



In This Issue

- **Update: PSI Council Elections 2015**
- **Understanding Corbally**
- **Summary of Fitness to Practise activities 2009-2014**
- **Legislative Update**
- **Upcoming CPD Opportunities**
- **Other Notices**
- **In the matter of Part 6 of the Pharmacy Act 2007**

[Print Version »](#)

- **Subscribe**

Overview

This newsletter contains a number of items relating to the PSI's complaints and disciplinary processes. This includes statistics compiled on the processing of complaints that have been received by the PSI since commencement of Part 6 of the Pharmacy Act in 2009.



The PSI's Fitness to Practise Unit has also provided an overview of the recent Corbally decision, its background and context as it relates to the Pharmacy Act and the PSI's disciplinary structure and procedures. The fitness to practise function is one pillar of the PSI's regulatory system aimed at protecting the public interest and safeguarding patient welfare.

An update is provided in relation to the Council Elections 2015; the declaration of candidates and the issuing and completion of ballot papers.

Amendments to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 are also highlighted. This concerns prescriptions issued in one EU/EEA Member State and intended to be dispensed in another.

Update: PSI Council Elections 2015

Following the February call for nominations, eight candidates have been formally declared for the 2015 election for appointment to the PSI Council. The list of candidates has been published on the [PSI website](#) and ballot papers will shortly be sent by post to the electoral register. This register was established by the returning officer, Registrar Marita Kinsella, on 18th March and comprises all pharmacists on the PSI's Register of Pharmacists on that date, and who are all entitled to vote in the election. Ballot papers will be sent to each pharmacist's correspondence address as it appears in the Register of Pharmacists, and should be received by Tuesday 31st March 2015.

The ballot paper will include: a list of candidates in alphabetical order, the candidate's area of practice; the name and address of each candidate's proposer and seconder; the latest date and time by which ballot papers shall be returned to the returning officer; and instructions on the voting procedure or a reference to an enclosure setting out such instructions.

Completed ballot papers are to be returned to the Returning Officer by **5.00pm on Wednesday 15th April 2015**. The counting of votes will take place within 2 days of the election date as per the Council Rules. At the conclusion of the count, the returning officer will declare the results and give notice in writing to the Minister for Health to facilitate their appointment. The election results, including details of the poll and count, will be published on the PSI website.

Completing the ballot paper:

In participating in the election please follow the instructions contained with your ballot paper. In order to avoid common errors which can result in ballot

papers being deemed invalid, please ensure that:

- The space on the back of the envelope for your name, signature, registration number and date are fully completed,
- The correct name (as it appears on the Register) is provided on the back of the envelope,
- The correct registration number is provided on the back of the envelope,
- The ballot paper is enclosed in the small white envelope. Loose ballot papers are not valid as the voter can be identified.

Understanding Corbally

In light of the recent Supreme Court decision in the case of Corbally v. Medical Council & Others, the PSI's Fitness to Practise Unit highlights for your information the background and outcomes to that decision, and places this in the context of the PSI's disciplinary structure and procedures.

The PSI Council has applied the High Court judgement in Corbally since it was handed down and is giving consideration to any further implications which may arise out of the Supreme Court decision. The PSI has always, and continues, to comply with the principles of natural justice and relevant decisions of the courts in relation to Fitness to Practise matters.

The Corbally case arose initially following an incident involving a Consultant Paediatric Surgeon, Professor Martin Corbally, when he incorrectly described the procedure to be performed on a patient in his handwritten outpatient note, and which later resulted in a complaint being made against Professor Corbally to the Medical Council. A finding of poor professional performance was made against him and he was admonished by the Medical Council. [Continue reading](#) 'Understanding Corbally' on the PSI website.

Summary of Fitness to Practise activities 2009-2014

As part of the ongoing monitoring and evaluation of performance of the PSI's statutory complaints process, the Fitness to Practise Unit has collated statistics on the processing of complaints received since the commencement of Part 6 of the Pharmacy Act in 2009. The complaints and disciplinary process of the PSI is provided for under Part 6 of the Act.

Some of these statistics are outlined below and additional information is available on the [PSI website](#). The statistics include complaints received between August 2009 and December 2014.

As of 31st December 2014, the PSI had received 270 complaints. 95% of these were considered by the PSI's Preliminary Proceedings Committee (screening committee) within six months of receipt.

Of these 270 complaints, 69 complaints (26%) were found to warrant further action and were referred to either the Professional Conduct Committee or Health Committee for inquiry, or for mediation, as of 31st December 2014.

