small Business to outline the regulatory burdens affecting the pharmacy sector. There has been positive noise coming from the Department with regard to changes in this area.

We also met with the RSA to discuss the proposed changes to the new driving licence. This issue is on-going.

We have also introduced a quarterly business trends survey to monitor members' views and experiences from a business perspective. We have issued a number of press releases identifying business issues including the impact on pharmacy from reduced sales and the cost of commercial rates

Business Training – progress with Strategies for Growth and Sales & Merchandising training and provide online training through IPU Academy

Strategies for Growth Business Training sessions have been a big success with members. Training sessions will be held again in 2013. Sales & Merchandising training will be rolled out to members in late 2013 with distance learning and classroom style sessions. We launched a new fully accredited ILM Diploma in Leadership & Management Training Programme for members in February 2013. This training programme will help to develop a wide range of fundamental management skills by assisting students in gaining the comprehensive knowledge required by a first-line manager or supervisor.

IPU Review Articles – produce a series of relevant business articles for members

Over the course of the last year, there have been many business articles in the IPU Review; articles on areas such as merchandising,

security, planning, customer service, tax and business regulations have been provided to help members in their business.

Business Briefings – identify topics for evening briefings to take place in Butterfield House

Briefing sessions were held at the Regional Meetings during October 2012. Members who attended were briefed on the new IPU VAT Scheme, the new IPU Member Assistance Programme (MAP), Day 1 Income Protection and How to deal with Planning issues.

VAT Roadshow – hold roadshows around the country to explain the new IPU VAT Scheme to members

The new IPU VAT Scheme received Revenue approval with effect from 1 September 2012. The VAT Review Group, along with Baker Tilly Ryan Glennon, prepared a short presentation on the new scheme which was delivered at the Regional meetings.

ECommerce – work with ITSG to provide ecommerce opportunities for members

The IPU, working in conjunction with Pfizer, has developed a website development tool to assist members in setting up their own websites. Over 200 pharmacies now use this tool. The IPU also launched our own IPU online stationery store. Members now have direct access to purchase pharmacy stationery consumables and marketing material for their pharmacy via the IPU website.

Business Review Consultancy – continue to promote consultancy through IPU Review, eNewsletter and at IPU Conference

Business Review Consultancy was developed by the Business Steering Group to assist members in getting the most from their front of pharmacy. Darren Kelly, Business Development Manager, will go to their pharmacy and give them one day of his time and expertise for a small fee. Over thirty pharmacies have availed of this service to date and the feedback has been excellent.

Review of Pharmacy Sector – assist members in benchmarking their businesses using reports from dispensary systems, EPOS and PwC reports

As part of the Annual Review, we developed a dashboard that members who participated in the Review would receive. This dashboard will help members benchmark their business against businesses of a similar turnover. The final report of the Annual Review was released in December 2012

Bernard Duggan,
Chairman, CPC

Employee Pharmacists' Committee (EPC) Report 2012-2013

The Employee Pharmacists' Committee (EPC) represents the interests of community pharmacy employee members of the Irish Pharmacy Union. The Committee is chaired by Caitriona O'Riordan with Sarah Magner as Vice-Chairperson. The mission statement of the EPC is: *"To promote the professional and economic interests of employee pharmacists and constructively engage with other Committees of the Union and other stakeholders through the Employee Pharmacists' Committee."* Currently there are 1,069 community employee members of the IPU, which comprise 54% of the full membership.

The EPC has met four times since the 2012 AGM (May, September and November 2012 and March 2013). The EPC continues to have active representation on other IPU Committees, with an allocation of three employee representatives on the Executive Committee and four representatives on the Community Pharmacy Committee. This representation guarantees that the views of employee pharmacists are voiced and heard on the other Committees of the IPU, therefore empowering employee input into decisions and in the development and implementation of IPU policies.

Communications

The EPC has continued to communicate through publishing articles in the IPU Review Magazine which have covered topics such as *Make Yours an Interview-Winning CV*, *Dispensing an Extemporaneous Prescription*, *Diary of a Tutor Pharmacist, Part 1, 2 and 3* and *Countdown to Christmas*. The EPC believe that in these challenging times in the community pharmacy sector, employee members must be provided with information on up-to-date issues. The Committee is currently preparing an article highlighting some of the issues where specialised assistance was provided by the IPU, over the last year, when committee members encountered a problem they could not resolve on their own.

The EPC also publishes a column in the *IPU Review* reporting on each EPC meeting, while the regional representatives email a meeting update to employee members in their region.

The EPC continues to encourage fourth year students and pharmacy interns to become involved with the IPU. To date, 122 fourth year students and pharmacy interns are in receipt of the IPU weekly employee e-newsletter.

Events

The EPC hosted an Employee Seminar in Cork on 13 November 2012 in the Silversprings Moran

Hotel, Cork, organised by Caitriona O'Riordan and Sarah Magner. This Seminar was open to all pharmacists and trainee pharmacists. The total attendance was 74, consisting of 26 members (three proprietor pharmacists and 23 employee pharmacists), 30 non-member pharmacists, three pharmacy interns and 15 4th year students. The Seminar focussed on Wound Management, tailored specifically to pharmacy, delivered by Clinical Educators as well as a brief outline of the *'Benefits of IPU Membership'*.

Increase and Retain IPU Membership

Throughout the year the EPC endeavoured to encourage non-members to sign up to IPU Membership. The Membership Secretary wrote to all pharmacists who didn't avail of the free introductory year and to all pharmacists working for a group where the group was no longer affiliated to the IPU.

The EPC has requested that the Executive Committee investigate the possibility of employee members paying their annual subscription by direct debit in instalments.

Representation & Services

The EPC will continue to pursue its objectives with intent and to actively represent the interests of employee members. It will also ensure that the IPU continues to provide services and assistance to employee members within the community pharmacy sector. The coming years will be taxing for all in community pharmacy. It is vital, now, more than ever, that employee pharmacists have a representative body which supports on their behalf. The EPC will continue to be this body and it urges the involvement of more employees on both a regional and national platform within the IPU in order to reinforce the resolve of employee pharmacists both in the IPU and throughout the profession.

Conclusion

The EPC urges employee members to use their membership to the full and keep themselves well-versed by reading the e-newsletter, General Memoranda, IPU Review magazine and other information presented by the Union. In June 2010 all IPU Members were assigned with an *@ipumail.ie* email account, the EPC would advise employee members who have not activated their account to do so without delay. The EPC would also recommend that employee members check the **'Employee Pharmacists'** section of www.ipu.ie on a regular basis.

I would like to thank all the members of the EPC for all their work over the last year and the staff of the IPU, in particular Seamus, Roisin, Pamela, Jill and Darren for their support and advice on all matters. I would in particular like to thank the Secretary to the EPC, Susan McManus, for her hard work and dedication to the EPC and the President, Rory O'Donnell, for his direction and assistance throughout the year.

Caitriona O'Riordan,
Chairperson, EPC

Communications Report

The Communications Team have an important role in communicating key messages to the media, the public, stakeholders and members. A wide range of communications tools are used to keep members up-to-date on ongoing and urgent issues. Press releases are issued regularly, promoting the role of the pharmacist and highlighting issues of concerns to pharmacists to the media. Communications with the public is strengthened with advertising campaigns throughout the year.

The Communications Team consists of Jim Curran, Aoibheann Ni Shúilleabháin, Wendy McGlashan and external advisors, who all invest a great deal of time, effort and resources in working with the media to brief journalists on issues affecting community pharmacy.

Media Relations

There has been a substantial amount of media coverage since the last AGM. Regular press releases are issued by the IPU, promoting the role of pharmacists and raising concerns affecting community pharmacists. We receive regular coverage in the national media, including RTE One's *Six-One News* and *Nine News*, as well as current affairs programmes such as *Drivetime*, *The Last Word* and *The Right Hook*. Many of these are available to watch on the IPU YouTube Channel, showing the strength of spokespersons representing the IPU. The national newspapers also carry regular articles and interviews with IPU representatives.

Some of the key issues that arose during the last year were:

- Pharmacists respond to harsh measures announced in Budget 2013 5 December 2012
- IPU Pre-Budget Submission 2013 1 November 2012
- **Pharmacist's Advice** – there were many press releases issued over the past year with pharmacists offering advice on a range of issues. Pharmacists were in the media advising students on how to protect against stress at exam time, the “dos” and “don'ts” of giving medicine to young children, the dangers of getting healthcare advice online, antibiotic awareness, tips for fighting colds and flu, and much more.
- **Pharmacy Business** – in the last year, press releases have been issued with a focus on the pharmacy business. With the support of statistics from surveys of members, the IPU highlights key challenges that were affecting pharmacies,

including dropping sales. Press releases also called for cuts in commercial rates and highlighted the extent and impact of crime on pharmacies.

- **Advocating for Patients** – the IPU issues press releases advocating on behalf of patients of pharmacies. It was the IPU who highlighted to the public and media that the HSE were withdrawing Gluten-Free products from State Schemes in September. We also welcomed the reduction in the price of medicines. Following the announcement of the Budget and increase in the Prescription Levy, the IPU renewed its call to exempt certain patient cohorts from the levy.

A list of all the press releases issued is available on page 58.

IPU Spokespersons do great work throughout the year in taking time out from their pharmacies to be interviewed and brief journalists. Media Training took place last September for a number of new regional spokespersons.

Advertising Campaign – ‘Ask Your Pharmacist First’

The IPU continues to promote the ‘Ask Your Pharmacist First’ message with national radio and poster ad campaigns. In July 2012, a poster ad campaign ran throughout pharmacies to explain to patients what pharmacists do with the prescriptions they receive. In October 2012, a radio advertising campaign was launched to promote the Vaccination Service through pharmacies. 73% of adults 65+ (390,000 people) heard the vaccination ad once or more, with the average adult 65+ hearing it 7.6 times. 68% of adults 25-44 (983,000 people) heard the ad once or more, hearing it 6.5 times on average.

A further radio ad campaign ran in December, promoting the retail side of pharmacy in the run-up to Christmas. 75% of adults 65+ (400,685) heard the ad one or more times, with the average adult 65+ having 10.7 opportunities to hear the ad. 939,632 of adults 25-44 (65% of audience) also heard it once or more, with the average adult

25-44 having 6.6 opportunities to hear the ad.

The radio ads were broadcast on RTE Radio One, Today FM, 2FM and Newstalk, supported by key regional stations including 4FM. Members were sent posters to complement the radio ads and reinforce the message visually.

Communications to Members

Communications to members continue to develop and uptake continues to increase. Usage of the IPU website is growing, as well as time spent on the website. The IPU Review and monthly General Memorandum are vital resources of information for members. The open rate of IPU News, the weekly e-newsletter, is also increasing with more members accessing their IPUMail regularly. Following on from the launch of the IPU Facebook page in December 2011, a Twitter account was launched in September 2012. Social media is another tool for communicating with both members and the public, and numbers of followers to our pages are growing each week. The SMS Service is another communications tool to get information to members quickly on important updates and deadlines. The *On Your Side and By Your Side* booklet was sent to all members again for 2013, which highlights the benefits of being an IPU Member as well as details of all the support and services that the IPU provides.

Political Engagement

A delegation from the IPU met with the Minister of State for Health with Responsibility for Primary Care, Alex White, T.D. in March 2013, to outline concerns around FEMPI; Reference Pricing and Generic Substitution Legislation; PSI fees and Bankruptcy and PSI Registration. The delegation informed the Minister of the potential role of proposed new pharmacy services as part of the Government's healthcare strategy. Meetings have been held with Opposition spokespersons on Health with regard to legislation on Reference Pricing and Generic Substitution and other issues of concern to the profession. An IPU delegation addressed the Joint Committee on Jobs, Enterprise and Innovation and Taoiseach Enda Kenny, T.D.

International Pharmacy Matters

1. PGEU Report

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists in 32 European countries including EU Member States, EEA countries and EU applicant countries. Overall, PGEU represents over 400,000 community pharmacists in Europe through their professional bodies and pharmacists' associations. PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

The IPU is represented at PGEU by Darragh O'Loughlin, Head of Delegation, Pamela Logan, Director of Pharmacy Services, and Jill Lyons, PCRS Contract Manager. The IPU has been very active within PGEU over the past year, ensuring that community pharmacy is considered in a wide variety of EU Directives. 70% of legislation in Ireland comes from EU Directives so it is vital that lobbying is done at this level rather than waiting for transposition into Irish legislation.

Directives and Dossiers

PGEU actively worked on a range of Directives and Dossiers throughout 2012/13:

- Falsified Medicines – the creation of a system of authentication of medicines at pharmacy level and the regulation of the sale of medicines through the internet;
- Data Protection Legislation – to establish the conditions to access and process health records;
- Transparency Directive – related to the timing of pricing and reimbursement decisions;
- Good Distribution Practice Guidelines – to ensure a harmonised level of quality of medicines is maintained throughout the supply chain; and
- Professional Recognition – a revised system of recognition of the professional qualifications of pharmacists from other Member States.

Medicines Authentication/Falsified Medicines Directive

PGEU, EFPIA (manufacturers), GIRP (wholesalers) and EAEPC (parallel distributors), among others, have collaborated on a stakeholder approach to medicines authentication – the European Stakeholder Model (ESM). These stakeholders will meet with the Heads of EU Medicines Agencies in Dublin on 23 April 2013 (under the Irish Presidency) to further explain the proposal. Darragh O'Loughlin represented PGEU at this meeting.

The European Commission has undertaken an economic impact assessment of medicines authentication to make sure that unnecessary costs are not being imposed by the Directive. The draft report supports the ESM model as being the most economic and efficient. Other findings in the draft report are:

- Medicines authentication may require some national authority supervision;
- The cost to pharma should be less than 1% of their profits;
- Community pharmacies will need to spend around €100/pharmacy for technical adaptation and €250/scanner;
- Medicines authentication should occur at point of dispensing in pharmacies;
- Wholesalers should only have to do random authorisation.

It is not clear yet what assumptions have been made about generics. The report assumes that community pharmacies have a net profit margin of 8%. The final report should be published in a few months.

PGEU has commissioned an IT consultant to look at the costs of medicines authentication from a community pharmacist's perspective.

He will:

- a. Conduct a survey of dispensary software in the EU;
- b. Speak to software providers about the technical requirements for medicines authentication; and

- c. Outline the costs and challenges for community pharmacists in implementing medicines authentication.

The ESM has selected a service provider to produce the EU hub and 'off-the-shelf' regional hubs. The system will be cloud-based and linked to Microsoft Azure. The intellectual property will belong to the European Medicines Verification Organisation (EMVO), the non-profit organisation set up under the ESM, with PGEU as one of the seven founding stakeholders. Work will commence on the EU hub now but we will wait for the Delegated Acts to publish the safety features – expected late 2013 – before the regional hubs are developed. Costs are currently estimated at 0.5€cent/pack, considerably less than first estimated. Once the Delegated Acts have published, Member States will have three years within which to introduce medicines authentication, probably by 2017.

A potential unforeseen side-effect of the Directive is the requirement that, from January 2013, all active pharmaceutical ingredients (APIs) imported from outside the EU will need written confirmation from the exporting country's competent authority that the API was produced in accordance with applicable GMP (Good Manufacturing Practice) standards. India and China have been slow to comply with this; consequently, this could lead to increased shortages of medicinal products.

Proposal on Data Protection Legislation

In 2012, the Commission started a revision of the data protection legislation. Health data is for the first time defined and specifically regulated. This regulation will establish the conditions to access and process health records, whether they are automated or not. It will also regulate data stored for reimbursement purposes or pharmacovigilance-related data.

The legislation proposes that health data can only be processed under a specific law and for specific purposes. In addition, such a law must comply with the requirements established in the regulation. Some of the requirements include:

In relation to the data subject:

- Explicit consent in writing;
- Provide information on the processing;
- Access to data (free of charge);
- Right to rectification, right to be forgotten and erased (data needs to be erased if this is requested by the data subject);
- Right to data portability; and
- Communication of a personal breach to the data subject (within 24 hours).

In relation to the data processing:

- Keep appropriate documentation;
- Implement data security requirements;
- Prior authorisation and probably an impact assessment;
- Co-operate with the supervisory authority;
- A designated Data Protection Officer if data on >500 people is kept.

The proposal for a Data Protection Officer has been condemned by small businesses and is unlikely to be adopted at the LIBE Committee. PGEU is concerned about the explicit consent required for data processing – this could cause problems for reimbursement. There is also ambiguity in the Proposal about ‘public interest’ therefore PGEU is proposing that pharmacy data should be covered by ‘public interest’. PGEU is concerned about the Delegated Acts process as it is not transparent and there is no consultation. It would be preferable if the Delegated Acts were watered down and left to national authorities.

Transparency Directive

The existing Directive related to the timing of pricing and reimbursement decisions. The revised Directive proposes:

- Coordination of Health Technology Assessments (HTAs);
- Reduced timescales for reimbursement decisions – 60 days for patented and 30 days for generics; and

- Increased enforcement for non-compliance, especially in relation to generics.

Good Distribution Practice (GDP) Guidelines

The GDP Guidelines ensure that a harmonised level of quality of medicines is maintained throughout the distribution chain in the EU. The GDP Guidelines are being revised to take into account new requirements for wholesale distributors and brokers established in the Falsified Medicines Directive. PGEU’s main concern was the original proposal of a period of five days for returns from pharmacies of medicines to wholesalers. We understand that this is now likely to say that medicines can be returned by pharmacies to wholesalers ‘*within an acceptable time limit, for example 15 days*’.

Directive on the Recognition of Professional Qualifications

This Directive establishes the conditions for the recognition of titles and qualifications of professionals within EU Member States. Pharmacists and five other professions (doctors, nurses, vets, midwife and architects) are automatically recognised without the need to undertake further ‘*compensation measures*’, i.e. additional training or experience. In 2011, the Commission launched a revision in order to modernise the Directive. The Commission proposed significant changes to the recognition regime, including new proposals on the provisions regulating the pharmacist’s course of study.

