

Publications and Disclosure Policy in Fitness to Practise matters

Title:	Publications & Disclosure Policy
Version:	2.0
Effective Date:	5 th October 2023
Review frequency:	Annually
Author:	Manager Legal Affairs & Fitness to Practise
First approved by PSI Council:	15 th December 2022
Date of last update by PSI	05 October 2023
Council:	



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Introduction

The PSI first published a Publications & Disclosure Policy in 2016. Due to intervening legislative changes which impact decisions in Fitness to Practise matters and complaints since the 2016 document was first published, it was decided to create a new document to reflect those changes. This 2022 policy document replaces in its entirety the 2016 document.

The Pharmaceutical Society of Ireland ("the PSI") is the independent statutory regulator of the pharmacy profession, established by the Pharmacy Act 2007 ("the Act"). It is charged with the safe and effective regulation of registered pharmacists and registered retail pharmacy businesses ("pharmacies") in Ireland.

The primary function of the PSI is to protect and to promote the health, safety and well-being of patients and the public.

The legal framework established by the Act, including the disciplinary (also known as fitness to practise) processes provided for under Part 6 of the Act, aims to ensure that the pharmacists and pharmacies on its registers are fit to practise and are appropriately regulated. The Act was amended by the Regulated Professions (Health and Social Care)(Amendment Act) 2020 ("the 2020 Act"), which took effect in early 2021.

It is the Council's policy to operate the disciplinary processes established under Part 6 of the Act in the most transparent manner possible, having regard to the public interest and the provisions of Part 6. One of the ways it achieves these aims is through the publication of the outcome of disciplinary proceedings. The purpose of publication includes:

- protecting the health, safety and wellbeing of the public,
- upholding standards of practice and the promotion of confidence in the profession of pharmacy and the regulation of the profession,
- providing learning opportunities for pharmacists in relation to the conduct which gave rise to a substantiated complaint
- making the public aware where a pharmacist/pharmacy is subject to restrictions on their practice
- serving as a deterrent for practitioners in relation to similar conduct.

This document:

- explains what level of publication and notification will usually be made at each stage of the disciplinary process, where Council is required to consider the issue of public notice of sanctions following the conclusion of that process;
- sets out Council policy in determining how it will assess whether publication shall be made "if it is in the public interest to do so" and where those obligations arise;
- provides guidance in relation to the "public interest test", where it is required;

- sets out the usual manner and duration of publication;
- sets out how any other notifications are made and to whom; and
- provides general information in relation to how and where the PSI publishes information relating to fitness to practise matters.

The PSI first published a Publications & Disclosure Policy in 2016. Given the level of intervening legislative changes which impact decisions in Fitness to Practise matters and complaints since the 2016 document was first published, it was decided to create this new document. This new 2022 policy document therefore replaces in its entirety, the 2016 policy document.

Where to find related information

The <u>PSI website</u> contains the notices of sanctions imposed following the conclusion of disciplinary proceedings arising from complaints against pharmacists and pharmacies, together with notifications of pending inquiry hearings and general information to assist understanding of the complaints process, including about how a complaint may be made. It contains useful <u>guides</u> to support a complainant and <u>those subject to a complaint</u>.

The PSI maintains online, publicly accessible and <u>searchable registers</u> of pharmacists and pharmacies where the names and other details of registrants are available.

The PSI also issues a <u>newsletter</u> several times each year. This includes notices of the sanctions imposed following the conclusion of disciplinary/fitness to practise matters and links to our website where further detail is published, if relevant.

The Pharmacy Act (as amended) can be accessed here.

About the Public Interest

In certain circumstances, the PSI is obliged under the Act to assess whether it is in the "public interest" to publish or share certain information. This is commonly known as the "public interest test" and references to the "public interest" appear throughout this document. Please refer to **Appendix A** for matters to which the Council of the PSI may have regard to when assessing whether it is in the public interest to publish or share certain information.

A. General Information – Different stages of the complaint process

Receipt of Complaints

When a complaint against a pharmacist and/or pharmacy is made under Part 6 of the Pharmacy Act 2007, a copy is provided to the pharmacist(s) and pharmacy owner(s) involved so to allow them to make any observations in relation to the complaint if they wish to do so. Any observations received are usually then given in turn to the complainant, for their own observations and response.

The PSI keeps complainants and pharmacists/pharmacy owners informed of all the steps taken in the statutory complaints process and when decisions are expected to be made.

At this stage, no information is published or shared by the PSI to the general public in relation to the complaint.

Preliminary Consideration/Screening of Complaints

The Preliminary Proceedings Committee ("PPC") is the statutory committee which considers the complaint received once observations have been made and exchanged and it advises the Council, in accordance with their responsibilities under the Act, whether there is sufficient cause to warrant further action being taken against the relevant pharmacist and/or pharmacy in relation to the complaint. Where the PPC decides to take further action, the complaint is referred either for Inquiry or for Mediation.

Decision to Take No Further Action: Where the PPC, with the agreement of Council, decides to take no further action in relation to a pharmacist or pharmacy, the complaint process under Part 6 of the Pharmacy Act is concluded. No details of the complaint are published.

Decision to Take Further Action: Where the PPC decides to take further action in relation to a pharmacist or pharmacy, the decision is communicated to the complainant and the pharmacist/pharmacy, and the Inquiry or Mediation process commences. There is no publication in relation to the complaint at this stage.

Interim Suspension: Section 45

Section 45 of the Act provides that the Council may apply to the High Court for an order suspending, on an interim basis, the registration of a pharmacist or pharmacy against whom a complaint has been made. This occurs where the Council considers there is a risk to the health and safety of the public of such magnitude that a pharmacist or pharmacy's registration should be suspended pending the conclusion of the complaint process.

Section 45 proceedings are heard before the High Court in private, unless the pharmacist or pharmacy owner requests that they are held in public and the Court agrees to this request.

