The Pharmacy Regulator
An Rialtóir Cógaisíochta

External Protected Disclosure (Whistleblowing) Policy

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1. Introduction

The Protected Disclosures Act 2014, as amended by the Protected Disclosures Act 2022 (the Protected Disclosures Acts), enables workers to raise a concern regarding potential wrongdoing in the workplace by ensuring that safeguards exist should reprisals be taken against them.

The purpose of this policy is to set out the Pharmaceutical Society of Ireland's (PSI) procedure for dealing with protected disclosures received by the Registrar/Chief Officer of the PSI as a prescribed person listed in the Protected Disclosures Act 2014 (Disclosure to Prescribed Persons) Order 2020.

This legislation prescribes the Registrar as a recipient of protected disclosures regarding all matters relating to the regulation of the profession of pharmacy and pharmacies in the State, including the PSI's responsibility for the supervision of compliance with the Pharmacy Act 2007.

A disclosure made to the Registrar, as a prescribed person, is a protected disclosure if the following conditions are met:

a) You reasonably believe that the relevant wrongdoing is within the remit of the Registrar as they have regulatory functions within the area, which are the subject of the allegations.

b) The information you disclose and any allegation in it came to your attention in connection with your employment, which is outside the PSI, and the allegations are substantially true (this is a higher standard than is required for disclosure directly to your employer).

2. What is Whistleblowing?

Whistleblowing occurs when a worker raises a concern or discloses information that relates to wrongdoing, illegal practices, or unethical conduct that has come to their attention through work. A protected disclosure is defined as:

"a disclosure of information which, in the reasonable belief of the worker, tends to show one or more relevant wrongdoings; came to the attention of the worker in connection with the worker's employment; and is disclosed in the manner prescribed under the Act" (Protected Disclosures Act 2014, as amended).

Relevant wrongdoings are broadly defined in the Protected Disclosures Acts and include the following:

- The commission of an offence;
- The failure to comply with a legal obligation other than one arising under the worker's contract;
- A miscarriage of justice;
- Endangering the health and safety of any individual;
- Damage to the environment;
- Unlawful or improper use of the funds or resources of a public body or other public monies;
- Any act or omission by or on behalf of a public body that is oppressive, discriminatory, grossly negligent or constitutes gross mismanagement;
- Any information that would tend to show that any of the above matters has been or may be concealed or destroyed and
- A breach of law, defined as acts or omissions that are either unlawful or that defeats the object or the purpose of the rules, is occurring or likely to occur.

3. To whom does the policy apply?

This policy applies to all workers (external to the PSI), including employees at all levels, for example, agency workers, independent contractors, trainees, student interns working on placements, volunteers, unpaid trainees or an individual who acquires information on a relevant wrongdoing during a recruitment process or other pre-contractual process as a pharmacist or working in a pharmacy and office holders, e.g., shareholders in a pharmacy.

4. Our Commitment

The PSI is committed to maintaining an open culture with the highest standards of honesty and accountability where workers can report any concerns in confidence. All workers are encouraged to raise genuine concerns about possible improprieties at the earliest opportunity and in an appropriate way through their employer's internal channel and procedure first.

The objective of this policy is to enable workers to raise concerns about possible wrongdoing in the workplace, external to PSI so that these concerns can be addressed in a manner appropriate to the circumstances of the case. The PSI is committed to ensuring that all workers who contact the prescribed person are listened to and relevant actions are taken to address their concerns, as appropriate, and/or that the information is referred, in line with the legislation, to another prescribed person and/or the Office of the Protected Disclosures Commissioner.

5. Aims of the Policy

This policy aims to:

- Encourage you to feel confident and safe in raising concerns and disclosing information in relation to suspected wrongdoing;
- Provide guidance as to how to raise such concerns;
- Reassure reporters that they should be able to raise genuine concerns without fear of reprisals, even if they turn out to be mistaken;
- Give effect to the obligations and provisions of the Protected Disclosure legislation.

