2017 ANNUAL REPORT OF IPU EXECUTIVE COMMITTEE

IRISH PHARMACY UNION

The voice of community pharmacy

IPU national pharmacy conference

PROGRAMME OF EVENTS

FRIDAY 5 MAY

3.00pm – 6.00pm	**Registration**
3.30pm – 4.30pm	**Tradeshow Exhibition**; Tea/Coffee – *Hogan Mezzanine Foyer*
4.30pm – 5.30pm	**Future Proof: Unlocking the potential of pharmacy through innovative retail solutions** – *Hogan Mezzanine 2*
5.30pm – 6.00pm	**Tradeshow Exhibition**; Tea/Coffee – *Hogan Mezzanine Foyer*
6.00pm – 7.15pm	**AGM Reports** – *Davin Suite*
7.15pm – 8.15pm	**Tradeshow Exhibition**; Pre-Dinner Drinks Reception – *Hogan Mezzanine Foyer*
8.15pm	**Dinner** – *Player's Lounge*

SATURDAY 6 MAY

8.30am – 1.30pm	**Registration**
9.00am – 10.00am	**Investing in Volatile Times** – *Hogan Mezzanine 2*
	Dementia – Understand Together: Transforming services through integration, partnership and innovation – *Davin Suite*
10.00am – 10.45am	**Tradeshow Exhibition**; Tea/Coffee – *Hogan Mezzanine Foyer*
10.45am – 11.45am	**PCRS Roundtable Discussion** – *Hogan Mezzanine 2*
11.45am – 12.30pm	**Tradeshow Exhibition** – *Hogan Mezzanine Foyer*
12.30pm – 1.30pm	**The Public's Usage & Attitude towards Pharmacy & Pharmacy Services** – *Davin Suite*
	A Straight Forward Approach to Ostomy Appliances in a Retail Pharmacy Environment – *Hogan Mezzanine 2*
1.30pm – 2.30pm	**Lunch** – *Hogan Mezzanine 1*
2.30pm – 3.30pm	**Tradeshow Exhibition & Dessert** – *Hogan Mezzanine Foyer*
3.30pm – 4.30pm	**Leadership, Communication and Teamwork – the 3 key platforms to taking you and your business to the next level** – *Hogan Mezzanine 2*
4.30pm – 6.00pm	**AGM Motions** – *Davin Suite*
7.30pm	**Pre-Dinner Drinks Reception** – *Hogan Suite Foyer*
8.00pm	**President's Dinner & Ball** – *Hogan Suite*

SUNDAY 7 MAY

9.00am – 12.00pm	**Registration**
10.00am – 11.00am	**Nutrition, Lifestyle and Functional Medicine in Chronic Illness** – *Davin Suite*
	Funding Pharmacy Growth – *Hogan Mezzanine 2*
11.00am – 11.15am	**Tea/Coffee** – Hogan Mezzanine Foyer
11.15am – 12.15pm	**Methotrexate – the myths and truths** – *Hogan Mezzanine 2*
	Making your Numbers Count – *Davin Suite*
12.15pm – 12.30pm	**Tea/Coffee** – *Hogan Mezzanine Foyer*
12.30pm – 1.15pm	**Benevolent Fund Meeting** – *Hogan Mezzanine 2*
1.15pm	**Lunch** – *Hogan Mezzanine 1*

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The Financial Statements for the Irish Pharmacy Union and IPU Services Ltd are available on the IPU website – **www.ipu.ie**.

EXECUTIVE COMMITTEE 2016-2018

President:	Daragh Connolly
Vice-President:	Carmel Collins
Hon. Treasurer:	Stephen Nolan

Regional Representatives (8)

Ann Marie Horan	Dublin
Stephen Nolan	North East
Conan Burke	North West
Gerry Guinan	South
Vacant	South East
Peter McElwee	Midland
Joanne Hynes	West
Carmel Collins	Mid-West

Community Employee Group (3)

David Carroll *(stepped down September 2016)*
Bernard Duggan *(stepped down September 2016)*
Sinead Ryan *(appointed 1 March 2017)*
Elaine Clarke *(appointed 1 March 2017)*

Past President

Kathy Maher

Co-options

Gemma Dwyer
Padraig Loughrey
Oliver McGuinness
Caitriona O'Riordan

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

2017 IPU AGM AND IPU SERVICES LTD AGM Friday 5 and Saturday 6 May 2017

(confined to paid-up members of the IPU)

AGENDA

Chairperson: Mr Daragh Connolly, President

FRIDAY 5 MAY	
6.00pm	**1. Welcome**
	2. One minute's silence in memory of pharmacists who died since the 2016 AGM
	3. Minutes of IPU 2016 AGM
	4. Minutes of IPU Services Ltd 2016 AGM
	5. Financial Report and Consolidated Accounts 2016 a. Adoption of Audited Statement of Accounts of IPU b. Appointment of Auditors of IPU and IPU Services Ltd c. Adoption of Directors' Report and Audited Statement of Accounts of IPU Services Ltd
	6. Overview from the Secretary General
	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
7.15pm	**End of First Session**
SATURDAY 6 MAY	
4.30pm	**9. Report on Motions from 2016 AGM**
	10. 2017 AGM Motions
	11. Open Forum
6.00pm	**Closing of AGM Procedures by IPU President Daragh Connolly**

MESSAGE FROM THE PRESIDENT
Daragh Connolly

It has been a great honour to represent my profession and colleagues as President of the Irish Pharmacy Union over the past year. It has been a very busy year for everyone in our profession since the last IPU National Pharmacy Conference and it seems hardly that long ago that I congratulated Kathy on a superb tenure as President.

Dear Colleagues and Friends,

The first cohort of pharmacists have submitted their CPD portfolios for review and we are delighted at the feedback they have given the IPU for the relevance and ease of use of the sessions provided at the conference and through IPU Academy during the year. The value of CPD is how we use it to create better outcomes for our patients and the teams we lead. CPD's application is its purpose.

We have seen the launch of the *Future Pharmacy Practice* report by the PSI, which highlighted that patients want us to provide more services to our communities and to take a lead in the streamlining of obsolete practices, which generate so much duplication of effort and increase risk of error. A previous *Public Survey - Attitudes to Pharmacy in Ireland* found that 96% of the Irish public have never had cause to fault the professional service we provide. We have tirelessly engaged with the previous and current Government regarding achieving better outcomes and value for patients through modernising services such as EHC, Minor Ailment Scheme, Vaccination, Medicines Use Reviews, Healthmail, New

Medicines Service, Health Screening, Electronic Prescribing, High Tech, Naloxone and ORT. Progress has been swifter in some areas than others. This leads to an inevitable frustration both within the IPU Executive but also in the profession as a whole. A firm sign that our advocacy to help make a more efficient health service in Ireland is working are the changes to legislation already enacted to allow us to make a start with EHC.

We have seen nationally and internationally a shift in legislation that recognises problem drug use, illicit or not, must be treated first and foremost as a healthcare issue. This year will see the first safe injection centre open in Dublin to help reduce the number of overdose deaths. As the most accessible and qualified experts in our communities, pharmacists should and will be at the vanguard of this change.

Since our last conference, it has unfortunately become obvious of our need for a better way of working with the State. Our contractual relationship has been fraught on an ongoing basis and has, at times, bordered on being contemptuous. We will continue to work through our current contract whilst seeking a better way of delivering value for individual patients and the State alike. It is a pity that there seems to be a contractual priority list for varieties of healthcare professionals when what is needed is a patient contract outlining where and how each citizen will be treated for their healthcare needs. As we have borne the overwhelming burden of cutbacks in the budgets in primary care, our spend levels are now proportionately far below better run health systems. It is a fair question to ask on behalf of our patients if any efficiencies have been created in secondary care to produce better outcomes for patients. Unfortunately, we already know the answer.

The trust and esteem our profession enjoys has not come about by accident. Ours is a very hardworking profession that has an obvious fault of not making a fuss about the good we do, seen and unseen. It is the role of the IPU to advocate on behalf of your role as a healthcare expert in your community. It is an honour to do so. The IPU represents and advocates for its members as it can only be as strong as its membership. I thank you personally and on behalf of the entire profession for your dedication to your profession and ultimately to your patients and communities. We have earned the right to be proud of our profession.

I wish to thank the very hardworking team in Butterfield House for making our conference an event we can be proud of as it shows our profession at its best. Pharmacists are renowned for being excellent multitaskers and those skills will be put to good use at this year's conference. We will take the opportunities offered to advance our education, business, advocacy, leadership and management skills, while testing new ideas, catching up with old friends and making new ones. Please also take the opportunity to relax and enjoy the social aspect of our conference. I hope you will return to your practice invigorated, enthused and undaunted by the challenges and opportunities another year will bring.

The IPU's *2017-2021 Statement of Strategy* will be launched at the conference. This strategy document is not the work of any one individual; it was very much a team effort. It sets out a clear course for the next four years and is challenging, far-reaching and ambitious.

Finally, on your behalf, I would like to take this opportunity to thank our Secretary General, Darragh O'Loughlin, for his enthusiasm, hard work and dedication to the IPU and its members. His counsel to me in my role as President and countless other members has been of huge value, seen and unseen.

Daragh Connolly MPSI
President, IPU

MINUTES OF THE 43RD ANNUAL GENERAL MEETING OF THE IRISH PHARMACY UNION AND IPU SERVICES LTD

Crowne Plaza Hotel, Northwood, Dublin 22 & 24 April 2016

Friday 22 April – AGM Reports

Present: IPU President Kathy Maher and 43 members.

In Attendance: Darragh O'Loughlin, Jim Curran, Ciara Enright, Darren Kelly, Wendy McGlashan, Róisín Molloy and Patrice O'Connor.

Apologies: Apologies were received from five members.

1. The President welcomed the attendance to the 43rd 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, family members and Enda Ryan, former Secretary General, who had died since the 2015 AGM.

3. **Minutes of 2015 AGM**
The report of the 42nd Annual General Meeting was taken as read. The report is available on the members' section of www.ipu.ie. The report was proposed by Carmel Collins, seconded by Stephen Nolan, unanimously approved and signed by the President.

4. **Financial Reports and Accounts 2015**
Bernard Duggan (Honorary Treasurer) presented the IPU's Financial Report and took queries from the floor.

He said that the total income for the year was €4,756,852 compared to €4,945,466 in 2014 which represented a 4% decrease in overall income for the year. This was largely due to the decrease in revenue received from the sale of the IPU Product File to external customers.

Revenue through membership subscriptions and levy income: membership had increased due to a small increase in membership numbers from 2,140 in 2014 to 2,146 in 2015, while

levy income had continued to rise due to the continued increase in the number of medical cards being issued by the HSE in 2015. This trend had begun to level off towards the end of 2015.

Other areas of note in income included advertising in the IPU Review, courses and the conference sponsorship:

- Advertising in the *IPU Review* continued to grow in 2015;
- Courses represented all the courses being provided by the IPU for members and non-members. The Technician and MCA courses continued to perform well. Some 430 members joined IPU Academy in 2015 in addition to the 2146 IPU members who could also avail of the service. There were also a number of business-focused courses running, for which there had been a good uptake; and
- **Conference Sponsorship**
  The IPU ran two conferences in 2015: the IPU National Pharmacy Conference and the PGEU Conference. There was an increase in sponsorship revenue from the IPU National Pharmacy Conference in excess of €40k due to the change in the sponsorship structure. While the PGEU Conference generated income totalling €43k, the corresponding charges in relation to the PGEU Conference are reflected in the expenditure resulting in a small profit for the IPU.

Total expenditure for the year was €4,209,390 compared to €4,307,949 in 2014, which represented an overall 2% decrease in expenditure.

The Treasurer highlighted a number of areas where increased expenditure occurred and outlined the reasons:

- Legal Expenses & Consultancy;
- IT;
- Repairs and Renewals;
- Course Expenses;
- IPU Product File; and
- hmR.

The IPU continued to introduce initiatives in 2015 to expand the value of membership of the IPU. In 2013, a free Irish Medicines Formulary was provided to each member who renewed their subscription. In 2014, fully paid-up members received both a free BNF for Children and a BNF. In 2015, members were able to avail of the Member Assistance Programme from the VHI which provides telephone assistance for any IPU Member or their staff should they require it.

By year-end, the Mullally and Haire legal cases had moved towards resolution and, as such, the provision of €950,000, which was in the previous year's accounts to cover possible further costs in these cases, had been written back into the accounts.

Following the presentation, the following motion approving the accounts was proposed by Marie McConn, seconded by John Carey and carried unanimously: "That the Executive Committee Report and Audited Statement of Accounts for the Irish Pharmacy Union for the year ended 31 December 2015 as submitted to this meeting be and are hereby adopted."

The following motion was proposed by Marie McConn, seconded by Peter McElwee and carried unanimously: "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."

5. IPU Services Ltd AGM

The accounts were presented by the Treasurer and on the proposal of Stephen Nolan seconded by John MacNamara it was resolved: "That the Directors' Report and Audited Statement of Accounts for the year ended 31 December 2015 as submitted to this meeting, be and are hereby adopted."

This motion was carried.

The minutes of the 2015 AGM of IPU Services Ltd were taken as read.
In conclusion, the Hon Treasurer thanked Ciara Enright, Secretary to the Finance Committee and his colleagues on the Committee for all their work over the past two years and wished the incoming Treasurer, Stephen Nolan, all the best for his time in office.

MINUTES OF THE 43RD ANNUAL GENERAL MEETING OF THE IRISH PHARMACY UNION AND IPU SERVICES LTD CONTINUED

6. IPU Secretariat Report

The IPU Secretariat Report was circulated to members by post in advance of the meeting and a more detailed report was published on the members' section of **www.ipu.ie**.

7. Group Reports

a. Pharmacy Contractors' Committee (PCC) Report

This report was presented by Eoghan Hanly, 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

The CPC Chairman was not present. An overview of the CPC report was included in the President's report. 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. Employee Pharmacists' Committee (EPC) Report

This report was delivered by Sheila O'Loughlin, 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. Communications 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.

9. President's Address

The President gave a brief overview of the work of the IPU over the previous 12 months, which is attached *(see page 18)*.

10. Open Forum

Items discussed included:

a. The need to get more pharmacies to reply to the annual review of the sector as it was felt that, in the main, it was the larger pharmacies that were participating. It was noted that hmR data would be of assistance in future surveys;

b. The number of pharmacies in hmR, which, at the time of the meeting, was 50% of IPU member pharmacies;

c. The process for unwinding of FEMPI;

d. The necessity to get the PCRS paper workload down/simplified. The Secretary General said that more electronic exchange was being implemented, which would streamline the process. The PCC strategy is to get a new, streamlined contract;

e. The Secretary General replied to Barra Nevin who asked what there was to prohibit the Government from reducing reference pricing to the absolute minimum. He said that if the reimbursement price went too low companies might not market their drugs but it was up to the PCRS to ensure that drugs were available for patients; and

f. Marie McConn said that the PCRS were back to underpaying claims.

The President then adjourned the AGM until Sunday 24 April at 12.30pm.

Sunday 24 April – AGM Motions

Present: IPU President Kathy Maher and 41 members.

In Attendance: Darragh O'Loughlin, Jim Curran, Darren Kelly, Wendy McGlashan, Róisín Molloy and Patrice O'Connor.

Apologies: Apologies were received from five members.

10.Report on Motions from 2015 AGM

The report on motions from the 42nd Annual General Meeting was taken as read.

11. 2016 AGM Motions

The following motions were proposed in accordance with Article 30 of the Constitution. All motions were debated and considered by the meeting and then passed.

a. **"That this AGM calls on the Government to recognise pharmacy as a crucial element of primary care and to allocate the necessary resources to developing pharmacy services in order to alleviate pressures caused by the persistent GP manpower crisis and ensure easy access for patients and the public to safe, convenient and cost-effective healthcare."**

Proposed: Kathy Maher
Seconded: Carmel Collins

In proposing this motion, Kathy Maher stated that "with increasing demand for health services and shrinking resources, the healthcare system is under unprecedented pressure. The service is near breaking point, with hospitals overstretched and GPs struggling with their existing workload.

In a recent survey published in the Irish Medical Times, GPs were found to have been overrun by "a tsunami" of visits from children under six being brought to their surgeries because the service is now free for children, which has had a knock-on effect on their ability to provide prompt appointments for other patients who are genuinely unwell.

The demands on the health system and on GPs in particular are set to increase further. Free GP care for the under 6s and the over 70s, and the planned extension of free GP care to the whole population, combined with an ageing population, will have a major impact on the future.

A workforce planning exercise carried out late last year by the HSE's National Doctors Training and Planning Unit concluded that there is a significant undersupply of GPs in Ireland at present and that, by 2025, the predicted shortage of GPs will be anything from 493 to 1,380 – depending on increased levels of access to free GP care.

But it's not just about alleviating the workload of GPs. Patients benefit too.

There is clear evidence to show that pharmacy-based services in other jurisdictions have led to considerable improvements in patients' health outcomes and considerable savings to healthcare budgets. In England, Scotland and Canada, for example, where demand for GP services exceeded the available capacity, the unique skills and expertise of pharmacists have been used to enhance access to healthcare.

In response to the shortage of GPs in Canada, pharmacists' scope of practice has been extended to include Chronic Disease Management: monitoring patients with chronic illnesses, renewing and adjusting their prescriptions to ensure tighter control of their symptoms. This is done in collaboration with the patient's doctor, not in competition, and has been found to deliver better treatment outcomes, with reduced morbidity and mortality.

Data from Scotland shows that in-depth Medicine Use Reviews conducted by pharmacists, with patients suffering from chronic illnesses, reduced hospital readmission rates by a third.

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Extending pharmacist services in this way has resulted in better access to primary health care and a substantial reduction in morbidity and mortality rates from illnesses such as heart disease and diabetes.

Pharmacists in Ireland have the requisite expertise, skill-set and accessibility to introduce services like Health Screening, a Minor Ailment Scheme, New Medicine Service or Chronic Disease Management, all of which would assist in delivering on the Government's programme of improving the health and wellbeing of people living here.

The ability of pharmacists in Ireland to deliver additional key services is beyond doubt. The introduction of the flu vaccination service, reclassification of Emergency Hormonal Contraception and a smoking cessation service has shown that pharmacy can deliver, in a cost-efficient manner, services that patients want and avail of.

The public are hugely supportive of an extended role for pharmacists. Our independent market research confirms that 92% of the public are in favour of pharmacies providing a minor ailment scheme, with 94% in favour of pharmacies providing services to improve patient adherence to medicines.

Just last October, the Joint Oireachtas Committee on Health and Children published a report which recommended an expanded role for pharmacists, something which all the main political parties committed to in their recent election manifestos.

Pharmacists rank second only to nurses as the healthcare professionals most trusted by the public but, unfortunately, Ireland lags well behind other countries when it comes to allowing pharmacies to deliver additional services.

There is a lot of talk about creating a patient-focused health service delivered at the lowest level of complexity. Pharmacists already play a vital role in ensuring patient safety and wellbeing.

If allowed and if given appropriate resources to do so, pharmacists are willing, ready and able to help alleviate pressure on GP surgeries and on hospitals by providing a broader range of healthcare services to their patients and the public, in line with what happens in other countries.

We propose that this AGM calls on the Government to recognise pharmacy as a crucial element of primary care and to allocate the necessary resources to developing pharmacy services in order to alleviate pressures caused by the persistent GP manpower crisis and ensure easy access for patients and the public to safe, convenient and cost-effective healthcare."

This motion was carried unanimously.

b. "That this AGM calls on the Department of Health to commence negotiations with the IPU on a new Pharmacy Contract that is fit for purpose and which reflects the needs of patients and the practice of pharmacy in the 21st Century."

Proposed: Eoghan Hanly
Seconded: Ray McSharry

In proposing this motion, Eoghan Hanly stated that "in 1996, the then Pharmaceutical Contractors' Committee of the IPU, negotiated the terms of the current Community Pharmacy Contract with the Department of Health, in conjunction with regulations governing pharmacy establishment and location. At the time, it was regarded as a tremendous achievement and positioned pharmacy well for many years. However, time passes and circumstances change.

The associated regulations, which at the time and from our perspective, were a key part of the deal, were repealed in January 2002 by the then Minister for Health, Micheál Martin.

In 2008, the HSE, then embroiled in a bitter dispute with the IPU over pharmacists' right to representation in negotiations with the State, set out

a framework process for negotiating a contract and setting pharmacists' remuneration. However, no contract talks ever took place and the detested FEMPI Act – which we are all painfully familiar with – superseded any possibility of negotiation.

The Contract was revised in 2010, but this was simply for the purposes of updating some of the definitions contained within it and there was no substantive change to its provisions.

We are grateful to the IPU representatives that negotiated the terms of the 1996 agreement. The negotiations took many months and a lot of hard work and dedication on their part. The benefits that accrued to all of the parties to the 1996 agreement and the contract that resulted from it cannot be underestimated. However, that Community Pharmacy Contract is 20 years old this year and it is now apparent that it is in urgent need of review.

- Since 1996, a number of Schemes and Services have been introduced in a piecemeal manner and many disparate and, at times, confusing changes or restrictions in the terms and conditions and rules applicable to the schemes have been made;
- There is no clear process for consultation between the Department of Health and the IPU on matters of importance;
- The provisions of the Contract do not accurately reflect the legal or regulatory framework within which pharmacies operate today;
- The Contract is inflexible and increasingly does not support pharmacists to meet the needs of patients in modern-day Ireland;
- The process in place for making small changes to pharmacy ownership structures is unnecessarily convoluted;
- There are no provisions in relation to funding or updating IT infrastructure to create efficiencies and cost savings within the system, despite the obvious need to do so; and
- There is no defined dispute resolution procedure for unpaid claims, nor is there a clear sanctions policy to bind PCRS behaviour. Transparency and fairness require both.

In 2013, the then Minister agreed with the IPU that it was time for a new Pharmacy Contract to be put in place, in addition to a new GP Contract. In 2015, the Department of Health, driven by a political imperative, opened negotiations with the IMO on a new Contract for GPs. A new Pharmacy Contract is equally necessary.

The agreed framework for the GP negotiations should form the basis of any engagement between the IPU, the Department of Health and the HSE. There is recognition that pharmacists can deliver far more services than are currently delivered and it is obvious that the health service needs us delivering services.

Equally, it is clear from our dealings with them, that the PCRS needs a clear and balanced set of rules to govern the administration and payment of our claims, with a defined process for agreeing changes to reimbursement rules and a clear framework for agreeing the scope, operation and remuneration of all future new services.

We therefore call upon the Department of Health to commence negotiations with the IPU on a new Pharmacy Contract that is fit for purpose and which reflects the needs of the patients and the practice of pharmacy in the 21st Century."

This motion was carried unanimously.

c. **"That this AGM calls on the Minister for Health to review the Medical Card Prescription Levy; initially by exempting all vulnerable patients – including homeless patients, palliative care patients and others who require their medication changed on a daily or weekly basis, patients in residential care settings, patients with intellectual disabilities and patients receiving**

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treatment under the Methadone Treatment Scheme in respect of other medication that they may require – and ultimately by phasing it out over a three-year period."

Proposed: Ciara McCabe
Seconded: Michael Walsh

In proposing this motion, Ciara McCabe stated that "all of us in this room are well aware of the impact of the prescription levy, particularly on economically vulnerable patients. The levy at €2.50 has increased fivefold since it was first introduced in June 2010 at €0.50 per item. Many patients, particularly those on fixed incomes, just cannot afford to pay the levy. Instead, they gamble with their health every day either by reducing their medication or by stopping it entirely. The ultimate outcome is sicker patients, with more complex medical needs, needing advanced care in an already extremely overburdened health system. The imposition of the levy is creating more future demand for a health service that is already struggling to cope.

The impact of the levy can be seen from the findings of a Behaviour & Attitudes Survey on behalf of the IPU, undertaken in March of this year. In the survey, 28% of medical card holders said that they 'think twice' about taking their prescribed medicines because of the cost of the levy and 1 in 7 confirmed that they have not filled a prescription because of the levy.

There was a study published in March of this year which was funded by the Health Research Board, and co-authored by researchers in University College Cork (UCC) and Trinity College Dublin. This study only looked at the impact of the increase in the levy from 50cent to €1.50. However, it found that prescription charges on the medical card scheme led to reductions in the use of medicines by Irish patients, with some types of medicines being affected more than others.

In October of last year, the Government signed regulations exempting asylum-seekers living in direct provision from the levy in response to evidence that recent increases in the charge caused hardship among that group of people.

Putting economic barriers in the way of patients taking their medicine doesn't make sense. People living with heart disease, or at risk of the disease, should be focusing on getting better and keeping well, not worrying about how they're going to pay for their next vital prescription. Poor adherence to treatments, especially in the case of chronic illness and long-term patients, will mean more hospital stays, more pressure on our already struggling and depleting health service and more cost to the Exchequer in the treatment of these patients in the long run. Patients need to be supported not penalised.

In this motion, therefore, I am calling for a two-step approach. Firstly, I am calling on the Minister for Health to immediately exempt the following vulnerable patients from the prescription levy:

- Patients in residential care settings;
- Patients with intellectual disabilities;
- Patients receiving treatment under the Methadone Treatment Scheme in respect of other medication that they may require;
- Homeless patients including those in homeless shelters; and
- Palliative care patients and other patients who have their medicines changed on a daily/weekly basis.

Secondly, I am calling on the Minister for Health to review the Medical Card Prescription levy with a view to phasing it out entirely by steadily reducing the amount over a multi-year period."