If Council applies to the High Court, and the High Court makes an Order suspending the pharmacists/pharmacy's registration, the relevant entry on the publicly accessible Register of Pharmacists or Pharmacies will be updated in line with the Court Order or any other agreement, to reflect the suspension.

The Court may also make orders in relation to appropriate persons to be notified of the Order. Where the High Court makes an Order suspending the registration of a pharmacist and the Council has reason to believe that the pharmacist is registered in another State, or has applied for registration in another State, and that the equivalent body to the PSI in that State may not be aware of the Order of the High Court, the Council must provide notice in writing to that body and provide it with a copy of the High Court Order and other documents relevant to the Order¹. An alert also issues under the IMI system² (see Section D below).

Committees of Inquiry

There are two Committees which may hear complaints referred to it and conduct Inquiries under Part 6 of the Act.

(a) The Professional Conduct Committee ("the PCC")

Inquiry hearings conducted by the PCC will normally be held in public unless the pharmacist, pharmacy owner or complainant requests that the Inquiry hearing is heard in private and the PCC agrees to that request.

(b) The Health Committee

Inquiry hearings conducted by the Health Committee will normally be held in private unless the pharmacist, pharmacy owner or complainant requests that the Inquiry hearing is heard in public and the Health Committee agrees to that request.

Sometimes, where an Inquiry hearing is held in public, the PCC or Health Committee may decide that certain aspects of the Inquiry hearing should be anonymised, to protect the privacy of particular witnesses or parties involved in the Inquiry.

Professional Conduct Committee: A notification of an Inquiry hearing before the PCC to be held pursuant to Section 42 of the Act will be published on the PSI website² approximately 7 days in advance of the Inquiry, with details of the time and venue (if the Inquiry hearing is not being held remotely). The media will also be notified by way of a media alert. No further details will be contained in either notification. The notifications will not include the names of the pharmacist/pharmacy that are the subject of the Inquiry.

¹ Section 56(4) of the Pharmacy Act 2007

² Regulation 87, EU (Recognition of Professional Qualification) Regulations 2017

Any person, including persons from the media, may attend a public Inquiry hearing held before the PCC. This includes an Inquiry hearing held remotely.

Health Committee: No notification of an Inquiry hearing before the Health Committee to be held pursuant to Section 42 of the Act will be published unless the Committee has decided to hold the Inquiry in public. If it is to be held in public, a notification will be published on the PSI website approximately 7 days in advance of the Inquiry hearing, with details of the time and venue (if the Inquiry hearing is not being held remotely) for the Inquiry. The media will also be notified by way of a media alert. No further details will be contained in either notification. The notifications will not include the names of the pharmacist/pharmacy the subject of the Inquiry.

Any person, including persons from the media, may attend a public Inquiry hearing held before the Health Committee. This includes an Inquiry hearing held remotely.

At the conclusion of an Inquiry conducted by the PCC or Health Committee, the Committee is obliged under the Act to provide a report to the Council setting out its findings. The report will also be given to the pharmacist/pharmacy owner. This report may include, where relevant, any recommendations in relation to sanction. The range of sanctions which can be imposed following an Inquiry in respect of a pharmacist and/or pharmacy owner under the Act are set out in section 48(1)(b). (See Part B below).

Once the Council has considered the Committee report and if it decides to impose sanctions, it must apply the provisions of Sections 56 and 57 of the Act in relation to:

- public notice of any sanction imposed following its consideration of the report of a Committee; and
- whether to publish all or part of the Committee report, and/or all or part of the transcript of any part of the inquiry proceedings
- whether any notifications to other regulators are required ³

Where an application is required to be made to the High Court to confirm sanction, the Council may not publish anything which is inconsistent with any decision of the High Court.⁴

Mediation

Where the PPC decides that there is sufficient cause to take further action in relation to a complaint, and where it considers it appropriate, it may refer a complaint for mediation instead of to Inquiry. The complainant and the pharmacist/pharmacy owner must consent to this.

³ Section 56(4) of the Pharmacy Act 2007

⁴ Section 57(3) Pharmacy Act 2007

Mediation is a confidential process and no information given during the course of mediation can be disclosed in any other proceedings. All records, reports or other documents received by a mediator are confidential. All views expressed and/or admissions made during the course of a mediation are confidential. This includes where the complaint is not resolved by mediation and is instead referred for Inquiry. The only record of the mediation is the report prepared by the mediator for the Council. This report sets out either:

- the terms of resolution; or
- confirms that it was not possible to resolve the complaint through mediation.

The terms of resolution can include the consent to the imposition by Council of a sanction(s) on the pharmacist/pharmacy owner and will usually address the issue of public notice. The Council must apply the requirements of Sections 56 and 57 of the Act in relation to public notice of sanction in any event.

The Council shall decide on this issue when it considers the Mediators Report at any private meeting, noting whether any consent to give public notice of sanction has formed part of the terms of resolution. Where the issue of public notice of the sanction was not dealt with as part of the terms of resolution, submissions can be made to the Council at that time in relation to publication.

In relation to any undertakings given as part of the terms of resolution of a mediation, the PSI will only publish those where it has been agreed on consent to publish, and only in the form and manner of publication as prescribed in the terms of resolution.

For further information on mediations, please see also the **Council Mediation Guidelines**.

B. Sanctions and public notice of sanctions under Part 6 of the Act

The list of sanctions available to Council under Part 6 of the Pharmacy Act is set out in section 48(1).

Under section 57(1) of the Act, the Council **must** give public notice of the following actions:

- (a) the cancellation of a registration;
- (b) the suspension of a registration;
- (c) the attachment of conditions to a registration;
- (d) the prohibition for a specified period of a pharmacist or pharmacy ownerfrom applying for restoration to the register;
- (e) the restoration of a registration;
- (f) the removal of conditions from a registration; and
- (g) the expiry of a suspension.

The Council will automatically give public notice of the imposition of the sanctions listed at (a) - (d) above, once the sanction has been confirmed by the High Court. It will give public notice of the actions listed at (e) - (g), after the relevant actions to give effect to those sections, have been taken.