6. What types of concerns or disclosures can be made?

A concern or disclosure should contain information which tends to show wrongdoing, such as possible fraud, crime, danger or failure to comply with any legal obligation, which is in the remit of the PSI, has come to your attention in connection with your employment and about which you have a reasonable belief that the information is substantially true. Relevant wrongdoings are broadly defined in the Protected Disclosures Acts and include the following:

- The commission of an offence;
- The failure to comply with a legal obligation other than one arising under the worker's contract;
- A miscarriage of justice;
- Endangering the health and safety of any individual;
- Damage to the environment;
- Unlawful or improper use of the funds or resources of a public body or other public monies;
- Any act or omission by or on behalf of a public body that is oppressive, discriminatory, grossly negligent or constitutes gross mismanagement;
- Any information that would tend to show that any of the above matters has been or may be concealed or destroyed and
- That a breach of law (including European Union laws) defined as acts or omissions that are either unlawful or that defeat the object or the purpose of the rules is occurring or likely to occur.

Disclosures of wrongdoing may also be made by workers in respect of other relevant employment-specific or profession-specific obligations, which may not be covered by the definition of wrongdoing in the Protected Disclosures Acts and may be covered by other statutory protection for disclosures.

Information received that does not fall within the PSI's remit will be transferred to another prescribed person and or to the Protected Disclosures Commissioner.

A protected disclosure should contain information which tends to show wrongdoing. The information should contain specific factual information that tends to show a relevant wrongdoing to allow the appropriate assessment and investigation of the disclosure. Workers are not required or entitled to investigate matters themselves. This responsibility lies with the prescribed person.

As it is not possible to know at the time of disclosure whether the disclosure would subsequently be deemed to be protected under the Act, all disclosures from workers will initially be treated as if they meet the criteria in the Protected Disclosures Acts.

Once a protected disclosure has been made in accordance with the legislation, it is not possible for you to withdraw the disclosure and reporting persons are required to cooperate with a prescribed person.

The Guide for Making a Protected Disclosure to a Prescribed Person is included in Appendix A.

7. Safeguards and Penalisation

A worker who makes a disclosure and has a reasonable belief of wrongdoing should not be penalised, even if the concerns or disclosure turn out to be unfounded. The term reasonable belief does not mean that the belief has to be correct. Workers are entitled to be mistaken in their belief so long as their belief is based on reasonable grounds. Workers are not expected to prove the truth of an allegation; however, they must have a reasonable belief that there are grounds for their concern. The Protected Disclosures Acts prohibit any employer from penalising an employee for having reported a relevant wrongdoing or for making a disclosure.

A disclosure made in the absence of a reasonable belief will not attract the protection of the Protected Disclosures Acts. In addition, disclosure of a wrongdoing does not necessarily confer any protection or immunity on a worker in relation to any involvement they may have had in that wrongdoing.

Motivation is irrelevant when determining whether or not it is a disclosure protected by the Act. All protected disclosures should be dealt with regardless of the worker's motivation for making the disclosure, and the worker should be protected so long as the worker reasonably believes that the information disclosed tended to show a wrongdoing.

Examples of penalisation include any unfair or adverse treatment (whether acts of commission or omission), including suspension/dismissal, coercion, withholding of training, negative performance assessment, intimidation or harassment, disciplinary action, demotion, loss of opportunity for promotion or withholding of promotion, transfer of duties, reduction in wages or working hours, discrimination, threats, injury damage or loss, threat of reprisal, harm, including to the persons reputation or other unfavourable treatment arising from raising a concern or making a disclosure on the basis of reasonable belief for doing so.

If you believe that you have been penalised for making a disclosure you should utilise your employers' internal procedures for dealing with workplace complaints. You can also refer a complaint to the Workplace Relations Commission within six months. If you believe you have been penalised, you may also seek interim relief from the Circuit Court under the Protected Disclosures Acts.