This motion was carried unanimously.

d. "That this AGM calls on the Minister for Health to engage promptly with the IPU on the recommendations of the Joint Committee on Health and Children on expanding the role of the pharmacist, namely:

- **Establishing a New Medicines Service;**
- **Introduction of Medicine Use Reviews;**
- **Consideration of what other steps could be taken to enhance the role of the pharmacist in the provision of primary care to patients;**
- **Assessment of a financial incentive mechanism for pharmacists to supply biosimilars;**
- **A detailed analysis of the potential of community pharmacists to expand their role by delegating prescription authority to them; and**
- **The reclassification of a wider range of medicines from prescription-only to non-prescription."**

Proposed: John O'Connell
Seconded: Roma O'Loughlin

In proposing this motion, John O'Connell stated that "on 9 October 2015, the Joint Committee on Health and Children published its Report on the Cost of Prescription Drugs in Ireland. The IPU made written and oral presentations to the Committee. The report made a number of important recommendations, intended to reduce the long-term cost of pharmaceutical drugs and increase the use of generic drugs in Ireland. In addition to recommendations to reduce the cost of medicines, the report also called for a number of new pharmacy services to be introduced.

NMS, MURs and Role of Pharmacist
In relation to the role of the pharmacist, the Oireachtas Committee considered the potential for community pharmacists to play a more proactive role in reviewing prescription use. In this regard, the IPU highlighted the UK's New Medicine Service as an example of best practice. We also discussed Medicines Use Reviews, whereby community pharmacists meet with patients with long-term illnesses to carry out joint reviews of their prescriptions on an annual basis.

The findings from the evaluation of the New Medicine Service suggest that such reviews have the potential to enhance patients' lives, reduce the number of hospital stays, and result in more effective use of prescription drugs.

Medicines Use Reviews were previously recommended by the Joint Committee in 2007. An MUR pilot project, prepared for the HSE's Primary Care Group in 2012, recommended that MURs should be implemented as a practice-based service, supported by the HSE. In Scotland, MURs have reduced hospital re-admission rates by more than 30% for elderly patients suffering chronic illnesses and taking multiple medications.

Consequently, the Committee recommended the establishing of a New Medicine Service and the introduction of Medicines Use Reviews, where patients with long-term illness jointly review their prescriptions with pharmacists on a regular basis. The Committee also recommended that the Minister should consider what other steps could be taken to enhance the role of the pharmacist in the provision of primary care to patients.

Prescribing and Switching
In relation to prescribing and switching, the Oireachtas Committee acknowledged that, although pharmacists have no role in the setting of reimbursement prices for medicines, the role of the community pharmacist is recognised as integral to the provision of advice to patients on generic substitution. Under the Health (Pricing and Supply of Medical Goods) Act 2013, pharmacists must supply a substitute generic product (via the designated Interchangeable List) if a proprietary branded drug is not explicitly requested in handwriting on the prescription by the GP.

The Committee further acknowledged that the role of the pharmacist extends to improving patient awareness including supporting patients to make healthier lifestyle choices. Consequently, the Committee said that, considering

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the wide knowledge possessed by community pharmacists and their proximity to patients, a detailed analysis of the potential to expand their role with respect to the delegation of prescribing competencies merits further consideration. The Committee also supported the reclassification by the Health Products Regulatory Authority (HPRA) of a broader level of medicines from prescription-only to over-the-counter, in line with best practice in other EU countries.

Biosimilars
With regard to biosimilars, according to the HSE, the High Tech Drug scheme is the only PCRS scheme which has seen an increase in expenditure from €315m (in 2009) to €485m (in 2014), or 54%. In the future, the expectation is that new medicines will, in the main, be in the High Tech area. As such, the Committee felt that action in this area was viewed as necessary.

One option proposed is for the State to enact legislation to facilitate the listing of biosimilar medicines as "interchangeable", something which is currently prohibited. It was stated that this could reduce the State's pharmaceutical bill, treat more patients within existing budgets, and allow improved access for patients to newer, innovative medicines.

The Committee, therefore, recommended that the potential application of a financial incentive mechanism for pharmacists to supply biosimilar versions of products on the High Tech Drug scheme should be assessed.

Conclusion
It is refreshing to see a Committee as influential as the Joint Committee on Health and Children make such innovative recommendations on expanding the role of the pharmacist and we now call on the Minister for Health to engage promptly with the IPU on these recommendations."

This motion was carried unanimously.

e. **"That this AGM calls upon the Department of Health and HSE to immediately roll out a national Pharmacy Minor Ailment Scheme following the completion of the three-month pilot scheme."**

Proposed: Sheila O'Loughlin
Seconded: Sarah Magner

In proposing this motion, Sheila O'Loughlin stated that "Community pharmacists deal routinely with minor ailments as part of their normal practice, giving advice to patients on how to treat self-limiting conditions and distinguishing between minor illness and major disease. By giving appropriate advice and recommending effective treatments, community pharmacists play a major role in keeping minor ailments out of the GP surgery. Furthermore, they act as a filter for referral where a GP consultation is needed.

The Minor Ailment Scheme is an internationally-recognised extended pharmacy service, which demonstrates how pharmacists can improve public health access, shape future services and broaden pharmacy roles to deliver quality patient care and improve health outcomes.

The basis of the GMS Scheme is to provide full pharmaceutical services for persons who are unable, without undue financial hardship, to provide such services for themselves and their dependants. The primary aim of a Minor Ailment Scheme is to enable medical card patients to receive treatment for common illnesses free-of-charge directly from their local community pharmacy in a timely manner and without the need for a visit to the GP; such a scheme would be cost-neutral to the Exchequer.

In the UK, the Royal College of General Practice and the College of Emergency Medicine have estimated that one in seven GP consultations and one in 12 A & E attendances could have been dealt with by a visit to a pharmacy. Improving the accessibility of treatment

for minor ailments in a pharmacy setting through a Minor Ailment Scheme would facilitate more prompt treatment of ailments, thereby improving the quality of life for patients, and would alleviate pressures on GP surgeries and prevent unnecessary use of Accident and Emergency services.

The IPU is currently working with the HSE on a three-month pilot Minor Ailment Scheme in four towns around the country. We now wish to ensure that the scheme becomes a national service once the pilot is complete.

We therefore call on the Department of Health and HSE to immediately roll out a national Pharmacy Minor Ailment Scheme following the completion of the three-month pilot scheme."

This motion was carried unanimously.

f. "That this AGM calls upon the HSE to roll out a pharmacy-based anticoagulation service in areas of the country where such a service is not easily accessible."

Proposed: Jonathon Morrissey
Seconded: Ultan Molloy

In proposing this motion, Jonathon Morrissey stated that "treatment with warfarin requires regular monitoring of the International Normalised Ratio (INR) to ensure the patient's level of anticoagulation is maintained within a safe range. The aim is to maintain patients within their therapeutic range for the maximal possible time (which is known as the percentage time in therapeutic range or TTR).

In order to ascertain appropriate rates of INR control with warfarin, clinicians review past results and calculate the amount of time the INR results were within their defined range, with optimal therapy considered when the TTR is > 70%.

The non-vitamin K oral anticoagulants (NOACs) first became available in Ireland in 2008. Not all patients are suitable for warfarin therapy due to labile INRs or drug allergies so the availability of NOACs afford the opportunity to treat a larger cohort of atrial fibrillation patients than was previously possible.

The number of people being treated with NOAC therapies under the Community Drug Schemes has risen steadily; in October 2013, 10,131 patients were dispensed a NOAC, while 33,585 were dispensed warfarin. One year later, in October 2014, 16,272 patients were dispensed a NOAC and 30,620 patients were dispensed warfarin. The NOACs represent a considerable cost to the HSE; total drug expenditure on NOACs amounted to €1.5 million for the month of October 2014 alone, in comparison to a total drug expenditure on warfarin of €0.4 million during this time.

Non-compliance with warfarin therapy is not considered a suitable reason for choosing a NOAC above warfarin therapy, due to the short elimination half-life associated with the NOACs and the consequent risk of reduced anticoagulation if there is poor compliance. Warfarin therapy is also less expensive than newer treatments, even when taking account of the cost of monitoring through warfarin clinics or GP practices.

For these reasons, the HSE's Medicines Management Programme (MMP) considers that there is little difference, in terms of health outcomes, between warfarin therapy and NOACs, when warfarin is well tolerated and the INR remains within range. Consequently, the MMP has re-affirmed that warfarin is the preferred oral anticoagulant for stroke prevention in non-valvular atrial fibrillation. As with previous MMP Preferred Drugs initiatives, prescribers are encouraged to consider the preferred drug when initiating anticoagulant therapy.

The difficulties arising from insufficient anticoagulation services in primary care in Ireland have been well documented. Most patients attend a hospital warfarin clinic to have their INR tested, typically having to wait for several hours before

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their results are confirmed. Indeed, in some parts of the country, there is no such clinic. Some GP practices also offer this service. Community pharmacists, as experts in medicine, have an ideal skillset to manage patients on warfarin successfully and are well placed to provide such a service.

Dermot Twomey, a community pharmacist from Cloyne, Co Cork, has been running an anticoagulation clinic in his pharmacy since 2010, in conjunction with the Consultant Haematologist at Cork University Hospital. His results have met with the international standard for the provision of anticoagulation services, with TTR readings consistently above 70%.

In a meeting with the IPU in July 2015, both the Minister for Health and the Minister of State for Health indicated their support, in principle, for widening anticoagulation management services through community pharmacy and expressed a desire to see a proposal for such an initiative brought forward through the HSE.

There is international evidence of the value of such a pharmacy service. A report on New Zealand's Community Pharmacist-led Anticoagulation Service (CPAMS) showed that pharmacy sites achieved a mean TTR in excess of 70%. Compliance with appointments was excellent at 83.1%. The great majority of patients found the CPAMS to be convenient and accessible, preferable to the previous system, and expressed confidence in the pharmacist to perform the service. The predicted budget impact is a net reduction in anticoagulation-associated costs of approximately NZ$177 million over five years (for 80% of patients managed under the CPAMS) or NZ$111 million over five years (for 50% of patients managed under the CPAMS).

We therefore call upon the HSE to roll out a pharmacy-based anticoagulation service in areas of the country where such a service is not easily accessible."

This motion was carried unanimously.

g. **"That this AGM calls on the Department of Health and the HSE to implement the recommendations of the Joint Committee on Health and Children on medicine shortages, namely:**
   - **Maintain strong surveillance on the impact of national medicine price policy on the medicine supply;**
   - **Prepare a contingency plan to consider certain export controls should medicine shortages arise;**
   - **Examine the feasibility of introducing concessionary pricing where medicine supply is an issue;**
   - **Commission a future-focused assessment of the challenges posed by pricing, supply and demand for pharmaceuticals in Ireland."**

Proposed: Daragh Connolly
Seconded: Caitriona O'Riordan

In proposing this motion, Daragh Connolly stated that "medicine shortages are an ongoing problem that is putting patients' health at risk. On a daily basis there is a shortage of one medicine or another and in many cases a nationwide shortage of critical prescription medicines.

Results from a survey of members undertaken in August of last year highlighted the scale of the problem, with 99% of pharmacists indicating that they had experienced medicine shortages in the previous three months. Nearly a third (30%) had encountered shortages of 20 or more medicines, and nearly half (46%) of pharmacists believe that their patients' health outcomes had been "adversely affected by medicine shortages.

Patients can sometimes wait for weeks to get a new supply of a common drug. Not only is this putting their health at risk but it is causing undue stress, fear and anxiety for them. Instead of directing their efforts and professional expertise towards the needs of patients, pharmacists are spending anything from

five to 30 hours plus a week resolving medicine shortages and firefighting on behalf of our patients.

Adding to these concerns is the fact that pharmacists typically receive little or no warning that these medicines are going out of stock and there is often little information on when these stocks will be replenished. It is extremely inconvenient and poses a risk to the health of some patients to have to return to a doctor to have a new prescription written because the medicine that they should receive is out of stock; indeed, quite often, there is no alternative available on the Irish market.

Falling medicine prices are adding to the problem as more medicines are either being exported out of the country to other jurisdictions where medicine prices are higher, or are simply not being supplied.

We, as pharmacists, as healthcare professionals, have a responsibility to ensure, as best we can, that key medicines are available to our patients as and when they require them. It is not our responsibility alone, however. The Department of Health, the HSE, manufacturers, wholesalers and regulators need to coordinate a national plan to deal with medicine shortages, which would include putting steps in place to prevent medicine shortages and a comprehensive communications plan to gather and publish accurate, timely information on shortages before they occur.

This is an extremely serious situation that needs to be urgently tackled. To address this ongoing problem and to ensure there is a steady supply of medicines available in pharmacies, we are proposing that this AGM calls on the Department of Health and the HSE to implement the recommendations of the Joint Committee on Health and Children on medicine shortages, namely:

- Maintain strong surveillance on the impact of national medicine price policy on the medicine supply;
- Prepare a contingency plan to consider certain export controls should medicine shortages arise;
- Examine the feasibility of introducing concessionary pricing where medicine supply is an issue;
- Commission a future-focused assessment of the challenges posed by pricing, supply and demand for pharmaceuticals in Ireland."

This motion was passed with 1 vote against.

h. "We wish to propose that the IPU engages in a process of membership consultation prior to making submissions to the PSI, Department of Health or any other relevant bodies."

Proposed: Nicola Cantwell
Seconded: Marie McConn

In proposing this motion, Nicola Cantwell stated that "Richard Collis and I, as [PSI] Council members, have found huge value in the feedback from the public consultations from pharmacists when trying to ensure that the voice of community pharmacists is heard when discussing the issue of patient safety and welfare. Looking at the positivity and engagement at the conference this weekend, it is obvious that the IPU is the only credible voice of community pharmacy in Ireland and we need to encourage more involvement from members to keep pharmacy at the heart of the community. Many people don't want to engage with the PSI, (to raise their heads above the parapet) nor have they the time to get involved with IPU committees. I think that setting up membership consultations will encourage those who haven't gotten involved previously to get involved. It could be as simple as a note in the memorandum alerting members that there is an open PSI consultation, a looming budget or other issue with an email address and a cut-off date for comments. There are 2,246 IPU members, all of whom have ideas and comments, and it would be of huge value to the Union if we could get even more people involved. It is all about communication, and an initiative like this can only serve to strengthen the IPU.

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Following a detailed discussion, the following amendment to the motion was proposed by Ultan Molloy, seconded by Nicola Cantwell and agreed with one abstention and one vote against.
"We wish to propose that the IPU encourages further member engagement prior to making submissions to the PSI, Department of Health or any other relevant bodies."

The amended motion was put to the meeting and passed with 4 abstentions and 4 votes against.

12. Open Forum

The President thanked the organisers of the conference for all the work in making the weekend such a success. She thanked the IPU Secretary General and staff, committee members and colleagues for their support during her two-year Presidency and wished the incoming Officers, President Daragh Connolly, Vice-President Carmel Collins and Hon Treasurer Stephen Nolan all the best for the next two years. She then passed the chain of office to the new President of the IPU.

Daragh Connolly paid tribute to the outgoing President and presented her with a bouquet of flowers. He briefly addressed the meeting and then closed the 43rd Annual General Meeting of the Irish Pharmacy Union.

President's Address at AGM – 22 April 2016

Vice-President Daragh Connolly, Honorary Treasurer Bernard Duggan, Secretary General, Darragh O'Loughlin, fellow members of the Irish Pharmacy Union.

We are here this evening to discharge the requirements of the Annual General Meeting of the Irish Pharmacy Union. We are also here to attend our sixth IPU National Pharmacy Conference and I would like to welcome you all for what promises to be a fantastic event.

Even though the economy continues to improve, we know that our sector is still faced with a number of significant threats and challenges. The FEMPI cuts, reference pricing, falling medicine prices and new business models are contributing to what remains an extremely difficult environment. While in the last 12 months there have been some tentative signs of improvement in front of pharmacy, dispensary revenues continue to struggle.

The rush to drive down the price of medicines, regardless of the impact on supply, continues to challenge us. The IPU has consistently warned the Government of the impact on supply of medicines from setting the price too low. The evidence confirms that our warnings are justified. This is a problem which continues to get worse and an issue that we will continue to keep on the Government's radar.

The considerable regulatory burdens imposed by the PSI, through Fitness to Practise and the increased amount of legislative requirements, is becoming onerous and a serious impediment to pharmacy practice. The fact that we have to pay, by international standards, extortionate fees to fund the operation leaves a sour taste.

As your representatives, we in the IPU are extremely conscious of these issues and we have made every effort to try and alleviate these difficulties by addressing them head-on with the relevant powers that be. At the same time, we continue to promote the sector as a key element of the healthcare system. Outstanding Court actions have been settled and written commitments have been received from Government that the reversal of FEMPI would commence imminently. Although the amounts indicated for restoration to pharmacists are almost laughably low, the main thing is that the process has already begun.

We made written and oral submissions to the Department in February setting out clearly our view and we now await the outcome.

I will be telling the Minister tomorrow that what has been offered is unacceptable and it is our intention to continue to push for equitable and proportionate reversal of the cuts, in line with other similar groups.

We have had a number of meetings with the PSI to discuss, among other issues, Fitness to Practise and Corbally, wholesale deliveries to pharmacies and PSI fees and minor administrative changes to registration details.

We have worked with the PCRS in our efforts to get them to address serious failings from pharmacy's perspective in the administration of State schemes and this has resulted in some improvements. However, we recognise that there is still a long way to go. Restrictions to reimbursement of medicines should not come at the expense of pharmacists whose only crime is trying to ensure their patients receive the medicines they need. We will continue to press for practical improvements in communication and information flow to pharmacists so that we can be assured of reimbursement before medicines are ever dispensed, rather than depending on hope and goodwill afterwards.

As a result of our constant political lobbying efforts, two favourable Oireachtas Committee presentations (2014 and 2015) have resulted in positive recommendations from the Committee for further expansion in pharmacy services. In addition, the IPU is a valued participant in the development and implementation of the Government's eHealth Ireland strategy. It is important that the IPU is regarded positively by policy makers as a proactive and constructive stakeholder in health and that pharmacists are positioned as the go-to profession for the roll out of any new service.

As a result of these efforts, Ministerial approval has been gained for enhancement of the role of the pharmacist and changes have been implemented. Regulations are now in place to allow the expansion of pharmacy vaccination and we await PSI and IIOP action to allow those new vaccines to be administered. Moreover, a Minor Ailment Scheme pilot is about to get underway; and legislation to allow for non-prescription supply of emergency contraception on the GMS, which we formally proposed following last year's conference, has been drafted and is awaiting passage through the Oireachtas.

We are also working hard for the introduction of other additional services, including Medicines Use Reviews, New Medicine Service and a Health Check Service, and have made strides in getting more medicines reclassified, with Dovonex Psoriasis Ointment and Voltarol 2% Gel approved already this year; but we still have a way to go.

Of course, we need to be adequately remunerated for delivering any new services. The introduction of additional services is not for everyone, but it is incumbent on us, as your representatives, to do everything we can to reinforce our position in the healthcare system, to protect our existing resources and to expand our role in areas that can enhance our offering to patients and consumers, and introduce additional income streams.

We all know that there are other health professions who are opposed to any expansion of our role, who claim that pharmacists are a commercial entity only interested in driving footfall and we are not qualified to deal with patients and offer advice on minor ailments. Nonsense. As pharmacists, we are only interested in one thing and one thing only, and that is providing the safest and best healthcare possible to our patients, acting in partnership with other healthcare professionals, not against them.

The narrow-minded opposition of others won't put us off. What I will be telling the Minister is that we are ready, willing and available to provide additional healthcare services that the public wants and which the system needs. We have the expertise, we are accessible and we have the trust and respect of our patients. I will also be telling him that Government needs to support the contribution that pharmacy makes to patient care. They need to realise that instead of taking resources out of pharmacy, which depletes existing services, they should be investing in pharmacy, as a key component of a first-class healthcare system, especially in light of the pressures in other areas of healthcare, where A & E Departments are at breaking-point and getting an early appointment with a GP is becoming more difficult by the day.

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Through hard work and determination, we have made a lot of progress over the last couple of years. Relationships with Government, the Department of Health, the HSE PCRS and the PSI have improved and now provide a basis for constructive discussions on the issues that matter to IPU members. But there is still some way to go and we will continue to work constructively, with whatever administration is in power, with a view to building on the progress we have made to date.

By any objective measure, the IPU is today in a far more positive place than it was a short number of years ago.

Membership numbers have never been higher than they currently stand and the proportion of pharmacies that are members is also considerably higher. Engagement and communication with pharmacists has also been strengthened, all of which solidifies the IPU's position as the only credible voice for community pharmacy in Ireland.

Our lobbying campaign was successful in ensuring that all the main political parties in the recent election referenced pharmacy in their party manifestos, with all of them supporting an expanded role for pharmacists. I can assure you that when a new government is formed, we will be actively engaging with the key participants to ensure that our policies are considered in a new Programme for Government.

Our advertising campaign, based on the slogan *"Ask Your Pharmacist First"*, remains an extremely potent vehicle for getting our message across to the public, with latest market research confirming that our TV ads have doubled viewership since they first appeared in 2014.

Our PR and media coverage continues to perform well. The media is fickle and prefers a good headline to a balanced or factual news story. There are some in the media and, it has to be said, within our own profession who try to undermine us at every opportunity for their own purposes. On this issue we are clearly aware that there have been a number of articles in the press recently in relation to the price of medicines. Our approach, in response, has to be, and is, strategically thought out. It is easy to respond in a knee-jerk fashion, but experience has taught us that this is not always the right response. I can assure you though that we will continue to defend the profession in the media at every opportunity, but only under the right and proper circumstances and not simply to have a row or to prolong any one individual's time in the limelight.

IPU Academy has been providing CPD to community pharmacists for three years and has gone from strength to strength, delivering a wide variety of live learning and eLearning courses. As new CPD requirements come to the fore, IPU Academy will continue to deliver to your needs. With CPD now mandatory and all of us obliged to use the e-Portfolio, I encourage everyone to attend IPU Academy events or participate in the webinars. They're informative, useful and designed to help us all comply with our CPD requirements.

In addition to this, the IPU, through the Business Department and the Business Steering Group, continues to explore ways of improving efficiency and maintaining and generating income streams to ensure a viable pharmacy model.

Training, both professional and business, continues to make massive strides with increasing numbers participating every year.

As I mentioned earlier, we are involved with the Government's eHealth Ireland strategy and we are participating in eHealth Ireland's ePharmacy Programme, which will bring together the whole range of health, wellbeing and social care stakeholders interested in developing a joint health agenda. We are also involved in a multi-stakeholder group that will plan and ultimately implement medicines authentication in Ireland as required under the Falsified Medicines Directive.

Our health campaigns continue to gain considerable traction and our recently launched Sexual Health Campaign received a significant amount of media coverage and support from other stakeholder organisations including the Irish Family Planning Association and the HSE Sexual Health and Crisis Pregnancy Programme. We plan to launch a further campaign on Men's Health in June.

The huge success of our involvement with RTÉ's Operation Transformation demonstrates the importance of pharmacy to our communities and the key contribution we can make to the nation's health. We are now

seen as a central part of the campaign, which is a huge achievement.

hmR Ireland continues to grow and is producing extremely powerful data and information, which is becoming an invaluable source in our negotiation with Government and other agencies. Pharmacy Watch has been launched and is providing participating members with vital information allowing them to make decisions about their business from a more informed perspective. The team from hmR is here this weekend so ask them to show the system to you. If you have not already signed-up to hmR, I would encourage you to do so.

I should also mention the fantastic achievement of the IPU Product File Department, with the support of the IT Programme Manager, in successfully achieving ISO Certification for 9001 (Quality) and 27001 (Information Security). The process highlights the value of the IPU Product File, which belongs to all of us, and we should be proud that it has cemented its position as the definitive pharmacy product catalogue in Ireland.

Following suggestions from members, we have also recently hired a Membership Liaison Officer who will be out and about visiting members in their pharmacies to offer support, establish your concerns and see what the IPU can do for you.

This is only a flavour of what we have done this last year on your behalf. I assure you that we will continue to promote your agenda by engaging constructively with Government, other healthcare professionals and with the public to ensure that the potential of pharmacy is realised and to develop services to support practising pharmacists. We will seek out and seize every opportunity to secure the future of community pharmacy. This is done with the huge support of members who are actively involved in our decision making and the implementation of our policies on the ground.

The sector has gone through many changes over the last number of years. We have had to endure difficult times, deal with uncertainties and at the same time deliver the same first-class level of professional service to our patients as we always have. But we are nothing if not resilient, and we have to be. We have faced many challenges in the past, and overcome them, and we will continue to do so into the future. With the amount of change happening today, it is difficult to establish what the future holds for our profession but I can assure you that the IPU, as your representative organisation, will continue to deal with whatever comes our way. But it is not only important that we are prepared for all eventualities, it is essential that we in the IPU are ahead of the curve and that we are the ones influencing future policy, setting the agenda and shaping the future of the pharmacy sector.

It is vital that we have a united and strong IPU that will carry the community pharmacy agenda forward.

Before I conclude, I would like thank all our committee members, who have given of their time over the past number of years.

I would also like to take this opportunity to thank Vice-President Daragh Connolly, Honorary Treasurer Bernard Duggan 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.

I would like to pay particular thanks to our Secretary General, Darragh O'Loughlin, for his considerable efforts in promoting the sector and protecting the interests of our members and for his support, advice and guidance to me in my role as President.

Finally, as I prepare to hand over the chain of President to my worthy successor, I would like to thank you all for your support and kindness throughout my presidency. I am proud to be a pharmacist and proud of my profession. It has been a huge honour and a real pleasure to have been given the opportunity to serve this profession for the last two years. I have no doubt that you will extend your full support to Daragh Connolly as he takes office as President of the IPU and to our new Vice-President, Carmel Collins, and Honorary Treasurer, Stephen Nolan.

I would like to wish you all a very enjoyable evening and weekend.

