

## Public Consultation on the draft Pharmaceutical Society of Ireland (Fees) Rules 2014

### Submissions

No.	Name of Individual and Organisation	Pg
1.	Maríosa Kieran B.Sc. (Pharm), MPSI, M.Sc., Clinical Pharmacy Service Manager, Pharmacy Department, Mater Misericordiae University Hospital, Eccles St., Dublin 7	2
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13.	David Jordan, MPSI	13

No.	SUBMISSION	PSI RESPONSE
1.	<p data-bbox="275 233 632 256"><b>Maríosa Kieran B.Sc. (Pharm), MPSI</b></p> <p data-bbox="275 293 1188 316">I wanted to feedback some comments on the draft PSI rules published on the society website;</p> <ul data-bbox="323 354 1199 667" style="list-style-type: none"> <li data-bbox="323 354 1199 467">• The fees for first registration seem to be somewhat unfair considering that a high number of first applicants have just completed 5 years of training and have not been paid a professional salary. Could first registration fees not be equal to continued registration fees?</li> <li data-bbox="323 558 1199 667">• Is there a facility to reduce payment depending on when in the calendar year registration is completed? For example, if a pharmacist is registering for the first time in August, they have to pay €540 and then €380 again in December, which seems quite unfair.</li> </ul>	<p data-bbox="1241 329 1997 529">First time registration of an applicant, either through the national, EU or Third country route, encompasses both a recognition and registration activity from an administrative perspective. The fees are structured to recognize that a pharmacist who continues his/her registration is submitting an application on the basis of there being no change to the previous information supplied, and assessed. Hence the continued registration fee is lower than first time registration.</p> <p data-bbox="1241 561 1997 643">Registration fees are levied on an annual basis rather than a calendar basis - if a pharmacist registers on the 1<sup>st</sup> August 2014 their registration fee covers the registration period up until 31<sup>st</sup> July 2015.</p>
2.	<p data-bbox="275 708 447 730"><b>Niamh Gallagher</b></p> <p data-bbox="275 768 1209 816">I was reading the draft fees consultation and wondered if perhaps the registration fees for pharmacists might be taken down inline with the fees charged in the UK for registration @£240.</p> <p data-bbox="275 854 1178 967">Also, maybe consider people who are working part-time and take that into consideration for their fees or if they have taken a few months off where they weren't practising i.e. sick leave, maternity leave etc. And for busier pharmacies maybe they should pay more than quieter pharmacies?</p> <p data-bbox="275 976 436 998">Just a few ideas,</p>	<p data-bbox="1241 768 2007 881">Noted. Council have decided on the policy position of a fee reduction of 5% on the basis of an evidence based assessment of the activity of the organisation required under statute and the funding required to deliver on this obligation. Fees are continually kept under review by the PSI.</p> <p data-bbox="1241 914 2007 1174">The Pharmacy Act provides for a system of annual registration and an active Register only, and as such in order for a person's name to remain on the Register of Pharmacists or Retail Pharmacy Businesses, the person must apply for continued registration and pay registration fees on an annual basis. The current legislation implementing Government policy has not provided a facility or framework for registrants to remain on a divisional register either in a non-practicing capacity or occasional practice basis, or deliver services on an occasional or sessional basis. While this point is noted, the Act does not envisage pro-rata payments for defined time periods of active practice.</p>
3.	<p data-bbox="275 1211 415 1234"><b>Glyn Ratcliffe</b></p> <p data-bbox="275 1271 1199 1385">In the economic climate that pervades, whilst the fee reduction is most certainly welcome, is there not room for the fee to be paid in instalments? I for one would be happy to pay even in advance for the following year. For example to pay in 10 instalments throughout 2015 with the final payment received at the same time the whole fee would normally be due for 2016.</p>	<p data-bbox="1241 1271 1976 1385">Noted – The Pharmacy Act provides for a system of annual registration with certification issued for a full 12 month period. On this basis it is difficult, under the current framework of the Pharmacy Act, to envisage how the operation of an instalment payment system currently would be feasible.</p>

	<p>It may not seem an extremely large sum but coming as it does on top of Christmas, it is significant.</p>	<p>The PSI is mandated in legislation to levy registration fee 60 days before the expiry of the mandatory Certificates of Registration, which may occur at any date depending on the date of first registration. PSI does not have an entitlement to mandate payment at any earlier or other date.</p>
<b>4.</b>	<b>Michael Wade</b>	
	<p>I am glad to see that the PSI are providing this opportunity to contribute to the discussion on fees. I sincerely hope that the PSI will genuinely consider the opinions expressed here.</p> <p>Since the current recession took hold, remuneration to community pharmacies from private and community drug schemes has been severely reduced, as had customer discretionary spend. Everyone has been affected yet the PSI has refused to reduce the outrageously high fees charged for individual membership and registration of a pharmacy premises. The comparable rates charged by our nearest neighbours are up less than a 1/4 of the current fees charged in Ireland. Please take the opinions seriously as sent to this e-mail address and give them favourable consideration as this recession will remain until 2019 at least, according to recent reports in the National media.</p>	<p>Noted.</p> <p>PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge those functions and duties. The funding required to deliver on these legislative obligations is obtained through registration fees. The PSI is an independent professional regulator with full accountability to the State for effective regulation, with the registration fees it collects being the sole means by which the operational costs of the organisation are met. The State does not provide any direct funding to PSI to deliver on its regulatory mandate. In 2010, following an internal review of fees and the cost of regulation, the PSI Council sought a reduction in continued registration fees of approximately 10% for pharmacists, pharmaceutical assistants and pharmacies, which was subsequently approved by the Minister for Health. It is now seeking an additional reduction of 5%.</p> <p>It is important to note that the regulatory functions delivered by pharmacy regulators in other jurisdictions differ considerably in scope and range; for example in Northern Ireland the investigative and enforcement activity is carried out by the Northern Ireland Department of Health, Social Services and Public Safety rather than the Pharmaceutical Society of Northern Ireland. On that basis the funding requirements differ greatly.</p> <p>The fees are continually kept under review by the PSI.</p>
<b>5.</b>	<b>Louise McDonnell, MPSI</b>	
	<p>I would like to make two points on the fees charged by the PSI for membership.</p> <p>The first is that €380 per member is excessive and not comparable to other licensed professions.</p>	<p>Noted. Nationally a range of annual licensing/registration fees apply with</p>