In doing so, Council must ensure that the public notice given is not inconsistent with any decision of the High Court.

The Council **must** give public notice of the following sanctions if is satisfied that it is <u>in the</u> public interest to do so:

- the admonishment of a pharmacist or pharmacy owner
- the censure of a pharmacist or pharmacy owner

This may include sanctions arising from mediations and undertakings accepted by the Committee of Inquiry under section 46 of the Pharmacy Act 2007.

In general, where the Council imposes a sanction of admonishment or censure at a meeting, the Council will at the meeting at which the sanction is imposed, consider whether it is in the public interest to give public notice of the sanction.

As there is no requirement under the Pharmacy Act 2007 to seek confirmation from the High

Court in relation to the sanctions of admonishment and censure, but there is a right to apply to the High Court to cancel the sanction imposed by Council⁵ (other than from a mediation or following an undertaking), public notice will only be given after the time limit for bringing any application to the High Court has expired, no such application is brought, or the application has been heard by the High Court and the High Court has confirmed its decision.

⁵ Section 51 of the Pharmacy Act 2007 (as amended)

C. Council Meetings to consider the report of a Committee of Inquiry and publication of sanctions, report and transcripts

Once it receives the report of the Committee of Inquiry, the Council will meet to consider the report and to decide on the sanction(s) to be imposed, where relevant. These meetings are not held in public.

Where the Council is required to decide on the imposition of sanction, the pharmacist/pharmacy owner will be afforded an opportunity to make submissions to Council in relation to sanction, public notice of the sanction, and publication of the Committee Report and/or transcript. All submissions should be made in line with Council Procedures: Hearings regarding Sanctions and Public Notice/Publication⁶. The Council shall then decide whether it is in the public interest to make the publication.

In general, and regardless as to whether formal submissions are made, the Council will have to consider each complaint on a case-by-case basis and decide whether it is in the public interest to publish the Committee Report and/or transcript or any part thereof. If the Council decides to give public notice of sanctions, or to publish the Committee report and/or transcript or any part thereof, the report and/or transcript or relevant part thereof will appear on the PSI website. (See below for further information on where and how publication is made).

When considering reports of Committees of Inquiries, the following scenarios will arise:

Complaint not substantiated at Inquiry

Where the Council receives a report from a Committee of Inquiry indicating that the complaint has not been substantiated, the Council must dismiss the complaint. No sanction is imposed.

The Council must only consider whether it is in the public interest to publish:

- some or all of the transcript of the hearing before the Committee of Inquiry; and/or
- some or all of the report of the Committee of Inquiry.

If the Council decides that it is in the public interest to do so, it will publish some or all of the transcript or report⁷.

At the Council meeting where the Committee report is considered, the Registrar and the pharmacist/pharmacy owner may make submissions in writing in advance of the Council meeting in relation to publication, and they may attend the Council meeting to make short oral

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⁶ Council Procedures: Hearings regarding Sanctions and Public Notice/Publication dated 7th October 2021 (as may be amended from time to time)

⁷ Section 57(2) of the Act (as amended)

submissions.

Complaint substantiated at Inquiry

Where the Council receives a report from a Committee of Inquiry indicating that a complaint has been substantiated, the Council must impose one or more of the following sanction(s)8:-

- an admonishment or censure;
- the attachment of conditions to the registration of the pharmacist or retail pharmacy business, which may include restrictions on practice or, as the case may be, the carrying on of the business;
- the suspension of the registration for a specified period;
- the cancellation of the registration; or
- a prohibition for a specified period on applying for restoration to the Register.

Where the sanction of admonishment or censure is imposed, the Council must decide if it is in the public interest to give public notice of that sanction. In relation to all other sanctions, the Council must give public notice of the sanction, and it has a discretion in relation to foreign regulators and must only give notice when it is in the public interest to do so⁹.

The Council must also decide whether it is in the public interest to publish the Committee Report and/or transcript of the inquiry proceedings or any parts thereof. If Council decides that it is in the public interest to publish one or both of these, then it must do so.

In making its decisions on public notice of sanction and publication of Committee reports/transcripts, the Council may have regard to written and/or oral submissions from the Registrar and the pharmacist and/or pharmacy owner.

Where the Registrar and/or the pharmacist/pharmacy owner wishes to make submissions, those submissions are to be made in writing, in advance of the Council meeting. If either party wishes to make short oral submissions at the Council meeting, an opportunity will be afforded to do so. All submissions should be made in line with Council Procedures: Hearings regarding Sanctions and Public Notice/Publication¹⁰.

After the Council has imposed a sanction:

• The pharmacist/pharmacy owner is entitled to apply to the High Court to cancel the sanction decision within 30 days of receipt of the notification of the decision of

⁸ Section 48(1)(b) of the Act

⁹ Sections 56(4) and 56(5) of the Act

¹⁰ Council Procedures: Hearings regarding Sanctions and Public Notice/Publication dated 7th October 2021 (as may be amended from time to time)

Council¹¹;

- If no application to cancel is made within 30 days, the Registrar must apply to the High Court to have the sanction confirmed (except where the sanction is one of an admonishment or censure); and
- Once the sanction has taken effect, the Council must apply the requirements of Sections 56 and 57 of the Act in relation to public notice of sanction in accordance with its decision.

The Council may not publish anything which is inconsistent with any decision of the High Court made in respect of the Court's consideration of an appeal of sanction or a sanction confirmation application.

Consents and Undertakings – section 46 of the Act

A Committee of Inquiry may, in dealing with a complaint, request the pharmacist or the pharmacy owner to do one or more of the following¹²:

- (a) To undertake not to repeat the conduct to which the complaint relates;
- (b) To undertake to attend specified educational courses, training or other means of improving his or her competence to practise or to carry on a retail pharmacy business;
- (c) To consent to undergo medical treatment; or
- (d) To consent to being admonished or censured by the Council.