2016 AGM MOTIONS AND REPORT ON ACTION TAKEN

The following motions were proposed in accordance with Article 30 of the Constitution. All motions were debated and considered by the meeting and then passed.

1. ***"That this AGM calls on the Government to recognise pharmacy as a crucial element of primary care and to allocate the necessary resources to developing pharmacy services in order to alleviate pressures caused by the persistent GP manpower crisis and ensure easy access for patients and the public to safe, convenient and cost-effective healthcare."***

   Proposed: Kathy Maher
   Seconded: Carmel Collins

   Action
   The Minister for Health expanded the pharmacy vaccination service to include pneumococcal and shingles for the 2016/17 season. We have made a proposal for further expansion of the service and for pharmacists to be permitted to vaccinate patients in nursing homes, rather than only in the pharmacy, as is currently the case.

2. ***"That this AGM calls on the Department of Health to commence negotiations with the IPU on a new Pharmacy Contract that is fit for purpose and which reflects the needs of patients and the practice of pharmacy in the 21st Century."***

   Proposed: Eoghan Hanly
   Seconded: Ray McSharry

   Action
   A delegation from the IPU met with the Minister for Health in June 2016. At this meeting, the Minister was made aware that the current Community Pharmacy Contractors' Agreement is now 20 years old and while it was modernising contract and positioned pharmacy services well for many years, it was now in urgent need of review. The Minister indicated that, in his view, contracts for health professionals, including pharmacists, needed to be reflective of the role each profession plays in the delivery of healthcare within a single coordinated approach to health, rather than silos for each profession, and acknowledged that the future role of pharmacists and any contractual arrangements would need to be addressed in that context.

   Subsequently, the Pharmacy Contractors' Committee (PCC) formed a sub-committee, the purpose of which is to prepare a new draft Community Pharmacy Contractors' Agreement for consideration by the PCC, which is fit for purpose and reflects the needs of patients and the practice of pharmacy in the 21st Century, and which will form the basis of the IPU's engagement with the Department of Health (DoH) and the Health Service Executive (HSE) on the negotiation of a new pharmacy contract. The sub-committee will also make recommendations to the PCC in relation to its strategy for negotiations with the DoH and HSE. The sub-committee expects to complete its work by August 2017.

3. ***"That this AGM calls on the Minister for Health to review the Medical Card Prescription Levy; initially by exempting all vulnerable patients – including homeless patients, palliative care patients and others who require their medication changed on a daily or weekly basis, patients in residential care settings, patients with intellectual disabilities and patients receiving treatment***

under the Methadone Treatment Scheme in respect of other medication that they may require – and ultimately by phasing it out over a three-year period."

Proposed: Ciara McCabe
Seconded: Michael Walsh

Action
In our August 2016 pre-budget submission to the Department of Finance and the Department of Public Expenditure and Reform, the IPU again called for the phasing out of the prescription levy and at the very least that it not be applied to vulnerable patients. A number of press releases were issued throughout the year repeating this message, which generated media coverage including an appearance by IPU President Daragh Connolly on RTÉ Radio One's Morning Ireland. The Government reduced the prescription levy for the over 70s and their dependants in the budget. The IPU wrote to the Minister after the announcement in the budget seeking that the Government apply the reduction to all medical card holders.

4. ***"That this AGM calls on the Minister for Health to engage promptly with the IPU on the recommendations of the Joint Committee on Health and Children on expanding the role of the pharmacist, namely:***
   - ***Establishing a New Medicines Service;***
   - ***Introduction of Medicine Use Reviews;***
   - ***Consideration of what other steps could be taken to enhance the role of the pharmacist in the provision of primary care to patients;***
   - ***Assessment of a financial incentive mechanism for pharmacists to supply biosimilars;***
   - ***A detailed analysis of the potential of community pharmacists to expand their role by delegating prescription authority to them;***
   - ***The reclassification of a wider range of medicines from prescription-only to non-prescription."***

   Proposed: John O'Connell
   Seconded: Roma O'Loughlin

Action
In January 2017, with the support of an educational grant from Pfizer, we commenced a New Medicine Service (NMS) pilot. NMS aims to provide support for people who have been newly prescribed a medicine for certain long-term conditions or therapies (asthma, COPD, Type 2 diabetes, hypertension, antiplatelet/anticoagulant therapy, statin therapy and chronic pain). It consists of a structured intervention at initiation of therapy with follow-up in the short term to improve medicines adherence and increase effective medicine taking. 96 pharmacies across 23 counties applied to participate. The pilot was registered as a clinical trial with ISCRTN and we received ethics approval from NUIG. The pilot ran for three months and we are now in the process of evaluating the results.

Following extensive engagement with all political parties in the run-up to the General Election campaign in 2016, the Department of Health Strategy 2016-2019, published in December 2016, committed to expand the role of community pharmacists in managing the health of their patients and medicine prescription.

We met with the Department of Health in March 2017 to discuss a pharmacy service whereby GMS patients can access EHC without a prescription directly from their pharmacist; legislation to facilitate this was passed by the Oireachtas in March 2017 following extensive lobbying by the IPU.

Dovonex Psoriasis was switched in May 2016 and Buscopan in April 2017. We are working with a number of other pharma companies on further switches.

In February 2017, the Minister for Health announced that he was going to publish a national policy on biosimilars in the near future.

5. ***"That this AGM calls upon the Department of Health and HSE to immediately roll out a national Pharmacy Minor Ailment Scheme following the completion of the three-month pilot scheme."***

   Proposed: Sheila O'Loughlin
   Seconded: Sarah Magner

2016 AGM MOTIONS AND REPORT ON ACTION TAKEN CONTINUED

Action
The IPU, in partnership with the HSE and the Department of Health, launched a pharmacy-based Minor Ailment Scheme (PMAS) pilot on 1 July 2016. The Pilot ran for three months in four towns across Ireland: Kells, Co. Meath; Roscommon Town; Edenderry, Co. Offaly; and Macroom, Co. Cork. The pilot allowed medical card patients to receive treatments for specific minor ailments under their GMS entitlements directly from their pharmacist without having to attend their GP surgery to obtain a prescription. The participating pharmacies were permitted to dispense specific OTC, GMS-reimbursable treatments for five conditions without prescription as per agreed protocols. Those conditions were: Dry Eye, Dry Skin, Scabies, Threadworms and Vaginal Thrush. The pilot is complete and the HSE is in the process of finalising the evaluation for publication. It is hoped that we can secure a nationwide rollout of a PMAS and that additional minor ailments will be added on in stages.

6. ***"That this AGM calls upon the HSE to roll out a pharmacy-based anticoagulation service in areas of the country where such a service is not easily accessible."***

   Proposed: Jonathon Morrissey
   Seconded: Ultan Molloy

   Action
   We proposed and discussed this with the previous Minister for Health and participated in a cross-stakeholder group of clinicians, pharmacy schools, HSE and PSI, which produced a report recommending that such a service be established.

7. ***"That this AGM calls on the Department of Health and the HSE to implement the recommendations of the Joint Committee on Health and Children on medicine shortages, namely:***

   - ***Maintain strong surveillance on the impact of national medicine price policy on the medicine supply;***
   - ***Prepare a contingency plan to consider certain export controls should medicine shortages arise;***
   - ***Examine the feasibility of introducing concessionary pricing where medicine supply is an issue;***
   - ***Commission a future-focused assessment of the challenges posed by pricing, supply and demand for pharmaceuticals in Ireland."***

   Proposed: Daragh Connolly
   Seconded: Caitriona O'Riordan

   Action
   The Department of Health (DoH) carried out a consultation on Medicine Shortages in 2012 to which the IPU made a submission. However, the Department has still not released their report on Medicines Shortages following that consultation. As the report is now 18 months old, it will need to be revisited before being published. It is up to the Medication Safety Forum, which is chaired by the DoH, to take the lead on this initiative. The IPU has raised the issue repeatedly with the relevant officials. At our meeting with the HPRA in March 2017, they confirmed that it is a priority for the HPRA to set up a stakeholder workshop to discuss and agree how best to handle medicines shortages.

8. ***"We wish to propose that the IPU engages in a process of membership consultation prior to making submissions to the PSI, Department of Health or any other relevant bodies."***

   Action
   Since the last AGM, we have made submissions to two PSI public consultations on behalf of IPU members – Draft Regulations on Videolink and PSI Customer Charter. Before we made the submissions, we put a note in the eNewsletter and/or GM asking for members' input into our submissions. No feedback was received for either submission.

OVERVIEW FROM THE SECRETARY GENERAL
Darragh O'Loughlin

1. Introduction

The Irish economy, once again, performed well in 2016, with positive economic growth and falling unemployment. Unfortunately, however, the economic improvement has not been reflected in consumer sentiment or pharmacy businesses. The continual implementation of reference pricing and the new Framework Agreement on the Supply of Medicines to the public Health Services between IPHA and the Government have exacerbated downward pressure on already weak pharmacy revenues, and Brexit-related concerns resulted in year-end consumer sentiment at a two-year low. As a result, average pharmacy operating profits fell further during the year.

The general election in 2016 saw the introduction of "new politics" and a terminally weakened Government. Following the appointment of a new Minister, and despite clear commitments from his predecessor, the Government has taken no tangible steps towards unwinding the cuts to payments to pharmacists and other professions which were implemented under the punitive Financial Emergency Measures in the Public Interest (FEMPI) Act. The IPU relentlessly continues to pursue an equitable unwinding of pharmacists' FEMPI cuts in line with any unwinding applied to other similar groups.

Close scrutiny of the HSE PCRS by the Comptroller and Auditor General has led to a tightening of audit and validation obligations for pharmacists and an increased emphasis on claims accuracy and probity. The increased administrative workload in pharmacies brings no benefit to pharmacists or their patients but is a feature of our increasingly regulated society. The IPU has sought, as far as is possible, to achieve a reasonable and proportionate approach by PCRS and to mitigate and minimise the imposition of the new requirements.

The IPU exists only to serve the interests of its members. There are comprehensive reports in this publication which illustrate the wide range of activities that the IPU engages in. The Executive Committee oversees the management of the IPU and the work of the three main IPU Committees – the Community Pharmacy Committee, Employee Pharmacists' Committee and Pharmacy Contractors' Committee – ensures the IPU's continued importance to and focus on the needs of practising pharmacists.

The members of the IPU's committees have worked hard all year to support the community pharmacy profession. The term of office of the current committees will finish at the end of this year. We are lucky to have so many hardworking and experienced committee members working on the committees on behalf of all members, at all times bringing the perspective and concerns of everyday practising pharmacists, and we hope that they will remain willing to do so into the future. The pooling of members' ideas, efforts and resources, matched with the enthusiasm of the pharmacists who give generously of their time, energy and experience, ensures that all pharmacists benefit from IPU services in their practices and their businesses and also ensures that we are here to support, advise and assist individual members whenever you need us.

2. Membership & Pharmacy Ownership (as at 16 March 2017)

a. Membership of the IPU

Community Proprietors		862		
Industry & Wholesale		5		
Community Employees		1,398*		
Hospital		0		
Army, Academic & Admin		2		
Associate Members		7	2,272	

b. Number of Community Pharmacies

Pharmacist Owned:				
Single shops	674			
Chains	745	1,419		
Non-Pharmacist Owned:				
Single shops		61		
Chains		264	325	(1,743)

c. Total Number of Chains (2 and over)

	Pharmacist	Non-Pharmacist		
Two pharmacies	114	7		242
Three	45	1		138
Four	12			48
Five	10			50
Six		5		30
Seven	4	2		42
Eight	4			32
Nine	1			9
Ten	1	10		110
Eleven	2			22
Thirteen	1			13
Sixteen	1			16
Seventeen	1			17
Twenty	1			20
Twenty-Six	1			26
Thirty	1			30
Thirty–One	1			31
Sixty		1		60
Eighty-Three		1		83
Ninety		1		90
	(745)			**(264)**

**Notes on Employee Membership*
728 are Supervising Pharmacists availing of the free membership for additional pharmacies. Three are Supervising Pharmacists in non-pharmacist owned pharmacies and are covered by the sub paid by the pharmacy. 57 are availing of the free first-year membership. 16 are joint pharmacy owners who pay a CE subscription.

3. Administration Unit

The Administration Unit has three staff members. Róisín Molloy is responsible for all aspects of membership and the management of the Secretary General's office. Patrice O'Connor looks after membership support 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 issues.

4. IPU Product File Unit

The IPU Product File is managed by Fiona Hannigan and her team: Ger Gahan, Tara Kelly, Eilish Barrett and Alan Collins. 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;
- Medicine Shortages; and
- Discontinued Lists.

IPU Product File Update

- **ISO Certification awarded to IPU Product File**
  - Stage 2 Audit, February 2016;
  - ISO Certification for 9001 (Quality) and 27001 (Information Security), February 2016; and
  - ISO Certification maintained, through quarterly audits.

- **IPU Product File Distribution**
  - Work has commenced on developing a new distribution method for the IPU Product File;
  - Vendors were consulted with and provided with a status update at quarterly meetings; and
  - Test environment for the new distribution method was made available to vendors.

- **Enhancements to the IPU Product File**
  - Route of Administration Field added in May 2016; and
  - Snomed CT Affiliate Licence for mapping to IPU Product File was granted in December 2016.

5. Contractual Issues

The Contract Unit consist of two staff members, Derek Reilly, Contract Manager and Secretary to the Pharmacy Contractors' Committee (PCC), and Aoife Garrigan, Contract Administrator.

As PCC Secretary, Derek plays a key role in developing and promoting PCC initiatives and the resolution of issues arising with the HSE, PCRS and the Department of Health. The Contract Unit spent much of the year liaising directly with the HSE PCRS in an effort to resolve the numerous contractual queries and payment issues that arose.

The PCC Secretary met with the HSE PCRS regularly throughout the year as part of a number of fora including the Joint Consultative Group, which facilitates consultation and negotiation between the HSE and the IPU; the Joint Operational Group, in which issues involving processing payment of claims and resolving queries raised by individual pharmacy contractors are dealt with; and the Pharmacy Interface Project, whereby the pharmacy interface between pharmacy contractors and the PCRS will be upgraded to the benefit of all parties.

In addition to assisting with the above, Aoife is responsible for compiling information on raids and robberies that have occurred and highlight any trends which have been identified. She is also responsible for notifying members of forged and stolen prescriptions in circulation via the IPU eNewsletter.

OVERVIEW FROM THE SECRETARY GENERAL CONTINUED

6. Communications and Public Affairs

Jim Curran, as Director of Communications & Strategy, oversees the IPU's internal and external communications and is responsible for developing the IPU's strategy. The Communications Team, which includes Aoibheann Ní Shúilleabháin and Ciara Browne, are responsible for promoting the interests of the IPU and the membership through effective communications with members, media, the public and other parties that influence the sector. Jim is responsible for overseeing business development and policy research, as well as the new strategy statement for the IPU, which will cover the period 2017-2021. Jim is also Secretary to the Executive Committee and represents the IPU on external committees.

Aoibheann coordinates the communication activities for the IPU across multiple channels. She is responsible for IPU publications, particularly the *IPU Review* and the Annual Report, as well as the annual IPU National Pharmacy Conference. She manages the IPU's website, **www.ipu.ie**, as well as coordinating advertising and marketing campaigns. Aoibheann oversees the branding of the IPU.

Ciara assists with all IPU communications and is responsible for the production of IPU News (the weekly eNewsletter) and the monthly GM. She coordinates the IPU's presence on social media channels and is an editorial associate of the *IPU Review*. She also assists with media coverage for the IPU.

Communications update since the last AGM

- **Communications with Members:** Communications with members continue to improve, with the IPU website, IPU News (the weekly eNewsletter) and the IPU's social media channels all seeing an increase in uptake from members. The monthly GM is sent to members by email and post. Regular communications are sent to keep members up-to-date with vital current information to run an efficient pharmacy.
- **Advertising Campaigns:** The IPU continues to promote the *'Ask Your Pharmacist First'* message with national radio and television ad campaigns. The 2016 advertising campaign consisted of five segments: three radio ads and two television ads. The ads were broadcast at different stages throughout the year, according to the issue being highlighted, receiving extensive national airplay, and were also well-received on social media.
- **Publications:** The *IPU Review*, IPU Yearbook & Diary and Annual Report are all produced in-house.
- **Annual Review:** The Annual Review of the Sector is part of an ongoing annual series that authoritatively tracks changes in community pharmacy. It enables us, as a representative body, to promote members' interests based on credible facts that are measured consistently over time. The 2015/6 review was carried out by Fitzgerald Power.
- **Submissions:** The IPU makes submissions on behalf of members on a range of issues. A number of these submissions are available on **www.ipu.ie**.
- **Market Research:** The IPU undertook market research amongst the general public on their pharmacy usage and attitudes towards pharmacy.

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 and provides valuable networking opportunities for pharmacists. 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 & Ball is also held over the weekend of the conference.

7. Pharmacy Services

The Director of Pharmacy Services, Pamela Logan, coordinates 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 Professional Development and Learning Manager and has been instrumental in the setting up of IPU Academy. IPU Academy has gone from strength to strength in 2016, providing members with access to high-quality learning opportunities and offering them support and assistance in complying with obligations under the regime of mandatory continuing professional development. Liz also oversees IPU NET, our online web-based platform designed to support members in the delivery of new pharmacy services. Alma Barr, Education and Event Coordinator, assists Liz with IPU Academy and also organises the IPU National Pharmacy Conference.

Alan Reilly is our ICT Programme Manager, responsible for developing the IPU's IT strategy.

8. Training & HR Department

Susan McManus, Training & HR Manager, organises and coordinates a selection of training courses for pharmacy staff. Janice Burke assists Susan in this department. 130 Pharmacy Technicians graduated in March 2017. There are 207 students at present partaking in Year 1 and 196 students in Year 2 of the course. In addition, 417 attended continuing professional development (CPD) for qualified pharmacy technicians in 2016. 134 students completed the Medicines Counter Assistant (MCA) Course in 2016 in seven venues around the country and 11 students completed the Medicines Counter Assistant (MCA) Refresher Course. 103 students completed the Interact course and 24 completed the Interact Plus course. The fifth cohort in the Diploma in Leadership and Management commenced in September 2016 with 12 enrolments, while 25 students completed the Supervisory Development Course in 2016. Six students completed the Award in Leadership and Management in 2016. Eight people enrolled onto the Pharmacy Retail Sales course in October 2016 and 31 purchased the 'Medicines in Care Homes' training package in 2016. The Dublin and Dun Laoghaire Education and Training Board (DDLETB) Pharmacy Sales Traineeship course was administered in a number of educational institutes and senior colleges around the country.

Another addition to the Training Department's portfolio is the Return to Community Pharmacy Practice course, launched in January 2017, with seven candidates attending. The material has been developed for pharmacists returning from a career break, e.g. maternity leave or a sabbatical or for newly registered pharmacists from another jurisdiction.

Susan also acts as Secretary to the Employee Pharmacists' Committee (EPC), co-produces the IPU Yearbook and Diary and Wall-Planner, and advises members on human resource issues.

9. Business Services

The Business Development Manager, Darren Kelly, is responsible for business services and advice to members, along with Jim Curran. Darren and Jim represent IPU members on a number of strategic retail forums that have enabled us to provide a platform for a structured engagement between the retail sector and relevant Government departments and agencies on areas such as crime prevention, upward-only rent issues and town centre issues. As part of the IPU Business Strategy to assist members in engaging with digital marketing and social media to enhance their business offering, we ran a number of training programmes for pharmacies in 2016. The workshops were fully attended and feedback was extremely positive. We also ran a number of Essential Pharmacy Store Management training programmes around the country in September and October 2016. All sessions were full and feedback from attendees was very positive.

OVERVIEW FROM THE SECRETARY GENERAL CONTINUED

The IPU Business Department held its annual Business Briefings, entitled "Increase your Pharmacy's Efficiency", around the country in June 2016. Four expert speakers covered a range of topics: Customer Perceptions of Pharmacy; Maximising Retail Potential in your Pharmacy; Why you have Financial Planning and Employment Law – How to ensure compliance. Seven sessions were held and over 100 members attended.

Members are kept up-to-date with current legislation through notices in IPU communications. The business *Tip of the Week* was introduced to the eNewsletter this year and has proven to be very popular with members. 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**.

Darren operates the IPU Retail Review Consultancy Service, which is available to members at a discounted rate. Over 100 pharmacies have availed of this service to date. Darren visits pharmacies for a full-day retail review, develops a retail plan and implements 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**. Members can contact the Business Department for advice and information on the Business Helpline 01 406 1558.

Joyce Mulpeter joined the IPU in February 2017 as the Member Relationship Manager. Joyce has over 25 years' experience in business and will be calling to pharmacies throughout the year, ensuring they are up-to-date on ongoing issues and are aware of additional services that we are providing.

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

10. External Consultants

MKC Communications (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. Legal advice is provided by DAC Beachcroft on an ongoing basis and by Beauchamps solicitors in relation to specific matters.

11. Main Committee Meetings

The number of committee meetings was:

	'16	'15	'14	'13	'12
Executive Committee	5	7	7	5	7
Community Pharmacy Committee	4	5	4	4	4
Pharmacy Contractors' Committee	4	6	2	3	6
Employee Pharmacists' Committee	3	3	5	4	4
Finance Sub Committee	6	5	6	5	6
All Committee Meetings	0	0	0	0	1

12. Conclusion

The business environment for pharmacy is constantly changing and getting increasingly difficult. Pharmacies need better and faster information to run their businesses effectively and profitably. In order to ensure that our members have access to the best business intelligence available, the IPU launched Health Market Research (hmR) in 2014 in partnership with ANF, based in Portugal, to collate anonymised data from pharmacists' systems, aggregate the information and deliver best-in-class benchmarking and trend reports to participating members. The Pharmacy Watch service has been adopted by more than 1,100 pharmacies and is delivering accurate and up-to-date information to participating pharmacies. It also provides the IPU with essential information and analysis on the evolving state of the overall pharmaceutical market and the impact of ongoing reimbursement changes, which allows for more effective engagement with Government, the HSE and the media. I would encourage all of you to participate, as the benefits to all of us increase with the number of participants and the purpose of the project is solely to benefit IPU members.

I am lucky to work with a great team in Butterfield House, who are fully united in their determination to represent and serve the community pharmacy profession to the best of their ability. We will continue to innovate in order to effectively assist our members in ever-changing circumstances, while working ceaselessly to represent, advocate for and defend the community pharmacy sector, and promote the valuable work that pharmacists do every day in every town, village and community in the country. We are grateful for the incredible support we get from our members, without which we could not function, and we are always keen to receive your feedback, either directly or via your committee members.

Darragh J O'Loughlin
Secretary General

PHARMACY CONTRACTORS' COMMITTEE (PCC) REPORT 2016-2017

The Pharmacy Contractors' Committee (PCC) is chaired by Eoghan Hanly, with Grainne O' Leary as Vice-Chairperson. The committee held four meetings in 2016 and two meetings so far in 2017. Three further meetings are scheduled for this year. The PCC's mission statement is:

> ***Advocating and negotiating on behalf of community pharmacy contractors with government and its agencies to secure fair remuneration and equitable contractual terms for the delivery of services to patients.***

Over the past 12 months, the PCC has dealt with a variety of issues and has progressed a number of different items on behalf of the contractor members of the IPU. The following is a summary of the key issues dealt with since the last AGM.

HSE Contract Matters

- Participating in regular meetings as part of the Joint Consultative Group to resolve issues and minimise the impact on members;
- Working with the HSE PCRS at the Joint Operational Group to resolve individual member issues;
- Advocating for the streamlining of the Long Term Illness Scheme;
- Agreeing a flyer with the HSE PCRS to inform patients of the need for NOAC/ Fampyra approval, thereby supporting them to receive reimbursement;
- Requested HSE PCRS to issue an updated list of Exempt (unlicensed) Medicinal Products from 2010 to ensure clarity and correct reimbursement;
- Issued a poster advising patients who are aged 70 and over to make themselves known, thereby supporting members in securing the correct payment of the prescription levy from patients; and
- Worked with the HSE PCRS to provide a Hardship FAQs to provide clarity for members.

Joint Consultative Group

The purpose of the Joint Consultative Group (JCG) is to allow direct liaison, discussions, consultation and negotiations between senior representatives of the IPU and PCRS, with the objective of seeking agreement on matters pertaining to the administration of the Community Drug Schemes and associated remuneration and reimbursement of pharmacists. The JCG has met on six occasions in the past 12 months. The PCC, in what was a difficult year, with increased audit and probity from the HSE PCRS, continues to advocate strongly through the auspices of the JCG on behalf of members. The following are just some of the main issues tackled during the past year.

- Phased dispensing was on the agenda for much of the year, given that this element of pharmacy fees now accounts for almost €100m per year, it was under very close scrutiny by the Comptroller and Auditor General and the HSE. The IPU sought to mitigate and advocate on behalf of all members and there was regular correspondence between IPU and the HSE on this matter. Since May of last year, the phased dispensing fee rules are that there is a requirement for

multiple supply occasions. The IPU has consistently argued that this rule should not be applied retrospectively. We have supported members with individual advice, as well as through the weekly eNewsletter and FAQs.

- In May of last year, the HSE issued a circular advising pharmacists that they could make a disclosure in cases where owings claims were made without a 'genuine expectation' that the patient would return and that no legal or disciplinary process would be invoked if such disclosures were made. The PCC has kept this process under constant review and has raised concerns on behalf of members on both a collective and individual basis. Attempts by the HSE and Department of Health (DoH) to introduce a reduced fee for owings where no ingredient is dispensed were successfully resisted by the PCC.
- The introduction of third party verification for GMS prescriptions was intended to commence not long after the 1996 contract but was never implemented until this year. The PCC raised a number of concerns on behalf of members, resulting in some common sense measures being applied whereby once a pharmacy makes 'reasonable efforts' to obtain signatures they will be reimbursed, and in nursing home settings, that the signature of the person in charge signing for all medicines received is acceptable for probity purposes, rather than requiring that every prescription be signed.