	<p>Is there public access to the accounts of the PSI to prove that this amount is necessary?</p> <p>The second is that I believe there should be an option to pay a monthly standing order for PSI fees to avoid the need for Pharmacists finding this huge sum of money before christmas. We are not earning what Pharmacists used to earn in times past.</p>	<p>Doctors under 65 years paying €535, nurses paying €100; dentists paying €200, and Veterinary Practitioners paying €390.</p> <p>The PSI publishes its Annual Report and Financial Statement regarding its activities throughout the previous year. The Annual Report and Financial Statements of the PSI are published on the PSI's website and are made publicly available.</p> <p>The Pharmacy Act provides for a system of annual registration with certification issued for a full 12 month period. On this basis it is difficult, under the current framework of the Pharmacy Act, to envisage how the operation of an instalment payment system currently would befeasible.</p> <p>Also, the PSI is mandated in legislation to levy registration fee 60 days before the expiry of the mandatory Certificates of Registration, which may occur at any date depending on the date of first registration. PSI does not have an entitlement to mandate payment at any earlier or other date.</p>
<p><b>6.</b></p>	<p><b>David Carroll</b></p>	<p>PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge those functions and duties. Under the Pharmacy Act 2007, the PSI is responsible for:</p> <ul style="list-style-type: none"> <li>• prescribing the qualifications required for practice and accredit and monitor educational institutions and degrees, courses of studies, or programmes;</li> <li>• registering pharmacists, pharmaceutical assistants and pharmacies, and maintain the registers;</li> <li>• ensure compliance by pharmacists, pharmacy owners, and others, with the pharmacy and medicines laws of the State, through inspection and enforcement including the taking of prosecutions;</li> <li>• provision of advice, guidance and direction to pharmacists and pharmacy owners when required;</li> <li>• setting standards of professional competence and ethical conduct;</li> <li>• reviewing and promote the competence and conduct of pharmacists;</li> <li>• recognising, accrediting, and setting programmes of education and training to ensure the ongoing competence of pharmacists;</li> <li>• receiving and acting on complaints and information about the competence and conduct of pharmacists and pharmacy owners;</li> <li>• conducting inquiries into complaints and impose sanctions as</li> </ul>