Forty four of these complaints have been concluded and have been heard by way of 31 inquiries/mediation. Almost 70% of these were completed within two years. Of the remaining 25 complaints that had been sent forward for inquiry as of 31st December 2014, but where the inquiry has not yet been held, only six were received more than 18 months earlier. [\[Read more\]](#)

Legislative Update

Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)

The PSI would like to inform pharmacists of recent amendments to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) with a view to facilitating the recognition of medical prescriptions issued in another EU/EEA Member State. The amendments arise from legislative change at a European level regarding patients' rights in cross-border healthcare and the recognition of medical prescriptions issued in another EU/EEA Member State.

A link to the relevant statutory instrument, entitled Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014 (S.I. No. 504 of 2014), can be found on irishstatutebook.ie.

The amending regulations provide that prescriptions from the following practitioners practising in another EEA Member State may be dispensed in Ireland:

- (a) a registered medical practitioner,*
- (b) a registered dentist,*
- (c) a registered nurse, or*
- (d) a practitioner of status equivalent to a registered medical practitioner or a registered dentist, practising in an EEA state other than the State, or a member of a regulated health profession within the meaning of Article 3(1) (a) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 who is legally entitled to issue a prescription for the medicinal product concerned in the EEA state in which the prescription is issued, if the prescription has not been issued with a view to enabling the supply of a medicinal product by mail order.*

The amending regulations also provide that for such prescriptions to be legally valid in Ireland, they must:

- (a) be in ink or other permanent and unalterable electronic form and be signed and dated by the person issuing the prescription with his or her usual signature, either in handwriting or by electronic signature;*
- (b) clearly indicate the full name, including the full first name, of the person issuing the prescription and specify his or her professional qualification;*
- (c) specify the work address, including the name of the relevant EEA state, of the person issuing the prescription;*
- (d) specify the email address, and telephone or fax number (with the appropriate international prefix) of the person issuing the prescription;*
- (e) specify the full name, including the full first name, and date of birth of the person for whose treatment the prescription is issued; and*
- (f) specify the following details, where applicable, of the product to be supplied on foot of the prescription:*
 - (i) the common name of the medicinal product;*
 - (ii) the brand name of the medicinal product if-*
 - (I) the medicinal product prescribed is a biological medicinal product, or*
 - (II) the person issuing the prescription has deemed it medically necessary to include the brand name on the prescription and has stated on the prescription the reasons justifying the use of the brand name;*
 - (iii) the pharmaceutical form;*
 - (iv) the quantity;*
 - (v) the strength of the medicinal product; and*
 - (vi) the dosage regime.*

Pharmacists should be aware that practitioners are only entitled to prescribe medicinal products for which they are legally entitled to do in the EEA state in which the prescription is issued.

Furthermore, it should be noted that products classified as schedule 2 or schedule 3 controlled drugs may not be prescribed by practitioners in another EEA state for dispensing in Ireland and that such prescriptions may not be used to authorise the supply of any such controlled drug.

Corresponding arrangements and requirements are applicable to “outgoing” prescriptions.

Upcoming CPD Opportunities

M.Sc./P.Grad.Dip in Community Pharmacy, Trinity College Dublin

The School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin is now accepting applications to this course which is specifically designed to meet the needs of practicing community pharmacists. The distance-learning format facilitates participants in full-time employment. For further information and to apply, visit the [TCD website](#), email community.pharmacy@tcd.ie or phone 01 8963736. Closing date for applications is 31st May 2015 for the September intake.

Other Notices

HPRA Drug Safety Newsletter

The most recent HPRA Drug Safety Newsletter (DSN), issue 66, is available on the [HPRA website](#) and includes updates to support safe and appropriate use of the following medicines:

- Eligard (leuporelin acetate depot injection)-Risk of lack of efficacy due to incorrect reconstitution and administration process.
- Beta interferons: Risk of thrombotic microangiopathy and nephrotic syndrome.
- Mycophenolate mofetil (CellCept®) and Mycophenolic acid (Myfortic®)-New warnings about the risks of hypogammaglobulinaemia and bronchiectasis.
- Tecfidera (dimethyl fumarate) - Progressive Multifocal Leukoencephalopathy (PML) has occurred in a patient with severe and prolonged lymphopenia.

Safefood: “Let’s take on Childhood Obesity” Campaign

Safefood’s evaluation of their “Let’s take on Childhood Obesity Campaign” has shown positive results over the past year, with an increased awareness reported among parents that excess weight in childhood is associated with poorer health in later life. Safefood has also recorded encouraging behavioural changes around their core messages of reducing portion sizes, reducing the consumption of sugary drinks and treat foods, and encouraging children to be more physically active. This link contains the [Childhood Obesity Campaign Evaluation Summary](#).

The next phase of this campaign will start on Monday 13th April and will focus on the link between sleep and obesity. International evidence is now clearly linking short sleep duration with excess weight in children and adults. Pharmacists are in a prime position to support and educate parents and carers about any concerns they may have regarding their children’s nutrition. Pharmacists and members of the pharmacy team should try to engage with their patients to encourage them to eat healthily and signpost them to the resources provided by the Safefood campaign. Further information, leaflets and posters are available on the Safefood [website](#).