Joint Operational Group

The work of the Joint Operational Group (JOG) involves arrangements for processing payment of claims and resolving claim-related queries/issues raised by individual community pharmacy contractors and other operational / administrative arrangements. The JOG met six times in the past year. This forum has proved beneficial in resolving the majority of issues raised on behalf of members.

PCRS Pharmacy Interface Project

The purpose of this project is to enhance the electronic interface between pharmacy contractors and the PCRS. This project was delayed for a period of time while the HSE sought to introduce a reduced fee for owings. The issue was resolved with the owings fee remaining as is. The first deliverables of this project – electronic submission of Dental, EU claims, managing owings and enhanced XML listing – are due to be rolled out later this year.

Pharmacy Contract Sub Committee

The PCC formed a sub-committee, the purpose of which is to prepare a new draft Community Pharmacy Contractor's Agreement for consideration by the PCC, which is fit for purpose and reflects the needs of patients and the practice of pharmacy in the 21st Century and which will form the basis of the IPU's engagement with the DoH and the HSE on the negotiation of a new pharmacy contract. The sub-committee may also make recommendations to the PCC in relation to its strategy for negotiations with the DoH and HSE. The committee has met twice this year and expects to complete its work by August 2017.

Policy Matters

IPHA Agreement

The agreement between the State (DoH and HSE) and the pharmaceutical industry (IPHA) was announced on 20 July 2016. The announcement at the time gave pharmacists just over one week's notice to prepare for price reductions. The IPU made multiple representations to the PCRS, HSE, DoH and Minister for Health, insisting that we must, at a minimum, receive four weeks' notice of any price changes.

While the agreement states that it does not fetter or limit the exercise of the HSE's powers under the Health (Pricing and Supply of Medical Goods) Act 2013, the legislation which gives them power to set reimbursement prices unilaterally and which does not oblige them to give notice to pharmacists (except for reference prices) does not prevent the HSE from giving reasonable notice, nor does it prevent them from applying price reductions to reimbursement prices one month after they apply to ex-factory or wholesale prices. Of note in correspondence received from the DoH in July 2016 was that '*...with regard to the implementation of the price reductions, this*

PHARMACY CONTRACTORS' COMMITTEE (PCC) REPORT 2016-2017 CONTINUED

is an operational matter for the HSE.' The IPU continues to make representations on behalf of our members for minimum notice periods of all price changes from the DoH and HSE.

Financial Emergency Measures in the Public Interest (FEMPI) Act

The IPU met with the Minister for Health, Simon Harris, in June 2016, seeking that the DoH begin the long-overdue and previously committed unwinding of the reductions in payments to community pharmacy contractors under the FEMPI Act. The Minister undertook to re-examine the issue and then revert. However, despite repeated correspondence, the Minister has failed to follow up. The PCC regards this as unacceptable in circumstances where the previous Minister, Leo Varadkar, had committed to commencing the unwinding of the reductions in payments which were introduced under the Act and where the IPU participated fully and constructively in the statutory consultation process including making a detailed submission of how the FEMPI cuts for community pharmacy contractors should be reversed. The PCC continues to press, at every opportunity, the DoH and elected representatives to begin the process of unwinding FEMPI.

Government Policy

A submission was made to the Oireachtas Committee on the Future of Healthcare. The IPU submitted that the policy options available to the Government include expanding the role of the community pharmacist and introducing properly resourced pharmacy-based services, which have been shown to operate very effectively in other countries. The submission set out a menu of additional services that can be provided by pharmacists to the public to support and assist in the provision of universal healthcare for all of the population.

A further submission was made to the DoH as part of their public consultation process prior to developing their strategy for the period 2016-2019. The submission outlined how the development of pharmacy services is essential for the optimisation of healthcare in Ireland. This submission also set out priorities the DoH must adopt in planning their strategy with regards to community pharmacists.

COMMUNITY PHARMACY COMMITTEE (PCC) REPORT 2016-2017

The Community Pharmacy Committee (CPC) is chaired by John O'Connell, with Mark Sajda as Vice-Chair. 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.***

CPC is split into three sub-groups:

- **Professional Steering Group:** Louise Begley, Anna Kelly, Elizabeth Lang, Jonathon Morrissey, Sheila O'Loughlin and Mark Sajda.
- **Business Steering Group:** Mary Barry, Roy Hogan, David Gormley and Aidan Walsh.
- **IT Steering Group:** Jack Shanahan, Noel Stenson. Ann Marie Horan (Exec) and Michael Walsh (PCC) have been co-opted onto ITSG, along with David Reen, Joseph Haire and Ciaran Mulligan.

CPC has met three times since the April 2016 AGM (July and October 2016 and February 2017), dealing with a wide variety of issues. The following is a summary of the key issues dealt with over the last 12 months under the headings outlined in the CPC Strategy 2016-18, which was developed by CPC in April 2016.

Professional Issues

Promote the role of the pharmacist in Government and HSE Strategy

We met with the European Commission Representation in Ireland in April 2016 to discuss a range of issues in relation to Ireland's health policy. We met with the Department of Health's Director of Patient Safety & Clinical Effectiveness in May 2016 to discuss a Patient Safety Initiative proposal. We met with the Minister for Health in June 2016 to discuss a range of issues including Government healthcare strategy and health service reform. The Department of Health Strategy 2016-2019 has committed to expanding the role of community pharmacists in managing the health of their patients and medicine prescription. We met with the Department of Health in March 2017 to discuss a pharmacy service allowing GMS patients to access emergency hormonal contraception without a prescription directly from their pharmacist; legislation to facilitate this was passed by the Oireachtas in March 2017. We made a submission to the National Drug Strategy in October 2016 and met with the Minister of State for the National Drug Strategy in March 2017 to discuss our submission.

Work with relevant stakeholders to further improve accessibility of medicines through switches from POM to Pharmacist/ Pharmacy Only

We worked with Leo on a POM to P switch for Dovonex Psoriasis. For its launch in May 2016, we provided members with a template sales protocol. We made a presentation to IPHA Consumer Division on switching in March 2016. In April 2017, Sanofi switched Buscopan and we developed a sales protocol

COMMUNITY PHARMACY COMMITTEE (PCC) REPORT 2016-2017 CONTINUED

for members. We have been liaising with other pharma companies in recent months on proposed switches.

Pursue defined strategies to improve patient adherence and optimise medicines use
In Q3 2016, Pfizer gave us a grant to develop a pilot New Medicines Service. The pilot was scoped out in Q4 2016 and launched in Q1 2017; 96 pharmacies across 23 counties applied to participate. The pilot was registered as a clinical trial with ISCRTN in November 2016 and we received ethics approval from NUIG in January 2017. We engaged with Pharmapod to develop a platform for data collection. We are now in the process of evaluating the pilot.

Continue to extend the pharmacy vaccination service to include other vaccines, other injectables and other patient cohorts
We produced an FAQ on emergency medicines and extended vaccinations in June 2016. We wrote to the Minister for Health in July 2016, asking that pharmacy reimbursement for pneumococcal vaccination be included in the estimates for 2017. We produced SOPs, protocols and promotional materials for flu, pneumococcal and shingles vaccinations in August 2016. We made a proposal to the Minister for Health on expanding the pharmacy vaccination service in December 2016. We wrote to the Minister for Health in January 2017, advocating that pharmacists be allowed to vaccinate patients in residential care facilities.

Develop an anticoagulation service through community pharmacy
We proposed and discussed this service with the previous Minister for Health and participated in a cross-stakeholder group of clinicians, pharmacy schools, IIOP, HSE and PSI, which produced a report recommending that such a service be established.

Assist members in dealing with PSI/HSE/HPRA/DAFM inspections and Fitness to Practise issues
We assisted a number of members on FTP and other PSI issues. We made a submission to the PSI in March 2016 on the Pharmacy Assessment System. We developed a Pharmacy Assessment System Support Tool in November 2016.

Lobby for amendments to the Pharmacy Act 2007
We met with the Minister for Health in June 2016 and raised the issue of bankruptcy and PSI fees. We wrote to the PSI in June 2016 asking for clarification on the status of Irish students studying pharmacy in the UK following the Brexit vote and wrote to the Department of Health regarding Brexit in December 2016. We met with the PSI in October 2016. We wrote to the Minister for Jobs, Enterprise and Innovation in December 2016 in relation to PSI fees.

Maintain and strengthen relationships with Pharma, Schools of Pharmacy, IIOP and patient groups to assist in the provision of CPD and other relevant learning
IPU Academy was awarded an educational grant by GSK to support the development and delivery of the *Update on the Management of Allergies* module for the IPU Academy Autumn Programme 2016. The development and delivery of the *Infant Nutrition* module for the IPU Academy Autumn Programme 2016 was supported by an educational grant from Nestle. A number of meetings were held with pharma companies (Pfizer, Kabi Fresenius, AbbVie, Novartis and Boehringer Ingelheim) to explore potential opportunities to partner together in developing educational initiatives for the Autumn Programme 2016 and Spring Programme 2017. The IPU *Adrenaline Administration Training Pack* was supported by Lincoln Medical, Bausch & Lomb, Mead and Alk-Abelló, and distributed to pharmacies in Q2 2016.

In August 2016, IPU Academy and the School of Pharmacy & Pharmaceutical Sciences, Trinity College Dublin, signed an agreement to review and accredit IPU Academy Programmes. IPU Academy broadcast the following live national webinars: in association with Fresenius Kabi on the topic of *Malnutrition – A Patient Focus* in November 2016; in association with Pfizer on the topic of *Epilepsy – The Clinicians Perspective* in November 2016; in association with Pfizer on the topic of *Health Living/Ageing* in January 2017; and in association with Novartis on the topic of *Heart Failure Management* in February 2017. IPU Academy has partnered with Abbvie to host five eLearning symposia on *Biologic and Biosimilar Medicines* on the IPU Academy Learning Management System.

Continue to develop IPU Academy to support members' engagement with CPD
A Coaching and Training course (QQI level 6 awarded by the Institute of Leadership & Management) was delivered to IPU Academy tutors in 2016. In order to support recording CPD activity in the ePortfolio, we created short eLearning presentations (five minutes' duration) for each topic in the IPU Academy Programmes, describing "*Integrating your attendance at an IPU Academy course into your ePortfolio*". CPD articles were commissioned and published in the *IPU Review* each month.

Develop Services Frameworks for innovative pharmacy services
In conjunction with the HSE, we launched a Minor Ailment Scheme pilot in July 2016 in 19 pharmacies in four towns. We provided participating pharmacies with protocols, surveys and promotional materials. We worked with Hibernian Healthcare to develop Pharmacycare, a platform for paid services in community pharmacy. Members are encouraged to sign up to Pharmacycare as the more pharmacies are signed up, the more services we can attract.

IT

Maintain the IPU Product File as the definitive file on the Irish market for medicines and medical devices
VMP Classification is now complete and is available via Web Service Distribution. The IPU Product File continues to adhere to ISO standards and requirements, with ongoing internal and external audits. We successfully secured an Affiliate Licence for Snomed CT in Q4 2016 to enhance clinical coding and interoperability of the IPU Product File and work has commenced on mapping Snomed CT to the IPU Product File.

Promote the adoption of the IPU Product File as the HSE/eHealth Ireland National Medicinal Product Catalogue
We submitted a proposal to eHealth Ireland in Q2 2016, offering the IPU Product File as the main source for the National Medicinal Product Catalogue (NMPC). We met with the HSE Project Manager for ePharmacy and the HSE Project Manager for Primary Care in Q2 2016 to discuss the proposal. In Q1 2017, we met with the HSE Project Manager for ePrescribing to discuss the usefulness of the IPU Product File as the main data source for the NMPC.

Continue to work with HIQA's eHealth Standards Advisory Group (eSAG) on the development of pharmacy-related standards
We participate in HIQA's eHealth Standards Advisory Group. We participated in other HIQA working groups to develop the Draft eDispensing Dataset and Clinical Data Architecture (CDA); the National Standard for a Dispensing Note and CDA was published in January 2017. In Q3 2016, we consulted on the Draft National Standard for a Procedure Dataset and Clinical Document Architecture Template.

Continue to work with the HSE and eHealth Ireland on the implementation of the eHealth Strategy for Ireland
We met with the Department of Health's Assistant Secretary R&D and Health Analytics and the Head of ICT in Q2 2016 to discuss our IT agenda and our work with eHealth Ireland. We frequently meet with project managers from eHealth Ireland to assist with progressing their ePharmacy Programme. The IPU is represented on the National ePrescribing Steering Group. In Q1 2017, we provided eHealth Ireland with three personas as part of their Electronic Health Record (EHR) project. In January 2017, the IPU hosted a meeting with Julie James, a Specialist Informatics Consultant with a long-standing relationship with the IPU, on the concept of a Medication Profile within a Summary Care Record. Representatives from HIQA, ICGP, the HSE and eHealth Ireland attended. In March 2017, the IPU joined the eHealth Ireland Access to Information Steering Committee; this committee will have direct input into enabling digital solutions to be made available effectively in the healthcare environment in Ireland, e.g. the National EHR and Summary Care Record.

Work with the PSI and pharmacy system vendors on the standardisation of dispensary systems with the aim of getting certification to comply with pharmacy regulations
In March 2017, we wrote to the DoH regarding their intention to engage with a number of stakeholders about pharmacy computer software being independently validated and certified. We made them aware that the IPU IT Steering Group had done a significant amount of work, in association with the three system vendors, to produce a dispensary system specification that accurately reflects the current dispensary

COMMUNITY PHARMACY COMMITTEE (PCC) REPORT 2016-2017 CONTINUED

systems and how they comply with all medicines and pharmacy legislation.

Continue to foster good relationships with vendors with a view to developing a roadmap for dispensary system developments
In 2016, the IPU facilitated meetings with the vendors and the PCRS to help resolve various reimbursement system issues. In Q1 2017, the IPU met with vendors to discuss ICT developments for pharmacy.

Continue to work with the HSE PCRS on the implementation of the Pharmacy Interface Project, ensuring that the elements of benefit to pharmacy are delivered
The HSE PCRS Pharmacy Interface Project Group now includes the pharmacy system vendors (Clanwilliam, McLernons and Touchstore). The group meets on a monthly basis as part of the implementation phase of the project. The first phase deliverable has been agreed (Dental Claims, EU Claims, Owings and Enhanced XML Listings), with timelines to be finalised.

Participate in the Irish Medicines Verification Organisation (IMVO) to plan and ultimately implement medicines authentication in Ireland
We are actively participating in the IMVO to prepare pharmacies for medicines authentication in 2019.

Secure access to Healthmail and its connected agencies
Following an evaluation in Q4 2016, the IPU worked with Healthlink on a project to roll out Healthmail to community pharmacy. In April 2017, the IPU and eHealth Ireland launched Healthmail, agreeing design of the service and providing registration assistance, supporting material on the IPU website and an article in the IPU Review.

Develop a social network to connect members to professional learning materials through communication, trending activities, sharing of ideas and existing online resources
We met with Synergy (the company that provides the IPU Academy Learning Management System) to learn more about their product offerings with regards developing a social network and online space for IPU members to connect and share learning materials through communication, trending activities etc. We have asked Synergy to deliver a social network module as part of the upgrade to the IPU Academy LMS.

Develop strategies, policies and guidance to ensure members' compliance with all data protection legislation
In 2016, we reviewed the data protection arrangements of pharmacies in the context of data harvesting and data extraction, i.e. companies that extract and/or process pharmacy data. This is a project we worked on collaboratively with all the system vendors and other companies with access to, and extracting information from, pharmacies, to ensure that everyone is protected and meeting data protection requirements. A letter was issued in September 2016 with advice for members.

Business

***Business Policy* – Continue to provide input into national policies affecting small businesses through the Retail Consultation Forum, Consumer & Competition Commission, National Retail Security Forum, Government Departments and other relevant organisations on areas such as rates, rent reviews, retail planning, budgets and to identify business trends and introduce policies accordingly**
As part of our involvement in the Retail Consultation Forum, we are part of the Retail and Digital Economy Group, which is looking at how to create a self-help guide for business owners, identifying the key steps that need to be considered with regard to using digital and social media in the sector. We attended a meeting of the Retail Digital Economy Working Group in September 2016 to discuss the specific sectoral issues of concern around digital skills in the retail sector. This Group has now been renamed the Retail and Digital Skills Forum. The aim of the group is to provide retailers with the best-in-class retail and digital training for their employees. Our review of recent planning experience of retail pharmacy businesses in Ireland, prepared by our planning consultants BMA Planning, was completed and forwarded to the Minister for Housing, Planning, Community and Local Government.

***Business Support* – Build on relationships with independent pharmacies, symbol groups and chains to identify opportunities to support members through Retail Reviews, Membership Liaison, HR, Business Audit Tool, Business Advice, Business Mentoring Service and Affinity Schemes**

In May 2016, we took a stand at the UD Pharmacy Show. Members of the IPU team were available to over 500 members who attended the three-day event. 14 Retail Reviews were carried out in Q3 & Q4 2016. 2017 has started positively with four Retail Reviews carried out in Q1. The results have been very positive to date.

Business Training – Continue with the delivery of the Diploma in Leadership & Management and develop new business training programmes

We developed a beginner's programme in Digital Marketing & Social Media for members with no experience of using digital marketing or social media and a more advanced programme for members whose pharmacies would have some knowledge of using social media. Workshops were organised in May and September 2016 in four locations. All the workshops were fully attended and feedback was extremely positive. We also ran a number of Essential Pharmacy Store Management training programmes around the country in September and October 2016. All sessions were full and feedback from attendees was very positive. In September 2016, the fifth cohort of students began the Diploma in Leadership & Management. The IPU Online Retail Selling Skills Training course was held in October 2016. The Spring Business Programme began in February 2017 with a range of courses: Customer Service, Retail Merchandising, Pharmacy Store Management and Digital Marketing.

***Business Briefings* – Identify and deliver relevant business topics for half-day briefing sessions**

The IPU Business Department held its annual Business Briefings, entitled "Increase your Pharmacy's Efficiency", around the country in June 2016. We had four expert speakers covering: Customer Perceptions of Pharmacy; Maximising Retail Potential in your Pharmacy; and Why you have Financial Planning and Employment Law – How to ensure compliance. Seven Briefings were held and over 100 members attended.

***Business Intelligence* – Assist members in utilising hmR reports, report to members on global business trends, and continue to produce an Annual Review of the Sector, B&A survey and business trends surveys**

Behaviour & Attitudes public opinion survey results were sent to all members in May 2016. The results of the survey were one of the topics covered at the Business Briefings. The Annual Review of the Sector was published in July 2016. Business Trends Surveys were sent to members in July and October 2016, with articles on the results published in the *IPU Review*.

EMPLOYEE PHARMACISTS' COMMITTEE (EPC) REPORT 2016-2017

The Employee Pharmacists' Committee (EPC) represents the interests of community pharmacy employee members of the IPU. The EPC is chaired by Sheila O'Loughlin, who took over from Elizabeth Lang in February 2016, with Gillian McGrath as Vice-Chair, succeeding Sheila O'Loughlin. Currently there are 1,411 community employee members of the IPU, which comprises 62% of the full membership. 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 IPU and other stakeholders through the Employee Pharmacists' Committee.***

The EPC met three times since the 2016 AGM (June 2016, November 2016 and March 2017). 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 redesign of the IPU website in 2015 has facilitated the development of the Employee Pharmacists section of the site, providing easier access to the information required by employee pharmacists.

The EPC's article published in this year's March issue of the *IPU Review* provided a guide for employee pharmacists on pensions, outlining the employer obligations and staff options.

Events

In 2016, Sinead Ryan, on behalf of EPC, made a presentation at the *Pharmaconex – Pharmacist and New Graduate Seminar* on 16 November; 23 attendees signed-up to IPU membership.

Increase and retain IPU Membership

Throughout the year, the EPC endeavoured to encourage non-members to sign up to IPU membership. In order to assist in retaining current members, the EPC will be available at this year's IPU National Pharmacy Conference in Croke Park, Dublin, to meet and talk with employee members face-to-face.

Representation and 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 support to employee members within the community pharmacy sector.

Conclusion

The EPC urges employee members to use their membership to the full and keep themselves well-versed by reading the IPU weekly eNewsletter, General Memoranda, *IPU Review*, IPU Yearbook and Diary and other information provided by the IPU. In June 2010, all IPU members were assigned an @ipumail.ie email account and the EPC continually reminds 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.

COMMUNICATIONS REPORT 2016-2017

The Communications Team includes Jim Curran, Aoibheann Ní Shúilleabháin and Ciara Browne and external advisors, and has an important role in communicating key messages to the media, the public, stakeholders and members. A wide range of communication tools, including newsletters, emails, text alerts, social media, the *IPU Review* and the IPU website, 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 pharmacists' concerns to the media. The Communications Team invest a great deal of time, effort and resources in working with the media to brief journalists on issues affecting community pharmacy. Communications with the public is strengthened with advertising campaigns throughout the year.

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, raising concerns affecting community pharmacists and advocating on behalf of patients. We receive regular coverage in the national media, including on RTÉ, TV3, Today FM and Newstalk. The national newspapers, including *The Irish Times*, *Irish Independent*, *Irish Examiner* and *Herald*, also carry regular articles and interviews with IPU representatives. We also receive significant coverage in online media, medical journals and provincial media, with IPU spokespersons appearing frequently on local radio and quoted in local media.

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 on head lice, children's minor ailments, driving while taking prescription medicines, advice on colds and flu, the dangers of mixing alcohol and medicines, and much more. Some of the key issues that arose during the last year were:

- Call for tougher crime sentences;
- The price of medicines;
- Antibiotic awareness; and
- Warning on counterfeit medicines.

We thank IPU spokespersons, who do great work throughout the year, for taking time out from their pharmacies to be interviewed and brief journalists.

A list of all the press releases issued since the last AGM is in Appendix III.

Advertising Campaign – *'Ask Your Pharmacist First'*

The IPU continues to promote the *'Ask Your Pharmacist First'* message with national advertising campaigns on television and radio.

The 2016 advertising campaign consisted of five segments: three radio ads and two television ads. The ads were broadcast at different stages throughout the year, according to the issue being highlighted, and received extensive national airplay. The first ad campaign of the year was the Hay Fever radio ad which ran in the second week of May and encouraged people to 'Ask Your Pharmacist First' about their hay fever symptoms and the best treatment options available. Posters were sent to pharmacies to support the message.

The next segment of the campaign was the 'Toe to Go' TV ad, which ran for three weeks in June. The ad highlights the importance of seeking healthcare advice from a trusted healthcare professional. The ad was shown on RTÉ, TV3, UTV and on various channels in the Sky Media package, as well as on YouTube. The ad also ran on Farm TV in 21 livestock marts around the country. The ad would have been seen by two million adults and they would have had the opportunity to see it 3.4 times.

The next burst of radio ads ran in September to coincide with the flu season. The ad performed exceptionally well, airing on Today FM, 2FM, UTV and regional radio. 75% of adults 55+ would have heard the ad at least once and had the opportunity to hear it four times.

COMMUNICATIONS REPORT CONTINUED

The second of our TV ads returned to the screens at the beginning of October and ran for three weeks. The ad focuses on getting the wrong information by turning to the internet for advice. The ad appeared during programmes such as RTÉ One's *Six-One News*, *Coronation Street*, *Emmerdale*, *Eastenders*, *TV News at* 5.30 and an Irish soccer World Cup Qualifier. 65% of all adults would have seen the TV ad at least once. In addition to the television packages used for the previous TV ad, the ad appeared on video on demand. The ad would have been seen by 408,000 people through this medium.

The final radio ad of 2016 ran from 5 December for one week. The ad aired on national and regional radio stations and focused on the retail aspect of pharmacies.

Operation Transformation

The IPU supported Operation Transformation's Live Longer, Live Better campaign for 2017. This is the third year that pharmacies have partnered with Operation Transformation to offer the public support in achieving a healthy lifestyle and weight.

This year, we were involved in the Stroke and Heart Attack aspect of the campaign, which involved pharmacies carrying out free blood pressure measurements for one week from 26 January to 2 February. There was a huge response from pharmacies that wanted to take part in the campaign with almost 750 pharmacies signed-up to participate. Posters and patient record cards were also sent to participating pharmacies.

Community pharmacies' involvement in the campaign was highlighted on the television programme, as well as in regional media around the country.

Communications to Members

Communications to members continue to develop and uptake continues to increase. The *IPU Review* and monthly General Memorandum are vital resources of information for members. The open rate of *IPU News*, the weekly eNewsletter, is increasing with more members accessing their IPUMail regularly. Social media is another tool for communicating with both members and the public, and the number of followers on our Facebook, Twitter and LinkedIn accounts are growing each week. We also use SMS to get information to members quickly on important updates and deadlines.

Political Engagement

A delegation met with the Minister for Health in June 2016 to discuss Government healthcare strategy, medicine prices, unwinding of FEMPI, legislation and regulatory issues, and health service reform.

A meeting was held in March 2017 with the Minister for State for Communities and the National Drug Strategy to discuss the contribution that community pharmacists can make to the Strategy.

A number of meetings were held throughout the year with TDs to discuss issues of interest to the membership.

INTERNATIONAL PHARMACY MATTERS

IPU Annual Report on PGEU 2016/17

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, Kathy Maher and Pamela Logan. We have 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.

Over the past year, PGEU has been involved in a large number of directives and regulations and the following is a short summary of the main dossiers.