	<p>The PSI should use the large cash reserves it currently has to fund operations over the coming years and should set fees at a more modest and appropriate level.</p>	<p>appropriate;</p> <ul style="list-style-type: none"> <li>• working with other bodies about matters of mutual concern, patient safety and the public interest;</li> <li>• providing information and guidance to the public and to the political system on matters relating to our statutory functions;</li> <li>• reporting and being accountable to the Minister for Health, the Department of Health, and to the Oireachtas.</li> </ul> <p>PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge all of those functions and duties. The funding required to deliver on these legislative obligations is obtained mainly through registration fees. The PSI is an independent professional regulator with full accountability to the State for effective regulation, with the registration fees it collects being the sole means by which the operational costs of the organisation are met. The State does not provide any direct funding to PSI to deliver on its regulatory mandate. In 2010, following an internal review of fees and the cost of regulation, the PSI Council sought a reduction in continued registration fees of approximately 10% for pharmacists, pharmaceutical assistants and pharmacies, which was subsequently approved by the Minister for Health. It is now seeking an additional reduction of 5%.</p> <p>The funding required to deliver on these legislative obligations is obtained through registration fees, and the State does not provide any direct funding to PSI to deliver on its regulatory mandate.</p> <p>In establishing appropriate fee levels the PSI undertook in 2008 an evidence-based methodology for the determination of pharmacist and pharmacy registration fees. This included a review of national and international comparator organisations. This analysis showed that in comparison with other national and international regulatory bodies the PSI has a unique regulatory profile with onerous legal responsibilities and duties. It is important to note that the regulatory functions delivered by pharmacy regulators in other jurisdictions differ considerably in scope and range; for example in Northern Ireland the investigative and enforcement activity is carried out by the Northern Ireland Department of Health, Social Services and Public Safety rather than the Pharmaceutical Society of Northern Ireland. In the UK the General Pharmaceutical Council is responsible for regulatory function including inspection and enforcement, and the Royal Pharmaceutical Society of Great Britain provides professional guidance and support with registration fees are levied separately by both organisations. On that basis the funding requirements differ greatly.</p>
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	<p>Failure to do so will mean that many pharmacists working in non patient facing roles will allow their membership to lapse. The psi will therefore lose access to the skills, knowledge and experience of these pharmacists. This would not be in the public interest.</p>	<p>The fees are continually kept under review by the PSI.</p> <p>Currently, the PSI collects the bulk of its income in the November/December period as the great majority of its registration fees then become due. Its cash on hand therefore peaks at the end of the year and is used throughout the following year to fund the PSI's statutory functions. This is reflected in the cash figure in the PSI balance sheet in the annual accounts. The annual PSI Service Plan contains a budget which is based on activities for the year outlined in the plan and having regard to the Corporate Strategy of the organisation. The annual budgeted expenditure is based on costed projected activities for the year ahead which are generally balanced with the projected income for the same period.</p> <p>The PSI publishes an Annual report on its activities throughout the previous year which contains a Financial Report for the calendar year accompanied by Financial Statements. The PSI Annual Reports and Financial Statements are published on the PSI website and made publicly available.</p> <p>It may be noted from the information contained in the Annual Report 2012 (<i>publication of the Annual Report 2013 is imminent</i>) that the PSI held deferred income of €6.016 million (registration fees paid at the end of 2012 to fund PSI functions during 2013); it held a designated legal reserve fund of €2.5million (a fund, approved by Council, to protect against the need to increase registration fees in the event of legal challenges to the PSI in carrying out its statutory functions); a superannuation fund of €1.965 million (retained to comply with legislative obligations under the Pharmacy Act 2007), a surplus of €0.438 million (<i>see below</i>) after the disposal of property assets, and unrestricted cash of 1.816 million.</p> <p>In previous years the PSI had an excess of income over expenditure for reasons including delays in obtaining approval and consequential non-filling of projected staff posts and the delay in the commencement of the Irish Institute of Pharmacy.</p> <p>This was taken into account by the Council when arriving at its decision in relation to the fee reduction.</p> <p>This concern is noted.</p>
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<p><b>7.</b></p>	<p><b>Tim Kyne</b></p> <p>I wish to raise an objection to the fact that fees are payable at least one month before the years registration ceases and late fees are applied at that date.</p> <p>Most other bodies allow a one months grace period after registration is due , require backdating of fees to when they were due but don't apply a penalty until the grace period has passed. Why can the PSI not apply this approach?</p>	<p>Noted. The current legislative provision is that fees are levied sixty days in advance of the expiry date of the mandatory certificate of registration and which must be current. Payment must be made thirty days before the expiry date. This payment is required to form part of the submission of an annual application for Continued Registration.</p> <p>The process by which fees are charge is defined in the Pharmaceutical Society of Ireland (Registration) Rules (SI No. 494 of 2008). The majority of applications for registration and continued registration are made in accordance with the process and timeframes specified and in this context the application of penalty fees does not arise.</p> <p>Nationally other health regulatory authorities may operate varying deadlines and systems around payment of fees and application of penalty fees as determined by the relevant legislative position in their particular circumstances.</p> <p>A change in the due dates of fees would require further legislative change, including to the Pharmaceutical Society of Ireland (Registration) Rules (SI No. 494 of 2008).</p>
<p><b>8</b></p>	<p><b>Clodagh Cassidy</b></p> <p>I believe that the fees charged by the PSI to be far too high. In the interest of fairness I believe the cuts to fees should be far greater than the proposed 5%.</p> <p>The rates charged for registration of a pharmacist should be cut by at least 50% for continuing registration. This would make it a similar level to that being charged in the UK.</p>	<p>Noted. Council have decided on the policy position of a fee reduction of 5% on the basis of an evidence based assessment of the activity of the organisation as required under statute and the funding required to deliver on this obligation. In 2010, following an internal review of fees and the cost of regulation, the PSI Council sought a reduction in continued registration fees of approximately 10% for pharmacists, pharmaceutical assistants and pharmacies, which was subsequently approved by the Minister for Health</p> <p>PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge those functions and duties. The funding required to deliver on these legislative obligations is obtained mainly through registration fees. The regulatory services delivered by regulators in other jurisdictions may appear similar, but may also differ in scope and range; for example in the UK the General Pharmaceutical Council is responsible for regulatory function including inspection and enforcement, and the Royal Pharmaceutical Society of Great Britain provides professional guidance and</p>