If undertakings are requested and provided to the Committee of Inquiry, no finding is made against the pharmacist/pharmacy in relation to the allegations contained in the Notice of Inquiry.

Where a complaint concludes through the acceptance of an undertaking by a Committee of Inquiry, the inquiry is considered to be completed. The Committee will prepare a report for Council setting out the subject matter of the complaint, the evidence presented (if any) the undertakings accepted and any sanction consented to. The report will be provided to the Council and to the pharmacist/pharmacy owner.

The Council, at its meeting to consider the report, is required to impose the sanction in accordance with the undertaking and has no discretion in respect of the sanction to be imposed.¹³

The Council must also decide whether it is in the public interest to give public notice of the sanction (admonishment or censure). It must also decide whether it is in the public interest to

¹¹ Section 51 of the Pharmacy Act 2007 (as amended)

¹² Section 46 of the Pharmacy Act 2007 (as amended)

¹³ Section 48(3) of the Pharmacy Act (as amended)

publish the Committee report, or any part thereof, and/or the transcript or any part thereof of the proceedings of a committee of inquiry at an inquiry.

In line with the Council Procedures ¹⁴the Registrar and the pharmacist/pharmacy owner will be invited to and may make written submissions on public notice and publication of the report/transcript in line with Section 3 below, as well as short oral submissions at the Council meeting.

If the Council decides to publish the Committee report and/or transcript or any part thereof, the report and/or transcript or relevant part thereof will appear on the PSI website. *It should be noted that this will detail the undertakings*.

Submissions on Public Notice and Publication

Where the Council is required to make a decision on public notice of sanction and/or publication of a Committee report/transcript, this will usually be done at the Council meeting at which the Committee Report or Mediator's Report is considered.

The Registrar and the pharmacist/pharmacy owner may make submissions to the Council as to whether it is in the public interest to make such publication. Where submissions are to be made, these should be made in writing in advance of the relevant Council meeting in line with Councils Procedures¹⁵.

In publishing a Committee report and/or transcript, Council may, at its discretion, decide to do so in an anonymised and/or redacted format, or in any manner as it may consider appropriate, or may decide to publish an extract only from the relevant Committee report or transcript.

In the event that the Registrar and/or the pharmacist/pharmacy owner wishes to submit that an anonymised and/or redacted version of a Committee report and/or transcript be published, it should include with its written submissions for the Council's consideration, the draft anonymised and/or redacted version of the Report or transcript that it proposes be published. The Council may however deviate from any draft version and may decide independently which information should appear or be redacted.

In the absence of any submissions on publication, or any submissions not to publish, the Council will consider each complaint on a case by case basis, and shall give public notice of any admonishment or censure, and/or publish all of part of any Committee report or and/or

¹⁴ Council Procedures: Hearings regarding Sanctions and Public Notice/Publication dated 7th October 2021 (as may be amended from time to time).

¹⁵ "Council Procedures: Hearings regarding Sanctions and Public Notice/Publication" dated 7th October 2021 (as may be amended from time to time)

transcript where the Council considers that it is in the public interest to do so, in that particular case. Depending on whether the inquiry proceeded in private, or there is any particular reason to anonymise the parties, the Council may decide to publish on an anonymised or redacted basis, in the public interest.

D. Notification requirements relating to sanctions – who shall be notified

This section sets out the statutory obligations of the PSI to provide notification to various parties in relation to the outcome of the disciplinary process under Part 6 of the Act.

Pharmacist/Pharmacy Owner/Complainant

As soon as practicable after deciding to impose a sanction, the Council must notify the pharmacist or pharmacy owner and the complainant of:

- The sanction(s) imposed;
- The reasons for the imposition of the sanction(s);
- The date of the decision;
- Confirmation that the pharmacist/pharmacy owner may apply to the High Court for cancellation of the sanction decision within 30 days of receipt of the notification; and
- Confirmation that, if the pharmacist/pharmacy owner does not apply to the High Court
 for cancellation, the Council must apply to the High Court to confirm the sanction within
 60 days of the pharmacist/pharmacy owner's receipt of notification of the decision (this
 does not apply to an admonishment or censure).

Such notification will usually also confirm any decision the Council has made regarding public notice/publication of sanctions and/or Committee Reports and/or transcripts, and how publication will be made, where that is applicable.

Employers

Where a pharmacist is an employee and the Council knows the identity of the employer, it must notify the employer¹⁶ of:

- the imposition of any sanction;
- the restoration of any registration;
- the expiry of any suspension period; and
- the removal of conditions from a registration.

It must also notify the employer of any similar action in respect of a registrant taken in another State of which it becomes aware, if it believes that it is in the public interest to do so. Where it becomes aware of such a corresponding action <u>and</u> where it intends to notify an employer of this, it will usually write to the pharmacist/pharmacy owner notifying them of its intention to inform the employer, confirming the identity of the person(s) it will notify and the date by which the notification will issue.

¹⁶ Section 56(3) of the Pharmacy Act 2007 (as amended).

The Health Service Executive (HSE)

The Council must notify the HSE ¹⁷of:

- cancellation of a registration
- the suspension of a registration
- the imposition of any sanction;
- the restoration of any registration;
- the expiry of any suspension period; and
- the removal of conditions from a registration.

It must also notify the HSE of any similar action in respect of a registrant taken in another State and of which it becomes aware, if it believes that it is in the public interest to do so. Where it becomes aware of such a similar action <u>and</u> where it intends to notify the HSE of this, it will usually write to the pharmacist/pharmacy owner notifying them of its intention to inform the HSE, confirming the date by which the notification will issue.

Other Persons

Where the Council believes that it is in the public interest to do so¹⁸, it must also notify any other persons it thinks fit of:

- the imposition of any sanction;
- the restoration of any registration;
- the expiry of any suspension period; and
- the removal of conditions from a registration.

Where it intends to notify any other person, the Council will usually write to the pharmacist/pharmacy owner notifying them of this, confirming the identity of the person(s) it will notify and the date by which the notification will issue.