Medicines Authentication
All Member States must implement medicines authentication by 9 February 2019. The European Medicines Verification Organisation (EMVO) has produced tools to assist National Medicines Verification Organisations (NMVOs) in setting up a National Medicines Verification System (NMVS). Agreement has been reached by all EMVO stakeholders on the issue of data ownership. Data contained within the end user system will belong to the end user and EMVS/NMVS data and its further use must be agreed by all data owners. EMVO has developed an NMVO end user template contract which covers the obligations, rights and liabilities of pharmacies, wholesalers and NMVOs. End users, e.g. pharmacies, can 'sign' the final contract by ticking a box and agreeing to the T&Cs. Any future changes will be subject to prior consent.

Medical Devices Regulation
The Medical Devices Regulation was adopted by the European Council in March 2017. The regulation has a direct impact for pharmacies in both medical devices and in-vitro Medical Devices Regulations. The regulation establishes that pharmacists should record the medical devices they have been supplied with. In the case of implantable devices (class III) and a group of devices to be decided by implementing acts, pharmacists shall store and keep, preferably by electronic means, information about the devices which they have supplied or they have been supplied with. Instructions for use of self-testing devices must contain a statement directing the user to consult the appropriate healthcare professional before taking any decision of medical relevance.

Pharmacists must:

- Check that the manufacturer has assigned the Unique Device Identification (UDI) to the medical device;
- Check that the information supplied by manufacturer complies with labelling requirements;
- Keep a register of complaints about suspected incidents, non-conforming products and products recalls and reporting manufacturers and importers;
- Cooperate with other operators and competent authorities to eliminate risks of potential non-conforming devices (corrective action); and
- Comply with such obligations within the scope of their role and responsibilities.

PGEU GPUE

INTERNATIONAL PHARMACY MATTERS CONTINUED

The regulation ensures the compatibility of the new traceability system with the requirements set by the Falsified Medicines Directive; therefore, pharmacies will not need to invest in new technology to comply with two legal frameworks. The new regulation on medical devices was adopted on 7 March 2017 and will start applying three years after publication in the Official Journal, expected to be April 2017.

Veterinary Medicines Regulation
The main areas of concern in this regulation relate to internet supply; special licence to supply; recognition of cross-border prescriptions; and pharmacy records. The European Parliament (EP) adopted most of PGEU proposals initially; however, in February 2016, the EP published compromise proposals, which overturned some of PGEU's original proposals:

- In relation to the internet, the prohibition on supply of prescription-only veterinary medicinal products will only be limited to antimicrobials, psychotropics and biologicals/ immunologicals and national competent authorities will need to justify any further prohibitions;
- The new proposals advocate prohibiting prophylactic prescribing, i.e. if one animal on the farm gets sick, the vet can't treat the rest of the herd prophylactically; and
- The new proposals want the European Commission (EC) to make decisions about the disposal of veterinary medicinal products.

Most Member States are against the EP proposal and are expected to modify it in the Council position (to support Member States' right to prohibit the sale at a distance of prescription veterinary medicinal products).

Health claims for food
Health claims for food are regulated under EU law. Claims are subject to scientific assessment by the European Food Safety Agency (EFSA). EFSA's scientific evaluation helps to ensure that health claims made on food labelling and advertising enable consumers in making healthy diet choices. In May 2012, the EC published a list of accepted claims (80% of claims were rejected). No health claims for botanical ingredients have been accepted so far.

Therapeutic properties of herbal medicines (not food) are based on the concept of 'traditional use', which is considered not sufficient to support health claims for food under EU law. As a result, the authorisation of almost 2,000 health claims for botanicals are currently on hold at EFSA. Currently there is no clear distinction between use of botanicals in food supplements and traditional herbal medicines (the same botanical can be used in food and medicinal products). There are important differences between herbal medicines and food (manufacturing and quality standards, labelling regimes, different intent of medicines and food).

In June 2016, the EC launched an evaluation on current rules concerning health claims of plants and their use in foods in order to assess the current legislative framework in 28 Member States and its adequacy and the impact of possible changes (or absence of changes) in the regulatory framework applicable to health claims. Two main scenarios are being considered:

- A: not to accept traditional use as substantial evidence and forbid health claims for botanicals used in food; or
- B: consider traditional use sufficient for health claims in food.

PGEU made a submission to the consultation, pointing out that if health claims for food containing botanicals are allowed without a robust scientific assessment, this will have negative consequences for the traditional herbal medicines sector and will lower the quality of products containing botanicals, to the detriment of patients.

Proportionality Test Directive
The EC has proposed a directive on a proportionality test for the adoption of new or amended regulations for professionals covered by the Recognition of Professional Qualifications Directive, including engineers, accountants, real estate professionals, lawyers and healthcare professionals. The Commission is concerned that current regulations are not based on objective analysis and lack transparency, and therefore negatively impact on professional mobility and provide unjustified barriers to access professions. The proposal introduces a set of criteria for Member States' competent authorities, e.g. PSI, to use to conduct a mandatory evidence-led analysis of the need for and likely impact of a regulation before introducing or amending any professional regulations.

PGEU and the European bodies for dentists (CED) and doctors (CPME) have grave concerns that this directive, if applied to healthcare professionals, may have unintended consequences for patient safety

and have published a joint statement calling for the exclusion of said professions from the scope of the directive.

The EC's proposal introduces binding criteria which Member States must use when introducing any legal or administrative provision which may restrict access to or the exercise of regulated professions on public health grounds. It also calls for periodic review and modernisation of existing regulation. In practice, this means that before a Member State can adopt new or modify existing legislative, regulatory or administrative provisions restricting access to or pursuit of the pharmacy profession, the competent authority, e.g. PSI, will have the following obligations:

- Provide a detailed statement showing compliance with the principle of proportionality;
- State the reasons for considering that a provision is justified, necessary and proportionate which must be substantiated by objective evidence (qualitative and quantitative);
- Monitor the proportionality of regulation on a regular basis and having due regard to any developments;
- Involve independent scrutiny bodies to ensure the assessment of proportionality is carried out in an objective and independent manner;
- Take into account the economic impact of the measure, including a cost-benefit analysis with particular regard to the degree of competition in the market and the quality of service provided; and
- Carry out a comparison between the national measure at issue and the alternative and less restrictive solutions that would allow the same objective to be attained.

The obligations which the new directive imposes will place significant administrative and time-consuming burdens on Member States' competent authorities which it is feared will make it very difficult, if not impossible, to justify any new regulation of the pharmacy profession. Consequently, there will be no incentive to de-regulate or regulate the professions falling under the scope of the proposal.

Medicines Shortages
The European associations representing manufacturers (EFPIA), self-medication industry (AESGP), generics (MfE), parallel distributors (EAEPC), wholesalers (GIRP), hospital pharmacists (EAHP) and community pharmacists (PGEU) issued a Stakeholder Statement on Information and Medicinal Products Shortages in November 2016. The statement agreed on principles for improving collection, communication and transparency of information on shortages of medicines.

eHealth Statement
In November 2016, PGEU published a Statement on eHealth which included the following recommendations:

- Policy makers, ICT developers and other healthcare professionals should engage with pharmacists to develop eHealth policies and services at local, regional or national levels as appropriate;
- eHealth should be integrated into health systems complementing and supporting existing practice, with pharmacy potentially as a link between several services, organisations and infrastructures;
- Electronic health records should be linked with ePrescribing systems, allowing HCPs to access necessary patient information from the EHR (with possibility for read-write function);
- Communication and collaboration between patients, healthcare professionals and ICT developers is crucial to obtain the full potential of eHealth technologies and to build confidence and trust;
- When developing guidelines for eHealth, policy makers are called upon to meaningfully involve their end users; and
- The community pharmacy profession should be recognised, supported and adequately reimbursed for their continuous investment in eHealth, ICT infrastructure, eSkills of the workforce and contribution to improved health outcomes and reduced healthcare costs.

Waste Directive Reform
This directive, which is due to be adopted in 2017, will regulate waste disposal. In particular, the directive imposes strict conditions for the disposal of hazardous waste. Some medicines and medical devices fall under the hazardous waste definitions, e.g. sharps and narcotics. It is proposed that the recording of hazardous waste disposal must be in an electronic format and in electronic registries facilitated by Member States. Pharmacies offering waste disposal of medicines/sharps might need to adopt their recording practices to the proposed criteria.

INTERNATIONAL PHARMACY MATTERS CONTINUED

fip ADVANCING PHARMACY WORLDWIDE

Report on FIP Congress, Buenos Aires, 2016

Reducing the global burden of disease – Rising to the challenge
The 76th Annual World Congress of Pharmacy and Pharmaceutical Sciences was held in Buenos Aires, Argentina, from 28 August to 1 September 2016. The congress was hosted by the International Pharmaceutical Federation (FIP) in collaboration with the Confederacion Farmaceutica Argentina (COFA). FIP is the global federation of national associations of pharmacists and pharmaceutical scientists, and is a non-governmental organisation in official relations with the World Health Organisation. With 132 member organisations, FIP represents more than three million experts in medicines, supporting the responsible use of medicines around the world.

FIP President's opening address
In her opening address, President of FIP, Dr Carmen Peña, said that community pharmacy's important social role must not be forgotten. "Healthcare can no longer be separated from social issues. Pharmacists and other healthcare professionals need to be more concerned with continuity, integration of processes and socio-health coordination, which is an important but often forgotten role of community pharmacies."

Dr Peña used her opening address to focus on people — patients and healthcare professionals. "Today's patients have new demands; new needs. They are increasing in number and age. Many of our health systems were created in the 20th century for a society of patients with acute illnesses, but nowadays we live in a society of patients with chronic illnesses, many of whom require polymedication," she said.

"This new profile demands new areas of action from pharmacists in terms of home care as well as healthcare. Self-care and non-prescription medicines also deserve greater attention in this new era of healthcare," she added.

Dr Peña called for policies that enable cooperation and care coordination between healthcare professionals, with respect for their various functions, for the benefit of patients. However, she also said that fostering trust, improving communication and sharing information should include non-health professionals, such as hospital managers, lawyers and economists, all of whom are essential to building a new concept of healthcare.

Dr Peña gave particular mention to clinical records. Patients should be the ones to decide the extent to which information is shared among health professionals, empowering them to look after their own health.

"We need to rethink healthcare. We need to break down barriers and prevent patients from getting lost in labyrinths of specialties and bureaucracy. The system should follow patients, rather than patients following the system," she said.

Community pharmacies have the potential to vaccinate at least one in eight people right now
At least 940 million people live in countries where over 193,000 community pharmacies can potentially offer access to vaccination services, according to new research commissioned by FIP. Based on a global population of 7.4 billion, this represents at least one in eight people.

A survey of 45 countries, conducted by the FIP Collaborating Centre at University College London, found that nearly half (44%) have community pharmacy premises offering vaccinations, demonstrating the expansion and growing acceptance of pharmacy immunisation services around the world. An increasing number of countries are introducing immunisation rights specifically for pharmacists. In 13 of the 45 countries, pharmacists themselves have the authority to administer vaccines and, therefore, the potential to reach 655 million people, the researchers estimate.

The findings of this study were published in a global report *"An overview of current pharmacy impact on immunisation"*.

"The World Health Organisation (WHO) estimates that vaccination saves between two and three million lives each year. It is one of the safest, more efficient and cost-effective measures for preventing, controlling and eradicating life-threatening infectious diseases. The accessibility and distribution of community pharmacies make them a first point of contact for patients, providing an excellent opportunity to address low immunisation coverage," said Dr Helena Rosado, research scientist at UCL School of Pharmacy and co-author of the report.

"With the recognition of the role of pharmacists as immunisers in the latest FIP-

WHO guidelines on good pharmacy practice, we considered it a good time to see how far this has been implemented. This report offers, for the first time, an international overview of pharmacists' activities to support immunisation. We look forward to a day when pharmacists all over the world are recognised for their full potential and can add to the immunisations offered by other healthcare professionals, especially in hard-to-reach and high-risk populations," Dr Peña said.

The report includes in-depth case studies from Argentina, Australia, Belgium, France, Ireland, Philippines, Portugal, South Africa, Switzerland, UK and USA, with advancement examples that can potentially be adopted by other countries to advocate for a national immunisation strategy that actively involves pharmacists as part of the public health agenda. The findings also highlight that, in some countries, vaccine administration is part of the pharmacy undergraduate curriculum and that the perceived competition threat to other healthcare professionals providing immunisation services is diminishing.

Reducing the effect of medicines on the environment

Pharmacists and pharmaceutical scientists must take responsibility for mitigating the environmental consequences of medicines, according to an official policy statement adopted by the FIP Council in Buenos Aires. The policy specifies that this responsibility encompasses the entire course of medicines use, from manufacture and distribution to prescribing and dispensing, and to disposal and reduction of the discharge of metabolites of medicines into the environment.

The policy statement sets out a number of recommended actions for FIP member organisations (national professional associations of pharmacy and pharmaceutical sciences), schools of pharmacy, individual pharmacists and governments. For example, it recommends that pharmacists work to encourage rational prescribing practices, such as the use of starter doses and starter quantities and limiting the general number of doses prescribed (and dispensed) to reasonable amounts, and that they make counselling on the environmental impact of medicines part of their practice. The statement also highlights the contribution non-adherence makes to medicines waste.

The new FIP policy, *"Environmentally sustainable pharmacy practice: Green pharmacy"*, also says that "green" principles should be taught by pharmacy schools and it calls on governments to include appropriate environmental risk assessments as part of medicines approval processes.

"This statement of policy recognises the global challenge of the detrimental effect of pharmaceuticals on the environment. FIP believes that pharmacists and pharmaceutical scientists are well placed to give meaningful leadership in conquering this challenge and urges them, national organisations and governments to do so, ensuring at the same time that any solutions do not compromise access to medicines," said FIP Vice-President Ms Eeva Teräsalmi.

The 77th FIP Congress will be held in Seoul, South Korea from 10 to 14 September 2017.

2017 AGM MOTIONS

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

1. **"That this AGM calls upon the Department of Health and Health Service Executive to implement a national roll-out of both a Minor Ailment Scheme and a New Medicine Service."**
   Proposed: John O'Connell
   Seconded: Sheila O'Loughlin

2. **"That this AGM calls upon the Department of Health and Health Service Executive to extend phased dispensing service eligibility from GMS patients only to those on all of the Community Drug Schemes."**
   Proposed: Eoghan Hanly
   Seconded: Barry Brennan

3. **"That this AGM calls upon the Department of Health and the Health Service Executive to roll out the Pharmacy Needle Exchange Service nationally and to implement further recommendations of the Liverpool John Moore's University review."**
   Proposed: Mike Walsh
   Seconded: Janet Hanly

4. **"That this AGM calls upon the Department of Justice and Equality to treat possession of small amounts of illegal drugs for personal use as a health issue rather than a criminal issue."**
   Proposed: Daragh Connolly
   Seconded: Kathy Maher

5. **"That this AGM calls upon the Department of Health and Health Service Executive to deliver a National Primary Care ePrescribing System via a State-hosted public platform and an open specification in line with published standards."**
   Proposed: Jack Shanahan
   Seconded: Noel Stenson

6. **"That this AGM calls upon the IPU to ballot members to take action against any future proposed PSI fee increases."**
   Proposed: David Jordan
   Seconded: John Barry

FINANCIAL STATEMENTS FOR YEAR ENDED 31 DECEMBER 2016

1. Irish Pharmacy Union

A summary of the accounts has been circulated to members as part of the Executive Summary of the 2017 Annual Report of the IPU Executive Committee.

Financial Reports and Accounts for Year Ended 31 December 2016
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 are available on the members' area of **www.ipu.ie**.

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 2016. In accordance with Article 26.b of the IPU Constitution, the Trustees have appointed JPA Brenson Lawlor as Auditors for the IPU and IPU Services Ltd. Members will be asked to 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 2016 as submitted to this meeting, be and hereby are adopted."*

b. *"That this meeting agrees to the election of JPA Brenson Lawlor as Auditors for the IPU and IPU Services Ltd."*

2. IPU Services Limited

Financial Reports and Accounts for Year Ended 31 December 2016
At this Annual General Meeting of IPU Services Ltd, members are asked to consider the Directors' Report and the Auditor's Report on the Accounts for the Year Ended 31 December 2016. The full accounts and financial reports are available on the members' area of **www.ipu.ie**.

If the accounts are approved, members will be asked to resolve:

"That the Directors' Report and Audited Statement of Accounts for the year ended 31 December 2016 as submitted to this meeting, be and are hereby adopted."

APPENDIX I
A LIST OF SUBMISSIONS MADE SINCE THE 2016 AGM

The following submissions were made since the 2016 AGM, most of which are available on www.ipu.ie.

2016

- **Pharmacists: Delivering in the Community for the Community – Priorities for the New Government** – Department of Taoiseach, May 2016
- **Draft Regulations on Videolink** – PSI, August 2016
- **Draft Standards for Data Collections** – HIQA, August 2016
- **Pre-Budget Submission** – Department of Finance & Department of Public Expenditure and Reform, August 2016
- **Future of Healthcare** – Oireachtas Committee on the Future of Healthcare, August 2016
- **Draft Standard for eDispensing Dataset and CDA** – HIQA, September 2016
- **Statement of Strategy 2016-2019** – Department of Health, September 2016
- **Draft Misuse of Drugs Regulations** – Department of Health, September 2016
- **National Drug Strategy** – Department of Health, October 2016
- **Draft Standards for Procedure Data Set and CDA** – HIQA, November 2016

2017

- **Smoking Cessation HTA** – HIQA, January 2017 (online)
- **PSI Customer Charter** – PSI, January 2017 (online)

APPENDIX II
KEY CORRESPONDENCE SINCE THE 2016 AGM

PSI

- Brexit and Irish Pharmacy Students in the UK

Department of Health

- Follow-up to recent meeting
- Notice of IPHA Price Reductions
- Notice to Pharmacists re Price Reductions on Medicines
- Financial Emergency Measures in the Public Interest Act
- Pharmacist Vaccination in Nursing Homes

HSE

- Notice to Pharmacists re Price Reductions on Medicines

PCRS

- PCRS Pharmacy Interface Project – Owings
- Third Party Verification
- Proposed New Arrangements for Phased Dispensing
- Incomplete Claims Protocol – GP Visit Card Holders

Other Government Departments

- Regulation on Veterinary Medicinal Products
- Reduction of Price Capitation on Prescription Levy
- Retail Consultation Forum
- Directive on a Proportionality Test

Manufacturers

- Neupro® Distribution Policy – Impact on Pharmacists
- IPHA/DoH/HSE Framework Agreement on the Pricing and Supply of Medicines
- OFEV® Distribution Policy – Impact on Pharmacists

Other Matters

- Forged Prescriptions

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PSI

Brexit and Irish Pharmacy Students in the UK

Director of Pharmacy Services to Acting Registrar and CEO, PSI – 29 June 2016

The recent referendum vote in the UK, in which a majority of the population voted for the UK to leave the EU, creates some significant issues for the future recognition in Ireland of pharmacy qualifications gained in the UK. While I appreciate that it is early days since the vote and no official decisions have been taken regarding the process or timing for the UK to leave the EU, we have already started to receive queries from our members about the status of pharmacy students currently studying in the UK and those about to commence studies. I hope you can provide clarity on their situation.

Pharmacy students currently studying in the UK commenced their courses with the reasonable expectation that qualification and registration in the UK would lead to automatic recognition as pharmacists in Ireland. What will happen to such students who graduate after the UK has finally left the EU?

In addition, many students who have just completed their Leaving Cert will have applied to UK universities to study pharmacy. What will happen in their case, given that the outcome of the referendum was known before they commenced study?

In relation to other Irish pharmacists who are currently registered and practising in the UK but not yet registered in Ireland, are they entitled to automatic recognition now and at any time in the future or will a deadline to recognition be applied?

DoH

Follow-up to recent meeting

Secretary General to Minister for Health – 18 July 2016

Thank you for meeting with a delegation from the IPU recently.

As was said at the meeting, we welcome the commitment in the Programme for Government to expand the role of the pharmacist in patient care and wish to work constructively with the Department of Health and the HSE, as well as other healthcare providers and stakeholders, to ensure the best possible health service for patients. We were glad to note your acknowledgement that the last few years have been difficult for everyone in healthcare and your statements that the Government is now in a position to reinvest in healthcare and that the IPU would have an important role to play in the development of the 10-year vision for healthcare. We look forward to engaging with the committee which has been convened to progress this vision.

FEMPI

We were surprised at the position of the Department officials regarding the unwinding of FEMPI and the savage cuts to pharmacists' fees and payments which were implemented under the Act. Having clarified our position, we now anticipate immediate developments regarding the monies already due to be returned following the review of 2015 and await further information on the 2016 review which, under the legislation, was due to be carried out before the end of June.

DoH / HSE / IPHA Agreement

We note from recent media reports that an agreement has been reached between the State and the pharmaceutical industry on medicine pricing and supply for the next four years. We welcome the prospect of savings on medicine prices for taxpayers and the public and we look forward to full details of the specific medicine price reductions being made available.

In the meantime, despite the significant implications for pharmacists, we have been given no detailed information on implementation. As pharmacists cannot source medicines at the new lower prices until after the final details are known, they face significant financial losses on medicines held in stock – losses which cannot be mitigated

without adequate notice of price changes. In the absence of notice, there is a risk of disruption in the supply of medicines to patients as pharmacists cannot risk holding medicines which may be subject to overnight devaluation. As advised, we received a commitment from the previous Minister that a minimum of two weeks' notice would be given to pharmacists in advance of any price reductions being implemented. This commitment must be honoured.

We also wish to emphasise, in an environment of increasing medicine shortages, the importance of following the recommendation of the Joint Committee on Health and Children that the impact of national drug price policy on the drug supply be closely monitored in order to balance both cost reductions and continuity of supply for Irish patients.

Minor Ailment Scheme
Thank you for launching the Minor Ailment Scheme pilot, which is now underway. We will continue to cooperate with the HSE on gathering the information necessary for a robust review at the end of the three-month period, in order to be in a position subsequently to roll out a full Minor Ailment Scheme which will allow GMS patients to benefit from the same access to pharmacy services and appropriate non-prescription medicines as private patients currently enjoy.

Vaccination – Pneumococcal and Herpes Zoster (Shingles)
The previous Minister for Health introduced new legislation to facilitate pharmacy vaccination for pneumococcal and herpes zoster in October 2015. Whilst we always knew that shingles vaccination was not a HSE-remunerated service, we had an expectation that reimbursement arrangements would be put in place for pharmacists to administer the pneumococcal vaccine, as is already the case for influenza vaccination. It is disappointing, therefore, that Department officials did not include this for consideration in the estimates for 2016. We ask now that you ensure reimbursement of pharmacists for provision of pneumococcal vaccination is included for 2017.

Emergency Hormonal Contraception (EHC)
We await passage of the Health (Miscellaneous Provisions) Bill, which is required to facilitate reimbursement of non-prescription Emergency Contraception for medical card holders through community pharmacy, and look forward to engaging on a service to provide equity of access to EHC for medical card holders, in line with the recommendations of the HSE's 2010 Irish Contraception and Crisis Pregnancy [ICCP] Study.

IPU Patient Safety Initiative Proposal
We were pleased to briefly outline our Patient Safety in Medication Use proposal which aims to strengthen the foundations of patient safety through the introduction of a nationwide cloud-based system to collect data relating to errors and/or near-misses in the medication prescribing and dispensing process, allowing pharmacists, prescribers and other health professionals to learn from those errors in a structured process of error reduction and management.

Following our recent meeting with the Director of Patient Safety & Clinical Effectiveness in the Patient Safety and Quality Unit, Dr Kathleen MacLellan, to discuss and potentially advance the proposal, we note that the Department will continue to investigate the possibility of achieving the same objective through providing an interface for community pharmacists to use the National Incident Management System. We will await further updates from the Department.

Again, we greatly appreciate you taking the time to meet with us, particularly given the numerous competing demands on your time. We hope that you will take all of the above points on board and we look forward to working with you and your Government to deliver enhanced access to an improved health service to all Irish patients.

Notice of IPHA Price Reductions

Contract Manager to Assistant Secretary General, Primary Care Division, Department of Health – 22 July 2016
Further to the announcement on Wednesday 20 July of the agreement reached between the State (DoH and HSE) and the pharmaceutical industry (IPHA) with regard to the reduction in medicine prices, our members have still not received all of the information in relation to changes of medicine prices set for the 1 August; in fact, we only received the first notice of price changes late yesterday afternoon. There are now only five business days remaining until the proposed date of implementation of the price reductions.

APPENDIX II
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The IPU has written to the Department previously, emphasising the need to ensure pharmacists are given adequate notice of any changes. We have consistently advised the HSE PCRS of the need for maximum notice of price changes to be given, so that pharmacists are not left nursing significant unavoidable losses as a result of an agreement to which we are not party. In response to requests for information, the HSE PCRS has advised us that they are not yet in a position to provide details of all the new prices and are still awaiting details from some large drug companies as late as today.

The announcement on Wednesday gives pharmacists just over one week in which to prepare for the reductions. This is completely unacceptable. 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.

Pharmacy contractors experienced significant loss on the cost of their stock as a direct result of the lack of notice provided by the Department in previous years. It is important that pharmacists are not put in this position again. Even in the depths of the financial crisis, pharmacists were given a month's grace when price cuts were being implemented, whereby the lower prices were applied at wholesale level one month before they were applied at the point of reimbursement.

I request that the implementation date for the reductions is pushed back from 1 August to give pharmacists the opportunity to minimise any losses that will occur. This is in keeping with the notice given to the pharmaceutical companies in yesterday's agreement and in the precedent set in the Health (Pricing and Supply of Medicinal) Goods Act 2013.

This matter is of the utmost urgency.

Notice to Pharmacists re Price Reductions on Medicines

Secretary General to Minister for Health – 28 July 2016

cc. Mr Jim Breslin, DoH; Mr Fergal Goodman, DoH; Ms Anne Marie Hoey, HSE; Ms Kate Mulvenna, HSE; Mr Shaun Flanagan, HSE.