<p>I think it is very wrong that first time registrations are charged at a higher level. Newly graduated pharmacists are usually unemployed and often have large student debts and it is wrong to charge them €540. As new graduates the PSI should be supporting them for their first few years working in the profession and allow them on the register at a far reduced fee, or simply a nominal fee. It is very wrong that new graduates should have to borrow money to register with the PSI as is the case for many at the moment. I suggest a fee of €50 for the first 2 years of their professional career.</p> <p>I believe there should be reduced fees for pharmacists that are temporarily out of work, on sick leave, unemployed or on maternity or parental leave.</p> <p>All of the other fees charged by the PSI are far too high and I cannot see how they can be justified.</p> <p>For example to change the name of a pharmacy business with the PSI is €200, this is a fee to simply make an clerical change on the official register and issue a small certificate, a process that somehow takes the PSI many months to complete. The Companies Registration Office charge €20 for the same job and issue a new certificate within 10 days.</p>	<p>support. Registration fees are levied separately by both organisations. The fees levied by PSI with the approval of the Minister, are continually kept under review by the PSI.</p> <p>Noted. See also response to Submission No. 1 above. The approach proposed, whereby new graduates pay a lesser fee for a number of years would require a significant legislative change, but could be examined by the PSI Council. However, it should be noted that such an approach would result in other registered pharmacists and pharmacy owners essentially subventing the registration of new graduates. Parity would not apply.</p> <p>The Pharmacy Act provides for a system of annual registration. The Act does not allow for a part-time/reduced activity register.</p> <p>Fees are continually kept under review by the PSI. In 2008 the PSI commissioned an extensive review of its functions arising from the implementation of the Pharmacy Act 2007. The process was informed by a review of national and international comparator organisations (professional services and healthcare sectors); comparator analysis and benchmarking of international pharmacy regulators; review of the PSI current and projected costs associated with implementation of the Pharmacy Act 2007 and ongoing regulation of the sector; and consultation with national stakeholders. Arising from this extensive review the fees for registrants were set by the Council of the PSI and subsequently approved by the Minister for Health.</p> <p>The fee of €200.00 is a statutory fee in accordance with S. I. No. 495 of 2008 Pharmaceutical Society of Ireland (Retail Pharmacy Business) (Registration ) Rules, Rule 6 (1) (b) and S.I. No. 496 of 2008 Pharmaceutical Society of Ireland (Fees) Rules 2008. The change of pharmacy name is usually processed as soon as possible after receipt of the notification. Changes in trading name are dealt with under “Material change procedure”.</p> <p>Once the material change request, that involves a change of name, has been processed, the necessary certificate of registration is issued for the RPB in question.</p>
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<p><b>9.</b></p>	<p><b>Sheena Parker</b></p> <p>I wondered if it could be possible to give the option of paying the registration fees by direct debit on a monthly basis? I'm sure I'm not the only pharmacist who struggles to pay the fees in one lump sum...</p>	<p>The Pharmacy Act provides for a system of annual registration with certification issued for a full 12 month period. On this basis it is difficult, under the current framework of the Pharmacy Act, to envisage how the operation of an instalment payment system currently would be feasible.</p> <p>Also, the PSI is mandated in legislation to levy registration fee 60 days before the expiry of the mandatory Certificates of Registration, which may occur at any date depending on the date of first registration. PSI does not have an entitlement to mandate payment at any earlier or other date.</p> <p>If legislative change were to occur to facilitate this it may also be that instalment payments would incur an additional charge on a registrant to provide for the consequent increase in administrative costs.</p>
<p><b>10.</b></p>	<p><b>Thomas Doody</b></p> <p>This proposal to reduce fees by 5% is to be welcomed and I hope it will be delivered. I would also suggest that the fees could indeed be reduced further at a future date.</p>	<p>Noted. The fees are continually kept under review by the PSI.</p>
<p><b>11.</b></p>	<p><b>IPU</b></p> <p><b>1. Introduction</b></p> <p>The Irish Pharmacy Union (IPU) is the representative and professional body for community pharmacists. Its mission is to promote the professional and economic interests of its members. Members of the IPU aim to provide the best possible professional pharmacy service to all members of the public. They are committed to delivering a quality, accessible, personal and professional service that puts the patient first and has as its primary goal the optimisation of the health and well-being of society. Pharmacists are accountable for their professional conduct and strive to maintain the confidence and respect of their patients, customers, the State and other professionals in the healthcare field.</p> <p>The IPU welcomes the opportunity to make a submission to the Pharmaceutical Society of Ireland (PSI) on its Draft Pharmaceutical Society of Ireland (Fees) Rules 2014</p> <p><b>2. PSI Registration Fees</b></p> <p>The IPU recognises the importance of effective and transparent regulation; however, the cost of complying with all pharmacy professional and business regulations, not just those related to</p>	<p>Noted</p> <p>Noted. The PSI is cognisant that fees of registrants must reflect the cost of</p>

the PSI fees, is a significant burden for community pharmacies. Furthermore, retail sales in pharmacies, measured by both volume and value, have fallen to a greater extent in the last twelve months than have sales in any other retail channel, as shown in the Central Statistics Office figures. As a result, many pharmacists currently face grave financial pressures, a point which was acknowledged in the ESRI report entitled *Pharmaceutical Pricing, Prescribing Practices and Usage of Generics*.

The cost of registration with the PSI is out of line with international comparisons. As shown in Table 1 below, the new proposed registration fees for pharmacists and pharmacies are still well in excess of those in other similar jurisdictions. The IPU has been calling for a reduction in PSI fees since the introduction of the Pharmacy Act 2007; we consider the current proposal to reduce registration fees by 5% to be derisory.

A Table included in submission document entitled **Regulatory body fees comparison 2013**

**Source: Grant Thornton 2013**

	Ireland	United Kingdom	Australia	Canada	New Zealand
Regulating Body	Pharmaceutical Society of Ireland	General Pharmaceutical Council	Pharmacy Board of Australia	National Association of Pharmacy Regulatory Authorities	Pharmacy Council of New Zealand
Community Pharmacies	1,701	13,949	5,325	8,925	967
Pharmacists registration - initial fee	€570	£342	\$477	\$250 - \$980	\$345
Pharmacists registration - renewal fee	€400	£240	\$317	\$100-\$975	\$506
Operating license - initial	€3500	£789	\$486-\$1300	\$550-\$1400 + taxes	\$1053 + taxes
Operating license - renewal	€2,250	£221	\$292 - \$500	\$650-\$1400 + taxes	\$1053 + taxes

regulation and of its responsibilities to manage its resources cost effectively and prudently and continually works to maximise efficiencies.