PGEU proposed an extension to the list of pharmacists’ activities in order to ensure that current pharmacy practice is reflected in the Directive. The PGEU proposed list included:

- sourcing, preparation, testing, storage and dispensing of safe and secure medicinal products in pharmacies open to the public;
- medicines management and provision of information and advice on medicinal products and health related issues;

- supporting individual patients in the use of non-prescription medicines and self-care; and
- contributing to public health campaigns.

All of these amendments have been carried in Parliament. Now the Council needs to support these amendments. Parliament has also proposed that CPD should be made mandatory and that bodies that oversee CPD should be assessed for quality. There is also a concern that the Directive is being used to define post-graduate specialisations; this was not the intention of the original Directive. It is not clear if the Council will support these latest proposals.

2. Report on FIP Congress, Amsterdam

The International Pharmaceutical Federation (FIP) together with the Royal Dutch Pharmacists’ Association (KNMP) hosted the Centennial World Congress of Pharmacy and Pharmaceutical Sciences on 3-8 October 2012 in Amsterdam. Her Royal Highness, Princess Margriet of the Netherlands, was on hand at the Opening Ceremony to release the FIP Centennial Declaration and welcome over 5000 participants to Amsterdam for the centennial celebration and coinciding Roundtables and Ministers’ Summit.

During the Congress, FIP took its place at the table among Ministers of Health from around Europe at the Summit on *Increasing Responsible Use of Medicines - setting policies for better and cost-effective healthcare*. FIP urged pharmacists to bring forth proposals and take action in increasing the role of pharmacists in healthcare delivery. Such measures could contribute to decreasing healthcare costs by billions, as outlined in a recently released report from the IMS Institute. FIP President, Michel Buchmann, also encouraged pharmacists and physicians to work together and utilise both professions to their fullest potential. Such collaboration is an imperative step in the goal of increasing responsible use of medicines and realising optimal benefits for patients.

International Pharmacy Matters

(continued)

Through its 127 member organisations and 4000 individual members, FIP represents and serves almost three million pharmacists and pharmaceutical scientists around the world. The FIP President greeted the audience of almost 5000 pharmacists, pharmaceutical scientists, academics, researchers, students and guests who had come together for a week of pre-satellite symposia, workshops, lectures and meetings focused on this year's Congress theme – *Improving health through responsible medicines use*.

Mr Buchmann urged pharmacists to take action in five vital areas: transforming education to support the provision of new roles; developing inter-professional collaboration; demonstrating added value; helping patients to adhere to their treatments; and engaging in policy making.

Mr Buchmann went on to say *“It is imperative for the advancement of all sectors that we are able to work based on our true value and the contributions we make. Pharmacists’ added value must be recognised by governments because of our role in public health and patient safety – the benefits we bring to patients.”*

FIP Centennial Declaration

IPU President, Rory O'Donnell, joined leaders of other FIP member organisations in signing the FIP Centennial Declaration – *Improving Global Health by Closing Gaps in the Development, Distribution and Responsible Use of Medicines*.

Among the commitments made in the declaration are:

- To work with all sectors of society to foster development and worldwide access to medicines
- To fight for the elimination of sub-standard and counterfeit medicines
- To encourage pharmacists to expand their role in helping patients adhere to their medication regimes
- To expand public awareness that more positive health outcomes and important cost savings result when patients, physicians and pharmacists collaborate in selecting, monitoring and adjusting medication therapy.

The 73rd World Congress of Pharmacy and Pharmaceutical Sciences 2011 will take place in Dublin from 31 August to 5 September 2013. The theme of the conference will be “Towards a Future Vision for Complex Patients”. Pharmacists are encouraged to attend this exciting conference to meet and share experiences with pharmacy colleagues from all over the world.

2013 AGM Motions

The following motions, proposed in accordance with Article 30 of the IPU Constitution, are brought before the meeting for consideration:

1. Proposed: **Rory O'Donnell**
Seconded: **Kathy Maher**

*"That this AGM appoints ?? to be a Trustee of the Irish Pharmacy Union in accordance with Article 25 of the IPU's Constitution."
[Name will be announced at the AGM.]*

2. Proposed: **Bernard Duggan**
Seconded: **Daragh Connolly**

"That this AGM calls on the Department of Health to utilise the enormous potential of community pharmacies by expanding the role of the pharmacist so that more services are offered to patients through community pharmacies, which will benefit patients and help Government deliver on its Future Health Strategy and Healthy Ireland Framework."

3. Proposed: **Roy Hogan**
Seconded: **Michael Tierney**

"That this AGM calls upon the Minister for Health to delete Section 14 (1) (f) of the Pharmacy Act 2007 which prohibits pharmacists who become bankrupt from registering with the Pharmaceutical Society of Ireland."

4. Proposed: **Brian Walsh**
Seconded: **Fergus Brennan**

"That in light of recent decisions made by the HSE, this AGM calls on the Minister for Health to ensure that patient care remains of paramount importance and that decisions made by the Minister and the HSE do not adversely impact on patient care or undermine the capacity of the profession to play its part in the healthcare reform agenda."

5. Proposed: **Jack Shanahan**
Seconded: **Sean Reilly**

"That this AGM calls on the Department of Health to meaningfully engage with the IPU to help deliver a standards-based electronic prescription transfer system that will promote patient safety."

Appendix I

A List of Submissions Made During the Year

The following submissions were made during the year. All are available on www.ipu.ie.

2012

- ***FEMPI Review 5***
- DoH - May 2012
- ***Pharmacovigilance Regulations***
- DoH - July 2012
- ***Rapid Discharge Planning***
- HSE - Sep 2012
- ***National Integrated Care Guidance***
- HSE - Sep 2012
- ***Pre-Budget 2013 Submission***
- Departments of Finance &
Public Reform - Oct 2012

2013

- ***FEMPI Review***
- DoH - Jan 2013
- ***Medicines Shortages and ULMs
Consultation***
- DoH - Jan 2013
- ***Standardising Patient Discharge
Summary Information***
- HIQA - Jan 2013
- ***Alex White Briefing***
- Mar 2013
- ***Falsified Medicines Regulations***
- DoH - Mar 2013

Appendix II

Some Key Letters and Responses Received Throughout the Year

Topics

- FEMPI
- Financial Emergency Measures in the Public Interest Act 2009 (FEMPI)
- Reference Pricing
- Reductions in the Cost of Medicines
- PSI Matters
- Primary Care Centres
- Pharmacy Vaccination Service
- Benzodiazepines
- PCRS Communications
- Extemporaneous Preparations
- Pradaxa
- ICCPE / Pharmacy Training Grant / Continuing Education
- Driving Licence Photographs
- Other Matters
 - Bankruptcy
 - Switching
 - Directive on Recognition of Professional Qualifications
 - High Tech Medicines
 - National Consumer Agency (NCA) Survey

FEMPI

FEMPI – Letter 1

From HSE Contract Manager to Assistant Secretary General, DoH [14 May 2012]

Re: Financial Emergency Measures in the Public Interest Act 2009

I wish to acknowledge your letter of 10 May to Seamus Feely in relation to the Minister's Review under the Financial Emergency Measures in the Public Interest Act 2009.

I wish to confirm that the IPU will be making a submission to the Minister's Review. We would also welcome an opportunity to make an oral submission to the Department on Tuesday 5 June, if that date is available.

FEMPI – Letter 2

From Secretary General to Minister for Health [14 December 2012]

Re: Review under the Financial Emergency Measures in the Public Interest Act, 2009

We refer to a letter we received from Mr Paul Barron, Assistant Secretary of the Department of Health dated 13 December 2012, stating that on Budget day the Government had announced a review of the fees/allowances payable to health professionals, with an overall target figure of €70 million in savings to be achieved in 2013.

The letter indicates that you, in accordance with Section 9 of the Financial Emergency Measures in the Public Interest Act, 2009, have determined that a full review of payments to a number of professionals, including pharmacists, be carried out. The letter sets out the timeline for the consultation process, and the fact that the review shall include, but not be confined to, payments under the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2011. It then invites the Irish Pharmacy Union to provide a written submission to assist in your deliberations on the

matter. It also indicates that the Irish Pharmacy Union may make an oral submission, if it so wishes.

We wish to seek your assurances that the outcome of the review in relation to which Mr Barron wrote, has not been predetermined or prejudiced in light of the comments of the Minister for Public Expenditure and Reform, Mr Brendan Howlin, T.D., in his Address to Dáil Éireann on Expenditure Estimates 2013, on Wednesday, 5 December, 2012.

In particular, the Minister for Public Expenditure and Reform's comments: *"Professional fees for health service providers such as GPs and community pharmacists will be reduced to save €70 million."* cause significant concern. It seems that community pharmacists are being 'singled out' as one of those groups likely to be subject to reduced payments, prior to receipt by you of any submissions. It also seems that a set reduction in fees of €70 million has already been determined.

As you are aware, Section 9 (4) of the Financial Emergency Measures in the Public Interest Act, 2009, provides that prior to making a Regulation to reduce the amount or the rate of payment to be made to health professionals, or classes of health professionals, in respect of any services that they render to or on behalf of a health body, the Minister for Health and Children, or, at the Minister's direction, the health body concerned, *"shall engage in such consultations as that Minister considers appropriate"*. Section 9 (5) provides that such a Regulation shall fix amounts or rates that the Minister for Health and Children considers to be fair and reasonable, having regard to the matters which that Minister considers appropriate, including any or all of a number of factors. Those factors include *"any submissions made and views expressed during the consultations..."*.

The correspondence from Mr Barron inviting the Irish Pharmacy Union to provide a written and oral submission to assist in your deliberations on the matter, clearly indicates that you consider the written and oral submission of the Irish Pharmacy Union as an appropriate matter to which to have regard, in deciding fair and reasonable amounts or rates. We are

Appendix II

(continued)

therefore surprised by the Minister for Public Expenditure and Reform's comments.

Naturally, if the amounts or rates have already been decided, a request for written submissions would appear to be a pointless exercise, causing unnecessary expense and incurrence of time spent preparing written and oral submissions. More seriously, if those are in fact the circumstances, they would be indicative of a failure to follow the provisions of the Financial Emergency Measures in the Public Interest Act, 2009. This would clearly give rise to a claim that there has been an abuse of process, providing grounds to judicially challenge the outcome of the review/consultations.

We would be grateful if you would please clarify the statement made by the Minister for Public Expenditure and Reform, on 5th December 2012.

We would also seek your assurances that no set reduction in relation to pay or rates to pharmacists has been determined prior to the conclusion of the review/consultations. In the meantime, it is our intention as of now to make both a written submission and an oral presentation to your Department.

REFERENCE PRICING

Reference Pricing – Letter 1 From Secretary General to Minister for Health [12 September 2012]

Re: Health (Pricing and Supply of Medical Goods) Bill 2012

I am writing to you in relation to the Health (Pricing and Supply of Medical Goods) Bill 2012 (the Bill). The Irish Pharmacy Union (IPU) has a number of concerns about the proposed Bill. Whilst we welcome the introduction of generic substitution, we have concerns that the Bill does not fully address continuity of supply of medicines, medicine shortages and notice period to stakeholders. I wish to set out a number of suggested amendments to the Bill that we believe will address these concerns and ensure a constant supply of medicines to patients.

Continuity of supply:

- In relation to **Section 24(2)**, which appears to allow the HSE to review the reference price once every three months, the IPU would request that this be extended to six months to ensure that there is certainty in relation to stock-holding for wholesalers and pharmacists which in turn facilitates continuity of supply of medicines to patients. Therefore, we would submit that the following should be inserted in **Section 24(2)** in place of "every three months": "every six months".
- **Section 19** refers to the notice that the HSE must give to manufacturers when they make a relevant decision about whether to add, remove, retain or refuse to add an item on the Reimbursement List. There is no mention of any notice which must be given by the HSE to prescribers or pharmacists, both of whom, in the event of the removal of a listed item, will need to source an alternative medicine for their patients. It is submitted that all changes to the list should be notified to pharmacists, doctors and the IPU. Failure to do so will result in confusion

for pharmacists, doctors and patients and a possible delay in patients receiving the appropriate medicine. Therefore, we would submit that the following should be inserted in **Section 19(1)** and **(2)** in place of "to the supplier of the item or listed item the subject of the relevant decision": "to the supplier of the item or listed item the subject of the relevant decision and to prescribers and pharmacists".

- It appears that **Section 21(2)** lays out the criteria that the HSE will take into account when considering the proposed relevant price by the supplier of an item. This section should be amended to include two critical criteria – "the welfare of the patient" and "the impact of the relevant price on the continuity of supply of the relevant listed item".
- Similarly, it appears that **Section 24(3)** lays out the criteria that the HSE will take into account when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products. This section should be amended to include two critical criteria – "the welfare of the patient" and "the impact of the reference price on the continuity of supply of the relevant listed item within the relevant group of interchangeable medicinal products".

Medicine shortages:

- **Section 18(7)** appears to allow the HSE to remove a product from the Reimbursement List if its temporary cessation on the market causes patient disruption. **Section 18(8)** appears to allow the HSE to remove a product from the Reimbursement List if the manufacturer doesn't make enough to meet the demand in the State. We would be grateful if the Department of Health could clarify the circumstances in which these provisions would be utilised.
- It appears that **Sections 21(4)** and **24(4)** allow the HSE to use a competitive process to determine the relevant price of an item or a listed item and to set the reference price for a relevant group of interchangeable

medicinal products, respectively. **Section 21(2)(a)** provides that it is now intended to take into account the equivalent relevant price of an item in all other Member States where the item is marketed when considering the proposed relevant price. **Section 24(3)(c)** provides that, when setting a reference price for a relevant group of interchangeable medicinal products, it is now intended to take into account the equivalent relevant prices of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed when considering the proposed relevant price.

Tendering for medicines may lead to a price war resulting in smaller companies which provide medicines being driven out of the Irish market because it makes no financial sense for them to remain. In those circumstances, the power to supply could rest with one company only and the risk of medicine shortages could increase, as has been seen in other EU countries. Similarly, if the reimbursable or reference price of a medicine is set too low, there will be no incentive for manufacturers to market their products in Ireland, given the relatively small size of the Irish market. Consequently, increased reliance on very costly unlicensed medicines (ULMs) will cost the Exchequer and patients more in the longer term. The IPU would suggest that there should be an obligation on the Department of Health to make sure that there is a sufficient security of supply of medicinal products for patients and that any decisions taken will not lead to increased use of ULMs. We submit that this should be set out explicitly in the Bill.

Notice period to pharmacists and other stakeholders:

- It appears that **Section 6(5)** requires the IMB only to give notice to prescribers and pharmacists if they decide to remove a medicinal product from a group of interchangeable medicinal products or to remove a group of interchangeable medicinal products from the list of interchangeable medicinal products. It is essential that

prescribers and pharmacists are given sufficient notice of at least eight weeks to enable them to determine or source a suitable alternative medicine for the patient to ensure continuity of care. Therefore, we would submit that the following should be inserted in **Section 6(5)** in place of “*as soon as is practicable*”: “*as soon as is practicable but with a minimum of eight weeks’ notice*”.

- It appears that **Section 6** does not require the IMB to give notice to prescribers and pharmacists when medicinal products are added to a group of interchangeable medicinal products or a group is added to the list of interchangeable medicinal products; notification to prescribers and pharmacists only appears to be given for removals. Prescribers and pharmacists should be informed of all additions and deletions. Therefore, we would submit that the following should be inserted in **Section 6(5)** in place of “*Where a relevant decision which falls within paragraph (g) or (h)*”: “*Where a relevant decision which falls within paragraph (a) to (h)*”:
- **Section 24(6)** appears to provide that the HSE will give pharmacists four weeks’ notice of a change to a reference price. Wholesalers and pharmacists will need much longer than this to run down their stocks; otherwise they will suffer financial loss as a consequence of this short notice and will keep their stock levels very tight. This could lead to problems for patients. The IPU would request that pharmacists be given eight weeks’ notice of a change to a reference price. Therefore, we would submit that the following should be inserted in **Section 24(6)** in place of “*not later than four weeks*”: “*not later than eight weeks*”.

Supervision of compliance:

- **Section 32** appears to indicate that pharmacists will be required to adhere to the provisions of this Bill and that compliance will be policed by the Pharmaceutical Society of Ireland (PSI) under the Pharmacy Act

2007. However, the IPU is of the view that the provisions of this Bill are not regulatory but are related to contract and are suitably covered by the Community Pharmacy Contractor Agreement. Furthermore, it is submitted that this is recognised in the Bill. Consequently, the HSE is the appropriate body to police compliance with the legislation and not the PSI. The National Consumer Agency is also available to deal with any issues that arise for patients.

The problem with using the Pharmacy Act to police this Bill is that, under the current requirements of the Pharmacy Act, the PSI must refer all complaints to the Preliminary Proceedings Committee (PPC) for its advice on whether there is sufficient cause to warrant further action being taken. If the PPC advises that there is sufficient cause to warrant further action, the PPC can refer the complaint for resolution by mediation (albeit that the PSI has never utilised this option), or refer the complaint to the Professional Conduct Committee. Typically, the latter process can take up to 18-24 months and is extremely costly for both the PSI and the pharmacist concerned. It is not in anybody’s interests to provide that the burden of this process would apply to this piece of legislation. Furthermore, this is not a Fitness to Practise issue, rather a commercial one. It is inappropriate to utilise the Fitness to Practise mechanism for an issue which is not related to patient welfare or a pharmacist’s professional competence, but is purely economic.

Therefore, the IPU would recommend that these provisions be deleted from the Bill. However, if the Minister is adamant that this legislation be policed by the PSI, then an amendment should be made to Section 38(1) of the Pharmacy Act, stating:

As soon as is practicable after receiving a complaint, the Council shall either refer it to the Registrar for consideration and resolution or refer it to the preliminary proceedings committee for its advice on whether there is sufficient cause to warrant further action being taken.