Competent Authorities: notifications to third parties and IMI Alerts

The Act¹⁹ also requires the Council to give notification to the relevant bodies in other jurisdictions carrying out similar functions to the PSI, where any of the following actions are taken by the PSI in respect of a pharmacist:

- (a) the cancellation of a registration;
- (b) the suspension of a registration;

¹⁷ Section 56(1) of the Pharmacy Act 2007 (as amended)

¹⁸ Section 56 (1) of the Pharmacy Act 2007 (as amended)

¹⁹ Sections 56 (4) and (5) Pharmacy Act 2007 (as amended)

- (c) the attachment of conditions to a registration;
- (d) the prohibition for a specified period of a pharmacist or pharmacy owner from applying for restoration to the register;
- (e) the restoration of a registration;
- (f) the removal of conditions from a registration; and
- (g) the expiry of a suspension.

Where the Council has reason to believe that a pharmacist is registered in another jurisdiction, and certain actions to include the imposition of a sanction on them have not come to the attention of the relevant authority in that jurisdiction, the Council must notify that authority of the relevant action and may provide them with a copy of the relevant documents including the report of the Committee of Inquiry.¹ When exercising its powers under Section 56(4) of the Act, the Council will determine each case on its individual facts before making a decision on whether to disclose relevant documentation to a regulatory body in another jurisdiction. The disclosure of any such documentation will however generally be limited to the relevant report of the Committee and/or transcripts of relevant hearings and/or any High Court Order however the Council may provide any other documentation relevant to the action in question where the Council considers it appropriate and/or necessary to do so.

Where the Council has reason to believe that a pharmacist is registered in another jurisdiction, and it comes to the Council's attention that certain actions taken in another jurisdiction in respect of the pharmacist, to include the imposition of a sanction on them, have not been brought to the attention of the relevant authority in the jurisdiction in which the Council believes the pharmacist to be registered, the Council must give notice of the relevant action to that body, it if considers that it is in the public interest to do so². When determining whether it is in the public interest to give such notice under Section 56(5), the Council will have regard to the public interest considerations as set out in Appendix A of this document. Prior to making a notification pursuant to Section 56(5), the pharmacist will generally be notified in writing at least seven (7) days in advance of the making of any such notification. The Council may invite the pharmacist to make submissions in respect of whether the notification should be made. Where submissions are received, the Council will have regard to these in determining whether to make the notification. In the absence of any response from the pharmacist, the Council may proceed to make the notification pursuant to Section 56(5).

These obligations apply distinct from any obligation arising under the provisions of the Professional Qualifications Directive or the Professional Qualifications Regulations below.

The PSI is the "competent authority" in Ireland for the purposes of the Recognition of Professional

¹ Section 56(4) Pharmacy At 2007 (as amended) – delegated to the Registrar

² Section 56(5) Pharmacy Act 2007 (as amended) – delegated to the Registrar

Qualifications Directive²⁰ ("the Directive") in relation to pharmacists. The Directive only applies to authorities who are part of the European Union ("EU"), however the PSI also communicates with regulators in non-EU countries who fulfil a similar role to the PSI in their jurisdiction. In respect of similar regulators outside the EU, the PSI may be, but is not required to be, a party to a data sharing agreement or memorandum of understanding with that other regulator to facilitate the sharing of relevant information to protect the public interest and public health and safety.

The PSI has several obligations as a competent authority in relation to complaints and the notification of complaint outcomes to other competent authorities. Equally, it has statutory obligations under the Act to issue notifications in relation to certain outcomes following complaints to other third parties, which may include other regulators not specified as competent authorities under the Directive.

IMI Alerts: The PSI is required to issue a notification to the competent authorities in other Member States of the EU²¹, where a pharmacist's practice has been restricted or prohibited (even temporarily) in Ireland, or in other specific circumstances. There is an online notification system, called the Internal Market Information ("IMI") System, which facilitates these notifications. The PSI must make an IMI notification within 3 days of a decision restricting or prohibiting a person's practise as a pharmacist.

The information that must be included in the IMI alert is:

- (a) the identity of the professional;
- (b) the profession concerned;
- (c) information about the national authority or court adopting the decision on restriction or prohibition;
- (d) the scope of the restriction or prohibition; and

²⁰ Directive 2005/36/EC of the European Parliament and of the Council

²¹ Regulation 87, EU (Recognition of Professional Qualifications) Regulations 2017, S.I. No. 8/2017

(e) the period during which the restriction or the prohibition applies

Timing of statutory notifications and applications to the High Court

Statutory notifications (to the employer, HSE and any other persons) will not take place until after the sanction imposed has been confirmed by the High Court, where such confirmation is required. In the case of an admonishment or censure, the statutory notification(s) will be made after the expiry of the 30-day period allowed for an application to the High Court to cancel the sanction decision.

In the event that an application has been made by the pharmacist/pharmacy owner to the High Court to cancel the sanction, no publication or notifications will be made until after the High Court has given its decision.

The Council may not publish anything which is inconsistent with any decision of the High Court made in the context of its consideration of an appeal against sanction or an application to confirm sanction.²²

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²² Section 57(3) Pharmacy Act 2007 (as amended)

E. Anonymisation and Privacy Considerations

The Act provides that:

- Inquiry hearings before the Professional Conduct Committee be heard in public, unless an
 application to hold the hearing in private is made by the registrant or complainant and
 acceded to by the Committee; and
- Inquiry hearings before the Health Committee be heard in private, unless an application to hold the hearing in public is made by the registrant or complainant and acceded to by the Committee.

Irrespective of whether an Inquiry hearing was held in public or private, or a mediation was held which takes place in private, the Council is obliged to give public notice of all sanctions in accordance with section 57 of the Act. The form and manner of publication which may be decided by Council, may in certain cases, be subject to any final decision, where relevant, by the High Court.

Where the Inquiry hearing was heard in private or before the Health Committee, the Council may have regard to this in determining whether:

- it is in the public interest to give public notice of any sanction of admonishment or censure imposed; and
- it is in the public interest to publish some or all of the transcript and some or all of the Committee report; and
- any aspect of the publication should be anonymised.