In 2008 the PSI commissioned an extensive review of its functions arising from the implementation of the Pharmacy Act 2007. The process was informed by a review of national and international comparator organisations (professional services and healthcare sectors); comparator analysis and benchmarking of international pharmacy regulators; review of the PSI current and projected costs associated with implementation of the Pharmacy Act 2007 and ongoing regulation of the sector; and consultation with national stakeholders. Arising from that extensive review the fees for registrants were set by the Council of the PSI and were subsequently approved by the Minister for Health.

In 2010, following an internal review of fees and the cost of regulation, the PSI Council sought a reduction in continued registration fees of approximately 10% for pharmacists, pharmaceutical assistants and pharmacies, which was subsequently approved by the Minister for Health.

PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge those functions and duties. The funding required to deliver on these legislative obligations is obtained mainly through registration fees. The regulatory services delivered by regulators in other jurisdictions may appear similar, but may also differ in scope and range. On that basis alone the funding requirements would differ greatly and it is difficult to make direct comparison. By way of example

- the Medical Council does not maintain a register of premises and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation,
- the Dental Council does not have an inspection remit and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation,
- in the UK the General Pharmaceutical Council is responsible for regulatory function including inspection and enforcement, and the Royal Pharmaceutical Society of Great Britain provides professional guidance and support,
- in Northern Ireland the investigative and enforcement activity that is carried out by the PSI is conducted by the Department of Health, Social

	<p><b>3. Payment by Instalment</b></p> <p>The IPU has previously requested that the PSI reviews the current payment methods for payment of registration fees for both pharmacists and pharmacies. A number of registrants have indicated, for administrative purposes and for cash flow reasons, that they would like the option of paying the annual registration fee in instalments by direct debit. We see no reason why this could not be facilitated within the draft Fees Regulations.</p> <p><b>4. Pharmacy Interns</b></p> <p>Whilst we welcome that the fee payable for attending programmes of education and training for tutor pharmacists has been abolished, we have significant concerns that the PSI proposes to increase the fee payable in connection with an application to undertake the in-service practical training programme from €1,500 to €2,750. This is an extraordinary increase for pharmacy students to have to shoulder and we would ask that the PSI reconsiders this.</p>	<p>Services and Public Safety.</p> <p>There is a particular cost associated with the delivery of a regulatory service. PSI obtains funding through registrant fees. Economies of scale apply when a larger proportion of registrants fund the model. The principle of the PSI application of fees is to recover costs based on who causes the cost or who benefits and is subject to the activities undertaken</p> <p>Council have decided on the policy position of a fee reduction of 5% on the basis of an evidence based assessment of the activity of the organisation as mandated under statute and the funding required to deliver on this obligation.</p> <p>Noted – current legislation provides for a system of annual registration with certification issued for a year, and on this basis it is difficult to envisage how the operation of an instalment payment system currently would be feasible. If legislative change were to occur to facilitate this it may also be that instalment payments would incur an additional charge on a registrant to provide for the consequent increase in administrative costs. Historically and prior to the commencement of the Pharmacy Act 2007 the old PSI operated a system whereby pharmacists were provided with the option of paying their annual fee via Direct Debit. This system however proved to be administratively burdensome, was not utilised by any significant portion of the Register and in certain situations resulted in double payment issues which was inappropriate needed to be resolved. The system was discontinued as a result of the inefficiencies associated both with its delivery, and uptake. With the introduction of the Single European Payment Area (SEPA) and Government plans to shortly phase out the use of cheques, the PSI is examining and developing the option of offering a “Single Direct Debit Payment” facility to Registrants. It is hoped to progress this in early 2015.</p> <p>The fee paid by students to undertake the in-service practical training programme is linked to the annual student contribution for third level students, as determined by the Department of Education. PSI recognizes the impact this may have on students and in this context it is Council policy not to charge the relevant fee to undertake the Professional Registration Examination.</p>
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	<p><b>5. PSI Reserves</b></p> <p>The PSI Annual Report for 2012 (the 2013 Report not yet having been published) indicates that the PSI had an operating surplus in 2012 of €1,627,250 and net funds at the end of the year of €12,735,080. This level of wealth is neither appropriate nor necessary for a statutory regulator and provides further evidence that the excessively high level of fees levied on pharmacists and pharmacies by the PSI is not necessary for the proper functioning of the organisation.</p> <p><b>6. Conclusion</b></p> <p>In conclusion, we consider that it is essential that the PSI reduces the proposed fees significantly for 2014 and beyond, as the current and proposed fee levels are no longer sustainable or, indeed, even necessary.</p> <p>We are available to meet with the PSI to discuss the issues raised above or, indeed, any other relevant issues.</p>	<p>The PSI collects the bulk of its income in the November/December period each year as registrations fees become due. Its cash on hand therefore peaks towards year end. This is reflected in the cash figure in the PSI balance sheet in the annual accounts. The annual PSI Service Plan contains a budget which is based on activities for the year outlined in the plan and having regard to the Corporate Strategy of the organisation. The annual budgeted expenditure is based on costed projected activities for the year ahead which are generally balanced with the projected income for the same period. In previous years, the PSI had an excess of income over expenditure for a variety of reasons including delays in obtaining approval and consequential non-filling of staff posts and the delay in the commencement of the Irish Institute of Pharmacy.</p> <p>It may be noted from the information contained in the Annual Report 2012 (<i>publication of the Annual Report 2013 is imminent</i>) that the PSI held deferred income of €6.016 million (registration fees paid at the end of 2012 to fund PSI functions during 2013); it held a designated legal reserve fund of €2.5million (a fund to protect against the need to increase registration fees in the event of legal challenges to the PSI in carrying out its statutory functions); a superannuation fund of €1.965 million (retained to comply with legislative obligation under the Pharmacy Act 2007), a surplus after the disposal of property assets of €0.438 million and unrestricted cash of €1.816 million.</p> <p>All of this was taken into account by the Council when arriving at its decision in relation to the fee reduction.</p> <p>Noted</p> <p>Noted – PSI engages with the IPU and other organisations on all matters pertinent to its legislative remit.</p>
<b>12.</b>	<b>Boots Ireland</b>	
	<p>Boots is a leading provider of pharmacy services in Ireland, employing over 220 pharmacists in 75 registered retail pharmacy businesses across the country. We are committed to the provision of pharmacy services to the highest standards and welcome the opportunity to</p>	<p>Noted</p>