Appendix II

(continued)

We would also recommend an amendment to Section 40(1) of the Pharmacy Act so that it says:

If the preliminary proceedings committee advises...that there is sufficient cause to warrant further action...the committee shall either –

(a) refer the complaint to the Registrar for consideration and resolution, or

(b) refer the complaint for resolution by mediation...or

(c) refer the complaint to whichever of the following committees (“committees of inquiry”) it considers appropriate –

(i) the professional conduct committee

(ii) the health committee.

This would allow the Registrar to deal with failures to comply with this legislation in short course rather than spending up to two years and incurring extensive costs progressing through a full Fitness to Practise process resulting in an utterly disproportionate response to the initiating circumstances.

Other areas requiring clarification:

- We would be grateful if the Minister could clarify the precise meaning and intention behind **Sections 5(12), 5(13) and 19(6)**.
- **Section 13(1)** appears to provide that a prescriber can exempt a medicinal product from substitution by writing by hand “do not substitute” on the prescription. **Section 13(2)** refers to regulations that the Minister may make in relation to this exemption. We would be grateful if the Minister could clarify what kind of regulations he intends making under this section.
- The IPU notes that it is possible to commence some parts of this Bill in advance of other parts. We therefore propose that the parts to facilitate generic substitution be commenced in advance of the other parts of this Bill in order to facilitate patients in accessing cheaper generic medicines immediately.

- **Section 20** appears to allow the HSE to attach conditions to the supply of medicines. In drawing up such conditions the HSE should have regard to implications for patients already established on those medicines and the section should be amended accordingly. This is the only way to avoid a repeat of the Pradaxa debacle where the HSE applied rules retrospectively without telling pharmacists or patients, leading to total confusion.

- The IPU would ask that an amendment be made after **Section 26**, outlining the obligation that the Department of Health and the HSE have in implementing a Public Information Campaign to make sure that patients are well informed about this Bill and the changes that will happen as a consequence.

In order to implement generic substitution, significant changes will be required to be made to pharmacy and GP IT systems to accommodate the changes being brought about by the Bill. We therefore request that the Department of Health arrange an urgent meeting between the Department, the PCRS, the IT vendors and the IPU to ensure that all IT systems are capable of implementing this regime and that implementation is as seamless as possible. The level of IT development work required is considerable and will be costly to develop.

Finally, the IPU would also submit that this Bill provides an ideal opportunity to introduce Medicine Use Reviews (MURs) and a New Medicines Service (NMS), as was done recently in the UK. The purpose of these initiatives is to improve compliance, reduce leakage to secondary care and reduce wastage of medicines.

All the above points are vital for the successful implementation of the Bill. The IPU would welcome an early meeting with your Department to discuss these amendments further.

Reference Pricing – Letter 2 From Secretary General to Chairperson Fine Gael Internal Health Committee [1 November 2012]

Re: Meeting with Internal Health Committee

I am writing on behalf of the Irish Pharmacy Union (IPU) requesting an opportunity for a small delegation to present to the Fine Gael Internal Health Committee. The delegation would like to outline the role of pharmacy in healthcare and the significant contribution the sector can make to the delivery of healthcare services.

A positive response to our request would be greatly appreciated.

Reference Pricing – Letter 3 From T Cody, Primary Care, DoH to Secretary General [5 November 2012]

Re: Health (Pricing and Supply of Medical Goods) Bill 2012

I refer to your letter of 12th September 2012 which outlined a number of concerns regarding the Health (Pricing and Supply of Medical Goods) Bill 2012.

On the 5th October last, the main issues of concern raised in your letter, namely, continuity of supply; medicines shortages; notice periods to pharmacists and other stakeholders; and supervision of compliance were discussed in detail with Ms Jill Lyons and Mr Jim Curran.

In relation to continuity of supply; medicines shortages; and notice periods to pharmacists and stakeholders, the Department considers that there is currently sufficient provision in the legislation covering these areas. In particular, the Department considers that continuity of supply is implicitly provided for throughout the proposed legislation (e.g. Schedule 3, Part 3) and there is no need to include an explicit reference to this issue in the Bill. Similarly, patient safety is a central tenet of the proposed legislation with Section 20(1) (a) making specific reference to this issue in the context of the conditions

that the HSE may attach to the supply and reimbursement of listed medicinal products.

It is therefore not proposed to take on board the legislative amendments proposed for these issues in your letter. However, it would continue to be open to the IPU to discuss any operational issues of concern to pharmacists with the HSE during the implementation phase of the legislation.

The Department acknowledges the IPU concerns regarding the proportionality of using the Pharmaceutical Society of Ireland (PSI) to police compliance with the provisions of the Bill under the Pharmacy Act 2007. This issue was provisionally discussed at our meeting and I advised I would consult with my colleagues on the pharmacy legislation side of the Department. Some of the points raised by the IPU regarding section 32 of the Bill relate to the operation of the complaints process under the Pharmacy Act and have implications in relation to complaints generally rather than just to complaints arising under this Bill. The points raised by the IPU will be considered in the context of reviewing the Pharmacy Act 2007 and other related legislation. However, at this point I wish to advise that the Department is not considering amending this provision of the Health (Pricing and Supply of Medical Goods) Bill.

You also sought clarification on a number of other aspects of the Bill. These were not discussed in detail on the 5th October and I will now outline the Department's position with respect to each issue.

■ **The precise meaning and intention behind Sections 5(12), 5(13) and 19(6)**

Section 5(12) essentially enables the IMB to remove a product from the group of interchangeable medicinal products it is currently listed on if the Board is no longer satisfied that it can be safely substituted. Section 5(13) provides for the same approach in the context of a group of interchangeable products.

On commencement of Section 17, the list of medicinal products currently reimbursed under the GMS and Community Drug Schemes shall be deemed to be listed as

reimbursable items. Section 18(4) provides that the HSE shall not later than the 3rd anniversary of the date of commencement of section 17 treat each deemed listed item as if it was not on the Reimbursement List but was subject to an application under section 18(1). (The period provided for in section 18(4) may be extended to five years with the approval of the Minister for Health.) Section 18 (5) provides that the HSE may review a listed item at any time.

Section 19(6) provides that where the HSE reviews an item under section 18 (4) or 18 (5) see definition of deemed application - and makes a determination the item shall cease to be a deemed listed item and any conditions attaching to the deemed listed item shall cease to be a deemed condition once the necessary notification periods under Sections 19(1) and 19(3) are complied with. In practice, following review, an item will either be retained on the Reimbursement List, whether or not subject to conditions, or removed from the Reimbursement List.

■ **Regulations under Section 13(2)**

Section 13(1) of the Bill provides that a prescriber can, if satisfied that a branded interchangeable medicinal product prescribed for a patient should not be substituted on clinical grounds, exempt the prescription from substitution by writing '*do not substitute*' beside the relevant product on the prescription. Section 13(2) provides that the Minister may make Regulations requiring prescribers to state the reasons for utilising the exemption to substitution provision in Section 13(1). It is important to note that this is an enabling provision which the Minister may invoke if considered appropriate having assessed the practices of prescribers under this provision.

■ **Phased Commencement of the Bill**

There is scope for phased commencement. However, there is no intention to introduce the generic substitution provisions of the Bill prior to the reference pricing provisions.

■ **Conditional Reimbursement**

Section 20 allows the HSE to attach conditions to the supply or reimbursement of listed items in the interest of patient safety; cost-effectiveness; maximising appropriate use of the listed items concerned; and appropriately applying the resources available to the HSE. As patient safety is a key criterion underpinning this section and indeed is a fundamental concern underpinning all provisions of this Bill, the HSE will not introduce conditions under this section without fully evaluating their impact on the welfare of patients.

■ **Public Information Campaign**

The Department has established an Implementation Group on Generic Substitution and Reference Pricing which will consider all aspects of the Bill's implementation. A key element of this Group's work is developing a communications strategy to ensure that all stakeholders, including patient groups, are fully informed of the implications of the legislation. In this context, the Group is currently working on a draft patient information leaflet and comment has already been sought from the IPU. In addition, stakeholder group meetings will be arranged in the near future to further consult with key stakeholder groups.

■ **Medicine Use Reviews (MURs) and New Medicines Service (NMS)**

I understand that the report on the Medicine Usage Review pilot carried out in 2010 is due this month. The Department will consider the issues arising from that report. Meanwhile it is not intended to amend the Bill to provide for Medicine Use Reviews and a New Medicines Service.

I hope this clarifies the position with respect to the issues raised in your letter. Should you require further clarification on any aspect of the Bill, please feel free to contact me.

Appendix II

(continued)

Reference Pricing – Letter 4
From Secretary General to Assistant
Secretary General, DoH
[13 February 2013]

Re: Implementation Group Meeting

I wish to refer to the Implementation Group meeting that took place in the Department on the 7 February last in relation to the proposed introduction of Reference Pricing and Generic Substitution and changes that need to be made to Pharmacy IT systems.

I understand that at the meeting, the HSE circulated three detailed documents for review which addressed a number of issues some of which were totally unrelated to the introduction of Reference Pricing and Generic Substitution. The proposals tabled by the HSE would require significant consideration before they can be advanced. The appropriate forum in which these issues should be addressed is through the IPU/HSE Joint Consultative Group. Frankly, the implementation of Reference Pricing will be complicated and costly enough to implement without unnecessarily introducing additional processes that will further complicate matters at this time.

We are also surprised at the proposals from the HSE and Department seeking considerable data input from pharmacists. From its perspective, the IPU has indicated that it would co-operate with the introduction of Reference Pricing and Generic Substitution. This commitment was made on the basis that there would be agreement on all implementation matters and administration burden would be kept to a minimum. Pharmacists will be prepared to capture the two vital pieces of information necessary which are the details of the medicine dispensed and whether the prescriber had specifically requested “no substitution” in any particular case. The capture of any other information will not be possible.

It is important to realise that the capture of information is an expensive business particularly in these difficult economic times when pharmacy payments have already been substantially reduced and are under threat of further

reduction. In the circumstances, I wish to seek an urgent meeting with you to discuss the matter further in advance of the next meeting with the HSE on 25 February.

Reference Pricing – Letter 5
From Secretary General to
Secretary General, DoH
[1 March 2013]

Re: Patient Safety Issues

I am writing to you in your capacity as Head of the Department of Health but also as Chairman of the HSE to outline a number of issues which raise patient safety concerns.

1. Generic Substitution/Reference Pricing

a. ‘Do Not Substitute’ Regulations

The Health (Pricing and Supply of Medical Goods) Bill 2012, which is passing through the Dáil at present, states that where a prescriber wishes, for clinical reasons, to be exempt from substitution, they must write “Do Not Substitute” in their own handwriting on the prescription. Pharmacists are concerned that GPs will not write “Do Not Substitute” in their own handwriting, as is currently the case for many prescriptions for controlled drugs. We would like the HSE to advise, in writing, what a pharmacist is supposed to do if presented with such a prescription. Must they refuse to dispense? Must they send the patient back to the GP? The PSI has taken pharmacists to task for dispensing CD prescriptions which were incorrectly written. Pharmacists want to ensure that a patient’s needs are met but do not wish to leave themselves exposed to sanctions by the PSI or HSE; so clarity on this issue is critical.

b. Allergies to Generic Excipients

Another concern that pharmacists have expressed regarding the forthcoming legislation for generic substitution arises when they are aware that a patient is

allergic to excipients in a particular generic medicine. The GP may not prescribe the medicine by brand name and/or does not write “Do Not Substitute” in their own handwriting. Obviously, the pharmacist cannot dispense a medicine to a patient which they know will cause harm, yet they will not get paid if they dispense the brand and, more importantly, they will fall foul of the legislation if they do dispense the brand, leaving themselves open to sanctions by the PSI as well as not being paid by the PCRS. Again, we would welcome a definitive response on this issue.

c. Short Implementation Time

The IPU met with the HSE and the Department on 25 February 2013. During this meeting it was indicated that the Bill is expected to be enacted shortly. Given the lack of clarity and agreement on a number of issues, including IT developments and communication with patients, the IPU would be concerned about any attempt to implement the legislation without adequate planning and preparation.

d. Cost of Counselling

The legislation will place a significant additional cost on pharmacists in ensuring patient welfare and safety by counselling patients on the use of generic alternatives and dealing with patients who do not wish to avail of the cheaper medicine. In any system, pharmacists must be rewarded adequately for their professional input in ensuring that the introduction of the reference pricing legislation does not affect patient care. We wish to have an early meeting with you to discuss the cost of implementation, which is vital to ensure that patients do not end up in hospital unnecessarily with all its attendant costs.

e. IT Developments

The IPU previously flagged this as a significant area of concern for pharmacists. Our experience of dealing with the HSE on IT developments has not been positive and there was no agreement on this at this week's meeting.

The HSE is seeking considerable data input from pharmacists. From its perspective, the IPU has indicated that it would co-operate with the introduction of Reference Pricing and Generic Substitution. This commitment was made on the basis that there would be agreement on all implementation matters and administration burdens would be kept to a minimum. Pharmacists will be prepared to capture the two vital pieces of information necessary which are the details of the medicine dispensed and whether the prescriber had specifically requested "no substitution" in any particular case. The capture of any other information will not be possible. The HSE accepts that the capture of data at their end is an expensive business but does not seem to realise that it is equally expensive at the pharmacy end. This is particularly so for pharmacists in these difficult economic times when pharmacy payments have already been substantially reduced and are under threat of further reduction.

2. Other Issues

a. Pradaxa 150mg Capsules

PCRS has recently confirmed to the IPU that they will not reimburse the supply of 2 x 75mg Pradaxa Capsules under any circumstances. We have tried to point out that, in some instances, a GP may prescribe 2 x 75mg Pradaxa because a patient has difficulty in swallowing the larger 150mg capsule. PCRS responded to this by saying "*the implication that it is inappropriate to displace the fundamentals of appropriate claiming practices whereby the most suitable formulation to satisfy the dosage requirement of the patient is*

supplied by the dispensing pharmacist is disconcerting". Pharmacists clearly would wish to exercise professional judgment on these matters. However, pharmacists need an assurance that when they exercise that judgment, it will be recognised by the HSE and they will be paid the appropriate amount for their intervention, given the patient risks involved. We would be interested in your guidance and views on this matter.

b. Pradaxa 35-day Supply

PCRS will only reimburse pharmacists for supplying a 30-day supply of Pradaxa to prevent venous thromboembolism (VTE) post hip or knee replacement surgery. Pradaxa is licensed for a 35-day supply for this indication. Presumably, this is because the marketing authorisation holder and the Irish Medicines Board considered that a 35-day supply was needed to prevent VTE. PCRS's rationale for this decision is that patients are likely to spend five days in hospital after surgery; therefore they only require a further 30-day supply post-discharge. However, it is becoming evident in the community that patients are discharged much earlier, even the day after the surgery. Yet, when the patient presents a prescription to the community pharmacist for a 35-day supply, typically prescribed by their consultant, the pharmacist must inform the patient that they are only entitled to a 30-day supply. Once again, the paymaster is making the clinical decisions and the issue that then arises is where does the liability lie if the pharmacist ignores the requirements of the prescriber and only dispenses a 30-day supply? This could result in the patient suffering from VTE, with possible fatal consequences, so clarity on this issue is also necessary.

c. PCRS Approval for Pradaxa Supply

PCRS has insisted that patients who require Pradaxa for atrial fibrillation

receive approval from PCRS before any medicine can be supplied by the pharmacist. Yet pharmacists are increasingly experiencing patients arriving in their pharmacy with a prescription but no approval letter. Who will be held responsible if such patients suffer from a heart attack while waiting for approval to be granted by PCRS? Pharmacists need advice on the approach they should adopt in these situations and confirmation that if they exercise their professional judgment and dispense the medicines, the HSE will then pay for it.

d. Supply of Medicines without Prescription

We are aware of a number of occasions recently where the PSI has prosecuted pharmacists for supplying a prescription-only medicine without prescription. Typically, the medicine was one that the patient had been on for a long time but their prescription was out-of-date and they hadn't had the opportunity to get a new one from their GP. None of the patients involved came to any harm and the pharmacist was doing their best to look after the needs of their patients, as laid out in the Code of Conduct for Pharmacists. These are frequently elderly or vulnerable patients. Pharmacists believe that they should not leave such patients without a supply of their vital medicine. Invariably the prescription is supplied in a matter of days. Pharmacists should not be prosecuted for looking after their patients. Pharmacists need clarity on this issue as they are currently between a rock and a hard place given the approach of the Society on the matter.

In conclusion, these issues arise where the strict application of regulations and scheme conditions can conflict with primary concern of pharmacists to look after their patients' welfare. They are sufficiently serious to warrant absolute clarity and I look forward to hearing from you.

Appendix II

(continued)

Reference Pricing – Letter 6
From Secretary General to Minister of State
for Health
[2 April 2013]

Re: Follow-up to Meeting with IPU

Thank you for taking the time to meet with officials from the Irish Pharmacy Union (IPU) on 21 March 2013. I would like to take this opportunity to reiterate that pharmacists can play a greatly expanded role in primary care as part of the overall healthcare reform, as we set out in our presentation to you.

At our meeting, we discussed our concerns about generic pricing and, in particular, the need to ensure that there is adequate time for implementation of the legislation, especially to ensure that the necessary IT interventions are put in place.

We also discussed our concerns about ongoing regulation costs in relation to the Pharmaceutical Society of Ireland (PSI), the criminalisation of pharmacists for technical breaches of regulations under the Pharmacy Act and the removal of a pharmacist from the PSI register if they are declared bankrupt. In relation to the latter point, we are aware that you intend to make amendments to the Pharmacy Act to facilitate some parts of the Health (Pricing and Supply of Medical Goods) Bill 2012 and would request that you use this opportunity to delete Section 14(1)(f) of the Pharmacy Act 2007 at report stage. This would enable a pharmacist to continue to practise their profession in the event that they are declared bankrupt, provided they comply with all other ethical, legal and professional requirements.

Please do not hesitate to contact us if you require further detail on any issue raised in this letter or at our meeting.

Reference Pricing – Letter 7
From Secretary General to
Assistant Secretary General, DoH
[10 April 2013]

Re: Implementation Group Meeting

I wish to refer to my previous letter dated 13 February 2013 to which there has been no reply.