The Council, in making its decision regarding complaints/inquiries which may have anonymisation or privacy issues may also give consideration to whether:

- (a) there has been any direction by the Committee which requires anonymisation or privacy in a certain format and/or,
- (b) compelling arguments have been made to the Council as to why publication should not be made or should be made in an anonymised form and/or,
- (c) the inquiry hearing took place in private and if so the reasons for this.

The Council may also consider whether the public interest is best served through transparent reporting on the outcomes of complaints in an un-redacted and un-anonymised format.

The Council will however consider each matter where it is required to consider publication of a transcript or report and public notice of sanction on a case-by-case basis giving particular consideration to the guidance in relation to the public interest test as set out in Appendix A of this document and to the factors as set out above.

Where the inquiry related to health issues or impairment however, the Council would usually give public notice of the sanction, where it is required to do so, in an anonymised manner. Where it also decides in such a matter that it is in the public interest to publish the transcript and/or the Inquiry report it will usually publish in a redacted and anonymised form also. This form of publication is to protect the privacy of the pharmacist/pharmacy owner particularly if there is

ongoing impairment or health issues.

See also Section F below dealing with content of public notices.

F. Content of Public Notices

Professional Conduct Committee (PCC) Inquiries

Where the Council gives public notice of a sanction following an Inquiry before the PCC, it will usually:

- publish the fact of the sanction and the effective date of the sanction;
- identify the pharmacist/pharmacy owner on whom the sanction has been imposed; and
- where conditions have been attached to a pharmacist or pharmacy's registration, publish the detail of the condition(s) that have been attached.

If it considers it is in the public interest to do so, the Council will also publish:

- some or all of the transcript of the proceedings of the Committee of Inquiry; and
- some or all of the report of the PCC.

It is open to Council, at its discretion, to publish the transcript or report in a redacted form, to protect the privacy of any party or person involved, where it considers it appropriate to do so. In any event, no publication shall be made which is inconsistent with any Order of the High Court, where applicable.

Notice of Sanction will be published on the PSI website for the duration of the time period set out in the table at Appendix D. It will also be published in the PSI newsletter issued following the sanction(s) taking effect.

Sanctions will also be reflected as appropriate on the public register of pharmacists/retail pharmacy businesses maintained by the PSI, in the manner set out at Appendix D. The public register is accessed through the PSI website. The Council will only publish in accordance with any decisions regarding anonymity and privacy nothing shall be published which is inconsistent with any Order of the High Court.

Health Committee Inquiries

Where the Council gives public notice of a sanction following an Inquiry before the Health Committee, it will usually:

- publish the fact of the sanction;
- identify the pharmacist/pharmacy owner on whom the sanction has been imposed unless the Council has decided to anonymise the pharmacist; and
- where conditions have been attached to a pharmacist or pharmacy's registration, publish only the fact that conditions(s) have been attached to the pharmacists/pharmacy's registration, unless Council decides that it is appropriate to publish the detail of the conditions. It will indicate that if further information is required in relation to the conditions attached, enquiries should be made with the Registrar. Consideration may be given as to how the information appears on the

public register as opposed to the website.

Where the Council has decided that it is in the public interest to publish:

- some or all of the transcript of the proceedings of the Committee of Inquiry; and
- some or all of the report of the Health Committee,

publication will be made in accordance with the Council's decision, particularly with regard to any anonymisation, privacy or redaction. In any event, no publication shall be made which is inconsistent with any order of the High Court, where applicable.

Notice of Sanction will be published on the PSI website for the duration of the time period set out in the table at Appendix D. Notice of sanction will also appear in the PSI newsletter issued following the sanction(s) taking effect.

Sanctions will also be reflected on the public register of pharmacists/retail pharmacy businesses maintained by the PSI, as appropriate, in the manner set out at Appendix D. The public register is accessible through the PSI website. The Council will only publish in accordance with any decisions regarding anonymity and privacy and nothing shall be published which is inconsistent with any Order of the High Court.

High Court Orders and Publication

Section 57(3) of the Pharmacy Act 2007 (as amended) provides that the Council shall not publish anything under that section which is inconsistent with any decision of the High Court made in the context of its consideration of a sanction confirmation or sanction cancellation application.

Where an application to the High Court is necessary to confirm a sanction imposed (this applies to all sanctions except admonishment and censure), or if an application is made to the High Court to cancel the sanction, no publication will take place by the Council until after the High Court has given its decision.

The applications before the High Court to cancel or confirm sanctions are usually made in public. In certain cases, the High Court may decide to hear the application to cancel or confirm in private, or direct that the proceedings be anonymised so that the names of the pharmacist/pharmacy owner and other identifying details cannot be published in the media.

If the High Court holds a confirmation application or appeal hearing in private, and/or makes a direction in respect of the anonymization of certain aspects of the High Court proceedings, then the Council will amend its publication to reflect this.

G. Location of Public Notice

The PSI will usually give public notice of sanction and publish the Committee Report and/or transcript, where relevant, as soon as practicable after the taking effect of the sanction(s), in the following locations:

- (a) on the PSI website;
- (b) in the PSI Newsletter (an electronic newsletter); and
- (c) on the public register, as appropriate.

Where publications appear on the PSI website, the transcript and Committee report, where applicable, will appear together with the notice of sanction.

Notifications in the PSI Newsletter will be linked to the relevant publications on the PSI website.

PSI Website

Public notices of sanction are placed on the PSI website in the complaints section of the website.

The public notice will generally include:

- the registrant's name and registration number (unless anonymised in accordance with the Council or High Court decision);
- confirmation that a Mediation took place or an Inquiry before the PCC/Health Committee (as applicable) and the dates of that Inquiry or Mediation;
- the sanction(s) imposed by the Council including the detail of any conditions attached to registration, where appropriate;
- confirmation that the sanction was consented to by an undertaking (if applicable);
- the terms of resolution of the mediation, where publication of same was on consent (if applicable); and
- any other information which the Council or High Court has decided to publish

Where Council decided to publish the Committee Report and/or transcript, a copy of the relevant publication in the permitted form (i.e. redacted, anonymised etc.) will also be published with the notice of the sanction, provided it is not inconsistent with any Order of the High Court.