The Irish Pharmacy Union (IPU) recognises that the Agreement last week between the State (Department of Health and HSE) and the pharmaceutical industry (IPHA), which will reportedly save €600-€785m over the next four years, is a good deal for patients and a good deal for the State. The IPU is extremely concerned, however, at the lack of notice which has been afforded to pharmacists in advance of the planned implementation of price reductions on 1 August 2016. While it is legitimate that the State would seek to ensure maximum value for its spend on medicines, it is neither fair nor reasonable to impose losses on pharmacists, who have already suffered severe reductions in their incomes under the FEMPI Act, particularly when such a situation could be minimised or avoided.

As of today's date, pharmacists and the IPU still have not received comprehensive details of all the proposed price reductions. As a result, pharmacists will suffer significant losses on the value of medicines held in stock to meet the needs of their patients, losses which cannot be mitigated. On previous occasions when agreements with industry led to price reductions, the resulting lower prices were applied at wholesale level one month before they applied to pharmacy reimbursement, in order to allow pharmacists to acquire medicines at the lower prices in advance of supplying them to patients and being reimbursed at the lower price. There is no justification for not applying the same principle now. It is unfair and unreasonable to expect pharmacists to shoulder the immediate costs of an agreement to which they are not party.

We have consistently advised the Department and the HSE PCRS of the need for adequate and reasonable notice of price changes to be given to pharmacies. The new Agreement between the State and IPHA provides that suppliers of individual medicines will receive no less than 28 days' notice of any price reductions implemented under its terms (sections 7.2.2 & 8.2.2). Pharmacists should be entitled to no less consideration.

We wrote to the Department of Health last week (without reply), again outlining our concerns and seeking that the implementation date be deferred. Following repeated representations throughout 2015 seeking to have the 28-day notice period which applies to the setting of reference prices for interchangeable medicines under the 2013 Act extended to include all price reductions,

the IPU received a commitment from your predecessor, Minister Varadkar, that a minimum of two weeks' notice, and more where possible, would be given to pharmacists in advance of any price reductions being implemented. This commitment must be honoured.

Although the new, lower, ex-factory prices may take effect from 1 August, **the implementation date for the reimbursement price reductions must be deferred until 1 September**, to allow pharmacists the opportunity to mitigate what will otherwise be significant losses.

As the situation is now urgent, we ask that you give this matter your immediate attention.

Financial Emergency Measures in the Public Interest Act

Secretary General to Minister for Health – 19 August 2016

I write to you in relation to the failure, thus far, to implement the long-overdue unwinding of the reductions in payments to community pharmacy contractors which were introduced under the above Act.

In December of last year, following the then Minister's statutory review in 2015 of the operation, effectiveness and impact of the amounts and rates of payments to pharmacists fixed by regulation and his consideration of the appropriateness of those amounts and rates, the IPU was told that a formal process would be initiated under the FEMPI Act 2009 in January 2016 to commence the gradual unwinding of the measures previously implemented under the legislation. The amount indicated as being made available for return to pharmacists was €2.5 million, an extraordinarily low sum in the context of the magnitude of the cuts suffered by pharmacists. We protested our dissatisfaction with the sum at that time.

In January of this year, we were advised by the Department that the Minister proposed to make regulations varying the payments to community pharmacy contractors and that a formal consultation process was being commenced in that regard. In February, as part of that consultation process, the IPU made both written and oral submissions in which we welcomed the Minister's decision to commence the unwinding of the FEMPI measures but reasserted our view that the proposed sum was derisory, given the scale of the reductions suffered by pharmacists.

In a meeting in February this year, which took place between the written and oral submissions from the IPU, your predecessor, Minister Varadkar, acknowledged that the sum was less than we had anticipated but indicated that it should be interpreted as a token of the Government's genuine intent to commence the gradual alleviation of the impact of FEMPI on pharmacists, rather than as the totality of the unwinding.

In our meeting with you in June, the consultation process having long concluded, we sought an update on the status of the proposed regulations to vary upwards the payments to community pharmacy contractors and expressed our great surprise at the reported position of the Department officials regarding the unwinding of FEMPI and the savage cuts to pharmacists' fees and payments which were implemented under the Act. We were glad of the opportunity to clarify our position that, contrary to the apparent misunderstanding on the part of Department officials, at no time did the IPU express a view that the money being made available, however little, should not be paid to pharmacists.

Notwithstanding all of the forgoing, and in spite of correspondence from the Chief State Solicitor dated 8 January 2016, which stated that it was the Minister's intention to consider, determine and implement, as soon as possible following the consultation process, regulations which would have the effect of varying, whether by formula or otherwise, the amount or rate of payment to contracted community pharmacies, no regulations have yet been implemented to give effect to that intention.

In addition, we await further information on the 2016 review which, under the legislation, was due to have been carried out before the end of June. We note the statement in paragraph 43 of his Annual Review and Report on the FEMPI Acts that the Minister for Public Expenditure and Reform is of the view that a gradual amelioration of the impact of payment reductions for health professionals is appropriate.

It is utterly unacceptable that, a full eight months since the Department of Health first indicated that money cut from community pharmacy contractors' payments was budgeted for return to pharmacists, seven

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months since the Chief State Solicitor gave a commitment that it would happen as soon as possible and six months since the consultation process concluded, no funds have been returned to pharmacists. This must now be done without further delay.

Secretary General to Minister for Health – 29 September 2016

We have not yet received a reply to our letter of 19 August regarding the failure, thus far, to implement the long-overdue unwinding of the reductions in payments to community pharmacy contractors which were introduced under the above Act (copy enclosed).

This is a serious matter which, given the length of time that has passed since the statutory consultation process, now requires your immediate attention. We would be grateful for an immediate response.

Secretary General to Minister for Health – 01 February 2017

I am writing to you in connection with the unexplained and unjustifiable failure to implement the long-overdue and previously committed unwinding of the reductions in payments to community pharmacy contractors which were introduced under the above Act.

In January 2016, in settlement of an action before the Supreme Court, the Irish Pharmacy Union's solicitors received a letter from the Chief State Solicitor, stating that it was the intention of the Minister for Health to initiate a formal consultation process under Section 9 of the FEMPI Act 2009 before the end of January 2016 in relation to the regulations made pursuant to Section 9 in relation to payments to community pharmacy contractors, and that the indicative amount available in respect of community pharmacy at that time was approximately €2.5m in 2016. The letter further stated that it was the Minister's intention to consider, determine and implement, **as soon as possible following the conclusion of the consultation process**, regulations which, with the consent of the Minister for Public Expenditure and Reform, would have the effect of varying, whether by formula or otherwise, the amount or rate of payment to contracted community pharmacies under the powers conferred on him by Section 9(1) of the Act as amended in 2015. A copy of this letter is attached.

On 27 January 2016, the IPU was notified that the Minister for Health, in exercise of his powers under the FEMPI Act, proposed to make Regulations varying the payments to Community Pharmacy Contractors and was initiating a period of consultation to which the IPU was invited to make a written submission and, if we wished, an oral submission. Our written submission was sent to the Department of Health on 12 February. A copy is attached.

In a subsequent meeting on 15 February 2016, the then Minister for Health, Leo Varadkar, acknowledged receipt of the IPU submission. The IPU expressed our dissatisfaction with the indicative amount suggested and stated our view that no reasonable, fair or thorough review which had regard to all the matters requiring to be considered by the Minister could have arrived at such a figure. The Minister acknowledged our position and said that this was the only money currently in the budget for the unwinding of FEMPI.

He suggested that, at least, it was a gesture to give confidence to pharmacists (as to GPs) that the Government was sincere in its intent to gradually unwind FEMPI over the coming years.

Following this, as part of the consultation process, we were invited to make an oral submission on 23 February 2016. At this meeting, the IPU restated our position that we considered the proposed figure of €2.5m to be paltry and derisory and that we believed that no complete, objective or fair review which properly considered the matters required to be considered under FEMPI could have arrived at such a figure. The officials present revealed that there had been no comprehensive or in-depth review of the contracted professions but that, rather, the figure proposed was that which was available at that time in their budget.

Following your appointment as Minister, we met on 23 June 2016. At that meeting, we queried why the regulations had not yet been made, despite the commitment given by the Chief State Solicitor and your predecessor that it would be done as soon as possible following the conclusion of the consultation process. It then appeared that our position, which had been repeatedly been made clear to Department officials, had been misrepresented to you and that you had been told that we declined the monies available. We expressed our surprise and clarified that, while we regarded the sum of €2.5 million as utterly insufficient, **at no time had we refused**

to accept it. You described the situation as a misunderstanding and undertook to re-examine the issue and then revert to us. However, following that meeting, there was no further communication to us on this issue.

On 18 July 2016, we wrote to you to thank you for having met with us and remind you of your commitment to re-examine the FEMPI misunderstanding. This letter was not acknowledged. On 18 August 2016, we once again wrote to you, outlining our expectation of immediate developments regarding the monies already due to be returned following the review of 2015 and seeking further information on the 2016 review which, under the legislation, had been due to be carried out before the end of June. This letter was also not acknowledged. Finally, on 28 September, we wrote again, pointing out that we had not yet received a reply to our letter of 18 August regarding the failure, thus far, to implement the long-overdue unwinding of the reductions in payments to community pharmacy contractors. This third letter also went unacknowledged and unanswered. Copies of all three letters are enclosed.

In the meantime, the Minister for Public Expenditure and Reform in his June 2016 Annual Review and Report on the Financial Emergency Measures in the Public Interest Act stated the following:

Paragraph 37: "As required under the legislation, **measures applied to contracted Health Professionals** and certain other groups under section 9 of the Financial Emergency Measures in the Public Interest Act 2009 **are also being considered in the context of the overall unwinding of FEMPI legislation**."

Paragraph 43: "**I also find that it is appropriate**, taking account of the improvements brought about in the public finances, the continuing risks which remain and the need to meet our commitments to have a prudent fiscal policy under the Stability and Growth Pact, and subject to the amendments effected in the measures through the FEMPI Act 2015... (d) to maintain provisions in the legislation which provide for the reduction of payments to health professionals but allow, subject to the considerations of the Minister for Health and other Ministers of Government under sections 9 and 10 of the FEMPI Act 2009 and Government's priorities for the health service, **for a gradual amelioration of the impact of payment reductions.**"

In circumstances where your predecessor committed to commencing the unwinding of the savage reductions in payments to community pharmacy contractors which were introduced under the FEMPI Act, where this commitment was echoed in correspondence from the Chief State Solicitor writing on behalf of the government, and where the IPU participated fully and constructively in a statutory consultation process, there is no justification for withholding the monies which were proposed for return to pharmacists, however paltry the sum. Furthermore, it is utterly unacceptable that our correspondence in relation to this issue has been ignored on an ongoing basis.

This is a very serious matter which, given the length of time that has passed since the statutory consultation process, requires your immediate attention.

We are now seeking an urgent meeting with you to resolve this issue.

Pharmacist Vaccination in Nursing Homes

Secretary General to Minister for Health – 13 January 2017

Further to our proposal to you on 5 December 2016 regarding expansion of the pharmacy vaccination service, I am writing to propose that, given the current flu outbreak and its impact on patients and their families, pharmacists should be facilitated in vaccinating patients in nursing homes or other residential care settings, especially against seasonal influenza.

This month, the Health Protection Surveillance Centre (HPSC) reported that, "influenza is actively circulating in community and hospital settings in Ireland. Influenza-like illness (ILI) rates have risen to 51 per 100,000 population during the week ended 1 January 2017 and are above baseline threshold levels. Influenza hospitalisations and outbreaks in residential care facilities are at high levels and are continuing to increase. Influenza A (H3) is currently the main influenza virus circulating in Ireland, mainly affecting those aged 65 years and older. Influenza is expected to increase over the coming weeks and to continue circulating in the community up to mid-February."

Given the current and predicted future shortage of GPs, it is vital to ensure that all

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patients in residential care facilities have ready access to a healthcare professional who can provide appropriate and timely vaccinations. This could and should be their local community pharmacist. Improving access to and uptake of vaccination would go some way towards assisting in reducing demand on A&E and hospital services.

Enabling such a pharmacy service would only require a minor amendment to S.I. No. 525 of 2011, which currently restricts pharmacists to supplying and administering vaccinations "at the premises of the retail pharmacy business in which he or she carries on that professional practice". Given the well-publicised difficulties faced by GPs in responding to the current outbreak, an immediate removal of this unnecessary restriction would allow pharmacists to use their existing skills to help alleviate the situation by protecting these vulnerable patients from further spread of illness.

I look forward to hearing from you on this matter and would welcome an opportunity to discuss it in greater detail.

HSE

Notice to Pharmacists re Price Reductions on Medicines

Secretary General to Director General, HSE – 29 July 2016

cc. Mr Simon Harris T.D., Minister for Health; Mr Jim Breslin, DoH; Mr Fergal Goodman, DoH; Ms Anne Marie Hoey, HSE; Ms Kate Mulvenna, HSE; Mr Shaun Flanagan, HSE.

As you are no doubt aware, an agreement was announced on 20 July 2016 between the State (the Department of Health and the HSE) and the pharmaceutical industry (IPHA). This agreement will reportedly save €600 - €785m over the next four years. A large proportion of these savings will come from pharmacists who are not party to the agreement. The IPU publicly welcomed the agreement and appreciates that it is a good deal for patients and for the State.

As you are also no doubt aware, pharmacists around the country are extremely concerned and angry at the lack of notice given by the HSE of the prices reductions as of 1st August 2016. Pharmacies will suffer significant losses on the value of medicines held in stock to meet the needs of patients under the State schemes. They now face a considerable devaluation in the value of their stocks and have been given no time to run down their stocks to minimise their losses. Quite unbelievably, as of today's date, pharmacist contractors and the IPU have still not even received comprehensive details of all the proposed reductions.

We wrote to the Minister yesterday in relation to this matter and are copying him on this letter.

We have been advised to make the following points to you:

1. The HSE is a monopsonist buyer of medicines under the State schemes from pharmacist contractors.
2. The HSE sets the reimbursement price it will pay those pharmacist contractors for those medicines.
3. The HSE can change the reimbursement price at any time utilising the provisions of the Health (Pricing and Supply of Medical Goods) Act 2013 (the "2013 Act").
4. The effect of a price change can be seriously deleterious to the pharmacist contractors concerned.
5. The HSE can change the reimbursement price with as much or as little notice to pharmacist contractors as it chooses.
6. It is clearly not unreasonable that given such potential seriously deleterious effects, pharmacists should legitimately expect the HSE to cooperate with them and give reasonable notice of changes to the reimbursement prices.
7. The HSE has consistently not given reasonable notice to pharmacists of changes to reimbursement prices.
8. The IPU has written on numerous occasions to both the HSE and the Minister for Health noting the failure of the HSE to give reasonable notice to pharmacist contractors of changes to reimbursement prices and requesting on behalf of pharmacist contractors that such reasonable notice be given but the HSE has continued to fail to give such reasonable notice.
9. The latest price changes arise from the IPHA Agreement which sets the ex-factory price. Under Clause 7.2.2 and 8.2.2 of the IPHA Agreement, the

suppliers will receive a minimum of 28 days' notice of price reductions.

10 If the HSE proposes to alter the relevant price of a listed item under Section 21 of the 2013 Act, it is required to give the supplier at least 28 days in which to make representations to it regarding the proposal.[1] This means suppliers have at least 28 days' notice of proposed price changes and a further 28 days' notice if there is any modification to the initial price proposed.[2]

11. There has therefore been a consistent failure by the HSE to give reasonable notice to pharmacist contractors of changes to reimbursement prices, the effects of which may have seriously deleterious effects for those pharmacist contractors in the context of the HSE being a monopsony; of it setting the prices and changing the prices, where a period of 28 days is afforded in statute and contract to other parties which may be affected by the price change; and in the face of repeated requests for it to give such reasonable notice.

Pharmacists deal with patients under the State Schemes funded by the HSE every day of the week. The HSE and IPU are cooperating and making good progress on ensuring the provision of the best possible care to patients under the State schemes including initiatives such as the Minor Ailment Scheme and the Pharmacy Interface Project. We simply cannot therefore understand why pharmacist contractors, who provide exemplary service on behalf of the State, are being treated with apparent contempt and discourtesy, when the situation is readily avoidable.

It is regrettable and potentially very damaging to the relationship between the IPU and its members on the one hand and the Department of Health, the HSE and the PCRS on the other, that the HSE has yet again decided to implement price changes without giving reasonable notice to pharmacist contractors.

Yet again and for the record, we request the HSE to extend pharmacists the basic courtesy of providing them and the IPU from now on with a list of price changes at least 28 days before these changes are to take effect.

With regard to the current proposed change in reimbursement prices, although the new lower ex-factory prices may take effect from 1 August, **the HSE should defer the implementation date for the reimbursement price reductions until 1 September** to allow pharmacist contractors the opportunity to mitigate what will otherwise be significant losses.

As the situation is now urgent, we have been advised to write to you and apprise you of the position as outlined above and request that the matter be resolved as set out in the penultimate paragraph of this letter, to avoid the matter turning contentious. We therefore ask that you give this matter your immediate attention and we will make ourselves available to meet with the HSE at short notice, if required, to assist in such resolution.

1. Schedule 1 Part 3 Paragraph 2(c).
2. Schedule 1 Part 3 Paragraph 4.

Director General, HSE, to Secretary General – 9 August 2016

I refer to your correspondence of 29 July 2016 in the above matter and understand that you have likewise corresponded with the Minister for Health.

You will be aware that, in an effort to provide as much information as was possible at the time, the Primary Care Reimbursement Service provided the IPU on 15 July with the full portfolio of IPHA products on the GMS and High Tech databases whose prices could potentially be revised under any new agreement. This information would have enabled pharmacy contractors to exercise caution with stockholding during the second half of July.

Following the announcement of the IPHA Agreement 2016, the Corporate Pharmaceutical Unit within the PCRS disseminated files to suppliers for verification as agreed during the final stages of the negotiations with the Proprietary Pharmaceutical Industry. This had the inevitable consequence of delaying immediate release of the HSE revised databases but was a necessary step to ensure all relevant parties to the IPHA Agreement 2016 were aligned on a common understanding of price points.

The HSE notes that the Health (Pricing and Supply of Medical Goods) Act does not place an obligation to provide statutory notice period to pharmacy contractors but it will continue to provide as much notice as it can at an operational level.

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The HSE must deliver an ambitious service plan within available resources and, as it endeavours to protect the most vulnerable in society, cannot afford to defer for a month the efficiencies arising from the IPHA Agreement 2016.

I assure you that we value the important contribution that Pharmacy Contractors continue to deliver to their patients and clients on behalf of the HSE.

Secretary General to Director General, HSE – 10 August 2016

I refer to your letter dated 9 August 2016 in relation to the above matter. The IPU, having corresponded with the Minister for Health and the Department of Health, has been advised that the implementation of price reductions is an operational matter for the HSE.

We note your position that you will not accede to our request that the HSE should defer the implementation date for the reimbursement of price reductions until 1 September. This refusal, which we strongly protest, will result in significant losses for pharmacist contractors by virtue of the fact that most of them carry approximately four weeks' stock of medicines and will, throughout the month of August, be reimbursed at the new, lower, prices for supplying medicines which they had already purchased at the previous, higher, price.

We also note that you state 'the HSE will continue to provide as much notice as it can at an operational level to pharmacy contractors.' It is, however, our strongly held view that the HSE has consistently not given reasonable notice to pharmacists of changes to reimbursement prices, despite a commitment from the previous Minister for Health that it would do so. The IPU now seeks to engage with the HSE at the most senior level to secure for our members an agreed minimum period of notice in advance of any future price reductions being implemented. We view this as a reasonable request in the circumstances.

Given the importance of this matter, we would appreciate your proposed dates for an early meeting.

PCRS

PCRS Pharmacy Interface Project – Owings

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 24 October 2016

Further to our recent discussion regarding the PCRS/Pharmacy Interface Project, I wish to set out clearly our position in relation to item 3.8, *"Managing the risk of claims for medicine not yet dispensed ["Owings"]."* The PCRS has previously acknowledged that there are legitimate circumstances in which such owings can arise. Where there is a genuine expectation on the part of the pharmacist at the time a claim is submitted that a patient will return to collect the balance of a medicine owed to them, it has been acknowledged by the PCRS that it is legitimate for the pharmacist to claim for that medicine.

Currently, and since the 1996 Community Pharmacy Contractors Agreement (the Contract), the fee paid to a pharmacy where an owing arises, regardless of whether it is a full or a partial owing, is a standard dispensing fee plus the total ingredient cost. The dispensing fees payable are set out in Schedule One of the Health (Reduction in Payments to Community Pharmacy Contractors) Regulations 2013 and serve to remunerate the pharmacist for the costs involved in the dispensing process including the activities provided for in Clause Nine of the Contract.

The Memorandum agreed as part of PCRS/ Pharmacy Interface Project (PPIP), introduced a mechanism whereby the ingredient cost would be reimbursed to the pharmacy only if and when the patient actually collects the medicine, and the amount reimbursed would relate to the exact quantity of medicine supplied at the time the claim is submitted.

There is a significant but unquantifiable potential saving for the HSE PCRS in that the ingredient cost will only ever be reimbursed in circumstances where it is collected by the patient. There would also be greater clarity and transparency in relation to owings as a result of the interface developments which would prove beneficial to both the HSE and pharmacy contractors. It was never envisaged in the discussions regarding the PPIP that the HSE would seek to use it to alter or reduce a fee currently being paid to community pharmacy contractors.

Despite the IPU never having agreed to any reduction or alteration of the dispensing fee payable where an owing arises, the HSE sought to put forward a proposal at recent implementation meetings of the PPIP that a non-dispensing fee would be paid in cases where an owing arises and where a zero quantity of the item is supplied on the day, with the suggestion that this fee could subsequently be adjusted to a Schedule One dispensing fee when the item is collected and claimed. This proposal, which we fail to comprehend as having any rational basis, is outside the scope of the PPIP Memorandum as agreed between our respective organisations.

The non-dispensing fee exists for those situations where the pharmacist in the exercise of his/her professional judgement considers it to be in the patient's interest that they not dispense the medicine concerned. It is implied by this that the medicine is never going to be supplied in the context of the prescription in question and that, therefore, it does not require to be considered for the purposes of Clause Nine in the same way as would an item which is to be supplied or treated as an owing for supply in the future. An owing is different to a non-dispensing in that it constitutes an active dispensing and, as such, places further responsibility on a pharmacist. Because it is anticipated that the patient will collect the medicine in the near future, the pharmacist is obliged to consider this item in the context of his/her responsibilities under Clause Nine, including screening for any potential drug therapy problems which may arise out of the use of the medicine(s) prescribed such as those which may be due to therapeutic duplication, drug-drug interactions (including serious interactions with non-prescription or over-the-counter medicines or foods), incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse and/or misuse. It is for this professional activity and this exercise of professional skills and judgement that the dispensing fee is payable.

In summary, a Schedule One dispensing fee, which is currently paid to pharmacists in owings situations, should not be confused with a non-dispensing fee, which, as outlined above is completely different. The Clause Nine responsibility of a pharmacist is not diminished by virtue of an item being owed to a patient rather than collected on the day of dispensing. As such, nor should the professional fee paid to the pharmacist be diminished. Any suggestion to the contrary is and will remain unacceptable to the IPU and will serve to prevent the advancement of this project.

We are available to explain this position further to you if you believe it would be helpful. In the meantime, pending a satisfactory resolution of this wholly unnecessary situation, the PCRS/Pharmacy Interface Project must unfortunately remain on hold.

Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS, to Secretary General – 24 November 2016
I refer to your letter of 24 October 2016 in relation to the pharmacy interface project. I wish to advise that PCRS management met with the Department of Health in October with a proposal for progressing the owings issue which includes a payment of a dispensing fee within an owings ruleset and I await their response. I would like to invite the IPU to re-engage in the interface project in an effort to progress the project overall. The HSE in good faith has made a proposal to the Department of Health and are awaiting their response, but as previously communicated, the interface project is wider than owings with benefits to be realised for pharmacies and the HSE.

Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS, to Secretary General – 8 December 2016
I refer to my previous correspondence of 24 November 2016. The Primary Care Reimbursement Service has had further engagement with the Department of Health on the matter.

Further to those discussions, in the context of progressing the visibility and transparency provided through the Pharmacy Interface Project, I can confirm that the Department has agreed in principle to a full dispensing fee 'to remunerate the pharmacist involved in the dispensing process including the activities provided for in Clause Nine of the Contract' with the ingredient cost to be paid when the supply element is discharged when the patient returns 'in the near future' to collect the medicine.

The ruleset that will be attached to the payment of a dispensing fee in respect of owings will reflect:

1. The pharmacy contractor has a genuine expectation that the patient will

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return in the near future to collect the remainder of their prescription.

2. In accordance with Clause Nine of the Contract, there will be occasions that, while the product is listed on the prescription by the prescriber, the pharmacist in their professional judgement believes that there is a risk to the patient in supplying the product, e.g. where a potential drug therapy problem may arise. The pharmacist will discuss this with the patient. In such circumstances, no supply is occurring on that day or will occur in relation to that specific prescription form.
3. Items not supplied relating to a specific prescription form may only be claimed in the following exceptional circumstances:
   - Split supply of medication where the patient has been supplied with some of the prescribed drug/item and the remainder of the drug/item has been specifically ordered by the pharmacist, as the total quantity was not available in stock.
   - Where the prescribed medication is not a normal stock item, the item was not in stock on presentation of the prescription and was specifically ordered for the patient.
   - Where the patient paid the prescription charge and is returning to collect medication as they could not physically transport the full quantity on the day of the initial presentation of the prescription, e.g. bulk food products.
4. There is a requirement on behalf of the HSE that such owings/non-dispensed items charged to the HSE:
- Would be discharged before a further claim arises for the same item, i.e. in the subsequent month's supply, accommodation of the owing would occur in supplying the patient's medication requirement for that subsequent month.
   - Would be bagged, labelled and awaiting collections; or
   - Recorded with the date of dispensing/supply with the patient medication record indicating 'not collected'; or
   - Recorded with the date of dispensing/supply with the patient medication record indicating either 'returned to stock' or 'destroyed'.
5. For the avoidance of doubt, claims for items not supplied or intended for supply within a defined timeframe to patients could not be submitted to the HSE for payment. Owings files should therefore be reviewed monthly before claims are submitted to the HSE and only claims as outlined in 1 to 3 above and meeting the requirements of 4 may be submitted for payment.