Since February the Pharmacy Contractors' Committee (PCC) has met to discuss the implementation of the Reference Pricing and Generic Substitution Legislation and the impact these changes will have on the pharmacy business.

While the IPU has co-operated with the implementation of the Reference Pricing and Generic Substitution legislation, it is important that the Department and the HSE appreciate that there will be a significant increase in administration and patient counselling for pharmacists. All this extra work is a cost to pharmacists.

However, the PCC are prepared to work with the Implementation Group and the IT Vendors to provide the following information:

- Pharmacists will tick a box to note whether substitution occurred or not – there will be three options – Yes / No / Clinical Exemption and
- Pharmacists will also note what has been dispensed.

The PCC are confident that this satisfies the HSE legal obligations under the legislation while also keeping the level of administration and cost down for all parties involved. It will also enable the HSE to investigate the prescribing patterns of GPs. They already have access to considerable information including the pharmacist's yellow bundles which contain the GP's actual prescriptions.

It is important to realise that the capture of information is an expensive business particularly in these difficult economic times when pharmacy payments have already been substantially reduced and are under threat of further reduction. Any changes to the IT systems will have a cost so it is vital that such changes are kept to a minimum.

In conclusion, pharmacists cannot be expected to cover the cost of these changes and we look forward to discussing this matter with you.

REDUCTIONS IN THE COST OF MEDICINES

Reductions – Letter 1

**From Secretary General to CEO Unipharm, United Drug and CMR
[17 October 2012]**

Re: Recent Price Reductions – IPHA Agreement

I wish to refer to the recent price reductions agreed with the Department of Health and the Irish Pharmaceutical Healthcare Association (IPHA) which will lead to significant reductions to the cost of medicines.

Our members are concerned about the impact of these reductions on the value of their stock. In particular, they are anxious to establish what steps your company intends to take to protect your customers from this overnight stock devaluation and how you intend to compensate them for these losses.

I would welcome an early response from you which we will convey to our members in due course.

Reductions – Letter 2

**From HSE Contract Manager to Assistant Secretary General, DoH
[17 October 2012]**

Re: Reductions in the Cost of Medicines

I wish to refer to the recent announcement of a new agreement between the Department of Health and the Irish Pharmaceutical Healthcare Association (IPHA) which will lead to significant reductions to the cost of medicines. With two weeks to go until the implementation of the reductions, the IPU has still not been provided with a confirmed list of affected medicines.

The IPU has previously requested that the Department give adequate notice of any reductions to the cost of medicines. The announcement on Monday 15 October gives pharmacists only two weeks in which to prepare for the reductions. This is not acceptable. The

IPU and pharmacists should be alerted well in advance of the implementation date. A minimum of four-to-six weeks' notice is necessary to allow sufficient time for the IPU to update our IT system and to allow pharmacists adequate time to dispense stock reimbursed at the higher price.

You will remember that pharmacy contractors experienced significant loss to the cost of their stock as a direct result of the lack of notice provided by the Department in previous year. It is important that pharmacists are not put in this position again therefore I would request that the implementation date for the reductions is pushed back from 1 November to give pharmacists the opportunity to minimise any losses that will occur.

Reductions – Letter 3

**From Secretary General to Minister for Health
[2 November 2012]**

I have been asked by the Executive Committee to write you regarding the manner in which recent price reductions and product changes were introduced with effect from 1 November 2012.

On 15 October 2012, Press Releases were issued to inform the public that a new agreement had been reached between your Department and the Irish Pharmaceutical Healthcare Association (IPHA). As part of this agreement the price of medicines was to be reduced from 1 November 2012. The number of medicines involved was of the order of 1,700; nevertheless, the list of medicines affected by these changes was not produced until the 22 October 2012. When we contacted the Department about the short notice, we were advised that these price reductions were being implemented with effect from 1 November 2012, clearly without any regard for the consequences of these changes on the value of stock on pharmacy shelves.

This was followed by an announcement of a further agreement between the Department and the Association of Pharmaceutical Manufacturers of Ireland (APMI) on the 26 October 2012. The initial list of products affected by these changes appeared on the HSE website at lunchtime on

26 October. This list was then removed a few hours later, due to errors on the list, without any reference on the website or any communication with the IPU or its members. A revised list was then published on the website at 5pm that Friday evening, some five days before these changes were to be introduced over a public holiday weekend. This caused considerable confusion for everyone involved and, again, totally unfair to our members.

On Friday 26 October there was a vague indication to the IPU that there would be some changes to payments for Oral Nutritional Supplements (ONSs), the detail of which did not surface until the 30 October, again to be introduced with effect from 1 November. We received the list of price reductions for the ONSs on 30 October and were advised that a number of codes would be removed and replaced by new GMS Codes from 1 November. However, while we were advised of the products that this would affect, as of this morning we are still waiting on the new GMS codes for 199 products. This has meant that many commonly dispensed products currently have no active code! This is an appalling situation.

The IPU has repeatedly asked that reasonable notice be given of changes of this nature to ensure smooth implementation and yet, time and time again, no such notice or inadequate notice is being given. The IPU fully appreciates the severe pressure on the health budget at this time. However, this does not justify the unreasonable and disrespectful manner which these changes are being introduced. The consequences of this approach are that pharmacists are considerably out of pocket as the value of their stock falls and they are not being given a reasonable opportunity to run down their stock and minimise their losses. Most pharmacies are small businesses who, like all businesses at this time, are suffering the effects of the economic recession and low consumer confidence and this is all the more reason why the State should treat them fairly in these matters. These losses are in addition to the contribution that pharmacists will be making to the Exchequer as part of these price reductions.

Appendix II

(continued)

In conclusion, we would ask that:

- Pharmacists would be reimbursed at the old price for the first two weeks of November;
- Claims for ONSs would be reimbursed under the old GMS codes and the new GMS codes for the month of November; and,
- A commitment be given that such changes will not be forced through in future without giving pharmacists and other stakeholders adequate notice and time to run down their stock levels and minimise their losses.

In conclusion, the manner in which these changes have been implemented is totally unacceptable and cannot be allowed to happen again.

Reductions – Letter 4

**From Secretary General to S Flanagan,
Corporate Procurement Unit, HSE
[14 November 2012]**

Re: Reductions in the Cost of Medicines

I have been asked by the Pharmacy Contractors' Committee (PCC) to write to you about the proposed changes to medicine prices arising from the recent agreement with IPHA, which are due to be implemented from 1 January 2013.

I wish to request that the implementation date of 1 January 2013 be delayed to allow sufficient time to update our IT system and to allow pharmacists sufficient time to dispense stock at the price they purchased it from their wholesalers. In particular, we must at all costs avoid the debacle that arose in the implementation of the last round of cuts.

As you are aware, January is the worst month of the year for such a change to be implemented because of the potential effects on both stock availability and, more critically, patient access to medicines. During the Christmas and New Year period there is increased hospital discharge rates, reduced access for patients to GP services,

a reduced wholesaler delivery to pharmacies, an increased level of urgent prescriptions and unpredictable patterns of patient demand, which all routinely put pressure on the supply system. A reduction of this kind took place in January 2011 and cost pharmacists a significant amount of money. This reduction is on top of the other recent cuts to IPHA medicines, APMI medicines and Oral Nutritional Supplements, which were communicated and implemented in an unacceptable and unprofessional manner.

It is essential that there is continuity of supply for medicines for patients during this critical time; therefore, any reductions arising from the agreement with IPHA should apply to medicines dispensed from 1 February 2013.

The IPU is also seeking a definitive list of medicines which will be affected by these reductions. It is vital that we have this list of medicines as soon as possible, but at the latest by 1 December 2012, to ensure that we are able to update our IT system in time for the implementation date.

PSI MATTERS

PSI – Letter 1

**From Director of Communications &
Strategy to Minister for Health
[15 October 2012]**

Re: Pharmacist and Pharmacy Registration Fees 2013

I am writing to you to highlight the concerns of members of the Irish Pharmacy Union (IPU) with regard to the unsustainable level of annual registration fees charged by the Pharmaceutical Society of Ireland (PSI) and the undue burden that this places on community pharmacy.

The cost of registration with the PSI is out of line with international comparisons. The annual pharmacist registration fee is €400 (€570 on first registration) and each pharmacy must pay €2250 (€3500 on first registration) per year to register. In the UK the equivalent fees are £267 (£369 on first registration) and £221 (£789 on a first registration) for a pharmacy premises. Other international comparisons are attached for your attention.

In previous meetings with the PSI, we raised the issue of the exorbitant amount of fees for the registration of pharmacists and pharmacies and the PSI indicated that fees may be reduced taking account of changing circumstances.

In light of the drastic cuts in pharmacists' reimbursement in recent years under the Community Drugs Schemes and the current dire economic climate, our members would have an expectation of seeing a significant reduction in their pharmacy registration fees. In addition, our employee members have reported significant reductions in their salaries and again would expect to see a proportionate reduction in pharmacist registration fees. We are, therefore, calling for a review of the level of PSI fees for 2013 with a view to bringing them into line with other jurisdictions.

The IPU is happy to meet with you to discuss this issue further.

PSI – Letter 2
From President IPU to President PSI
[14 November 2012]

I wish to refer to our recent letter requesting a meeting with the Council of the Pharmaceutical Society of Ireland (PSI) and your response that you could not facilitate such a meeting at this time. This is very disappointing, as pharmacists around the country are becoming increasingly frustrated with the PSI and feel that no-one is listening to their issues and concerns. The purpose of this letter is to bring these concerns to the attention of all Council members and suggest ways in which we believe these concerns can be addressed. I would ask that you bring a copy of this letter to the attention of each Council member.

1. Inspections

Pharmacists are angry and frustrated that they are not given advance notice of PSI inspections. We have raised this issue on a number of occasions over recent years. Whilst the PSI has indicated that it will facilitate pharmacists in providing pharmacy services to their patients during an inspection, the reality is that pharmacists feel, naturally and understandably, pressurised to drop everything and attend to the inspector's requirements. I am sure you will agree that this is far from ideal from a patient safety point of view.

The purpose of inspections, as we understand them, is to review and raise standards in pharmacy and ensure compliance with regulations. We would advocate that this can be better achieved if pharmacists are given advance notice, of say two–three weeks, so that they can review all their procedures, etc, and make sure that their pharmacy is up to the required standard. This is an approach adopted by many public sector organisations. The existing approach is perceived by pharmacists as a fault-finding exercise, rather than a constructive attempt to improve standards.

More importantly, the giving of advance notice is a more cost-effective, efficient and

productive way to do business, particularly at a time of economic constraints and declining resources. We would also suggest that following an inspection that the Inspector would give a verbal account of the issues that need to be addressed to the pharmacist concerned and give them a reasonable period to put things right. This should be done before embarking on the costly exercise of putting very long reports into print and engaging in a long bureaucratic and costly correspondence exercise.

Of course, we understand and accept that there may be occasions when advance notice is not appropriate; e.g. where there are serious concerns about professional conduct or patient safety.

These views and perspectives are not in any way to cast any aspersions on any of the staff of the PSI involved in inspections. Rather, it is to highlight the fact that the social and economic environment in which we are operating is changing and public bodies must recognise these changes and respond to them through cultural, behavioural and administrative change.

2. Fitness to Practise

When the IPU supported the passage of the Pharmacy Act 2007 through the Oireachtas, it was never envisaged that Part 6 of the Act would be used to criminalise pharmacists for technical breaches of regulations; unfortunately, this is what appears to be happening. When a pharmacy is inspected, an inspection report is produced by the PSI and the pharmacist is given a number of weeks in which to respond. The pharmacist reviews all areas highlighted in the inspection report and addresses these issues, often at considerable expense. This is what the inspection process was designed to achieve; i.e. the improvement of pharmacy standards.

Instead of accepting the pharmacist's efforts or, indeed, making a further inspection to check that the new standards have been fully implemented, the PSI has, on occasions, brought the pharmacist through a Fitness to Practise (FTP) procedure, on

foot of a complaint from the Registrar. Even more worryingly, the pharmacist can also be hauled through the District Court and prosecuted for a range of offences, mostly technical in nature and where there was no evidence of harm being caused to patients. The outcome is a criminal record, trauma and a very hefty fine for the pharmacist concerned and considerable expense by the PSI, which will ultimately be borne by our members.

No other Regulator as far as we can establish treats their profession in such a way unless harm has been caused to a patient. Indeed, in one particular case, charges were preferred against a pharmacist of mature years who had resigned from the register on foot of the inspector's report. It is not apparent what public good was, or is, being served by bringing prosecutions in such cases other than the prosecuting body being seen to wield considerable power. Fortunately, in that particular case, the judge decided to apply the Probation Act when he heard the evidence from both sides.

For some unknown reason, Counsel for the PSI objected to the judge's ruling on the basis that the judge could not apply the Probation Act and the judge then imposed nominal fines on the company rather than the individual concerned. From the advice we have taken, there is nothing to prevent a Court applying the Probation Act in such cases and perhaps the PSI might confirm that this is the case and advise its legal representatives accordingly. Indeed, the judge in this particular case made some very interesting observations on the inevitable tension that will exist between the strict application of regulations and the need and pressure on the professional at the coalface to respond to the needs of patients, which are both pertinent and relevant.

Where the PSI decides to prosecute, it is also not clear to members why the PSI brings charges against the company and the same charges against the individual pharmacist, particularly in instances where the pharmacist is the main shareholder or

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owner of the business. Again, when the Act was being enacted, it was intended that this would only be used to deal with large organisations to prevent a situation arising where such companies could blame the pharmacist for poor professional performance while they themselves avoid prosecution or other sanctions, even if their policies or procedures were a contributory factor. The issue of the Company versus the pharmacist was also at the core of a decision by the European Court of Justice (ECJ) in dealing with a challenge by the EU Commission to the regulation of the pharmacy profession in other jurisdictions and is relevant in this context.

We would propose that matters arising from inspections are best addressed as set out in this and the previous paragraph. Equally, there is nothing to prevent the Registrar from taking such matters into her own hands and meeting the pharmacist to stress the importance of maintaining standards and putting down a marker for the future that further breaches could lead to stronger action being taken. We do not understand either why mediation, which is facilitated by the Pharmacy Act, cannot be utilised as an alternative to the very costly and formal FTP or legal proceedings.

3. Communications

We have in the past made our views known to the PSI on the tone and the content of communications to pharmacists and I do not intend to go into any more detail on the issue here. We have also expressed the view that making submissions on draft papers or guidelines would appear to be a waste of time and resources as, invariably, any views put forward appear to have little impact. This has given rise to a perception that the purpose of the exercise is simply to 'tick the box' and be seen as going through the motions of consulting with stakeholders.

I do not wish to re-open the recent vaccination episode, but suffice it to say that a significant number of pharmacists have chosen not to participate in vaccination

this year as they felt that the barriers put in place by the PSI were much too high, relative to what was being imposed on other professionals. We would appeal to the Council to ensure appropriate engagement with the IPU before the roll-out of any further vaccination refresher training requirements next year to ensure we do not kill off such an innovative service before it even has a chance to get off the ground.

4. PSI Fees

The cost of registration with the PSI is excessive and is out of line with international comparisons. The registration fee is €400 (€570 on first registration) per pharmacist per year and each pharmacy must pay €2,250 (€3,500 on first registration) per year to register. In the UK the equivalent fees are £267 (£369 on first registration) per pharmacist and £221 (£789 on first registration) of a pharmacy premises. It is difficult to justify the fees being charged in Ireland, relative to our nearest neighbour and in many other jurisdictions.

In light of the drastic cuts in pharmacists' reimbursement in recent years under the Community Drugs Schemes and the Government commitment to reduce red tape and costs on businesses, our members would have an expectation of seeing a significant reduction in their pharmacy registration fees. In addition, our employee members have reported significant reductions in their salaries and would expect to see a proportionate reduction in pharmacist registration fees. We are, therefore, calling for a review of the level of PSI fees with a view to bringing them into line with those charged in other jurisdictions. We have also written to the Minister for Health on this issue.

In conclusion, the views expressed in this letter are a fair reflection of how the PSI is perceived by pharmacists at this time. Obviously, we would have preferred to discuss the issues outlined in this letter with the Council in a face-to-face meeting. Nevertheless, we would appreciate the Council taking the time to review

these issues and to reflect on them and our suggested solutions, which are intended to be both constructive and helpful.

While we fully respect our mutually different roles and appreciate that we will not agree on everything, we believe that it is only by working together and taking account of our respective views that we can ensure that the pharmacy profession develops in the way we all want it to.

Our offer to meet with the Council to discuss these issues and, indeed, any other issues, is still on the table.

PSI – Letter 3
From Secretary General to
Acting Registrar, PSI
[18 February 2013]

Re: Notice of PSI Inspections

I wish to refer further to the correspondence between our respective Presidents last year.

One issue we raised in our letter was in relation to giving advance notice of pharmacy inspections. In his reply, the PSI President acknowledged that the PSI was mindful of the benefits of self-assessment methodologies and was considering the feasibility that a self-assessment system would have in expediting the inspection process.

The IPU launched a Pharmacy Self-Audit Tool on IPU NET, our web-based pharmacy support system, on 1 February 2013. We sent a copy of the audit to John Bryan for review on 17 January 2013. In only a short time, it is impressive that over 120 pharmacies have already started to complete the audit. This is indicative of the professional attitude that Pharmacists are taking in ensuring that they maintain the highest pharmacy standards. We would welcome an opportunity to give your inspectors a demonstration of the audit tool in our offices and hear their views on it.

Finally, you might also let me know if the PSI have given any further consideration to giving advance notice of all routine inspections.

PSI – Letter 4

**From Acting Registrar, PSI to Secretary General
[25 March 2013]**

Re: Notice of PSI Inspections

I wish to refer to your letter of 18 February 2013 in which you inquire as to whether the PSI has given any further consideration to providing advance notice of routine inspections.

As you may be aware, the Council of the PSI is in the latter stages of finalising its 'Corporate Strategy' for the years 2013 to 2017.