	<p>contribute to the cost of regulation of the pharmacy sector.</p> <p>Boots Ireland welcomes the proposed reduction of fees payable in respect of registration of pharmacists, retail pharmacy businesses and pharmaceutical assistants. However, it is submitted that the proposed registration fees remain excessively high, particularly in respect of the fees for the registration of retail pharmacy businesses. The proposed annual retention fee for a retail pharmacy business of €2,135.00 greatly exceeds the comparable fee in other jurisdictions, including in the United Kingdom where the equivalent fee is £221<sup>1</sup>. While it is acknowledged that a robust system of regulation for pharmacists and pharmacies has been a positive development which will allow for future expansion of the role of the pharmacist to additional pharmacy services, the cost of such a system of regulation must be proportionate</p> <p><sup>1</sup> <a href="http://www.pharmacyregulation.org/renew-pharmacies">http://www.pharmacyregulation.org/renew-pharmacies</a> [Accessed 4 July 2014]</p>	<p>PSI functions and duties are specified in the Pharmacy Act 2007 and the PSI has a statutory duty to discharge those functions and duties. The funding required to deliver on these legislative obligations is obtained mainly through registration fees. The regulatory services delivered by regulators in other jurisdictions may appear similar, but may also differ in scope and range. In 2008 the PSI commissioned an extensive review of its functions arising from the implementation of the Pharmacy Act 2007, in order to inform and assist in the determination of the appropriate fee levels. This review identified that in examining the range of responsibilities of regulators both nationally/internationally within the professional and healthcare sectors at that time, the PSI appeared to have a unique regulatory profile with onerous responsibilities and duties.</p> <p>On that basis alone the funding requirements would differ greatly and it is difficult to make direct comparison. By way of example</p> <ul style="list-style-type: none"> <li>• the Medical Council does not maintain a register of premises and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation</li> <li>• the Dental Council does not have an inspection remit and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation</li> <li>• in the UK the General Pharmaceutical Council is responsible for regulatory function including inspection and enforcement, and the Royal Pharmaceutical Society of Great Britain provides professional guidance and support,</li> <li>• in Northern Ireland the investigative and enforcement activity that is carried out by the PSI is conducted by the Department of Health, Social Services and Public Safety</li> </ul> <p>It is difficult to make direct comparisons as illustrated - there is a particular cost associated with the delivery of a regulatory service. PSI obtains funding through registrant fees. Economies of scale apply when a larger proportion of registrants fund the model. The principle of the PSI application of fees is to recover costs based on who causes the cost or who benefits and is subject to the activities undertaken</p>
<b>13.</b>	<b>David Jordan</b>	
	In relations to fees charged by the PSI	The PSI reserve fund does not stand at €11 million. This is a misunderstanding