8. Confidentiality

The PSI is committed to protecting the identity of the worker raising a concern and ensuring that relevant disclosures are treated in confidence. The focus will be on the wrongdoing rather than the person making the disclosure. A person to whom a protected disclosure is made, and any person to whom a protected disclosure is referred in the performance of that person's duties, shall not disclose to another person beyond such persons authorised to receive or follow up on the disclosure concerned, any information that might identify the person by whom the protected disclosure was made. However, there are circumstances, as outlined in the Act, where confidentiality cannot be maintained, particularly in a situation where the worker is participating in an investigation into the matter being disclosed or where it is required by law.

The following are examples of specific cases in which the identity of the discloser may not be protected:

- The disclosure recipient shows that they took all reasonable steps to avoid such disclosure.
- The disclosure recipient has a reasonable belief that the discloser did not object to their identity being disclosed;
- Where the disclosure is otherwise necessary in the public interest or is required by law and
- The disclosure recipient had a reasonable belief that it was necessary for:
    (i) The investigation of the wrongdoing concerned,
    (ii) To prevent serious risk to the security of the State, public health, public safety or the environment, or
    (iii) The prevention of crime or prosecution of a criminal offence;

In the instances outlined above, the reporting person shall be informed before their identity is disclosed unless such information would jeopardise the related investigations or judicial proceedings.

The protections that apply within Section 16 of the Act also apply to any other named person in a protected disclosure.

9. Making a Concern Anonymously

There is a difference between an anonymous disclosure (where identity is withheld by the discloser) and a confidential disclosure (where identity is protected by the recipient). A concern may be raised anonymously under the Act.

However, on a practical level, it may be difficult to investigate such a concern. The Act does not place an obligation to accept and follow up on anonymous disclosures. We would encourage workers to put their names to allegations, with our assurance of confidentiality where possible, in order to facilitate appropriate follow-up. This will make it easier for us to assess the disclosure and take appropriate action, including an investigation if necessary. A worker who has disclosed a wrongdoing cannot obtain redress under the Act without identifying themselves.

10. Records

Records of concerns raised, including the outcome, will be maintained in line with the PSI's Record Retention Policy and Data Protection Statement. These records will be maintained in a confidential and secure environment. A summary report outlining the number of protected disclosures received by the PSI will be included in the Annual Report and published on the PSI website.

11. Review

If a reporting person is not satisfied with the outcome of the initial assessment, they can request a review of that decision in writing, and it will be reviewed in as far as possible by a person designated by the Registrar who has not been involved in the initial assessment, investigation or decision. Reviews can be made in respect of the following:

- Any decision made to disclose the identity of the discloser (except in exceptional cases) and

- The outcome of any assessment/investigation undertaken in respect of the protected disclosure.

Where a decision is taken to disclose the identity of the discloser, where at all possible, the discloser should be offered a review before their identity is disclosed. The review process should ensure that there is no entitlement to two reviews in respect of the same issue.

12. Independent Support and Advice

There are a number of agencies that can provide confidential support and advice to workers considering making a protected disclosure. Information about what wrongdoings can be reported as protected disclosures, how to make a protected disclosure and how to obtain protection from penalisation for having made a protected disclosure can be found on the Department of Public Expenditure and Reform website and the Citizens Information website. The Transparency International Ireland Legal Advice Centre provides free legal advice to anyone who wishes to disclose wrongdoing, particularly under the Act. Workers can access this via the Speak Up helpline on 1800 844 866.

A worker can report a relevant wrongdoing that is in breach of European Union (EU) law to a relevant institution, body, office, or agency of the EU.

A worker could also seek advice from their trade union or solicitor about the operation of the Act prior to making a disclosure. When the worker seeks advice from a trade union, barrister or solicitor about the operation of the Act, this discussion is also a 'protected disclosure'. (It is sufficient to be protected that the purpose of the discussion was that the worker was seeking advice about the operation of the legislation). Advice on the operation of the Act can be sought at any stage, including in advance of making a protected disclosure and during the subsequent process in both internal and external channels.

Information on workers' rights and entitlements under employment legislation can be found on Workplace Relations Commission.