For details of publications which may appear on the PSI Website and the duration of publication, see Appendix D.

PSI Newsletter

The public notice of sanction will usually be published in the PSI Newsletter, with a link to the relevant page on the PSI website where the sanction and any other authorised information is

published, as soon as practicable after the sanction(s) takes effect. The newsletter is circulated electronically to PSI registrants, Council and Committee members, and those who subscribe to the newsletter. The notification will usually name the registrant (if not anonymised).

Public Register

The Public Register of pharmacists and pharmacies is accessible by any member of the public through the PSI website.

Where a sanction has been imposed on a pharmacist/pharmacy owner, the public register will be updated to reflect this as and from the date upon which the sanction takes effect, where public notice of the sanction has been given. The entry for the relevant pharmacist or retail pharmacy business name will be amended to include:

- (a) the fact of a sanction:
- (b) whether or not there are conditions attached to registration. Where relevant, the conditions may be published.
- (c) if registration has been suspended and if so for how long

The detail of conditions arising from health/impairment matters will not be visible on the public register. Instead, the register will confirm that conditions are attached to the pharmacists registration with a direction to contact the Registrar for any queries.

Where a suspension has been imposed by way of sanction, or an interim suspension is in place pursuant to an Order of the High Court under section 45 of the Pharmacy Act 2007, the fact of that suspension and the effective dates shall appear on the public register, along with any other direction as may have been given by the Order of the High Court regarding the suspension.

If a registrant gives an undertaking not to practise, whether as part of any disciplinary process (including pending the resolution of a complaint) or otherwise, the fact of that undertaking and the terms of the undertaking will be recorded on the public register against the registrant's name, where the registrant has agreed to this being reflected on the register.

Cancellations of registration or prohibitions on applying for restoration to the register will not appear on the public register because once the registration is cancelled, the person/entity is removed from the register.

Publication of sanction(s) on the public register will be made in accordance with the timelines as set out in Appendix D.

H. Other learnings

The Council may direct that a summary, anonymised document should be published containing learnings for the profession following the outcome of any concluded complaint. These are notified in the PSI newsletter and published on the PSI website.

The Executive of the PSI also retains the discretion to publish learnings, even if not directed by the Council, in an effort to assist the education of, and the provision of guidance to the profession, and to promote and uphold professional standards in the pharmacy profession generally. The content of the proposed learnings document will usually be provided to the pharmacist/pharmacy owner before it is published.

Certificates of Current Professional Status

Pre- Sanction: If a certificate of current professional status is requested in relation to a pharmacist at any stage of the complaints process prior to a sanction being imposed by Council/the High Court, a certificate is issued limited to confirming that there are no restrictions on practise in respect of the pharmacist, if that is the case. However, such a certificate may indicate that there is an ongoing investigative process. Normally, such a certificate is sent in draft form to the registrant, advising them that the certificate will issue as drafted within seven days, after which, it is issued to the requestor.

Post-Sanction/Determination of Complaint: Where a request is made for a certificate of current professional status in relation to a pharmacist who has been the subject of sanctions imposed by the Council, the certificate provided will show:

the fact that they were the subject of a complaint referred to Mediation or Inquiry before
the PC/Health Committee (as applicable); and sanction(s) imposed. In cases where an
admonishment or censure was imposed, these will only appear on a Certificate of Current
Professional Status for 2/3 years respectively, from the date that the sanction takes
effect.

Where any complaint was found unsubstantiated, the Certificate shall not make reference to the fact that a complaint was made.

Information for Employers

Prospective employers are required to check the <u>PSI public register</u> and be satisfied as to a pharmacist's registration status before employing them. If an employer has a query in relation to the registration status of a pharmacist, they should make a written request to the Registrar of the PSI for information.

I. Conclusion

This document has been prepared by the Council of the PSI to provide guidance on its publication and disclosure policy regarding statutory fitness to practise complaints and disciplinary proceedings. It may be updated from time to time.

This document is not binding on the Council. The provisions of the Act take precedence over any guidance contained within this document. Nothing in this document should be construed as legal advice. Any person the subject of a disciplinary process under Part 6 of the Act is advised to take independent legal advice.

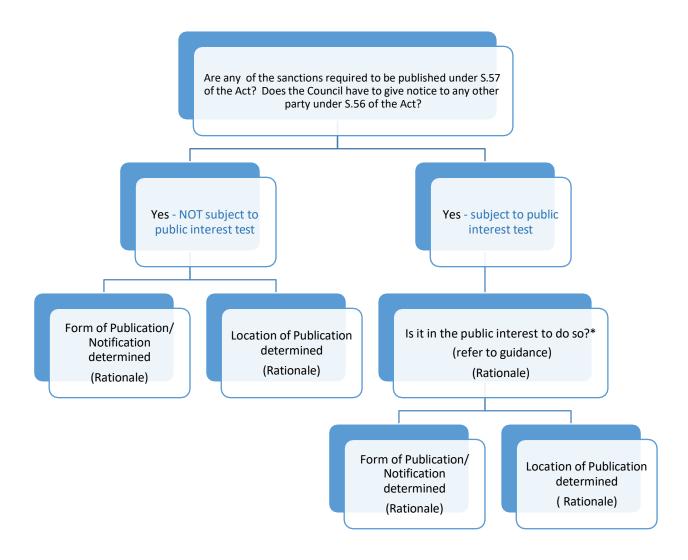
Media queries about PSI regulatory processes should be directed to the Communication and Engagement team by email to communications@psi.ie.