<p>Initially it was stated that one of the reasons for high registration fees was that the PSI needed to build up a reserve in case it was challenged in the courts. This reserve fund now stands at over €11 million. There is now little justification in continuing to charge excessive fees to pharmacists and community pharmacies to grow this fund further.</p> <p>Last year the PSI generated a surplus of over €1 million. This equates to approximately €550 per pharmacy. That is to say, the PSI could reduce registration fees to community pharmacies by €550 per annum and still generate a surplus each year.</p> <p>Also in relation to a reserve fund, what happened to the funds of the old PSI upon its dissolution and the proceeds of the sale of Shrewsbury Road. These funds could greatly reduce the burden on Irish pharmacists to continue funding the PSI.</p> <p>When compared to the UK and Northern Ireland the costs of registration of community</p>	<p>of the ongoing financial position of the PSI and of the manner of its funding. The PSI publishes an Annual report on its activities throughout the previous year which contains a Financial Report for the calendar year accompanied by Financial Statements. The PSI Annual Reports and Financial Statements are published on the PSI website and made publicly available.</p> <p>It may be noted from the information contained in the Annual Report 2012 (<i>publication of the Annual Report 2013 is imminent</i>) that the PSI held deferred income of €6.016 million (registration fees paid at the end of 2012 to fund PSI functions during 2013); it held a designated legal reserve fund of €2.5million (a fund, approved by Council, to protect against the need to increase registration fees in the event of legal challenges to the PSI in carrying out its statutory functions); a superannuation fund of €1.965 million (retained to comply with legislative obligations under the Pharmacy Act 2007), a surplus of €0.438 million (<i>see below</i>) after the disposal of property assets, and unrestricted cash of 1.816 million.</p> <p>The PSI collects the bulk of its income in the November/December period each year as registrations fees become due. Its cash on hand therefore peaks towards year end. This is reflected in the cash figure in the PSI balance sheet in the annual accounts. The annual PSI Service Plan contains a budget which is based on activities for the year outlined in the plan and having regard to the Corporate Strategy of the organisation. The annual budgeted expenditure is based on costed projected activities for the year ahead which are generally balanced with the projected income for the same period. In previous years the PSI had an excess of income over expenditure for reasons including delays in obtaining approval and consequential non-filling of staff posts and the delay in the commencement of the Irish Institute of Pharmacy.</p> <p>This was taken into account by the Council when arriving at its decision in relation to the proposed fee reduction.</p> <p>The Pharmacy Act 2007 determines in Schedule 1 the mechanism by which any surplus following the disposal of assets may be spent, this would include any proceeds from the sale of Shrewsbury Road. This specifically includes development of education, research, or any other public purpose. It may not be spent to reduce registration fees.</p>
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<p>pharmacies is excessive to say the least. The GPhC in the UK regulates 47,000 pharmacists and 14,000 pharmacies and has a budget of only €26 million. That is nine times as many pharmacists and 26 times as many pharmacies but only three and a half times the budget.</p> <p>The PSNI regulates 2,100 pharmacists and 550 pharmacies and has a budget of €1.25 million. That is 30% of the number of pharmacists and 40% of the number of pharmacies yet it does all this with only 17% of the budget of the PSI.</p> <p>€2,250 to register a pharmacy in Ireland, €195 in Northern Ireland and €277 in the UK. Ten times the cost for one tenth of the work.</p> <p>The question must be asked what is the PSI spending money on that the GPhC and the PSNI are not? Is the PSI needlessly duplicating the work of other government and semi-state agencies? HIQA for instance inspects hospitals. Is it really necessary for the PSI also to inspect hospital pharmacies? Ditto the HSA and the HSE.</p> <p>Are the tasks being carried out being expanded to fill the available budget rather than what is</p>	<p>There is a particular cost associated with the delivery of a regulatory service. PSI obtains funding through registrant fees. It is government policy that regulatory systems are intended to be self-funded, and accordingly as a regulated profession pharmacy has to cover the cost of that regulatory system. PSI has very extensive responsibilities (referenced in submission response No. 6) under law and these must be carried out and appropriately funded. Economies of scale apply when a larger proportion of registrants fund the model. It is also worth noting, and as referenced previously in this document that in establishing appropriate fee levels initially the PSI undertook in 2008 an evidence based methodology for the determination of pharmacist and pharmacy registration fees. This included a review of national and international comparator organisations. In this examination it appeared that the PSI at that time had a unique regulatory profile with onerous responsibilities and duties.</p> <p>On that basis alone the funding requirements would differ greatly and it is difficult to make direct comparison. By way of example</p> <ul style="list-style-type: none"> <li>• the Medical Council does not maintain a register of premises and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation</li> <li>• the Dental Council does not have an inspection remit and does not have statutory responsibility for the inspection of premises, or the investigation and enforcement of legislation</li> <li>• in the UK the General Pharmaceutical Council is responsible for regulatory function including inspection and enforcement, and the Royal Pharmaceutical Society of Great Britain provides professional guidance and support,</li> <li>• in Northern Ireland the investigative and enforcement activity that is carried out by the PSI is conducted by the Department of Health, Social Services and Public Safety</li> </ul> <p>PSI functions and duties are specified in the Pharmacy Act 2007. PSI has a statutory duty to discharge those functions and duties. The PSI works within its remit as the primary regulator of the practice and profession of pharmacy in the delivery of its responsibilities. Other agencies may conduct similar activities for their own purposes and remit e.g. contractual issues, employment issues, health and safety.</p> <p>The activities of PSI are subject to audit and the Audit Committee of the PSI, maintains an oversight of this activity. The role of the Audit Committee is to examine the adequacy of the nature, extent and effectiveness of accounting</p>