As part of those discussions, the HSE committed to the Department of Health that the following rules would apply:

1. The fees per pharmacy would be capped at 2.5% of spend for dispensing and non-dispensing fees to provide a level of assurance that the 'genuine expectation' element was respected by community pharmacies.
2. The HSE will actively monitor claiming activity and address any outliers that may emerge in communities of practice.
3. The visibility would be used to inform the HSE of GPs who are continually prescribing items no longer required by the patient with a view to (i) enabling review of the patient's requirements and (ii) appropriate and cost effective prescribing/improving the repeat prescribing protocols at GP Practice level.

As indicated in previous discussions on this matter, the HSE reserves the right to review the arrangement within a two-year timeframe of it becoming operational and may make amendments/adjustments as appropriate.

While the interface project is wider than 'owings' with benefits to be realised for pharmacies and the HSE, we believe that the Department agreement to the FEMPI schedule of fees for the visibility offered in relation to 'O' line type claims is a significant step forward and look forward to your engagement with the project as a whole.

We can discuss further at the JCG meeting on 12 December.

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 11 January 2017
Further to your correspondence of 8 December 2016 and our subsequent Joint Consultative Group (JCG) meeting on 12 December 2016, the IPU welcomes the agreement by the Department of Health to continue paying the current dispensing fees in respect of medicines placed in owings, to remunerate the pharmacist involved in the dispensing process, in particular the activities provided for in Clause Nine of the Contract.

The Memorandum of Understanding (MoU) which was agreed as part of the PCRS/Pharmacy Interface Project (PPIP) introduces a mechanism whereby the ingredient cost will be reimbursed to the pharmacy only if and when the medicine is supplied to the patient. The arrangements set out in your most recent correspondence are in keeping with the terms of the MoU and can form a basis for moving forward with the PPIP. However, we do not understand why you would now seek, in a technical project, to introduce an arbitrary cap for owings of 2.5% (or any other proportion) of spend for dispensing and non-dispensing fees. This goes beyond what has been agreed in the MoU for the PPIP. Your stated objective to provide a level of assurance for the 'genuine expectation' element of an owing is redundant once there are agreed arrangements in place for managing owings.

It is deeply frustrating, when we have consistently endeavoured to make progress on the basis of settled agreements, that you have again sought to make post hoc alterations or insert additional restrictive terms or conditions to a project document that has already been agreed between us. As our concerns in relation to the fee element have largely been addressed, the IPU proposes that we set aside this notion of an arbitrary cap for inclusion in future discussions on a new contract and, meanwhile, press ahead on the basis of what has already been agreed between us. Additionally, we should each commit to jointly reviewing the project, including the implementation of the arrangements for owings, after years one and two and then, following these reviews, make whatever amendments or adjustments that we both agree are necessary or desirable.

Subject to your agreement that we both stick to the existing agreement, the technical work of the PPIP can recommence later this month and any practical or technical matters arising from the implementation of the new arrangements, including in relation to owings, can be addressed through that forum. Proposed changes to our contract or remuneration should be dealt with separately.

We are, as always, available to clarify our position with you as necessary.

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 30 January 2017
As set out in our correspondence of 11 January 2017 regarding the above, the IPU remains concerned at the proposed imposition of an arbitrary 2.5% cap on any legitimately earned fee. However, we note your explanation of the intent in your letter of 23 January and the subsequent assurances given at the IPU PCRS Joint Operational Group meeting last week that, in circumstances where a pharmacy's non-dispensing fees reach 2.5% per pharmacy of spend for dispensing and non-dispensing fees, while their claims may be reviewed, payments to the pharmacy will not be affected.

We also note and agree with your proposed schedule for joint periodic reviews of the implementation of the interface project, including as it relates to owings.

We confirm that we will re-engage with the PCRS Pharmacy Interface Project (PPIP), as our concerns regarding the fee element of the owings portion of the project have largely been addressed.

We will now liaise with you to schedule the next meeting of the PPIP so that the technical work of delivering what has been agreed in the MoU may proceed.

Third Party Verification

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 28 October 2016
I refer to your recent correspondence to pharmacists advising them of your wish that third party verification be introduced on the GMS scheme, which the scheme has not previously been subject to that requirement. As you are aware, it is our position that the requirement for third party verification of GMS prescriptions will impose a disproportionate additional administrative burden upon pharmacy teams and will distract

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from patient care. The proposal adds no value for the patient, nor does it add value to the pharmacy service they receive. Despite this, the HSE has indicated a strong imperative to implement the measure.

We have now completed a nationwide round of consultations with our members in relation to this proposal and a number of issues have arisen which will require resolution before implementation can be considered, chief amongst which is that there will inevitably be certain circumstances in which patient signatures will not be possible to capture. Some examples are set out below, but this list is by no means exhaustive:

Emergency Supply
GPs will frequently phone or fax a pharmacy to request that medicine be dispensed to a patient, with the original prescription being forwarded afterwards. In these situations, it will not be possible to get the prescription signed at the time of dispensing, as the document will not be present in the pharmacy at that time.

Literacy Challenges
Poor literacy levels are more prevalent among lower socio-economic groups, who are also more likely to hold a medical card. As such, many GMS patients will not be in a position to sign the form and pharmacists will not wish to risk humiliating them by asking them to.

Nursing Home GMS Residents
It will not be feasible for residents of nursing homes to sign individually for their medication; indeed, many would be physically incapable of doing so. A protocol needs to be put in place whereby the person in charge of a nursing home or other staff member can acknowledge receipt of medication on behalf of a group of residents, whether by way of imprinting the nursing home rubber stamp on the prescription forms or by signing a single statement acknowledging receipt of a multi-patient medicines delivery.

Relationship of Person Collecting
Why is this necessary? We have a concern that this may give rise to a potential breach of the Equal Status Act. Is there a particular person who by virtue of their relationship to the patient is not eligible to collect a prescription on someone's behalf? It should be sufficient for signatories who are not the patient to print their names alongside their signatures.

Ongoing Monitoring and Review
PCRS must commit to a joint review of the implementation of the circular over the next six months in order to address jointly any unintended consequences or unanticipated issues arising from the imposition of this new requirement.

Public Awareness
Lastly, for a change as significant as this to be introduced, requires that all stakeholders are made aware of it sufficiently far in advance of implementation. All GMS patients must be made aware that they will now be required to acknowledge receipt of the medications dispensed to them by signing prescriptions. The HSE needs to give consideration to how it proposes to communicate this change in partnership with the pharmacists who are expected to implement it.

For the reasons set out and for others as yet unforeseen, it must be accepted that, even with the best endeavours of pharmacists, not all prescriptions will be co-signed by patients on every occasion. Despite the disproportionate regulatory requirements and administrative burden placed on pharmacists, patient care must remain their priority. Pharmacists who dispense prescribed medicines in good faith to eligible patients must be paid for doing so in all circumstances, including where it has not been possible to secure a patient signature. The system has to be flexible enough to accommodate the existing needs of patients and the obligation and desire of pharmacists to meet those needs. If pharmacists are to engage with this proposal, HSE PCRS must accept their bona fides and commit to ensuring that they will continue to get reimbursed for all items dispensed in good faith.

Pharmacists have cooperated on an extensive range of changes in recent years, many of which have come at the expense of pharmacists and pharmacy resources and were of benefit to the HSE and/or the State rather than to pharmacists. The recent attempt to force this measure through without having given consideration to the issues and consequences which will inevitably arise is, at best, misguided and will not work. Discussions and negotiations are required and, if solid assurances are provided of a reasonable and proportionate approach that safeguards patient access to medicines and ensures the continued reimbursement of pharmacists, then an implementation in 2017 can be considered. In the absence of such discussions

and assurances, we consider that the measure is not ready to be implemented.

Contract Manager to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 11 January 2017
Further to the JCG meeting of 12 December 2015, the IPU wishes to set out practical proposals for third party verification of GMS prescriptions in the context of Residential Settings/Nursing Homes.

Patients on admission to a nursing home are normally asked to give consent for the supply of their medication from a named pharmacy. We understand that the HSE/PCRS will accept the signature of the person in charge of a nursing home or their nominated staff member when receiving medication on a patient's behalf. It is current practice in many pharmacies that the person in charge signs to acknowledge the receipt of medicines on a dedicated form and that this form is then retained in the pharmacy. It is not practical nor necessary to expect the person in charge to sign each prescription individually. The person/nurse in charge have onerous workloads as it is and, in some cases, they have indicated to pharmacies that they are not in a position to provide multiple signatures. The collection of multiple signatures from the same individual on a single occasion will not improve the audit trail for HSE/PCRS any more than would a single, dated, signature on a more comprehensive list of patients and medications.

The relevant PSI guidance states that, when delivering/dispensing to Nursing Home/ Residential settings, the delivery method used should incorporate an itemised verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is handed to the patient or carer. This, according to the PSI, entails obtaining a signature from the person in charge – something which pharmacies therefore already do. There is no requirement in the PSI guidance for a separate signature per prescription.

The PSI also requires that the original prescription must be physically present in the pharmacy and must be reviewed by a pharmacist before the medicine is dispensed and/or supplied. They also require that the delivery method used must safeguard confidential information about the patient and their medication. If prescriptions were to be removed from the pharmacy in contravention of the PSI guidance, there is a small but unacceptable risk of prescriptions being lost and that confidentiality could not be guaranteed.

It is our position that as long as there is a verifiable signed audit trail, fully in compliance with PSI guidance for medicines dispensed and delivered to patients in Nursing Home/ Residential Care settings, this will satisfy the probity requirements of the HSE/PCRS and therefore negates the need for individual signatures on every prescription form.

We remain available to discuss with you as necessary.

Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS, to Contract Manager – 03 February 2017
I refer to your letter of 11 January in relation to the above.

The reason for extending third party verification to Medical Card Prescriptions have been clearly outlined by the HSE.

In addition, the Community Pharmacy Contractor Agreement for Provision of Services under the Health Acts (January 2010) Clause 14 states:

1. The pharmacy contractor shall make arrangements to supply on an appropriate claim form, in relation to any medicines dispensed under clause 1(1) (b), such information as may be deemed relevant by the chief executive officer following consultation with the Pharmaceutical Contractors Committee.
2. The pharmacy contractor shall cooperate with the chief executive officer and the Primary Care Reimbursement Service in the discharge of any statutory obligations imposed upon them including the obligation to establish the accuracy of claims.

However, I note your observations in relation to the risk of prescriptions being lost and that confidentiality could not be guaranteed. In maintaining a verifiable signed audit trail, pharmacists must ensure they keep comprehensive documentation to satisfy the HSE as to the supply of the medication at patient level to Nursing Homes on a particular day, in the event this is requested for validation purposes. For nursing home

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patients only, it will be sufficient for a copy of the signed delivery records (as required by the PSI) to be attached to the prescription bundle.

The HSE will request on occasion further supporting documentation from pharmacy contractors.

Proposed New Arrangements for Phased Dispensing

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 11 January 2017
I refer to your correspondence of 8 December 2016 regarding the HSE PCRS proposals to introduce validation enhancements for phased dispensing, and to our subsequent meeting on 12 December.

As we have previously made clear, the IPU is willing to discuss reasonable and proportionate validation enhancements around the existing phased dispensing arrangements as set out in the 1996 Community Pharmacy Contractor Agreement.

The vast majority of pharmacies we represent conduct their business in a professional and ethical way, putting the needs of their patients first and foremost at all times. We understand the HSE's need for greater probity and audit at this time but this must be done in a way that is practical and fair, and does not impinge unduly on the daily work of community pharmacists.

The existing phased dispensing arrangements are set out in correspondence dated 30 September 1996 from the then GMS board and in the 2006 PCRS Handbook, *Information and Administrative Arrangements for Pharmacists*. Appendix A of your letter of 8 December introduces some terminology which does not form part of the existing arrangements. For example, neither the reference to the 'totality of the month's medicines' nor the explicit requirement for 'multiple supply occasions' appear in the original agreement or in the PCRS Handbook. The latter requirement was first stipulated by the HSE in May 2016.

As regards the specific proposals you have put forward, we have some observations.

It is our view that the exemption from your proposed new validation process for phased dispensing should apply to those aged 70 years and over as was set out in your letter in March, rather than 80 years and over, which appears to be an arbitrary figure and not in keeping with current government practice of applying benefits to those aged 70 years and over. This must be seen in the context of the existing exemption from means testing for GP Visit cards for those aged 70 years and over, and the reduced prescription charges cap which is due to be introduced later this year.

The 'existing arrangements' that you propose keeping in place should not necessarily be limited to patients aged 70 years and over, and to those whose medicine is psychotropic in nature. There are other categories of patients for whom phased dispensing should still automatically apply and also other medicinal products, such as preparations with a short shelf life. We suggest further engagement between us to agree what criteria would apply to patients who would be automatically approved for phased dispensing and also which medicines would automatically be deemed approved.

For new patients, the application process will need to have a fast and efficient turnaround time for approval/not approved. If a 'same day' turnaround time cannot be guaranteed, patients ought to be 'approved' until such time as the pharmacy is notified that an application is 'not approved'. Pharmacists and, more importantly, their patients cannot be expected to wait a protracted period for approval before a necessary service can be commenced.

The initial design of the application as set out in 'Appendix B' is in keeping with current visibility norms and pharmacy awareness of the status of an application. It is our view that the declaration indicating the acceptance by the pharmacist of what is defined as phased dispensing by the HSE PCRS does not require a subsequent qualifying acceptance of what does not constitute phased dispensing. Additionally, the reference to invalid and fraudulent claims is unnecessary and potentially prejudicial, particularly in circumstances where there is no evidence of any intent to deceive.

The IPU believes that socio-clinical need is unrelated to economic means and that the likelihood of a patient requiring any particular service is not related to their eligibility under the community drugs schemes. Therefore, the facility to have medicines phased where that is appropriate for the patient in the

circumstances should not be limited only to those patients who have eligibility under the GMS scheme but should apply to all patients who have eligibility under the schemes.

Finally, your correspondence sets out your position that phased dispensing is not the same as providing a Monitored Dosage System (MDS). We welcome your acknowledgement that MDS is a quality enhancement service. The position you are now adopting with regard to payment for MDS will result in this service being withdrawn from many patients whom it will not suit to collect their medicines on a weekly basis, with consequential impact on their adherence to prescribed therapies and potential adverse effect on their health outcomes; therefore, in the interests of patient safety, we believe that the current requirement for multiple supply occasions, which was first stipulated on 5 May 2016 in your correspondence to pharmacies, should be waived where medicine is being presented to the patient in MDS.

We look forward to engaging with you further in relation to your proposals in the hope that a reasonable way forward can be found which meets your objectives and protects pharmacists' ability to provide vital services to their patients.

Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS, to Secretary General – 03 February 2017

I refer to your letter of 11 January in relation to the above.

Your letter raises a number of issues which I will address hereunder.

- In relation to the age limit applied to the new approval mechanism for 'phased dispensing', on further analysis, the HSE has found that age 70 is too young for many individuals to require dispensing and that it is more reasonable to propose that age 80 is more realistic at a juncture at which the level of phased dispensing is evidenced to increase. However, in response to your request, it is reasonable to provide for continuous review of the appropriate age with the experience and evidence from the data following implementation of the phased validation. Therefore, I propose that we can jointly review the experience after six months of operation and if this demonstrates that a lower age threshold would be appropriate, we can discuss the possibility of the age threshold reducing to 75 years. At a later stage, after we have assessed the implications of any age reduction from 80 years old, we can review further.
- I note you are seeking further engagement on the categories of patients for whom phased dispensing should still automatically apply and also other medicinal products. It would be helpful if this could be discussed jointly in an effort to progress the discussion. Where products have a short shelf-life, there is no intention to change existing arrangements.
- In relation to the approval process (required in the circumstances already specified), PCRS will designate staff to deal with applications for approval and our commitment will be in so far as possible to turn same around in a 24-hour period during the normal working week or on the first working day of the week following a weekend. Where a GP requests phased dispensing for a GMS patient online, approval will be contemporaneous. Where a pharmacist requests phased dispensing online and it aligns with the HSE criteria, approval will be contemporaneous. Where it does not align with the automatically approved criteria, turnaround will be 24 hours except at weekends. As with any new drug or service, awaiting approval is not unreasonable. However, where a patient is newly prescribed a 'risk' preparation (the list of which can be agreed between the parties), consideration could be given to applying the Emergency Dispensing arrangements.
- You raise issues in relation to the extension of phased dispensing to non GMS scheme and also the issue of MDS. Phased dispensing applies only to the GMS scheme and any extension of same is a matter for the Department of Health to consider and to fund. Similarly, MDS is also an issue which the Department of Health did consider some years ago and did not approve for implementation. Any revisiting of this position is a matter for the Department.
- The implementation for phased dispensing must be operated in line with the PCRS letters of 5 May 2016

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and that of 30 September 1996. The issue of dispensing on multiple supply occasions has always been clear and was further reinforced in the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2009; the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2011; and by a similarly worded provision contained in the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2013, which stated, *'phased dispensing fee – payable per drug item for each dispensing phase other than the first dispensing phase for which the standard dispensing fees is payable'*.

I trust the above clarifies the issues you raise and we look forward to progressing the implementation of this proposal with your cooperation from March or April 2017. Any further issues can be raised or clarified with myself or Ms Kate Mulvenna should you require.

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 15 March 2017

I am writing in response to our discussions at the recent Joint Consultative Group (JCG) meeting regarding your proposed validation enhancements to the existing phased dispensing arrangements and to set out our concerns.

The rules regarding phased dispensing, as set out in the PCRS Handbook, Information and Administrative Arrangements for Pharmacists, 2006 are:

(i) At the request of a patient's physician;

(ii) Due to the inherent nature of a medicinal product, i.e. product stability and shelf life;

(iii) Where a patient is commencing new drug therapy with a view to establishing patient tolerance and acceptability before continuing on a full treatment regime; and

(iv) In exceptional circumstances where the patient is incapable of safely managing the medication regimen.

There have been no changes to these rules since their introduction in 1996, save for the stipulation in May 2016 that patients who avail of phased dispensing must present in the pharmacy on multiple occasions in order to collect the next instalment of their medicines.

We note that no changes to criteria (i) to (iii) are proposed but that patients' entitlement to have a phased dispensing service provided at the discretion of the pharmacist under criterion (iv) above will in the future be subject to prior approval by the HSE PCRS.

It is our understanding that automatic approval for phased dispensing fees will apply if any one of the following criteria is satisfied:

- Where the patient meets standard phased dispensing criteria (to be agreed);
- Where there is an existing phased dispensing history;
- Following an application for approval by the GP; and
- Following pharmacy application and PCRS approval.

The proposal put forward at the JCG was more restrictive than was set out originally in your correspondence of 8 December 2016. The latest iteration of the proposal, i.e. the requirement that the patient be aged 80 years or over and be using psychotropic drugs and be receiving five or more items concurrently to be eligible for automatic approval, seems excessively restrictive. It remains our view that the age eligibility for phased dispensing should be 70 years, not 80, as indeed you first proposed in March and again in December of last year; and we welcome your agreement to keep this matter under review.

In light of the proposal to apply an age limit of 80, a more reasonable approach to the proposed eligibility rules would be that a patient should only need to satisfy any two of the three criteria in order to be automatically eligible for phased dispensing at the discretion of the pharmacist acting in the patient's interests.

You advised that, under the proposed new arrangements, it would be possible for GPs to apply directly to the HSE PCRS for a patient to have their medicines dispensed on a phased basis. It is essential that pharmacists are given real-time visibility of GPs requests and subsequent authorisations for phased dispensing on the pharmacy application suite,

to avoid unnecessary delays in providing this service to patients who have been adjudged to require it.

In relation to the approval process itself, we have concerns that non-pharmacist staff in PCRS, such as technicians, will be adjudicating on the professional judgement of pharmacists who, knowing the patient and his/her circumstances and capabilities, apply for approval to provide a phased dispensing service to that patient. We cannot agree to any arrangement under which a pharmacist's professional judgement is questioned and potentially over-ruled by non-qualified personnel.

Regardless of the finer detail of the arrangements that are eventually agreed and put in place, it is imperative that requests for approval in respect of new patients will at all times be prioritised over reviews of existing patient approvals. You have assured us that all approval decisions will be taken and communicated to the pharmacist within a 24-hour time frame. However, we are seeking an absolute commitment from HSE PCRS to keeping to this timeline.

Lastly, the proposed implementation date of 1 April is not reasonable or achievable and, in the interest of achieving a practical and workable solution, must be deferred to the 1 June 2017 or later to ensure a seamless transition to the new process for all parties concerned. Pharmacy contractors will need to be given adequate notice of the proposed changes, due to the workload implications and the impact on future patients. The ultimate commencement date for the enhanced validation process can be confirmed once we have agreed on the business rules and the system has been tested. You will understand that pharmacists cannot be expected to tolerate another hastily imposed last-minute change, such as was seen with the reduction in the GMS prescription levy this month.

We remain available to meet with you to explain our position further if needed.

Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS, to Secretary General – 24 March 2017
I refer to your letter of 15 March 2017.

You will be aware from previous discussions that there has been a significant rise in claims for phased dispensing in recent years. As the HSE addresses the anomalies presenting in our review of historical phased dispensing claims, it is clear that further validation is required.

Phased dispensing was introduced in 1996. For the avoidance of any doubt, I reiterate that where a phased dispensing claim is submitted, the requirement that an item be dispensed across multiple supply occasions has always been present through:

a. The 1996 Agreement
Paragraph 12(ii) of the April 1996 Agreement between the HSE and the IPU states as follows:

> *"Fee for phased dispensing – The Group recommends that the GMS dispensing fee should be paid in respect of each part of the necessary phased dispensing. An example of a prescription which requires phased dispensing would be a prescription for a month's supply of a paediatric antibiotic (which is unstable) which would be dispensed more frequently."*

It is clear from the language of the Agreement that a prescription that is "phased" is intended to be "dispensed more frequently" than a prescription that is not phased.

b. The Regulations
The Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2009, 2011 and 2013 all support that a phased dispensing fee is only payable in circumstances where a drug item is dispensed across multiple supply occasions. The 2013 Regulations currently in place state that:

> *Phased dispensing fee – payable per drug item for each dispensing phase other than the first dispensing phase (for which the standard dispensing fee specified in Schedule 1 is payable).*

The language obviously indicates that phased dispensing fees are payable only in circumstances where there is more than one dispensing occasion.

c. PCRS Handbook
The PCRS Handbook (Information and Administrative Arrangements for Pharmacists) also communicates the rule set out in the 30 September 1996 letter, and provides claiming directions

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for electronic claims submissions, as follows:

> *Electronic claimants should select the relevant category, change the Script Type to Phased Script, then select the appropriate phased reason plus the total phased dispensings being claimed, excluding the initial dispensing. Finally, enter the quantity to be dispensed on the day.*

The language above requires that the pharmacy inputs the number of total Phased Dispensings "excluding the initial dispensing". The use of the phrase "**initial** dispensing" indicates that there will be more than one dispensing occasion.

Furthermore, the Handbook references "the quantity to be dispensed on the day", again indicating that the full quantity would not be dispensed on one occasion.

In responding to your communication of 15 March 2017, I must also clarify that automatic approval will apply:

1. Where the doctor writes Phased Dispensing on the face of the prescription;
2. Following an application for approval by the GP on the GP application suite (removing the need to write phased dispensing on the face of future prescriptions); or
3. Following pharmacy application and subsequent PCRS approval where the pharmacist believes the criteria – *in exceptional circumstances where the patient is incapable of safely and effectively managing their medication regimen' pertains*

I can confirm that, where a GP makes an application for phased dispensing online, it is contemporaneously available on the Pharmacy Applications Suite.

Patients for whom phased dispensing claims have been historically submitted will be called into the review cycle at a time in the future. There is evidence that some pharmacies are endeavouring to enrol patients in their service developments to circumvent the intention of the HSE to be more equipped to monitor phased dispensing claims prospectively.

The review, as agreed, will include age criterion. We are not satisfied that it is appropriate to reduce the criteria further to that outlines in our letter of 3 February 2017 until after the first review period. In that review, we can discuss further building on experience with the enhanced validation system.

In inspecting and reviewing phased dispensing fee claims, we have encountered at pharmacy level, an unsatisfactory disconnect between submitted phased claims and the documentation held in the pharmacy to substantiate the patient assessment one would have expected to occur when determining *'exceptional circumstances where the patient is incapable of safely and effectively managing their medication regimen'*.

You have raised concerns that non-pharmacist staff in PCRS will be assessing applications received. Your concern is surprising in that in many pharmacies, non-pharmacist staff (technicians) play a key role in dispensaries, operating under the supervision of a pharmacist. I can confirm that the non-pharmacist (Pharmaceutical Assistant & Technician) staff will be discharging their duties under the supervision of a pharmacist as the HSE deals with applications received from pharmacies and queries arising. They will be operating under internal protocols and a negative decision will not be communicated back to the pharmacy without pharmacist signoff. The HSE expects that the online application system would enable sufficient particulars to be provided by the pharmacy for an assessment to be made in conjunction with reimbursement histories that PCRS already hold. Furthermore, for negative decisions by the PCRS, we have previously outlined that an appeal mechanism through the local HSE pharmacist will be available to the pharmacy to present further information.