Council has determined that the priority in regard to the inspection function for the next two years is to complete a full cycle of inspections by the end of 2014. Following that, the strategy envisages a transformation in how pharmacies are to be inspected. Obviously the manner in which this will be undertaken has not yet been agreed and will of course demand careful consideration. However, it is expected that this phase of the inspection programme will incorporate some form of a selfassessment methodology and may involve the PSI notifying inspected parties in advance.

In regard to the IPU Pharmacy Self Audit Tool, the inspection and enforcement team have reviewed the material provided to them by Ms Logan and have responded with their views. The team has also accepted your offer to demonstrate the Audit Tool.

PRIMARY CARE CENTRES

**From Director of Communications & Strategy to Acting Registrar PSI
[19 September 2012]**

Re: Proposed Primary Care Centre on Tonleeg Road, Dublin 5

I wish to bring to your attention proposals by the Health Service Executive (HSE) to construct a Primary Care Centre, under a public-private partnership, on the grounds of St. Monica's Youth Centre, the Vicarage, Tonleeg Road, Dublin 5 (planning application 2865/12).

A primary care centre will be built on lands surrendered back to Dublin City Council by St. Monica's Youth Centre. The GPs in the local Edenmore Health Centre have agreed to move to the new centre, in the event it is approved for planning permission. We understand that there is a retail element to this development, including a pharmacy which, it is envisaged, will make this project commercially viable. The indication is that the pharmacy can be a 'deal breaker', in that revenues generated from the pharmacy would help sustain the centre. The planning application is now before Dublin City Council.

The inclusion of a pharmacy in this health centre would do serious damage to other pharmacies in the vicinity, including those in the Edenmore Shopping Centre and reduce patient choice.

It appears that the HSE is prepared to push ahead with further developments using Tonleeg Road as a model of future primary care centres. The concern is that the HSE, while getting involved in this model of public-private partnerships, will promote the inclusion of a pharmacy in other planned primary care centres to make these projects financially viable.

I would ask that the Society investigate this development and similar developments on the light of PSI guidelines on these matters under Sections 63 and 64 of the Pharmacy Act.

Should you require further information, please do not hesitate to contact me.

PHARMACY VACCINATION SERVICE

**Pharmacy Vaccination Service – Letter 1
From Secretary General to Assistant Secretary, DoH
[13 September 2012]**

Re: Pharmacy Vaccination Service

I wish to bring to your attention our concerns about the difficulties facing pharmacists in contributing to the vaccination service this year.

When the Minister for Health announced in July last year that pharmacists could participate in the seasonal influenza vaccination campaign, community pharmacists in Ireland enthusiastically greeted this new extended role. Over 1400 pharmacists completed the Irish Pharmacy Union (IPU) vaccination training course, accredited by the School of Pharmacy, Trinity College Dublin (TCD), and 1208 pharmacies registered with the Primary Care Reimbursement Service (PCRS) to provide a vaccination service. Despite the delay in the legislation being enacted to facilitate pharmacists vaccinating, 9125 vaccinations were administered in 484 pharmacies throughout last season.

The IPU welcomed the Department of Health's decision to extend the vaccination cohorts to all at-risk groups this year and community pharmacists looked forward to vaccinating a significant proportion of the population. Research in the USA has proven that when pharmacists provide vaccines, everybody benefits – the pharmacist, other healthcare providers and, most of all, the patients and the wider community. In fact, because of the increased awareness within communities, the overall number of vaccinations has been shown to increase. The overarching aim for all healthcare professionals is to increase the vaccine uptake in at-risk groups and to reduce the morbidity, mortality and burden to the health service, particularly in primary care, associated with seasonal influenza.

On 9 July 2012, the Pharmaceutical Society of Ireland (PSI) published the Report of the

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Risk Review Group into the vaccination error that occurred in a minority of instances last year. Although the Report made a number of recommendations regarding vaccination training for all healthcare professionals, it did not make a specific recommendation that pharmacists must be re-trained or undertake refresher training this year before they could vaccinate. Nevertheless, on 16 July 2012, the PSI emailed all pharmacists, informing them that they had to undergo refresher training before they could vaccinate this year, both on-line and face-to-face. At that time, the IPU argued that on-line training would be sufficient and that face-to-face training was an unnecessary and costly burden on pharmacists. Regrettably, the PSI ignored our counsel and insisted that any on-line refresher training would not receive accreditation or approval from the PSI if it did not have some face-to-face element. Likewise, the PSI Council would not approve pharmacists to vaccinate this year if they did not complete such prescribed refresher training.

Community pharmacists are understandably angry about these developments. If they wish to vaccinate this year, they now have to take more time out of their pharmacies and incur locum costs, just to satisfy these unreasonable requirements. We fail to understand the reasons or the motivation behind imposing these requirements.

The PSI, without any consultation with key stakeholders, published the criteria for the refresher training on their website. It is quite clear that no practical thought was given to these criteria. There is much repetition in the curriculum and pharmacists will find themselves having to complete compulsory reading on a particular topic, then complete an e-learning module on the same topic, then have it delivered for a third time during the face-to-face session. No other healthcare professional would put up with such desultory and derogatory treatment.

The PSI, again without any consultation with key stakeholders, decided that vaccination of children and infants should be incorporated into the refresher training, despite the fact that children were not included in the full training course last year and despite the National

Immunisation Office (NIO) being quite clear that children were not to be included in the HSE cohorts this year or even next year (apart from the specific group of seriously ill children identified who will most certainly receive vaccination from their GP). Only when the IPU made a very strong case that it made no sense to train pharmacists to vaccinate a cohort for which it is certain they will not have an opportunity to vaccinate did the PSI back down on this requirement.

As a consequence, the IPU and our training partner, Hibernian Healthcare, have had to work within an incredibly tight timescale to produce a refresher training course and a full training course for pharmacists who did not receive training last year. Both courses are now with the PSI-appointed accreditor, TCD, for accreditation and several resubmissions have had to be made on relatively trivial matters. When we eventually receive accreditation from TCD, the courses have to undergo a further approval process by the PSI, whereby the whole PSI Council has to read through every document, at this stage about 80,000 words, before we can start delivering the training, notwithstanding that the PSI Council appointed TCD to accredit the courses. If the PSI Council makes any changes to the courses, they will have to be resubmitted to TCD once again for accreditation and then back to the PSI Council for approval. If this happens, we'll be lucky to be in a position to train pharmacists this side of Christmas.

Even if we do manage to get accreditation and approval for the courses within the next week or so, community pharmacists have understandably expressed their disappointment at the obstacles and costs being placed in their path that will prevent their participation in or significant contribution to the vaccination service this year. Pharmacists certainly did not make any money delivering vaccination services last year, given the start-up and training costs incurred. They had hoped to fare better this year but this seems highly unlikely now. The IPU President has written to all pharmacists, acknowledging their frustration but encouraging them to get behind this new initiative to show how successful pharmacists' involvement can be in such services.

We would welcome some intervention from your Department into this affair as a matter of urgency; otherwise we are unlikely to see any pharmacy vaccinations taking place this year, a consequence that will have significant economic implications for the HSE.

**Pharmacy Vaccination Service – Letter 2
From Director of Pharmacy Services to Mr
P Burke, PCRS
[27 September 2012]**

Re: Vaccination Training Grant

In September 2011, you confirmed that the IPU/Hibernian Healthcare Vaccination Training Course, which was accredited by Trinity College Dublin (TCD) and approved by the Pharmaceutical Society of Ireland (PSI), would be added to the List of Approved Courses for the training grant arrangements. It was subsequently given the code IPU08. We will be offering this ab initio course again this year to pharmacists who did not complete vaccination training last year.

In addition, the PSI has required that all pharmacists who completed vaccination training last year undergo some refresher training this year, including a face-to-face element. The IPU and Hibernian Healthcare have consequently developed a Refresher Vaccination Training Course which has also been accredited by TCD and approved by the PSI.

The cost of this half-day course, including an element of e-learning in advance of the face-to-face element, is €170. I would now ask that this Refresher Vaccination Training Course be added to the List of Approved Courses for the training grant arrangements and that a code is allocated.

**Pharmacy Vaccination Service – Letter 3
From Secretary General to Aviva Health
Insurance, Laya Healthcare & Glo Health
[31 October 2012]**

**Re: Pharmacy Vaccination and
Health Screening**

I am writing to you, on behalf of the Irish Pharmacy Union (IPU), the representative body for community pharmacists, in relation to the possibility of Aviva Health reimbursing its members for pharmacy influenza vaccinations and health screening.

Last July, the Minister for Health announced that pharmacists could participate in the seasonal influenza vaccination campaign. Despite the delay in the legislation being enacted to facilitate pharmacists vaccinating, 9125 vaccinations were administered in 484 pharmacies throughout last season.

This season, we welcomed the Department of Health's decision to extend the vaccination cohorts to all at-risk groups and community pharmacists look forward to vaccinating a significant proportion of the population. Research in the USA has proven that when pharmacists provide vaccines, everybody benefits – the pharmacist, other healthcare providers and, most of all, the patients and the wider community. In fact, because of the increased awareness within communities, the overall number of vaccinations has been shown to increase. The overarching aim for all healthcare professionals is to increase the vaccine uptake in at-risk groups and to reduce the morbidity, mortality and burden to the health service, particularly in primary care, associated with seasonal influenza.

Data collated by the IPU for pharmacy flu vaccination to date shows that 23% of patients received seasonal influenza vaccination for the first time ever; of this category of first time patients, 78% were in the at-risk category; overall, of the patients who received seasonal influenza vaccination in a community pharmacy, 90% were classified as at-risk. I'm sure you will agree that it is beneficial, not just to the patient but to you as a health insurer, that vaccination uptake increases in Ireland, especially in the at-risk categories. When more people are vaccinated, less people end up in hospital with flu-related illnesses. In the circumstances, we would suggest that Aviva Health consider reimbursing its members for the cost of getting a flu vaccination in a community pharmacy.

Another new service being offered in

community pharmacy is health screening or health checks. This involves the pharmacist conducting a series of checks on the patient, e.g. blood pressure, blood glucose, cholesterol, BMI, and recommending either lifestyle advice or referral to the patient's GP. It is important to note that the pharmacist does not diagnose a particular chronic disease; rather they identify patients who are at risk and provide the appropriate advice or referral. The aim is to reduce the number of people developing chronic disease in the first place, thus reducing costs in secondary care, costs that are often met by health insurers. I'm sure Aviva Health welcomes such an initiative and we would suggest that patients who receive a health check or screening in their local community pharmacy be able to claim back the cost of the check from Aviva Health.

We are happy to meet with you, at your convenience, to discuss these issues in more detail.

BENZODIAZEPINES

**From Secretary General to R Shortall TD,
Minister of State for Health
[17 May 2012]**

Re: Reclassification of Benzodiazepines

Firstly, I would like to take this opportunity to thank you once again for attending the IPU National Pharmacy Conference in Galway last month. The delegates present found your speech about your vision for primary care most inspiring.

One issue that has been receiving a lot of media attention recently is the overprescribing and misuse and abuse of benzodiazepines. Pharmacists share your concerns about this issue and we would welcome the opportunity to engage with your officials to see how all healthcare professionals could work together to address these concerns.

Indeed, the IPU has been a key stakeholder in recent multi-stakeholder meetings to discuss this issue. We attended a meeting in Tralee in March where over 100 pharmacists, GPs, Gardaí and HSE drugs workers highlighted experiences from each other's perspectives. We will also be involved in a meeting this week in Cork between pharmacists, GPs, psychiatrists and the local drugs taskforce. We hope to encourage further such meetings around the country through the pharmacist representatives on the Regional Drugs Taskforces.

We have heard that the Department may be considering rescheduling benzodiazepines from CD4 to CD3. This would result in prescriptions having to be written in the prescriber's own handwriting, specifying the dose, form, strength and, in both words and figures, the total quantity of the medicine. Pharmacists already experience difficulty getting prescribers to follow these guidelines for existing CD3s. Extending this requirement to benzodiazepines would result in further duress for pharmacists and inconvenience for patients and would be unlikely to result in reduced prescribing of benzodiazepines.

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We would welcome a meeting with your officials to share what we have learned from the meetings in Tralee and Cork and to come to agreement on how the problem of overprescribing of benzodiazepines could best be addressed.

PCRS COMMUNICATIONS

PCRS Communications – Letter 1
From Secretary General to
Mr P Burke, PCRS
[13 November 2012]

Re: Communications

I wish to raise a number of issues with you.

Firstly, you wrote to me on 30 October 2012 to advise that you had written to the vendors of the Pharmacy Computing Software requesting that they outline how the Owings function is designed within their software and attached copies of said letters. These letters were reviewed by our Community Pharmacy Committee at their meeting of 7 November 2012.

The Committee was extremely concerned at the allegations made in your letter, which imply that pharmacists are deliberately defrauding the HSE by manipulating their systems to make duplicate or invalid claims. The Committee has asked that you withdraw this general allegation and write again to the vendors, clarifying that you had not intended to slander the entire community pharmacy profession.

Secondly, over the past year we have become increasingly frustrated at the lack of communication and engagement from your department. The lack of notice about the recent IPHA and APMI cuts, and the manner in which these changes have been implemented, is totally unacceptable and cannot be allowed to happen again. In addition, you would have been aware that you were going to make changes to payments for Oral Nutritional Supplements (ONS) for some time, yet we were not informed officially until 30 October, with an implementation date of 1 November. This is an appalling situation and totally unacceptable.

We received the list of price reductions for the ONS on 30 October and were advised that a number of GMS codes would be removed and replaced by new GMS Codes from 1 November. However, while we were advised of the products that would be affected, a list of the new codes did not arrive until late on Friday 2 November, which meant that many commonly dispensed

products had no active code for a number of days. The IPU predicts that this will result in a number of unpaid claims for ONS due to the manner in which this issue was handled.

The IPU has repeatedly asked that reasonable notice be given to changes of this nature to ensure smooth implementation and yet, time and time again, no such notice or inadequate notice is given. The IPU fully appreciates the severe pressure on the health budget at this time. However, this does not justify the unreasonable and disrespectful manner in which these changes are being introduced. The consequences of this approach are that pharmacists are considerably out of pocket as the value of their stock falls as they are not given a reasonable opportunity to run down their stock and minimise their losses. Most pharmacies are small businesses who, like all businesses at this time, are suffering the effects of the economic recession and low consumer confidence and this is all the more reason why the State should treat them fairly in these matters. We demand that such changes will not be forced through in future without giving pharmacists and other stakeholders adequate notice and time to run down their stock levels and minimise their losses. This issue has also been the subject of a separate letter to the Minister.

Thirdly, in relation to other communications with your unit, we find it disrespectful that you refuse to respond to our requests for clarification and resolution on a range of issues. Examples include:

■ **Vaccination:**

- Lack of response to letters sent on 19 and 27 September in relation to training grant codes for health screening and vaccination refresher training;
- Lack of response to email sent 12 September asking for clarification on vaccinations to patients from Northern Ireland;
- Lack of response to email sent 30 October requesting that the GP field on the PCRS Vaccination Recording

Website should not be mandatory; and

- Lack of any real engagement on linking IPU Net to the PCRS vaccination recording system.

■ Pradaxa:

- Withheld Pradaxa Claims dating back to October 2011;
- Incorrect information about claims being paid when they had not been paid;
- Lack of communication on the reason why these claims have been being withheld by the PCRS and the legal basis for doing so.

■ Recent Vendor Issue:

- Lack of response on a basic question about how the PCRS system deals with claims where a code was not provided by the PCRS

■ Non-Reimbursement of GMS Products:

- Lack of communication or notice on the withdrawal of GMS codes for Gluten Free products, Glucosamine, Orlistat and Omega-3;
- While an undertaking was given to pay these claims up to and including 3 September, all claims were initially rejected;
- Lack of clarification on queries made about these products being rejected along with all other medicines on the same prescription being rejected.

Fourthly, I have personally raised individual cases with you and promises that were made have not been fulfilled.

Despite assurances from your Department, through our Joint Consultative Group, that issues such as those outlined above will be addressed, we see no evidence that this is the case. As you are aware, we have put forward a detailed customer charter on how issues that arise in relation to claims should be dealt with, which

is in accordance with normal customer service norms and standards of administration in the public sector, but these too have gone nowhere.

In light of the foregoing, it is hardly surprising that the IPU has serious concerns about PCRS systems, general administration and communications. Recently, there has been a high level of claims rejected due to 'system error'. It is essential that the PCRS takes all steps to eliminate any potential areas where your systems and administration could be perceived as not operating in accordance with law and the terms of contracts.

If an acceptable process for dealing with these types of issues is not put in place by the end of the year it is our intention to seek a meeting with Dr Ambrose McLoughlin, Chairman of the HSE and Tony O'Brien, HSE Director General, to explore how these matters can be resolved to our mutual satisfaction.

PCRS Communications – Letter 2 From Secretary General to Mr P Burke, PCRS [15 February 2013]

Re: Communications

I wish to refer to my previous correspondence on this matter dated 13 November 2012 and your reply of 3 December 2012.

Since our previous letter, there have been a number of other developments, which again highlight the lack of communication and engagement from the PCRS on key issues.

■ High Tech Medicines (HTM) Scheme

Under the terms of the 1996 Agreement between the HSE and the IPU, the HSE are required to inform the IPU of new HTMs seeking approval under the HTM Scheme.

The Pharmacy Contractors' Committee would then review these new medicines under the HTM criteria and respond to the HSE.

In January 2013, the IPU Product File Department received a list of new GMS medicines to be included on the 1 February Update to Pharmacists. On this list, a new

HTM was included. This medicine had not been reviewed under the HTM Criteria. The IPU queried this oversight with the HSE. On 8 February the HSE wrote to the IPU stating that in future the HSE would only notify the IPU of the additions to the HTM Scheme at the same time as approvals were issued to the manufacturer involved.

There was no discussion with the IPU prior to this policy change. This is not acceptable and I am to request the immediate reinstatement of the existing arrangements.