In the matter of Part 6 of the Pharmacy Act 2007

Ms. Kate Kennedy MPSI (Registration No. 7178)

Following the submission of a report of the Professional Conduct Committee, the Council, at its meeting on 16th December 2014, decided to censure and attach the following conditions¹ to the registration in relation to the findings of Professional Misconduct and Poor Professional Performance made by the

Professional Conduct Committee in its report dated 16th November 2014 which are set out in *Appendix 1* attached to this notice:

That conditions be attached to Ms. Kennedy's registration as a pharmacist as follows:

1. Ms. Kennedy shall enter into an appropriate period of mentorship of not less than six months with a practising Superintendent Pharmacist to be approved by the Registrar so as to ensure her dispensing practices, protocols and procedures are compliant with all relevant legislation. The Superintendent Pharmacist shall oversee a review of standard operating procedures with regard to dispensing and ascertain that they are being adhered to. This condition will be discharged when a satisfactory report is submitted to the Registrar.
2. Ms. Kennedy must discharge the costs associated with the above mentorship.
3. Ms. Kennedy must provide the Council with evidence of satisfactory completion of the MSc in Community Pharmacy that she is currently undertaking at Trinity College, Dublin.

The reasons for the Council decision were as follows:

The Council considered that these were the most reasonable and proportionate sanctions having regard to the gravity of the allegations proven, all of the mitigating factors advanced on behalf of Ms. Kennedy, the protection of the public and sending the appropriate messages to the public and the profession.

Appendix 1:

Findings:

1. On dates between 1st August 2009 and 29th August 2012, caused or permitted the sale and/or supply of Mometasone Furoate to Patient A other than on foot of an original prescription and/or in so doing acted in breach of Regulation 5 and/or Regulation 7 and/or Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI 540/2003) (as amended).

FINDING: PROFESSIONAL MISCONDUCT

2. On dates between 1st August 2009 and 29th August 2012, caused or permitted the sale and/or supply of Mometasone Furoate to patients of Liberty Pharmacy Limited, 36 Lower Liberty Square, Thurles, Co. Tipperary other than on foot of an original prescription and/or in so doing acted in breach of Regulation 5 and/or Regulation 7 and/or Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI 540/2003) (as amended).

FINDING: PROFESSIONAL MISCONDUCT

3. On dates between 1st August 2009 and 29th August 2012 caused or permitted the sale and/or supply of a medicinal product to Patient A without adequate or proper record of formulation or preparation and/or without adequate or proper labelling and/or without therapeutic justification for the sale and/or supply of such medicinal product.

FINDING: POOR PROFESSIONAL PERFORMANCE

4. On dates between 1st August 2009 and 29th August 2012 caused or permitted the sale and/or supply of a medicinal product to patients of Liberty Pharmacy Limited, 36 Lower Liberty Square, Thurles, Co. Tipperary without adequate or proper record of formulation or preparation and/or without adequate or proper labelling and/or without therapeutic justification for the sale and/or supply of such medicinal product.

FINDING: POOR PROFESSIONAL PERFORMANCE

5. On dates between 1st August 2009 and 29th August 2012, failed to have

any proper or adequate regard for the possible adverse consequences for Patient A by the sale and/or supply of Mometasone Furoate to Patient A.

FINDING: PROFESSIONAL MISCONDUCT

6. On dates between 1st August 2009 and 29th August 2012, failed to have any proper or adequate regard for the possible adverse consequences for the patients of Liberty Pharmacy Limited, 36 Lower Liberty Square, Thurles, Co. Tipperary by the sale and/or supply of Mometasone Furoate to such patients.

FINDING: PROFESSIONAL MISCONDUCT

7. On dates between 1st August 2009 and 29th August 2012, caused or permitted the sale and/or supply of an extemporaneous prepared ointment containing Mometasone Furoate to Patient A and/or in so doing acted in breach of Regulation 6 the Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI 540/2007) (as amended).

FINDING: POOR PROFESSIONAL PERFORMANCE

8. On dates between 1st August 2009 and 29th August 2012, caused or permitted the sale and/or supply of an extemporaneous prepared ointment containing Mometasone Furoate to patients of Liberty Pharmacy Limited and/or in so doing acted in breach of Regulation 6 the Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI 540/2007) (as amended).

FINDING: POOR PROFESSIONAL PERFORMANCE

Footnote: 1. Such conditions having been subsequently confirmed by the High Court pursuant to Section 52 of the Pharmacy Act 2007 on 16th February 2015.

PSI House,
Fenian Street,
Dublin 2
Phone: +353 1 2184000
Fax: +353 1 2837678
Email: info@thepsi.ie
Web: PSI Website

Published by PSI
© 2015 PSI. All rights reserved.



Email Software by Newsweaver