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<p>necessary?</p> <p>Has there ever been an independent value for money audit of all of the PSI's activities? What is the benefit if any to the public or patients compared to the costs of each activity? Similar to QALYs when considering a medical treatment.</p> <p>In relation to staffing, the PSI currently has a staff of 35. One member of staff for approximately every 50 community pharmacies or one for every 143 pharmacists. The Medical Council has a staff of 51. They regulate 18,000 doctors, one member of staff for every 350 doctors. The Dental Council has a staff of 5 (yes single figures) and they regulate 2,600 dentists. One for every 500 or so. The Veterinary Council also has a staff of 5 and regulates 2,350 vets and 697 veterinary practices. One for every 490 vets or one for every 140 practices. Their registration fees are €535, €200 and €450 respectfully. While there cannot be a direct comparison between these bodies their work is not that dissimilar.</p> <p>The GPhC has a staff of 194. The break down is as follows  England: 186 staff, 22 inspectors, 40,231 pharmacists and 12,313 pharmacies: 1 staff member per 216 pharmacists &amp; 1 per 66 pharmacies. One inspector for every 560(!) pharmacies.  Wales: 3 staff &amp; 2 inspectors. 2263 pharmacists &amp; 745 pharmacies. 1 staff per 750 pharmacists and 1 per 372 pharmacies. One inspector for every 370 pharmacies.  Scotland: 5 staff &amp; 4 inspectors. 4254 pharmacists and 1279 pharmacies. One staff per 830 pharmacists and one per 250 pharmacies. One inspector per 325 pharmacies.  Over all 194 staff &amp; 28 inspectors. 46748 pharmacists &amp; 14337 pharmacies. One staff per 240 pharmacists and per 74 pharmacies. One inspector per 512 pharmacies.  PSI 35 staff &amp; 7 inspectors. 5100 pharmacists &amp; 1820 pharmacies. One staff per 146 pharmacists and 1 per 52 pharmacies. One inspector per 260 pharmacies.</p> <p>At the time of writing I am still awaiting figures of staff levels in the PSNI and GPhC. These may be more readily available to the PSI and some more direct comparisons can be made. If the budgets of these organisations are any indication then it would seem that the PSI is grossly over staffed.</p> <p>Again it must be asked, are staff of the PSI undertaking tasks that are not strictly part of the PSI's remit or could be performed by other agencies?</p>	<p>and internal control systems within the PSI, including risk management and to ensure that the PSI is complying with all aspects of the law, relevant regulations and good practice. The Audit Committee also oversees the work of the Internal and External Auditors.</p> <p>See notes above</p> <p>For a period in late 2013/early 2014 PSI inspectors undertook a pilot of announced inspections (regular 'systems' inspections), and at its February 2014 meeting Council considered a report on the results of the pilot and an overview of national and international inspection practices. PSI Council made the decision to undertake an overall strategic review to consider PSI inspection policy into the future.</p> <p>This pilot of unannounced inspections was concluded and PSI is currently on target to have all pharmacies inspected under the Pharmacy 2007 Act by end of 2014. it is of note that in carrying out this pilot few pharmacies availed of the 24 hour notice period to change staffing arrangements at the pharmacy for the purposes of the inspection. Also of note is that the PSI reviewed the resource implications associated with the unannounced inspection regime with the findings indicating that an announced inspection policy would be expected to result in an increase in the general costs to the organisation including increased administration, travel and subsistence expenditure and travel time.</p> <p>The strategic review of PSI's inspection policy is currently being undertaken, under the auspices of an expert group with ongoing reports to the Council at each meeting, with a view to commencement of its implementation in 2015.</p> <p>In trying to draw comparison across different regulatory organisations in different jurisdictions it is also worth noting that differing regulatory environments apply, with differences in the model and type of inspection delivered.</p> <p>Subsequent to an inspection visit by an authorised officer of the PSI, inspection reports are issued and significant follow-up and correspondence may ensue. Inspectors are also involved in the other activities examples of</p>
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<p>The PSI has 7 authorised officers. This is one for every 257 pharmacies. Allowing for holidays etc this means that each inspector can spend a full day inspecting a pharmacy and still every pharmacy would be inspected one per year. This sounds to me as a gross under utilization of resources. While on this point I would note that announced inspections can be much more efficiently carried out. While there will always be a place for unannounced inspections it would seem that it would be a much better use of inspectors time if the majority of regular inspections were announced. As above I do not have the number of inspectors for the PSNI and the GPhC to hand just yet but I feel that this also would be a useful comparison.</p> <p>What efficiencies and salary reductions have taken place as a result of the Croke Park and Haddington Road agreements and have these reductions been reflected in PSI expenses?</p> <p>The scale of the fees to community pharmacies in particular is at odds with the stated government policy of making things easier for small businesses. To put it in context. I have recently re-located my pharmacy. My biggest expense in this was the shop fitter. My second biggest expense was fees paid to the PSI! This was more than the cost of re-wiring a shell of a premises from scratch, more than the cost of replacing the entire shop front and more than the cost of installing a full security and CCTV system. Also in relation to small businesses the high level of the pharmacy registration fee is a disproportionate burden on the smaller pharmacies. After salaries and wages the PSI registration fee is amongst one of my biggest annual expenses. I feel that there should be a scale of fees based on square footage or something similar. Also I am disappointed that there is no facility to pay in instalments which might ease the burden somewhat.</p> <p>If you wish me to expand on any of these points I can be contacted at the above email address.</p>	<p>which include investigations, prosecution, provision of advice, Fitness to Practice hearings, query handling and educational activity</p> <p>PSI staff are subject to the terms of the Croke Park and Haddington Road agreements including the reduction in salaries, increased working hours and increased efficiencies, which have been implemented by PSI/</p> <p>It is government policy that regulatory systems are to be self-funded, and accordingly as a regulated profession pharmacy has to cover the cost of the applicable regulatory system. PSI has very extensive responsibilities (referenced in submission response No. 6) under law and these must be carried out and appropriately funded. In establishing appropriate fee levels initially the PSI undertook in 2008 an evidence based methodology for the determination of pharmacist and pharmacy registration fees. The basis for the allocation of fees is to recover costs based on who causes the cost or who benefits with the cost of an activity directly attributable built into the fee levied on a particular cohort. Pharmacies are entitled to carry out a range of activities, including the sale and supply of medicines, that others are precluded from doing. Government has deemed that in this State the regulatory cost of ensuring that this service is delivered safely, professionally and in the best interest of the patient shall be borne by those allowed to deliver this service in a restricted environment.</p> <p>Noted– PSI welcomes continued engagement in all matters pertinent to its legislative remit.</p>
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