■ Implementation Meeting on Reference Pricing Legislation

The IPU attended an Implementation Group Meeting on Thursday 7 February to discuss the implementation of Reference Pricing legislation and the changes that needed to be made to pharmacy IT systems. The three IT system vendors were also in attendance at that meeting. The HSE informed the meeting that while they were implementing IT changes to enable the introduction of the Reference Pricing legislation, they decided they would take this opportunity to seek a number of upgrades, which the HSE felt would make the claiming system more efficient. The changes would cover electronic claiming for dental claims, EU claims, methadone claims and scheme authentication at point of dispensing.

The upgrades to facilitate the seamless implementation of the Reference Pricing legislation are complicated enough without additional upgrades being considered at this time. To include any other non-essential upgrades at this time is irrational and illogical.

The HSE is also putting forward changes to the system, which are not necessary under the legislation. Again, the HSE had taken the decision themselves without any discussions with the IPU.

Pharmacists will be prepared to capture the two vital pieces of information necessary which are the details of the medicine dispensed and whether the prescriber had specifically requested "no substitution" in any particular case. The capture of any other information will not be possible.

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■ Pradaxa Reimbursement Decisions

Since November 2011, communications from the HSE regarding Pradaxa and Xarelto have been chaotic, complicated and confusing. The HSE consistently make decisions on issues without communicating them to the relevant stakeholders. By doing this, they continue to place pharmacists in a situation whereby they are being asked to dispense medicines with the vague hope of being paid at some unknown date in the future. Having regard to patient care needs, pharmacists have up to this point tolerated the inefficient work methods of the HSE. However, the most recent communications from the HSE on these medicines will push pharmacists' patience to breaking point.

The HSE is now advising pharmacists that, despite what is written on the prescription, they are to be guided, not by their professional responsibilities to their patients, but by cost effectiveness considerations. This goes against the pharmacy contract and is not in the interests of patients. A number of critical patient issues arise from this decision which will be subject to a separate letter. I am also awaiting a response to my last email on the issue of paying pharmacists who dispensed 2x75mg before they were notified by the HSE of the change of policy in this area.

In relation to our letter of 13 November 2012, the following questions are still outstanding:

■ Vaccination:

- Lack of response to letters sent on 19 and 27 September in relation to training grant codes for health screening and vaccination refresher training;
- Lack of response to email sent 12 September asking for clarification on vaccinations to patients from Northern Ireland;

- Lack of response to email sent 30 October requesting that the GP field on the PCRS Vaccination Recording Website should not be mandatory;
- Lack of any real engagement on linking IPU Net to the PCRS vaccination recording system; and
- Lack of response on up-to-date pharmacy vaccination figures.

■ Recent Vendor Issue:

- Although the HSE responded on how the PCRS system deals with claims where a code was not provided by the PCRS, we are still waiting on clarification on how these claims can be resubmitted to the PCRS.

It is extremely disappointing that despite recent assurances that communications from the HSE would improve, we continue to see decisions made without prior discussion or agreement with the IPU which is not in the interests of the HSE or pharmacists.

PCRS Communications – Letter 3 From Mr P Burke, PCRS to Secretary General [25 February 2013]

I refer to your letter of 15 February 2013 re: communications, of which, some of the commentary refers back to your letter of 13 November 2012. I have already responded to the vaccination issues in my response of 3 December 2012 and I will deal here with the issues, which have arisen since the beginning of the year to which you refer.

High Tech Medicines

In 2012 the Government agreed challenging timelines, as set out in the 2012 IPHA Agreement, for approval to allow medicines to be available to eligible persons. The HSE communication of 8 February 2013 was designed to ensure that these timelines could be met. However, in the light of your stated

objections, we can notify you at an earlier stage in the process.

In order to meet the established timelines this will mean that the IPU will be asked to confirm that the Union has 'no objections' to products which may not ultimately be approved by the HSE under the High Tech arrangements.

I note that the IPU has rarely raised queries in the past during the month set aside for this aspect of the process, and the fact that the requirement for PDF to agree has been rendered obsolete over the last two years, perhaps it is appropriate we should revisit and review this aspect of the arrangement.

Implementation Meeting on Reference Pricing Legislation

The IPU portrayal of the recent meeting in the Department of Health is simply not correct. As you know, the HSE is not a customer of pharmacy software vendors and we are not in a position to "seek upgrades" in the manner suggested. The HSE simply articulated at the meeting that it is entirely reasonable to have a project where each vendor can deliver enhanced software to meet the needs of their pharmacy customers.

This was specified as an opportunity for pharmacy software vendors to add value to their software. The vendors can choose the level to which they would aspire to become certified (in terms of the capability of their software to interact with PCRS) from the four levels available and this is a decision for pharmacy software vendors in conjunction with their pharmacy clients.

It is the HSE view that the enhancements, should a vendor wish to develop and implement them, are very much to the benefit of pharmacists i.e.

- They will facilitate automated electronic claiming for Dental prescriptions, EU claims, Methadone Claims including electronic correction claims to minimise / avoid any claim rejects
- The early pay cycle will offer faster cash turnaround for all schemes

- A reduction in administrative work for pharmacists and the HSE i.e. coding not required
- Near real time reporting on monthly submissions, which reduces reclaims and providing pharmacists with the option to address claims promptly within the payment cycle.

The HSE has previously made the IPU aware in correspondence and at formal meetings of our obligation to manage and reduce our operating costs wherever possible to ensure best value for money for the taxpayer. This means that all aspects of processing must be reviewed critically to ensure maximum efficiency. In line with these matters and the associated draft correspondence, the content of which has previously been shared with the IPU, I will be writing, in the coming days, to all pharmacists setting out the dates for revised administration arrangements. A copy of that correspondence is enclosed.

The HSE believe that it is rational and logical and an efficient use of resources for all concerned to deliver three projects (one per vendor) now, including all current upgrades, rather than a potential twelve projects over the next number of months. The HSE has committed to supporting one project per vendor at no charge and will seek an explicit commitment from each as to which interface level they are committed. If a vendor, at the behest of their pharmacy customers, decides to limit the scope of their project, and the functionality which is available to their customers, this is entirely their prerogative. If a vendor decides to reduce the scope of the project, we will still commit to delivering the project.

It should be noted that commitment to a single project by a vendor does not preclude for phasing some of the deliverables. The objective is simply to maximise the efficiency through which full functionality capability can be delivered.

All of the data items required for reference pricing were clearly flagged in the stakeholder meetings held in November 2012 by the Department of Health. However, I will update the

Department of Health of your position in relation to this issue.

Pradaxa Reimbursement Decisions

The HSE faced a huge challenge when the extended indication for the treatment of SPAF was approved by the EMA. The estimated budget impact for Schemes was very significant. The HSE sought guidance from the Department of Health in July 2012 and corresponded with all stakeholders including Hospital Physicians in relation to an individualised approval mechanism on the 25 July 2012. Such arrangements are a recognised rate limiting mechanism in other jurisdictions and the HSE is satisfied that the individualised mechanism served this purpose.

You have referred to the Pharmacy Contract. As you are aware, Clause 9(1) of the Terms and Conditions of Agreement to the Community Pharmacy Contractor Agreement provides for a review of the medicine therapy of the individual for whom the prescription is issued. It is further provided in sub-clause (4) that "*[t]he review provided for in sub-clause (1) shall also include an examination of the rational and cost effective use of the medicine prescribed, including the choice of the medicine and the potential for wastage.*" It remains the HSE's view that the continued supply of Pradaxa 2x75mg against the backdrop of a reimbursable Pradaxa 150mg is neither rational nor cost effective.

I do not accept the point in your email communication that pharmacists were not aware of the fact that they would not have carte blanche regarding reimbursement for dispensing 2x75mg Pradaxa. We were very clear to the IPU and to pharmacists, through the agreed reporting mechanism, i.e. their monthly printout, in relation to those claims that are not reimbursed. In addition, in order to be reimbursed it was and is a requirement that approval to dispense Pradaxa for particular indications would first be obtained from the HSE. We made this clear in our Circular 010-12 in July 2012.

Furthermore, the implication that it is appropriate to displace the fundamentals of appropriate claiming practices whereby the most suitable formulation to satisfy the dosage requirement of the patient is supplied by the

dispensing pharmacist is disconcerting. To even suggest that it would be appropriate to pay double the cost because either or both GP and Pharmacy Computers have not updated their medication histories is regrettable. Taxpayers would find it really difficult to understand that resources could be consumed in the manner suggested by the IPU, as the HSE continues its focus on sustaining essential services for the most vulnerable in our communities.

Vaccination

As referred to in previous communications, the HSE is awaiting clarification from the Department of Health in relation to (i) Vaccination Grants and (ii) Treating patients from Northern Ireland.

In relation to claims submitted for reimbursement without the correct code, it is necessary for Pharmacies to resubmit claims for items for which they did not enter a pharmacy code prior to submission, in line with the established and agreed process.

As you know we have put in place a specific Customer Service function to maintain and develop communications between pharmacists and the HSE. I believe that the IPU and the HSE should work this process to ensure that the issues discussed above can be managed appropriately.

I believe that we should also hold a Joint Consultative Group (JCG) meeting as you and I discussed recently and we should agree how we can further work in improving communication streams to the benefit of all. I will ask my office to contact the IPU later today and arrange a meeting of the JCG in the coming weeks.

Appendix II

(continued)

EXTEMPORANEOUS PREPARATIONS

From Director of Pharmacy Services to Chief Pharmacist, DoH [11 July 2012]

Re: Regulations regarding Extemporaneous Preparations in Pharmacies

I am writing to you on behalf of the Irish Pharmacy Union (IPU) in relation to regulations regarding extemporaneous preparations of medicinal products in community pharmacies.

The Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007), Paragraph 5, allows for an exemption to the requirement of a manufacturer's authorisation for

“the extemporaneous manufacture of a medicinal product in response to a bona fide unsolicited order to fulfil a special need and which is carried out – in a dispensing pharmacy by or under the personal supervision of a pharmacist

- *in accordance with the specifications of a registered medical practitioner or registered dentist for use by his or her individual patients on his or her direct personal responsibility, or*
- *for the purpose of maintaining a stock of medicinal product for dispensing exclusively in such pharmacy to meet the orders of the aforementioned registered medical practitioner or registered dentist, or*
- *in accordance with the prescriptions of a pharmacopoeia for supply to patients attending that pharmacyand, provided in each case that the medicinal product concerned is not the subject of any advertisement or representation and that no other medicinal product of appropriate composition, that is the subject of a marketing authorisation, is available for use in the circumstances”.*

Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) also allows for exemptions from the authorisation requirements. Paragraph 2 specifies that the regulations: *“shall not apply to the sale or supply of a medicinal product in response to a bona fide unsolicited order, formulated in accordance with the specifications of a practitioner for use by his individual patients on his direct responsibility, in order to fulfil the special needs of those patients....”.*

In recent weeks, the IMB has contended that their interpretation of these regulations is that pharmacists can only supply an extemporaneous medicinal product if it is on foot of a prescription. The IPU would contend that this was not the intention of the regulations when they were drafted. Pharmacists are taught how to prepare a range of extemporaneous medicinal products while at university. Generations of pharmacists have produced pharmacy-specific formulations designed to meet the *“special needs of their patients”*. It would be a sad, sad day for the practice of pharmacy if pharmacists were now prohibited from utilising their professional skills to respond to the individual needs of their patients. The IPU would ask the Department for urgent clarification on this issue.

We raised this issue in our recent submission to the Department on the Transposition of Directive 2010/84/EU and Regulation 1235/2010/EU on Pharmacovigilance but felt that the issue was so important as to warrant a separate letter.

Please do not hesitate to contact me if you would like any further information or clarification on the points raised in this letter.

PRADAXA

From Director of Pharmacy Services to Mr P Burke, PCRS [15 February 2013]

Re: Pradaxa Dispensing

I wish to highlight some serious concerns about the manner in which the HSE is dealing with the matter of Pradaxa.

Since November 2011, communications from the HSE regarding Pradaxa and Xarelto have been chaotic, complicated and confusing. Time after time, the HSE has made decisions on issues of supply without communicating them to the relevant stakeholders, i.e. prescribers, pharmacists and patients. By doing this, the HSE continues to place pharmacists in a situation whereby they are being asked to dispense medicines with the vague hope of being paid at some unknown date in the future and patients unsure of whether they will get the medicines that have been prescribed for them.

Having regard to patient care needs, pharmacists have, up to this point, tolerated the inefficient work methods of the HSE. However, the most recent communications from the HSE on these medicines has pushed pharmacists' patience to breaking point.

Following queries on the matter, the HSE issued the following advice to the IPU:

■ Supply of 2 x 75 mg Pradaxa

The IPU accepts that the HSE wishes to restrict dispensing to the most cost effective formulation for Pradaxa. However, pharmacists received no notification that from October 2012 their claims for 2 x 75mg would be rejected. The PCRS has also confirmed that where the GP prescribes Pradaxa 2 x 75 mg due to patient care issues (i.e. difficulty in swallowing) these claims will also be rejected. The HSE has stated that no matter what formulation is prescribed, no claims for Pradaxa 2 x 75mg will be reimbursed.

This is a worrying development for pharmacists and patients as the HSE is now advising a pharmacist that despite what is written on the prescription they are to be guided, not by their professional duty, but by cost effectiveness. This breaches the pharmacy contract and may adversely affect patient care.

- **Supply of 30 Days of Pradaxa for VTE**
The IPU has raised the matter of the 30 day supply of Pradaxa for Venous Thromboembolism (VTE). Again the advice from the HSE is that even though the prescription may be for a 35 day supply, they will only reimburse 30 days.

This raises professional, contractual and liability concerns for pharmacists. It is also pushing pharmacists into a situation whereby they are policing prescribing habits of GPs and Hospital Consultants. This is completely unacceptable.

- **Waiting time for letter of approval for Pradaxa**

Pharmacists are receiving a number of complaints from patients who are present at the pharmacy with prescriptions but no approval letter. Can you please ensure that all prescribers are aware of their obligations to ensure that patients have an adequate supply of medicines when they are discharged from hospital?

While the IPU understands the tough economic situation that we all find ourselves in, it is completely unacceptable for the PCRS to advise pharmacists to breach their contract and professional obligations.

ICCPE / PHARMACY TRAINING GRANT / CONTINUING EDUCATION

Letter 1

**From Secretary General to Assistant Secretary General, DoH
[12 November 2012]**

Re: ICCPE Funding

We have written to you on a number of occasions over the past year or two, expressing concern about the future of the Irish Centre for Continuing Pharmaceutical Education (ICCPE) and its funding in the context of establishing the Irish Institute of Pharmacy.

In the last few weeks, a HSE official has informed the Management Committee of ICCPE that it must wind up its affairs by the end of the year and that all future ICCPE funding will transfer to the Institute.

Funding for the ICCPE was agreed between the Irish Pharmacy Union (IPU) and the Department of Health as part of the 1996 Community Pharmacy Contractor Agreement. The purpose of this funding was to enable community pharmacists to continually update their professional skills by attending approved continuing education courses in the practice of pharmacy. ICCPE has delivered admirably on this remit since its inception, despite ongoing staffing issues as a consequence of the HSE recruitment embargo.

The Pharmaceutical Society of Ireland (PSI) has previously confirmed that the new Institute will not deliver continuing education; rather it will accredit and commission providers of continuing education.

The IPU feels it is imperative that no decision should be made about the future of the ICCPE or its funding without first having discussions and agreement with the IPU on the matter.

We would welcome a meeting with you, as a matter of urgency, to discuss this matter.

Letter 2

**From Secretary General to Assistant Secretary, DoH
[19 December 2012]**

Re: Pharmacy Training Grant

In September 2011, the Department of Health confirmed that the IPU/Hibernian Healthcare Vaccination Training Course, which was accredited by Trinity College Dublin (TCD) and approved by the Pharmaceutical Society of Ireland (PSI), would be added to the List of Approved Courses for the training grant arrangements. It was subsequently given the code IPU08. We offered this *ab initio* course again this year to pharmacists who did not complete vaccination training last year.

In August 2012, the PSI informed us that all pharmacists who completed vaccination training last year needed to undergo refresher vaccination training this year, including a face-to-face element. The IPU and Hibernian Healthcare consequently developed a *Refresher Vaccination Training Course* which was also accredited by TCD and approved by the PSI.

The cost of this half-day course, including an element of e-learning in advance of the face-to-face element, was €170. I would now ask that this Refresher Vaccination Training Course be added to the List of Approved Courses for the training grant arrangements and that a code be allocated.

In addition, the IPU and the Irish Heart Foundation joined forces earlier this year to produce *Cardiovascular Risk Assessment Training for Pharmacists*. The one-day course was designed to give participants:

- Individual practical experience of assessing cardiovascular risk including blood pressure, cholesterol, glucose, body mass index and waist circumference measurements;
- An understanding and knowledge of appropriate GP referral guidelines;
- An understanding and knowledge of advice to patients of appropriate lifestyle behaviours;

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(continued)

- Information on standards and quality assurance when conducting the risk assessments; and
- An overview of cardiovascular disease, risk factors and the range of interventions available to those at risk.

I'm sure you will agree that this course will prepare pharmacists to participate in the forthcoming HSE Clinical Care Programmes. The course was devised using the *PSI Generic Interim Accreditation Standards for Formal Programmes of Learning for Pharmacy in Ireland*. The training day was led by Dr Angie Brown, Medical Director of the Irish Heart Foundation and Consultant Cardiologist, supported by Irish Heart Foundation nurses and dieticians. A community pharmacist led a session on how to incorporate health checks into pharmacy practice.

The course cost €250 per pharmacist and the IPU would like you to include this training course on the list of courses eligible for the Pharmacy Training Grant.

Letter 3

**From Secretary General to
Assistant Secretary, DoH
[1 February 2013]**

Re: Continuing Education Funding/ Pharmacy Training Grant

I am writing to you to get some resolution on two issues that the Irish Pharmacy Union (IPU) has concerns about: funding for continuing education for community pharmacists; and the pharmacy training grant.

Funding for Continuing Education for Community Pharmacists

We have written to you on a number of occasions over the past three years, expressing concern about the future of the Irish Centre for Continuing Pharmaceutical Education (ICCPE) and its funding in the context of establishing the Irish Institute of Pharmacy.