In relation to your request to defer to 1 june 2017, we indicated at the JCG neeting an earlier start date. The HSE has confirmed to the Department of Health our plans doeo enhancing phased validations and the Separtment is anxious that we progress these on schedule. However, we will defer for a further couple of weeks and propse a demo of the system at the meeting scheduled for the JOG on 30 March 2017.

As outline above, it remains open for the GP to write phased dispensing on the face of the prescription where they are concerned for patient safety. The HSE has

not encountered any instance where the GP wrote a 'Phased Dispensing' request on the face of the prescription that the GP request was not discharged correctly by the dispensing pharmacy. It is the maximising of claims by the pharmacy, where no other healthcare professional is involved in the patient assessment, that is the risk for the HSE, a concern unfortunately substantiated by claiming behaviour in recent years.

Incomplete Claims Protocol – GP Visit Card Holders

Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 27 January 2017

I am writing in relation to an issue which has arisen in the case of GMS prescription forms erroneously issued by contracted General Practitioners to their GP Visit Card patients which has resulted in an apparent break with the Incomplete Claims Protocol by the HSE PCRS.

At the inception of the GP Visit Card scheme, the IPU recommended to the HSE PCRS that the new type card numbers should be in a different format to GMS numbers to differentiate them from medical card numbers and thereby avoid unnecessary confusion between the schemes at the points of prescribing and dispensing. However, GP Visit Cards were instead issued with numbers whose format is identical to GMS numbers.

You will be aware that, on occasion, some GPs issue GMS prescription forms to patients whose correct eligibility is under the GP Visit Card scheme and not the GMS Scheme. As a result, when a pharmacist is presented with a properly completed GMS prescription form, complete with a patient number in the correct format, the prescription may inadvertently be dispensed as a GMS prescription, through no fault of the pharmacist who is simply providing patient care under with the terms of their contract with the HSE. This is acknowledged by the HSE PCRS as an issue and has, for six years, been dealt with under the Incomplete Claims Protocol which was agreed between the IPU and the HSE PCRS and circulated to pharmacies in September 2010 (copy enclosed) and has operated successfully ever since.

It now appears that the HSE PCRS has, without notice, instituted a new practice, in breach of the Incomplete Claims Protocol, resulting in our members being refused reimbursement having dispensed medicines in good faith on foot of properly completed prescription forms in cases where GPs have issued GMS prescriptions for patients with GP Visit Card eligibility only. The agreed protocol and practice in place (until now) is that an invalid claim will be paid and reported on the pharmacy's detailed payment listing so that the pharmacist is alerted to the fact that the eligibility is not clear and has an opportunity to rectify this with the patient concerned.

In the absence of agreement with the IPU to make changes to the terms of the existing protocol or notice of your intention to break with the protocol, our members had a legitimate expectation that they would continue to be reimbursed as before.

At the March 2016 meeting of the Joint Consultative Group (JCG), a draft document, entitled *Incomplete Claims Protocol – Discussion Document* (copy enclosed), was circulated by the HSE PCRS. The IPU proposed at the following meeting in May, that Point 2 of the draft document, which states, "In cases where the card number does not exist, i.e. no record of previous eligibility over the last xx years the HSE will not honour such claims" be removed and that Point 1 be applied to all categories of claims. The IPU also proposed that the HSE PCRS writes to GPs to remind them not to write prescriptions for GP Visit Card patients on GMS prescriptions, which was subsequently done. The HSE PCRS did not raise the draft discussion document at any further meetings of the JCG.

It is redolent of bad faith for the HSE PCRS to have unilaterally imposed new practices without notification or discussion. The Relationship Values Charter agreed between PCRS and IPU sets out at Article 14 that "all existing agreements /arrangements will be respected and honoured in full". Therefore, we expect that the HSE PCRS will honour the existing Incomplete Claims Protocol and immediately reimburse our members for claims which were dispensed in good faith and wrongfully rejected.

A continuing failure by HSE PCRS to adhere to arrangements previously agreed will inevitably lead to difficult questions regarding the purpose of collaboration and the value or otherwise of agreements between us. Please give this matter your urgent attention.

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Secretary General to Assistant National Director for Primary Care Reimbursement and Eligibility, PCRS – 20 March 2017

The IPU in our correspondence of 27 January 2017 and again at the recent Joint Consultative Group (JCG) meeting expressed our disappointment that the agreed protocol and practice in place for managing GMS claims involving invalid medical card numbers (i.e. the Incomplete Claims Protocol) was breached without notice by HSE PCRS in the case of numbers which are valid for the GP Visit Card Scheme. The agreement in place is that all such incomplete claims are paid and reported on the pharmacy's detailed payment listing, so that the pharmacist is alerted to the fact that the eligibility could not be confirmed, and they and the patient concerned have an opportunity to rectify this.

The IPU therefore welcomes your commitment, given at the JCG, that the HSE PCRS will in future provide two months' notice on the itemised claims listing before ceasing reimbursement of affected claims. This will allow the pharmacist to alert the patient of the need to regularise their situation and/or eligibility prior to next visiting the pharmacy in order to continue to access their medicines. Can you please confirm this process is now in place?

As pharmacists were not notified of any changes to protocol and continued to abide by it, they therefore had a legitimate expectation that they would be reimbursed as before. Can you please confirm as a matter of priority that the HSE PCRS will honour the agreed protocol in place and immediately reimburse our members for claims which were dispensed in good faith and wrongfully rejected?

Finally, we anticipate that in future, the HSE PCRS will at all times consult with us in line with the Relationship Values Charter prior to any proposed changes to current agreements/ arrangements.

Other Government Departments

Regulation on Veterinary Medicinal Products

Secretary General to Minister for Agriculture, Food & the Marine – 12 May 2016

I am writing to you on behalf of the Irish Pharmacy Union (IPU), the representative body for community pharmacists, in connection with the reform of European legislation on veterinary medicinal products proposed by the European Commission.

We are aware of your role in the future Council discussion on the proposal on veterinary medicinal products and we would like to take the opportunity to draw your attention to some issues of crucial importance for us.

1. **Distribution of veterinary medicinal products through the internet**
   The Commission proposal aims at harmonising and removing existing restrictions on the internet sale of prescription medication [Article 108 and recital 56]. We believe Member States should be able to decide whether the internet selling of prescription veterinary medicines is allowed in their territory. The harmonisation of the conditions of supply of veterinary medicines must not jeopardise Member States' competences on health.

   We request that you include in the proposal a right for Member States to prohibit the sale at a distance of prescription veterinary medicinal products. Moreover, we strongly support the approach taken by the Institutions when regulating the sale at a distance of human medicinal products and we ask you to consider the solutions proposed in that legislation [DIRECTIVE 2011/62/EU TITLE VIIA].

2. **Special licences and distribution channels**
   The Commission proposal requires special licences in order to retail anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic veterinary medicinal products [Article 109 § 1]. The right of pharmacists to dispense medicines of this nature without a particular licence is recognised in all European countries. Moreover, it would be absurd if pharmacists were able to dispense

these kinds of medicines for humans under the normal pharmacy licence, but need a specific licence for veterinary medicinal products.

We call for the removal of the need for special licences for pharmacies when supplying and purchasing certain medicines.

In addition, we are concerned by the amendment proposed by the European Parliament (EP) regarding the distribution of non-prescription veterinary medicinal products [Amendment 232]. According to the EP, all retailers, including pharmacies and supermarkets, may sell non-prescription veterinary medicinal products without the need to be specifically authorised to do so. Thus, the EP is harmonising and deciding on the channel of distribution of certain categories of non-prescription veterinary medicinal products. If this proposal is carried, Member States will lose competences on deciding how to organise the distribution of non-prescription medicines.

We ask you to disregard the amendment proposed by the EP on the distribution of certain categories of non-prescription veterinary medicinal products.

3. **Record keeping**
   The Commission proposal [Amendment 229] establishes record keeping obligations when supplying non-prescription and prescription veterinary medicinal products. The obligation to record non-prescription veterinary medicinal products may impose an unnecessary burden on community pharmacies and the proportionality of the measure will need to be assessed at national level.

   We call for the right of Member States to decide whether to require the keeping of records for the supply of non-prescription veterinary medicines.

4. **Recognition of prescriptions**
   In relation to [Amendment 235], the recognition of prescriptions issued for human medicines prescribed for veterinarian purposes needs to be limited to avoid cross border veterinary prescription abuse.

   We call for a derogation to the recognition of veterinary prescriptions issued to cover human medicinal products in the cross border context.

5. **Right to refuse**
   Pharmacists' right to refuse recognition of prescriptions must be clearly stated in the core text of the Regulation [Amendment 236].

   We call for a provision in the core text establishing the right of pharmacists to refuse to dispense a prescription when this is justified on professional or ethical grounds.

We thought it would be helpful to set out our proposed amendments against the current text of the Regulation.

We would welcome an opportunity to meet to discuss these matters further.

Reduction of Price Capitation on Prescription Levy

Secretary General to Minister for Public Expenditure and Reform – 18 October 2016

I write to you on behalf of our members concerns in relation to the decision to reduce the cap on the prescription levy from €25 to €20 to those aged over 70. The IPU has consistently called for an alleviation of the burden of prescription charges from those least able to afford them and welcomes any reduction in fees which will allow easier access to healthcare for GMS patients. Indeed, in our pre-budget submission, we sought that the prescription levy be phased out in its entirety.

The decision to reduce the fee to those over 70, however well-intentioned it may be, is not practical or feasible for pharmacy staff to implement. Pharmacy staff should not be put in a position where they have to establish the age of their older patients at every encounter. The current medical card scheme is standard across all patients and does not discriminate against any card-holder on the basis of age. Problems will arise where families who are entitled to a medical card may have members who fall either side of the age divide. By way of example, the 69-year-old spouse of a 70-year-old will appear as being ineligible for the €5 cap reduction on the current IT system; although they are in fact eligible.

The administrative costs for the HSE to further develop the current IT system, with proper accountable standards, to identify and

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flag those over 70, and their family members, would be wasteful. Equally there would be additional administrative and financial burdens for individual pharmacies to implement this measure. Pharmacy staff will have to check the prescription charge status on their IT system of any medical card holder who appears to be over 70 years of age; this is simply not practical.

The only practical way for the scheme to work is to apply the reduction of €5 to all medical card holders. A cost benefit analysis should be conducted before the introduction of the reduced fee on 1 March 2017 and, to the extent that resources are available to alleviate the burden of this levy, they should be allocated towards exempting the most vulnerable, not simply those who have reached an arbitrary age.

Please contact us if you require any clarification or further information. We are available to meet with you as necessary.

Retail Consultation Forum

Director of Communications & Strategy to Minister for Jobs, Enterprise and Innovation – 7 December 2016

In response to your recent letter requesting members of the Forum to submit material to explain price differentials for customers between prices quoted in Euro and Sterling, I would like to confirm that in retail pharmacy this is not an issue for customers, as all pricing is generally shown in Euro.

However, while on the subject, there is serious concern from IPU members at the impact of a weaker Sterling, particularly for members who trade near the border. While the pharmacies impacted are attempting to compete as best they can, many have indicated to us that it is becoming increasingly difficult, particularly due to the high costs of running a community pharmacy in comparison to our Northern counterparts.

While wages, rents, insurance, energy and local charges are generally in excess of those across the border for all retail businesses, pharmacists have an additional cost in the form of regulatory fees, which places us at a further distinct disadvantage to pharmacies in Northern Ireland. The annual registration fee each pharmacy must pay to the Pharmaceutical Society of Ireland (PSI) is €2,135 (€3,325 on first registration). However, in Northern Ireland the annual registration fee for a pharmacy business is €185 (€135 on first registration), which is only a small fraction of the cost of registration in the Republic of Ireland. Given the demographic and regulatory similarities between the two jurisdictions, there is no satisfactory explanation for this extraordinary disparity.

I have raised this matter a number of times at previous meetings of the Forum.

I am happy to discuss this in greater detail with you at the next meeting of the Forum, if you think it would be helpful.

Directive on a Proportionality Test

Secretary General to Minister for Jobs, Enterprise and Innovation – 4 April 2017

I write on behalf of the Irish Pharmacy Union (IPU), the representative and professional body for community pharmacy, with concerns on the proposed Directive on a proportionality test. We are aware of your role in the future EU Parliament discussion on the proposal for a Directive on a proportionality test and we would like to take the opportunity to draw your attention to some issues of crucial importance to us:

1. **Special nature of healthcare professions**
   The Commission's proposal for the Directive on a proportionality test establishes an EU-wide legally binding framework for Member States' competent authorities to assess the proportionality of the regulation of more than 700 professions including healthcare professions. This is highly surprising given the fact that the European legislator has recognised the special nature of healthcare professions on many occasions in the past, including in the Professional Qualifications Directive and the Falsified Medicines Directive[1]. This was equally recognised by the European legislator during the preparation of the Services Directive which excludes health professions from its scope, by explicitly stating that such a horizontal instrument is not appropriate for health services[2].

   It is also contrary to the European Court of Justice's well established case-law, which acknowledges that it is the right of Member States to determine the

level of protection which they wish to afford to public health and the way in which that level is to be achieved[3]. The need to respect Member States' margin of discretion when assessing whether the principle of proportionality has been observed in the field of public health has been confirmed by such case-law. In particular, the Court of Justice has acknowledged that *"the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate"*[4].

2. Importance of regulation in European health systems

European health systems are consistently ranked among the top performing in the world and are recognised for providing high quality and accessible healthcare services to citizens. Article 168 of the Treaty of Functioning of the EU (TFEU) establishes the need for a high level of human health protection to be ensured in the definition and implementation of all Union policies and activities. In addition, this provision states that the organisation and delivery of health services to citizens is a responsibility of Member States. In general, and unless explicitly defined otherwise, Union action is therefore restricted to a complementary and coordinating function where added value can be achieved.

European health systems, as well as the access to and the practice of healthcare professions, are highly regulated at national level. These provisions are characterised by a high number of obligations and restrictions on the healthcare professionals. The main goal of such provisions is to ensure the highest quality of healthcare and the protection of patients and public health in general.

For instance, in the pharmacy profession, the opening of pharmacies in Ireland is subject to registration requirements and inspection. In addition, all EU countries have reserved certain activities for pharmacists (such as providing advice on use of medicines, dispensing, compounding, etc.). Pharmacists are subject to continuous professional development requirements and professional ethics and supervision, among other obligations. The application of such criteria has proven to be key in the organisation of national healthcare systems and guarantees high quality, safe and accessible pharmacy services throughout the national territory.

Furthermore, cost-containment for public health expenditure (either by the State budget or by Statutory Health Insurance) is an important goal of national regulation in the health sector. These economically specific circumstances of the health sector constitute an outstanding distinction from other economic sectors and call for a different approach.

We believe that Member States should remain fully responsible to define the conditions for access to and practice of healthcare professions, such as pharmacists, as well as to choose the most appropriate method to assess the proportionality and necessity of such requirements. When implementing new regulation for healthcare professions, Member States are best placed to consider the country-specific issues and take into account the interests of patient safety and quality of healthcare. In addition, given that health and life of humans rank foremost among the assets and interests protected by the TFEU, we would like to stress that the objectives of healthcare systems and the regulation of health professions (namely ensuring accessibility and quality) should always take priority.

3. Administrative burden versus evolution of health systems

Member States currently take into account the principle of proportionality in their respective health policies, including regulation of healthcare professions. Accordingly, professional regulation evolves along with the evolution of health systems and scientific developments. This proposal introduces an additional burdensome and time-consuming process which is not adapted to each country's realities and resources and has very limited added value. In addition, it generates a significant degree of legal uncertainty about the adoption of new requirements for the access to and exercise of healthcare professions. We are concerned that the proposal might demotivate Member States from introducing new, or amending existing requirements, which may be necessary and justified on the grounds of public health and in line with scientific and practice developments. Ultimately, this may be detrimental to both patients and public health.

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> In conclusion, we believe that it is not appropriate to address the regulation of healthcare professions, including pharmacists, in a general manner, together with other professions which perform professional activities of varying natures and which are subject to different legislative rules and have completely different safety implications. Healthcare policy decisions relating to the regulation of professions must serve the objective of attaining the best possible quality of care for every patient. Under no circumstances may quality of care, access to care or patient safety be put at risk by decisions driven by other agendas, in particular economic concerns. We therefore ask you to support the exclusion of health professions from the scope of this proposal.

In order to facilitate the reading, please find attached the set of amendments suggested by the IPU.

We would welcome an opportunity to meet with you to discuss the implications of this legislation for pharmacists. I look forward to hearing from you.

1. See Recital 26 of Directive 2005/36/EC "This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States (…)", and Recital 22 of Directive 2011/62/EU "When examining the compatibility with Union law of the conditions for the retail supply of medicinal products, the Court of Justice of the European Union ('the Court of Justice') has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the TFEU and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved (…)".
2. See Recital 22 of Directive 2006/123/EC "The exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided" and Article 2.2 (f) of the same Directive.
3. See, inter alia, judgement of the Court of 19 May 2009 in joint cases C-171/07 and C- 172/07 Apothekerkammer des Saarlandes and Others v Saarland, judgement of the Court of 19 May 2009 in Case C-531/06 Commission v Italian Republic and judgement of the Court of 11 September 2008 in Case C-141/07 Commission v Federal Republic of Germany.
4. Judgement of the Court of 11 September 2008 in Case C-141/07 Commission v Federal Republic of Germany (paragraph 51).

Manufacturers

Neupro® Distribution Policy – Impact on Pharmacists

Secretary General to Managing Director for the British and Irish Isles, UCB Pharma Ltd – 27 June 2016

The Irish Pharmacy Union is the representative and leadership body for community pharmacists, with a membership comprising approximately 2,200 pharmacists and more than 1,700 pharmacies. We have been informed by members that they have encountered a problem with the distribution arrangement for your product Neupro®.

The Health Service Executive (HSE) sets the price which they will pay to pharmacies for medicines dispensed on behalf of the State, based on a fixed margin above a notional ex-factory price. Manufacturers then typically provide their products to wholesalers at a price which allows the wholesalers to supply them to pharmacies at a net cost which takes account of the HSE reimbursement price. It appears, however, that under your distribution arrangement this is not the case.

There are only two full-line pharmaceutical wholesalers in Ireland, United Drug and Uniphar. Your company has chosen to distribute Neupro® through only one of those wholesalers, United Drug, which does not offer discounts to pharmacies which do not use it as their primary wholesaler. As a result, many pharmacies are paying a net price for Neupro® which exceeds the reimbursement price paid by the HSE. The details are below.

This places some of our members at a considerable disadvantage when dispensing these items on the State's community drug schemes. Because the price charged to them by the wholesalers for this product exceeds the HSE reimbursement price, the pharmacy suffers a loss on each occasion they dispense Neupro®. Given the tight margins that already exist in community pharmacies, these kinds of losses are not sustainable.

We would welcome your proposals to address this issue.

Tradename	Pack Size	Agent	Trade Price	Reimbursement Pr	Gmsno
NEUPRO 1MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	113.48	109.41	44528
NEUPRO 2MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	110.62	106.66	37915
NEUPRO 3MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	154.59	149.05	44529
NEUPRO 4MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	123.44	119.03	37942
NEUPRO 6MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	148.95	143.63	37957
NEUPRO 8MG/24HR TRANSDERMAL PATCH	28PATCH	U DRUG	171.77	165.7	37998

IPHA/DoH/HSE Framework Agreement on the Pricing and Supply of Medicines

Secretary General to Manufacturers – 23 August 2016

I wish to refer to the recent agreement which your company, as a member of the Irish Pharmaceutical Healthcare Association (IPHA), has entered into with the Department of Health and the Health Service Executive.

This agreement has brought about reductions in the prices of medicines supplied by your company. Our members are concerned about the impact of these reductions on the value of their stocks of medicines which had been purchased prior to the implementation of the agreement at the prevailing price and which, as a consequence of this agreement to which they were not party, will now be reimbursed at the new, lower, price. At this point, they are anxious to establish what steps your company intends to take to compensate them for the significant losses which they incurred as a result of the overnight devaluation in their stocks of the affected medicines.

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

I look forward to hearing from you.

OFEV® Distribution Policy – Impact on Pharmacists

Secretary General to General Manager, Boehringer Ingelheim Limited – 18 January 2017

The Irish Pharmacy Union is the representative and leadership body for community pharmacists in Ireland, with a membership comprising approximately 2,200 pharmacists and more than 1,700 pharmacies. We have recently been informed by our members of an issue with the distribution arrangement for your product OFEV® (nintedanib).

It is reported to us that patients have been advised by their consultant to go to their chosen pharmacy where they can collect the medicine "free of charge". It is noteworthy that you have not consulted with the pharmacy profession, the benefit of whose premises and professional services you presume to secure free gratis. Given the tight margins that already exist in community pharmacies and the significant professional and regulatory obligations which pharmacists must comply with, this kind of free service is simply not sustainable.
Pharmacists are healthcare professionals whose primary concern is the health and wellbeing of their patients. However, their time has a value and their professional services come at a cost. As such, it is presumptuous of you to assume that pharmacists would be prepared to provide their services free of charge in order to facilitate the particular reimbursement arrangements which your company wished to secure with the HSE.
It is a matter for each pharmacist to decide whether or not to charge for their services and, if so, to set the amount themselves. If it is your position that you do not wish to compensate the pharmacists for providing a dispensing service on your behalf then, in the interests of providing accurate information to patients, please make it clear in your written information to prescribers and patients that a charge may apply at the pharmacy.

If you believe it would be helpful, we would be pleased to discuss these issues with you further.

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Other Matters

Forged Prescriptions

Secretary General to Chief Executive, Medical Council – 3 October 2016

The Irish Pharmacy Union is the professional representative organisation for community pharmacists in Ireland, with a membership of 2,200 pharmacists working in over 1,700 pharmacies nationwide.

The IPU regularly receives notifications from community pharmacists, GPs and hospitals of forged or alleged forged prescriptions and of thefts of prescription notepaper. We disseminate this information to all of our members through our weekly eNewsletter and monthly General Memorandum in order to alert them to the specific incidences and reduce the risk of medicines being supplied on foot of a non-genuine prescription.

Over the past few months, there has been a significant increase in the number of forged or alleged forged prescriptions reported to us. I am bringing this matter to your attention as I thought it may be of interest to you. For your information, I attach a copy of all reports received during September and October 2016.

Please don't hesitate to contact me if you believe further discussion on this matter would be helpful.

APPENDIX III
A LIST OF PRESS RELEASES ISSUED TO THE MEDIA SINCE THE 2016 AGM

2016

May

9 IPU calls on new government to commit to expansion of role of pharmacists in Programme for Government

11 Pharmacists issue warning on Hay Fever and offer tips to help minimise symptoms

15 Statement in response to Sunday Business Post re 'GPs to slash drug prices by cutting out pharmacies'

June

1 Exam stress impacting students' health

9 Pharmacists warn that buying prescribed medicines online or from an unauthorised source can have potentially lethal consequences

14 Pharmacists Urge Men to Tackle Health Concerns

29 Nominate your Pharmacist for Pharmacist of the Year

30 Statement in response to Owings

July

1 New pharmacy-based Minor Ailment Scheme for medical card patients

18 Pharmacists welcome proposed cut in medicine prices

19 Pharmacists issue Safety Guidelines to Stay Safe in the Sun

20 IPHA AGREEMENT: Pharmacists Welcome Deal to Lower Medicine Prices

29 Brexit Vote in UK has Hit Business Confidence in the Irish Pharmacy Sector

August

24 Back to School – Pharmacists' Advice on Treating Head Lice

September

1 Pharmacists Offer Healthcare Tips to Electric Picnic Fans

6 Actavis Academy Training & Mentoring Bursary

29 Avoid the flu and get the vaccine - Pharmacists urge patients in at-risk category to get the flu vaccine

October

6 Pharmacists call for €2.50 Prescription Levy on Medical Card Holders to be Phased Out (Budget 2017)

11 Budget 2017: Pharmacists Welcome Small Movement on Prescription Levy, but Criticise Minimal Progress on Programme for Government Commitment

APPENDIX III
CONTINUED

November

4 Business Confidence among pharmacists continues to decline with many stating business environment is worsening

13 Pharmacists warn that antibiotic resistance is one of the most significant threats to patient safety in Ireland

18 Pharmacists warn drivers to be aware of possible dangers when taking prescribed medications

23 IPU Welcomes Call by the Pharmacy Regulator to Expand the Role of Pharmacists in Healthcare Delivery

December

9 Pharmacists reporting spike in respiratory and flu-like symptoms in last two weeks

15 Pharmacists Warn of the Dangers of Mixing Alcohol with Medicines

30 Thinking about New Year Resolutions?

2017

January

3 Pharmacists Advise Patients to get Flu Vaccination in Response to Significant Increase in Flu Rates

19 Crime against Pharmacies Reaching Crisis Levels

26 IPU joins with Operation Transformation to offer FREE blood pressure measurements in pharmacies

27 IPU urges Motorists to talk to their Pharmacist before Driving on Prescription Medication

February

28 National No Smoking Day: Pharmacists offer help to those wanting to stop smoking

28 IPU welcomes reduction in prescription levy for those aged 70 and over as 'only a first step' in necessary reforms

March

22 Pharmacists warn parents of health risks when giving medicines to children

27 Pharmacists Team Up with HSE to Promote Dementia Understand Together Campaign

30 IPU and eHealth Ireland launch Healthmail service for community pharmacy

April

12 IPU urges Motorists to talk to their Pharmacist before Driving on Prescription Medication

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