Appendix A- Public Interest Considerations

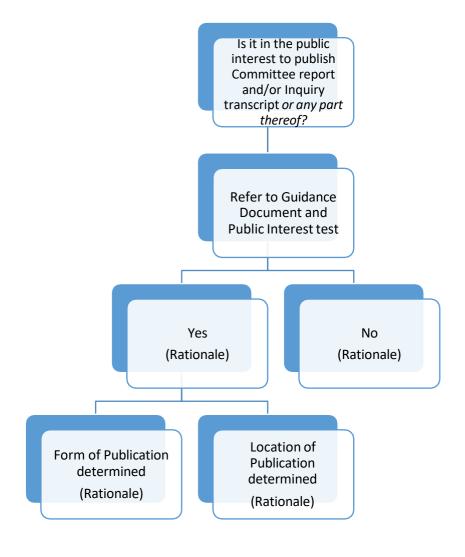
Some of the factors which may be taken into account by the Council in determining whether publication or notification is in the public interest include:

- The need to protect patients and the public;
- Maintenance of public confidence in the profession of pharmacy;
- Promoting and upholding of standards in the profession of pharmacy;
- Educating the profession of the lessons to be learned from complaints so asto minimise the risk of recurrence;
- What publication is proportionate in the circumstances;
- Whether the Inquiry was held in public or private;
- Whether any detail of the Inquiry was anonymised by direction of the Committee of Inquiry;
- Whether the particulars of the complaint are already in the public domain;
- The importance of putting some form of factual context in the publication so as to inform
 the profession and the public of the factors giving rise to the complaint, the findings of the
 Committee of Inquiry, and the sanction imposed;
- Whether any legal judgment or Court Order relating to the complaint is already in the public domain;
- The view of the Council in terms of the gravity and nature of the conduct;
- The potential for harm to patients arising from the conduct the subject matter of the Inquiry;
- The privacy of parties involved in the hearing or external parties referred to in the proceedings;
- The psychological impact of publication on the parties concerned; and
- Whether disproportionate reputational damage will be caused to the pharmacist/pharmacy.

Appendix B: Publication of Sanctions - Decision Tree



Appendix C: Publication of Transcript and /or Committee Report - Decision Tree



Appendix D: Public Notice Timeframes – PSI Website & Public Register

Public notices of sanctions, and publication of reports of Committees of Inquiry and/or transcripts of Inquiry hearings, will be published on the PSI website and Public Register (as relevant) for the following time periods and on the basis as set out below:

Sanction	PSI Website – Public Notice	Public Register - Registrant Record
Admonishment	2 years from the effective date of the sanction	2 years from the effective date of the sanction.
Censure	3 years from effective date of the sanction	3 years
Conditions	Until the date of expiry of the conditions, and for 2 years thereafter.	For the duration of the period during which conditions attach. Conditions in relation to health matters will not usually be visible on the public register and a notice will indicate that any queries should be directed to the Registrar.
Suspension of Registration	For the duration of the suspension and for 5 years thereafter.	Visible on the Register for the duration of the suspension. Status will show registration suspended by Order of the High Court and the date of the order.

Cancellation of Registration	Indefinitely, unless the registrant successfully applies to restore registration in which case it will be removed 2 years after date of restoration	Registrant will not appear on the register.
Prohibition from Applying for Restoration to the Register	Indefinitely, unless the registrant successfully applies to restore registration in which case it will be removed 2 years after date of restoration.	Registrant will not appear on the register.
Undertakings	Only in accordance with any Council decision or order of the High Court or Terms of Resolution following a Mediation or consent provided by a registrant	Register will reflect if an undertaking not to practise has been given and the terms of that undertaking, if the registrant has consented to this. An undertaking given under section 46 will not be reflected on the public register.
Interim Suspension of Registration pursuant to s45 of the Act	Publication will only be in accordance with any order of the High Court.	Status will show registration temporarily suspended by Order of the High Court and the effective date of the suspension period. The status will remain visible for the duration of the suspension period.
Committee Reports and Transcripts	Publication is linked to the public notice for the relevant sanction to which the Report and/or transcript refers and shall remain for the length of time specified for that sanction, and/or in accordance with any decision of the Council or High Court as relevant.	N/A

Appendix E: Sample Public Notice – PSI Website and Newsletter

Website - Sample Notice

IN THE MATTER OF PART 6 OF THE PHARMACY ACT 2007

Name of Pharmacist, MPSI (Reg. No. xxxx)

Name of Retail Pharmacy Business, (Reg. No. xxxx)

Following a hearing of the Professional Conduct Committee (PCC) into a complaint made against [NAME OF PHARMACIST/RETAIL PHARMACY BUSINESS], the Council considered the report of the PCC on XX/XX/XXX, and decided to [DETAIL OF SANCTION AND AGAINST WHOM], and to give public notice of that [DETAIL OF SANCTION] [in the public interest] in accordance with section 57 () () of the Pharmacy Act 2007, and to publish the [Report and/or Inquiry Transcript] of the PCC in the public interest in accordance with section 57(2) of the Pharmacy Act 2007.

View the Report of the Professional Conduct Committee here.

Effective Date of Decision: XX/XX/XXXX

Newsletter – Sample Notice

Under the Pharmacy Act 2007 (as amended) the PSI Council must give public notice of certain sanctions following a fitness to practise process, and for other sanctions, it must give public notice if it is in the public interest to do so. The Council may also decide to publish some or all of the report of a Committee of Inquiry, or the transcript of an inquiry. This information is published in the Complaints section of the PSI Website, in the Findings and Decisions page.

Following a hearing of the **Professional Conduct Committee** (PCC) into a complaint made against [NAME OF PHARMACIST/RETAIL PHARMACY BUSINESS] the Council considered the report of the PCC on (XX/XX/XXX) and decided to [DETAIL OF SANCTION AND AGAINST WHOM], and to give public notice of that [SANCTION] in the public interest. [The Council also decided that it was in the public interest/not in the public interest to publish the Committee report and/or Inquiry transcript.] View Notice and Report and/or Inquiry Transcript.