In October last, the HSE ordered the Management Committee of ICCPE to wind

up its affairs by the end of the year. The HSE confirmed at that time that all future ICCPE funding would transfer to the Irish Institute of Pharmacy which will implement a new Continuing Professional Development (CPD) system for pharmacists.

Funding for ICCPE was agreed between the IPU and the Department of Health as part of the 1996 Community Pharmacy Contractor Agreement. The purpose of this funding was to enable community pharmacists to continually update their professional skills by attending approved continuing education courses in the practice of pharmacy. ICCPE has delivered admirably on this remit since its inception, despite ongoing staffing issues as a consequence of the HSE recruitment embargo.

The Pharmaceutical Society of Ireland (PSI) has confirmed that the new Institute will not deliver continuing education; rather it will accredit and commission providers of continuing education. The IPU therefore feels that it is necessary for us to have a discussion to ensure that the funding agreed on in 1996 is ring-fenced to fund continuing education for community pharmacists into the future. This is especially important now more than ever, given that the Minister for Health has made it clear that 95% of healthcare should be delivered in the primary care sector and community pharmacists are willing to make a significant contribution to this care in the community.

Given the sudden closure of the ICCPE and to prevent a vacuum in Continuing Education (CE) developing, the IPU is developing and will deliver an inaugural IPU Academy Spring Programme. This CE programme is modelled on similar lines to the live learning programmes previously offered by the ICCPE.

Not surprisingly, the IPU will incur significant costs in the roll out of this Spring Programme and any subsequent programmes. Given that the funding for ICCPE was a contractual obligation, the IPU is of the view that the money previously allocated to ICCPE should not be directed to the Institute until the IPU and the Department have an agreement on how that money will be utilised for pharmacist education and training.

Pharmacy Training Grant

In July 2001, agreement was reached between the IPU and the Department of Health on a remuneration package for all pharmacist contractors, arising from the granting of automatic medical card eligibility for citizens over 70. As part of the agreement, it was also agreed that the Department would introduce Training and Education grants for pharmacists and their staff. Since then, pharmacists have been able to claim up to €1,270 per year as a contribution towards training themselves and their pharmacy staff. It is important to note that this is a contribution; many pharmacists spend much more than this on training.

In September 2011, the Department of Health confirmed that the IPU/Hibernian Healthcare Vaccination Training Course, which was accredited by Trinity College Dublin (TCD) and approved by the PSI, would be added to the List of Approved Courses for the training grant arrangements. It was subsequently given the code IPU08. We offered this ab initio course again this year to pharmacists who did not complete vaccination training last year.

In August 2012, the PSI informed us that all pharmacists who completed vaccination training in 2011 needed to undergo refresher vaccination training, including a face-to-face element. The IPU and Hibernian Healthcare consequently developed a Refresher Vaccination Training Course which was also accredited by TCD and approved by the PSI.

The cost of this half-day course, including an element of e-learning in advance of the face-to-face element, was €170. I would now ask that this Refresher Vaccination Training Course be added to the List of Approved Courses for the training grant arrangements and that a code be allocated. We have taken this issue up with the HSE but we understand that the matter has been referred to your Department for approval.

In addition, the IPU and the Irish Heart Foundation joined forces in 2012 to produce Cardiovascular Risk Assessment Training for Pharmacists. The one-day course was designed to give participants:

- Individual practical experience of assessing cardiovascular risk including blood pressure, cholesterol, glucose, body mass index and waist circumference measurements;
- An understanding and knowledge of appropriate GP referral guidelines;
- An understanding and knowledge of advice to patients of appropriate lifestyle behaviours;
- Information on standards and quality assurance when conducting the risk assessments; and
- An overview of cardiovascular disease, risk factors and the range of interventions available to those at risk.

I'm sure you will agree that this course will prepare pharmacists to participate in the forthcoming HSE Clinical Care Programmes. The course was devised using the PSI Generic Interim Accreditation Standards for Formal Programmes of Learning for Pharmacy in Ireland. The training day was led by Dr Angie Brown, Medical Director of the Irish Heart Foundation and Consultant Cardiologist, supported by Irish Heart Foundation nurses and dieticians. A community pharmacist led a session on how to incorporate health checks into pharmacy practice.

The course cost €250 per pharmacist and the IPU would like you to include this training course on the list of courses eligible for the Pharmacy Training Grant.

We would welcome a meeting with you to discuss both of these issues.

Letter 4

**From Director of Pharmacy Services to Head of Professional Development & Learning, PSI
[8 March 2013]**

Re: Eligibility of Training Establishments

I wish to refer to the eligibility criteria for recognition of a training establishment as

determined by the PSI. I note the following criteria from your website:

1. Convictions under medicines legislation (that includes human and veterinary medicines) and/or pharmacy legislation prior to application for recognition will lead to automatic ineligibility. If a conviction is being appealed through the Courts, the training establishment will be considered ineligible in the interim. The matter can be addressed again at the point of the appeal outcome.
2. Convictions under medicines legislation (that includes human and veterinary medicines) and/or pharmacy legislation during the period approved will lead to the automatic rescinding of the approved status. The automatic rescission will commence at the date of the conviction. In order to protect the tutee, the PD&L Committee will be entitled to recognise the duration of supervised training completed by the tutee at that training establishment. This will be carried out on a case by case basis by the PD&L Committee.
3. Furthermore, the pharmacy owner, or the nominated representative, will be required to inform the PSI and the tutee (pharmacy intern or TCQR applicant) with regard to all impending prosecutions once the relevant summons has been served, irrespective of the prosecuting agency.
4. Any sanction arising from proven complaints under Part 6 of the Pharmacy Act 2007 prior to application for recognition will lead to automatic ineligibility.
5. Any sanction arising from proven complaints under Part 6 of the Pharmacy Act 2007 during the period approved will immediately lead to the automatic rescission of the approved status. The automatic rescission will commence at the date the sanction is imposed by Council. In order to protect the tutee, the PD&L Committee will be entitled to recognise the duration of supervised training completed by the tutee at that training establishment. This will be carried out on a case by case basis by the PD&L Committee.
6. In the event that a pharmacy owner and/or superintendent pharmacist and/or supervising pharmacist for a training establishment has been convicted under medicines and/or pharmacy legislation or subject to any sanction by Council, and where the pharmacy owner and/or superintendent pharmacist and/or supervising pharmacist is neither the tutor pharmacist nor the pharmacy owner, this could have the effect of rendering the training establishment ineligible for recognition. The circumstances of each such matter would be required to be considered by the PD&L Committee on a case-by-case basis.
7. In the event of convictions other than those under medicines or pharmacy legislation, the tutor pharmacist/pharmacy owner will be required to inform the PSI as and when these occur. In such cases, the PD&L Committee may be required to determine if recognition of the tutor pharmacist/training establishment may be given or continued.
8. The decision of the PD&L Committee in such instances may be subject to an appeal to Council of the PSI by the registered pharmacist/retail pharmacy business.

I have a few questions about these criteria which I hope you will clarify.

1. In No. 1, it is unclear how long the automatic ineligibility will apply. Is this for life or for a period of time? Who decides this? It is unclear who the conviction applies to? If, for example, it was a conviction against the supervising pharmacist or an employee pharmacist and they moved on, would that training establishment then be considered eligible?
2. Again in No. 2, it is unclear as to who the conviction applies to. If an employee pharmacist was convicted and their employment subsequently terminated, would the training establishment then be considered eligible?
3. In No. 3, once the pharmacy owner has informed the PSI of the pending prosecution,

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(continued)

is the intern allowed to remain in situ pending the outcome of the case?

4. Similar questions arise in relation to No. 4. Does this cover sanctions against the pharmacy, pharmacy owner, superintendent pharmacist, supervising pharmacist, other employee pharmacists? Do sanctions against any one of them lead to automatic ineligibility? How long will this last? What if the employee pharmacist moves on? Is eligibility restored?
5. In criteria No. 5, the questions outlined in No. 1, 2 and 4 apply. In addition, perhaps you could clarify which particular sanctions result in the establishment becoming ineligible? Admonishment? Censure?
6. No. 6 seems to imply that if a pharmacy owner or superintendent pharmacist of a chain were convicted or sanctioned, all pharmacies in that chain would be considered ineligible. Is this really the case?
7. No. 7 requires the tutor pharmacist/ pharmacy owner to inform the PSI of all convictions other than those under medicines or pharmacy legislation. The PSI's continued registration process for pharmacists requires only notification of offences which would appear to have a bearing on a pharmacist's fitness to practise. Why is there a discrepancy between the two? Will a pharmacy be considered ineligible if the pharmacy owner was convicted of speeding, for example?

I would appreciate clarification on the issues outlined above.

I also find it extraordinary that pharmacists are being advised, when seeking clarification on any issue from the PSI, that *"it is PSI policy that all queries should be put in writing in order to ensure that the correct information can be provided"*. Pharmacists are under considerable pressure, financial and otherwise, as it is without having to take time out to put queries to the PSI in writing. I would ask that you review this policy.

DRIVING LICENCE PHOTOGRAPHS

Driving Licence Photographs – Letter 1 From Secretary General to CEO, Road Safety Authority for Health [29 November 2012]

Re: Photographs for Proposed New Driving Licence

I am writing to outline the concerns of the Irish Pharmacy Union (IPU) to the proposed capture of photographs for the new credit card style driving license being introduced in January 2013.

It is our understanding that SGS has been awarded the tender to administer the new driving license and it is the intention that, from September 2013, photographs for licenses will have to be directly captured in their premises on their machines. There will, apparently, be no option for individuals applying or renewing a license to post in a photograph or have their photograph scanned.

While the IPU is not against the introduction of credit card driving licenses, we would have serious concerns about the impact of this new policy not only on members, the vast majority of who supply photographic services, but also the serious inconvenience to the general public, who will no longer have the option of getting their photographs locally.

Many pharmacists have invested considerable sums on photographic equipment, which will become obsolete when the new initiative is introduced. The loss of income could potentially have an impact on jobs.

The IPU cannot see any justifiable reason why SGS cannot accept a scanned photograph or accept postal photographs as has been the case to date.

We would urgently request that you reconsider your stance on this issue and allow individuals the right to capture their own photo, in their local pharmacy, if they so wish.

The IPU would welcome the opportunity to discuss this issue in greater detail.

Driving Licence Photographs – Letter 2 From Secretary General to Minister for Transport, Tourism & Sport [6 December 2012]

Re: Photographs for Proposed New Driving Licence

I am writing to outline the concerns of the Irish Pharmacy Union (IPU) to the proposed capture of photographs for the new credit card style driving licence being introduced in January 2013.

It is our understanding that the Road Safety Authority (RSA) has awarded a tender to a company called SGS to administer the new driving licence. The intention, as confirmed by the RSA, is that from September 2013 photographs for licences will have to be directly captured on machines in premises to be set up by SGS nationwide. This will ensure that members of the public applying or renewing a licence from September 2013 will not be allowed to post in a photograph or have their photograph scanned.

While the IPU is not against the introduction of credit card driving licences we would have serious concerns about the impact of this new policy not only on members, the vast majority of who supply photographic services, but also the serious inconvenience to the general public, who will no longer have the option of getting their photographs locally.

Many pharmacists have invested considerable sums on photographic equipment, which will become obsolete when the new initiative is introduced. The loss of income could potentially have an impact on jobs.

Furthermore, the IPU does not accept that the RSA issues a tender that allows the successful recipient of that tender to exclude the services of a significant proportion of participants currently operating in the market, including pharmacists. This consequently raises competition issues, which we will be pursuing further.

The IPU would welcome the opportunity to discuss this issue in greater detail with you and your officials

**Driving Licence Photographs – Letter 3
From Secretary General to Chairperson,
The Competition Authority
[10 December 2012]**

Re: Proposed New Driving Licence

I am writing on behalf of the Irish Pharmacy Union (IPU) to put forward the concerns of our members, with regard to the introduction of a new driving licence in January 2013 and in particular the impact on members providing photographic services, when a single party begins administering the scheme from September 2013.

The Road Safety Authority (RSA) as the centralised licensing authority sought a service provider through an EU Tender process to administer the scheme on their behalf. The tender specified two potential options for bidders that would deliver either paper or digital photographs. A company, SGS, successfully applied for the tender. As part of its successful bid SGS will only accept photographs captured on their premises by their machines. This is despite the fact that they had the option to scan photographs brought in by applicants, which is the current situation. SGS did not present this as an option in their tender, which was accepted by the RSA.

The result of this exclusive contract will mean that members of the public applying or renewing a licence from September 2013 will be prevented from obtaining a photograph from a supplier of choice and having their photograph scanned. It will also have a devastating and unfair impact on the hundreds of companies, including community pharmacists, who have invested considerable sums on photographic equipment, which will become obsolete when the new scheme is introduced.

The awarding of this tender opens up serious competition issues, allowing only one provider of photographic services for driving licences, where previously there were a significant number of players. The awarding of the tender specifically excludes the vast majority of service providers to the benefit of one company, who will operate as a monopoly in the supply of photographs for

driver licences. The RSA should have insisted that any successful tenderer should be able to accept photographs in a number of different formats.

I would like to get your opinion on this matter and on any action the Competition Authority can take to ensure that consumer choice and a level playing field prevails in this market.

The IPU would also be happy to meet with you to discuss the issue in greater detail.

**Driving Licence Photographs – Letter 4
From Director of Communications &
Strategy to CEO, Road Safety Authority
for Health
[8 January 2013]**

Further to your correspondence of 8 January concerning an interview aired on the *'The Right Hook'* Radio programme on Newstalk, Monday 7 January about the new plastic card driving licence, we would like to respond to a number of issues raised in your letter.

We do not agree with a number of the points raised in your letter. The main purpose of the interview was to highlight the legitimate concerns that the Irish Pharmacy Union (IPU) has with regard to the capture of the photographs and how this is going to be done from September 2013.

Firstly, the IPU outlined that we welcomed the introduction of the new credit card-style licence.

In the process of the interview, while reference was made to one tender, this was relayed incorrectly; the intention was to outline the *'accepted tender'* as opposed to *'received one tender'*. We are happy to clarify this point to you.

Secondly, it is our understanding, as confirmed by the RSA, that there were two options provided in the original tender. While they may have been assigned *'equal weighting'* the point made is that the RSA should have insisted on both options being used by the successful bidder and not just accept the option that was provided by the bidding companies. This was not to question the RSA's procurement procedures but simply to question why both options were not insisted upon, considering that the option

of posted or scanned photographs is acceptable on the new credit card-style licence from 19 January.

Thirdly, I am confused at your reference that our spokesperson *"claimed that the Gardai verify photographs and identity of driving licence applicants"*. The reference in the interview was to passports and the identity security as part of the process of getting a passport. As stated already, we are not against the introduction of the credit card-style of licence, but the passport is the template for identity standards and photographs from pharmacies are accepted as part of the entire process of getting a passport. This was the point that our spokesperson was making.

There seems to be an element of confusion with regard to the entire process and who is responsible for what. For example, we were informed that a company, SGS, was awarded the contract. It has now come to our attention, through the media, that Credit Card Systems Ltd Ireland has the contract. We have been attempting, without success, to communicate with these companies to establish information, including:

- the type of photographic equipment that will be used when the new proposed system is up and running;
- the locations from which they will operate; and
- who has ownership rights to the photographs?

It may be worthwhile for the RSA to clarify these points and make the public aware of the actual process.

I trust this addresses your issues of concern and our delegation looks forward to meeting with you on 21 January.

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(continued)

**Driving Licence Photographs – Letter 5
From Director of Communications &
Strategy to CEO, Road Safety Authority
for Health
[9 January 2013]**

I am responding with regard to your letter dated 9 January 2013.

While the IPU acknowledges the concerns of the RSA, we have confirmed that an incorrect reference was relayed, inadvertently, with reference made to one tender. However, we find it difficult to accept that the content of the interview could be construed as questioning the integrity of the public procurement process.

The reference to the Passport Office was in direct response to your allegation that our spokesperson claimed that the “*Gardaí verify photographs and identity of driving licence applicants*”, which was not the case.

I also note that a number of points that you have concerns with were clarified on the “*Right Hook*” show yesterday evening. If you still wish to pursue this issue with the “*Right Hook*” show we would suggest that we forward the correspondence from both our Organisations clarifying each side’s position.

**Driving Licence Photographs – Letter 6
From Secretary General to Chairperson,
The Competition Authority
[11 January 2013]**

**Re: Proposed New Credit Card-Style
Driving Licence**

I am writing with reference to my letter of December 10 2012 (copy attached), where concerns were raised with regard to the introduction of a new credit card-style driving licence and its impact on our members who provide photographic services.

I wish to enquire whether the Competition Authority has formed an opinion on this matter and, if so, what action you propose to take.

The IPU would be happy to meet with you to discuss the issue in greater detail.

**Driving Licence Photographs – Letter 7
From Director of Communications &
Strategy to CEO, Road Safety Authority
for Health
[23 January 2013]**

Re: Driving Licence Changes

Many thanks for meeting with me on 21 January to discuss the concerns of the IPU with regard to the introduction of the new credit-card style driving licence. I would just like to clarify a few points from the meeting.

As I outlined, the IPU is concerned at both the inconvenience to consumers and the loss of business to members from September when photographs are due to be captured on-site. We are particularly concerned that this business is essentially being lost to a single company that will administer the process on behalf of the State. This loss of business and the knock-on impact on footfall will have an immediate effect on the 93% of pharmacies that provide photographic services.

It is the IPU’s preference that applications could be received after September by post, with the option to have photos scanned at the location points. While you have dismissed the postal option, you did outline that you will revert to SGS to establish if a scanning option is viable. While it would be preferable from the IPU’s viewpoint that digital capture was not an option, I would appreciate it if you can confirm when you would be able to revert with regard to the scanning option.

You outlined in the course of the meeting that the validation process is a one-off and that renewed driving licences can use photo ID’s, including those from pharmacies. Does this apply to lost and/or stolen driving licences of individuals that have been validated after September?

I look forward to hearing from you.

**Driving Licence Photographs – Letter 8
From Director of Communications &
Strategy to CEO, Road Safety Authority
for Health
[20 March 2013]**

Re: Plastic Card Licence

Many thanks for your recent letter regarding the implementation of the new Plastic Card Driving Licence in Ireland.

From the outset I would like to outline that the IPU is extremely disappointed that paper capture of photos will not be included as part of the process for new licences and licence renewals when the changes to the Driving Licence application takes place from September.

As outlined previously, the IPU is extremely concerned that a significant portion of business to members is essentially being lost to a service provider appointed by the State. This will have an impact on members currently providing photo services, particularly for those pharmacists that have invested considerable sums in equipment that will no longer generate the same level of business. Consequently, there is the real concern that jobs may be impacted.

We would appreciate it if this policy could be reviewed and that the paper capture of photos will be included as part of the application for a new or renewed driving licence and accepted as such by the service provider.

I look forward to receiving your response.

OTHER MATTERS

Bankruptcy – Letter 1 From Secretary General to Minister for Health [21 September 2012]

Re: Section 14 (1) of the Pharmacy Act 2007.

I am writing to you on behalf of the Irish Pharmacy Union (IPU) with regard to a serious issue impacting on pharmacists, which is not addressed in the Personal Insolvency Bill 2012.

Section 14(1)(f) of the Pharmacy Act 2007 provides that *'the Council shall register a person in the pharmacists' register if the person – is not an undischarged bankrupt.'* This provision effectively removes the right of a person, otherwise capable of registering as a pharmacist, to earn a livelihood if they are an undischarged bankrupt. This restriction is not imposed on other healthcare professionals and is not referenced in any existing bankruptcy legislation. It is unclear why pharmacists should be subject to this restriction, particularly as it relates to their financial situation and not their professional competence.

The IPU would appreciate if you would consider engaging with the Department of Justice with a view to using the Personal Insolvency Bill to introduce a provision to delete Section 14(1)(f) of the Pharmacy Act 2007. If this section was deleted, it would enable a pharmacist to continue to practice their profession in the event that they are declared bankrupt, provided of course that they comply with all other ethical, legal and professional requirements.

Should you or your officials require any further information or clarification on this matter, please do not hesitate to get in touch with me.

Bankruptcy – Letter 2 From Director of Communications & Strategy to Acting Registrar, PSI [12 April 2013]

Re: Section 14(1)(f) of the Pharmacy Act 2007

As you are aware, Section 14(1)(f) of the Pharmacy Act 2007 provides that *'the Council shall register a person in the pharmacists' register if the person – is not an undischarged bankrupt.'* This provision effectively removes the right of a person, otherwise capable of registering as a pharmacist, to earn a livelihood if they are an undischarged bankrupt.

The IPU has raised this issue on a number of occasions with the PSI and, recently, at a meeting with Minister Alex White T.D.

As discussed at a recent meeting between the IPU and PSI, there is now an opportunity to highlight this issue and to seek to have an amendment introduced in The Health (Pricing and Supply of Medical Goods) Bill 2012, to address this issue. This Bill is about to go to Report stage.

Due to the crucial importance of this issue to the profession we are seeking the assistance of the PSI in seeking an amendment to the Bill to have Section 14(1)(f) of the Pharmacy Act 2007 deleted. There appears to be broad political support for such an amendment.

We have proposed therefore that an amendment under Section 32 of the Bill be made for the *"Deletion of Section 14(1)(f) of the Pharmacy Act 2007"*. If accepted, this amendment would form a new subsection (e) on page 35.

Section 32 subsection (e) would therefore read *"Deletion of Section 14(1)(f) of the Pharmacy Act 2007"*.

The implementation of this amendment would enable a pharmacist to continue to practice their profession in the event that they are declared bankrupt, provided they comply with all other ethical, legal and professional requirements.

Please do not hesitate to contact me if you would like any further information or clarification on the issues raised in this letter.

Switching From Secretary General to Deputies Kelleher and Ó Caoláin [3 October 2012]

Thank you for taking the time to meet with Pamela and I yesterday to discuss the detail of and possible amendments to the Health (Pricing and Supply of Medical Goods) Bill 2012. I hope you found the meeting constructive.

You mentioned the attendance of the IMB at the Joint Oireachtas Committee on Health last Thursday. I thought the enclosed Self-Care Framework, which we launched on 20 September 2012, in conjunction with the Irish Pharmaceutical Healthcare Association (IPHA) may be of interest to you. The Framework advocates that the range of medicines made available to patients be expanded through switching. Recommendations of the types of medicines to be switched are in Annex 2.

Please feel free to contact me should require more information on these issues or indeed any other issues.

Directive on Recognition of Professional Qualifications From Director of Pharmacy Services to Chief Pharmacist, DoH [29 May 2012]

Re: IPU proposed modifications to the proposed Directive on Recognition of Professional Qualifications

I am writing to you on behalf of the Irish Pharmacy Union (IPU) in relation to the Directive on the Recognition of Professional Qualifications (RPQ).

The IPU is a member of the Pharmaceutical Group of the European Union (PGEU), the association representing more than 400,000 community pharmacists in 31 European countries. Within PGEU, we have considered the RPQ proposal and put together a series of suggestions that we believe are crucial to reflect the pharmacy practice and to allow the smooth recognition of pharmacy titles.

Appendix II

(continued)

We would like you to consider 17 amendments: 10 amendments to the provisions relating specifically to pharmacists and seven amendments to the provisions of general application. I encourage you to pay special attention to the pharmacist's specific amendments and in particular to our suggestion on pharmacy activities.

Please find attached for your convenience the complete set of amendments in a separate annex to this letter.

Amendments to provisions specifically relating to pharmacists

Pharmacy Activities

(suggested amendments 1, 2, 3, 4 and 5)

The **activities listed for pharmacies** in the Directive are clearly out of date; the current wording dates back to 1985. The list needs to be further extended to properly reflect pharmacy practice.

The IPU would like to add:

- **Sourcing and dispensing of safe and secure medicinal products:** Source: pharmacists ensure that patients receive the prescribed medicine. If the medicine is not available in their stock, pharmacists will obtain that medicine with the minimum delay. **Safe and secure:** pharmacists need to undertake the necessary steps to ensure that dispensed medicines are authentic and of high quality.
- **Medicines management and provision of information on health related issues:** **Medicines management:** pharmacists are experts on medicines and they must be able to help patients to achieve the best outcome of their prescribed treatment and at the same time minimise risks linked to side effects and potential interactions. In addition to information on medicines, they provide information on other issues such as medical devices and healthy lifestyles.

- **Support individual patients on non-prescription medicines and self-care:**

In all EU Member States, pharmacists help patients with minor ailments such as coughs or headaches and when appropriate advise on the non-prescription medication that needs to be taken to cure or relieve symptoms. Pharmacists support individuals in self-care (healthy lifestyle, independent management of one's condition) and when necessary refer the patient to other healthcare services or health providers.

- **Contribute to public health campaigns:**

Community pharmacists need to participate and contribute to public health campaigns organised to tackle specific problems, such as antimicrobial resistance, healthy lifestyles, cancer screening etc. The high accessibility of the community pharmacy networks facilitates the contact with citizens and therefore contributes to the effectiveness and outreach of those campaigns.

It is important to note that in our view, this expansion of the list of pharmacy activities is modest in scope, reflects current pharmacy practice in the vast majority of Member States and does not represent therefore an expansion of pharmacy services into areas reserved for other health professionals. This change will show the evolution of the pharmacist's profession and the commitment of our profession to face further challenges and roles decided by Member States within the context of their public health policies.

Delegated Acts by the Commission on pharmacists training

(suggested amendment 6, 7 and 8)

We have some concerns regarding the Commission proposal to decide, by delegated acts, some aspects of pharmacy training. The Commission proposes to decide on the **adequate knowledge of pharmacists and on pharmacist competences** through delegated acts. Decisions on this matter should be taken

following extensive discussions with Member States. Therefore we propose the use of the examination procedure for the adoption of such a decision. Pharmacists accept the use of delegated acts to amend the **course of training for pharmacists** (suggested amendment 5) but we would welcome in the provision a **clear mandate to consult with the relevant parties** before the adoption of the delegated acts.

The IPU would like to:

- Use the **examination procedure** to decide on the adequate knowledge of pharmacists
- Before deciding on the course of training for pharmacists, **the Commission must consult with the relevant parties**

Pharmacist traineeship

(suggested amendment 9)

The Commission proposes to complete the **six month traineeship in a block** at the end of the course of training. The new provision could be problematic for some countries that split the traineeship during the course of studies. Our amendment would maintain national flexibility in this respect.

The IPU would like to:

- Provide Member States with the **flexibility** to decide on the structure of the pharmacy course.

The IPU does not support PGEU's proposed amendment 10.

Amendments to provisions of general application

Partial Access (Suggested amendment 11)

We have strong concerns regarding the application of partial access to professions providing public health services. This proposal has the potential to create significant disruption, and possibly undermine the level of competences and quality of health care provision.

The IPU would like to:

- Introduce a **general derogation of partial access** for professions involved in public health services.

Language Knowledge

(Suggested amendment 12)

It is important to ensure the adequate language knowledge of health professionals dealing with patients. The Commission seems to be supportive of the idea of amending the Directive in this regard. However, **the proposal of the Commission lacks clarity and needs to be improved. In addition, limiting the language control to one language chosen by the applicant could be very problematic in Member States with several official languages** and where not all official languages are understood by patients.

The IPU would like to:

- Introduce some clarification regarding the language knowledge control.

European Professional Card (EPC)

(Suggested amendment 13, 14, 15 and 16)

I would also like to use this opportunity to mention some concerns and changes regarding the European Professional Card.

The IPU would like to:

- **Extend the deadlines** proposed to complete the procedure of recognition by competent authorities.
- **Delete *de facto* validation** (in cases where the competent authority is not able to solve the recognition within the relevant time periods).
- **Request that the original documentation** must be controlled at some point by the home Member State before entering the IMI System.

Alert Mechanism

(Suggested amendment 17)

We have a final point on the alert mechanism. In some Member States competent authorities are only able to exchange information on professionals when the decision adopted is definitive (not subjected to appeals).

The IPU would like to:

- Ensure that information on health professionals is exchanged when this is possible according to national legislation.

Thank you in advance for taking into consideration these suggestions. Please do not hesitate to contact me if you would like any further information or clarification on the points raised in this letter.

High Tech Medicines

From Secretary General to PCRS [14 February 2013]

Re: High Tech Medicines

I wish to refer to your letter dated 8 February 2013.

I would like to draw your attention to the Criteria for High Tech Medicinal Products Annex B in the Agreement on the Future Provision and Improvement of Community Pharmacy Services under the Health Act, 1970.

'Any medicines to be included or deleted from this Scheme will be the subject of agreement between the Department of Health, the Irish Pharmaceutical Healthcare Association and the Irish Pharmaceutical Union. The list of medicines will be reviewed on a regular basis by the above parties. This scheme will only consider medicinal products in respect of which their principal use is for the treatment of the primary medical condition for which they are authorised.' [emphasis added]

If the PCRS wish to discuss changes to this arrangement or any other agreement, the matter should be raised and agreed by both parties through the IPU/ HSE Joint Consultative Group. In the meantime, existing arrangements should continue.

National Consumer Agency (NCA) Survey From Director of Communications & Strategy to CEO, NCA [2 April 2013]

Re: Prescription Medicines Price Study

I am writing on behalf of the Irish Pharmacy Union (IPU) to outline our concerns at revelations in the Irish Times (Saturday 30 March) that a survey of medicine prices charged by pharmacies to private patients, for product and service, published by the National Consumer Agency (NCA) is flawed and contained inaccurate and misleading information.

The IPU is disappointed that the NCA, in attempting to justify the inaccuracies, has apportioned blame to the responding pharmacists. As a State agency with considerable resources it is your responsibility to ensure that the information published and reported is both accurate and fair.

It is regrettable that you did not share the outcome of the survey with the IPU in advance of publication, which would have helped to identify the errors contained in the report and accompanying press release.

I would respectfully suggest that it is important that you contact us in advance of conducting and publishing results of any future surveys being undertaken by the NCA that impact on the pharmacy sector.

Appendix III

A List of Press Releases Issued to the National Media during the Year on Various Matters

2012

28 April	Patient Safety Threatened by Shortage of Vital Medicines
26 April	Public want greater role for pharmacists – new survey
28 April	Pharmacists raise concerns about over-use of Antibiotics
28 April	Pharmacists warn of rise in heart disease – now responsible for 36% of all deaths in Ireland
29 April	Irish Pharmacy Union elects Donegal man as new President
29 April	Pharmacists Demand Right to Dispense Generic Medicines
29 April	Pharmacists hear that up to 1-in-3 adults may be suffering from Chronic Pain
14 May	Four-in-10 People Would Not Want to Know if a Loved One was Suffering from Depression
23 May	Students Warned to Protect Against Stress as Exam Time Begins
30 May	Pharmacists issue advice to help people stop smoking
08 June	Pharmacists Call for a cut in Commercial Rates
11 June	Look Out for New Emergency Contraception Logo in Pharmacies
27 June	Pharmacists Issue Safe Guide for Sun Holidays
09 July	Statement by the Irish Pharmacy Union
22 July	Business Trends Survey reveals challenges facing pharmacists
27 July	Pharmacists Concerned at Dropping Sales
02 August	Recession Increases Reliance on Community Pharmacists
17 August	IPU warns about Dos and Don'ts of giving medicines to young children
24 August	Getting Ahead of Head Lice
30 August	Pharmacists Warn Electric Picnic Revellers to Look after their Health this Weekend
03 September	HSE confirms withdrawal of Gluten-Free products from State Schemes
10 September	Limerick Pharmacists Urge Public to Take Part in Think Ahead Initiative
20 September	Expert Healthcare Group Proposes a Framework for Self-Care in Ireland
28 September	Pharmacists to Deliver Flu Vaccination to Patients from Next Week
15 October	Pharmacists Welcome Deal to Lower Medicine Prices
23 October	Pharmacists warn of dangers of using internet for buying medicines
01 November	IPU Pre-Budget Submission 2013
06 November	Pharmacies increasingly pessimistic about business prospects – IPU survey reveals
21 November	Pharmacists lead the way in the fight against antibiotic resistance
05 December	Pharmacists respond to harsh measures announced in Budget 2013
14 December	Pharmacists Give Tips for Fighting Colds and Flu
18 December	Pharmacists warn of the dangers of mixing alcohol with medicines over the festive season
28 December	Three-quarters of pharmacists victims of crime this year – Irish Pharmacy Union

2013

04 January	Pharmacists Concerned at Decision to Centralise Photos for Driving Licences
27 January	Majority of Irish Pharmacies Gloomy about Business Prospects – IPU Survey
11 February	Pharmacists promote the benefits of Giving up Smoking
04 March	Irish Pharmacy Union Graduation Day
15 March	Headache Awareness Week (16-23 March)
09 April	Pharmacists warn parents of health risks when giving medicines to children

Appendix IV

Letters Published in Newspapers

Irish Times, 1 June 2012

Sir, - When Mary Rose Burke "told" The Irish Times (Front page, May 29th) that Boots chain had been through "two world wars and depressions", she conveniently overlooked the causative history for these events, in place of being sensational.

History has shown that without greed, colonialism and expansionism these events would not have happened to the devastating extent that occurred.

History also shows that Britain and Germany were most culpable in sharing the blame for the grievances created that ultimately ended in two world wars. Ireland was faultless.

Worryingly, Irish Pharmacy is becoming the latest theatre of war between Britain and Germany (Boots versus Doc Morris/Unicare). Under a false guise of patient price benefit/value they are attempting to conquer the Irish Pharmacy market in the commercially viable areas while ignoring the national requirement for Pharmacy services.

The Irish public and particularly the Irish health administrators should not stand idly by. Currently we are in a phoney war; soon it will be all-out conflict.

Irish Pharmacy is not a toy for the playful amusement of our German and British friends. Both are welcome to compete in our market, fairly and honestly and present information and prices in a truthful sustainable manner. Ireland is more than cities and large shopping centres.

In attempting to divide the spoils of war between them the Irish public should be informed of the long-term danger of damaging the already wounded independent pharmacist, who, by the way, has also survived two world wars etc.

These two really are not any cheaper than the independent Irish-owned and staffed pharmacy. I know that because I am one. Proud Irish and happy to be both. They should play fair or go home. Ministers should represent the nation, not foreign greed.

Yours, etc,
JP Magner,
Howth Road, Killester, Dublin 3.

Irish Examiner, 5 November 2012

Potential Health Issues with E-Cigarettes

Your article (Nov 1) refers to e-cigarettes as "harmless".

According to the Pharmaceutical Society of Ireland's guidance these should not be supplied through retail pharmacy businesses in Ireland because their quality, safety and efficacy have not been appropriately established.

The FDA in the USA has also warned consumers about the potential health risks associated with electronic cigarettes.

A study in the University of Athens found they caused "significant airways resistance".

The cartridges contain chemicals filled with nicotine, flavour and other chemicals that are vaporised and inhaled by the user and have been found to contain carcinogens, including nitrosamines.

Industry sources say the products have improved since then, but because they are unregulated we cannot be sure.

I would suggest that while these products may have potential as a smoking cessation method in the future smokers and are probably less harmful than smoking, smokers should instead consider those products that have been approved for this purpose.

Conor Phelan,
Phelans Pharmacy,
Carrigaline, Co Cork

Irish Times, 20 April 2013

Sir, - The HSE, while teetering on the edge, has issued one more missive that should truly indicate dysfunction.

In its enthusiasm to cut costs it has issued a missive to all prescribers, signed by the DG designate, asking them to use "preferred drugs" from particular classes of medicines. In both cases it uses the two man proprietary names.

This is despite the stated objective of the Government and the HSE, that doctors would prescribe using generic names. Truly an organisation that needs some internal communication lessons.

Jack Shanahan,
Church Street,
Castleisland, Co Kerry.

Notes





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