13. Contact Details

Designated Individuals	Contact Details
Protected Disclosure Officer (Internal Channel)	Ms. Aoife Mellett aoife.mellett@psi.ie 01 218 4007
Protected Disclosure Officer (External Channel)	Ms. Damhnait Gaughan protecteddisclosure@psi.ie 01 218 4066
Registrar (Prescribed Person for the profession of pharmacy and pharmacies)	Ms. Joanne Kissane Joanne.kissane@psi.ie 01 2184000

14. Review and Approval of the External Protected Disclosure (Whistleblowing) Policy

This policy will be communicated as appropriate, and the procedures made under it will be subject to periodic review at least every three years.

Revision	Date	Description	Approved by
1	2014	Guide to Making a Protected Disclosure	ELT
2	15 March 2023	PSI External Protected Disclosure Policy	Audit & Risk Committee
3	23 March 2023	PSI External Protected Disclosure Policy	Council
4	18th March 2025	Review of PSI External Protected Disclosure Policy	Audit & Risk Committee
5	24th April 2025	Review of PSI External Protected Disclosure Policy	PSI Council

Appendix A Guide to Making a Protected Disclosure to a Prescribed Person

1. Making a Disclosure to a Prescribed Person

A worker must make a disclosure in the manner set out in the Act to gain the protections of the Act. As a first step, appropriate concerns should be raised with the individual's employer. Higher standards apply when a protected disclosure is made externally. Concerns should be raised with the PSI's Protected Disclosures Officer (external), following the steps outlined below. The contact details for the Protected Disclosure Officer can be found in Section 13 of this policy. If the Protected Disclosure Officer (external) is conflicted the concern should be raised directly with the Registrar, who will designate a person to manage the protected disclosure. Any processing of personal data carried out under the Act will be carried out in accordance with Data Protection legislation.

It is a criminal offence to report information that you know to be false, and you may be subject to a civil claim by any person who suffers damage resulting from the making of a report where the reporting person knowingly reported false information. You must have a reasonable belief that the information you give tends to show one or more wrongdoing.

2 How to raise a concern?

The earlier you express the concern, the easier it will be to deal with the matter quickly. Concerns may be raised verbally or in writing to the designated person within the PSI. Contact details for designated people are provided at the end of this document. Should you raise a concern verbally, we will keep a written record of our conversation and provide you with a copy after the meeting. Should you raise a concern in writing, we would ask you to:

1. Indicate that you are making a protected disclosure;
2. Provide your name, place of work, position in the organisation and confidential contact details;
3. Provide the date of the alleged wrongdoing (if known) or the date the alleged wrongdoing commenced or will commence or was identified;
4. Provide details as to whether the alleged wrongdoing is still ongoing;
5. Provide details as to whether the alleged wrongdoing has already been disclosed and, if so, to whom, when, and what action was taken;
6. Provide information in respect of the alleged wrongdoing and any supporting documentation
7. Provide the name of any person (s) allegedly involved in the alleged wrongdoing (if you believe this is necessary to expose the wrongdoing); and

8. Provide any other information that you think may be relevant.

If a disclosure is made to an individual in the PSI who is not a designated person, then the individual receiving the disclosure should advise the discloser to report the matter to the appropriate recipient as set out in this policy. If the discloser indicates that they are unwilling to do this, then the recipient should get consent from the discloser to receive the disclosure and refer it to the designated person in the PSI, either by email or phone. All PSI staff should be trained in relation to understanding the requirements of the Protected Disclosures Acts and how to identify a protected disclosure to enable them to refer it to the designated person.

3. How will we respond to disclosures raised?

Having raised your concern:

1. An acknowledgement of receipt of the disclosure will be made within seven days unless the designated person reasonably believes acknowledgement of the receipt would jeopardise the protection of the identity of the reporting person.

2. An initial assessment will be carried out by the designated person responsible for managing the disclosure, e.g. Protected Disclosure Officer or person(s) designated by the Registrar, which may include seeking additional information from you. The designated person will aim to complete the initial assessment within 30 days, with due consideration to the nature of the disclosure and the issues arising.

    a. If, having carried out such an initial assessment, the designated persons decides that the information is not within the remit of PSI, the information will be transferred to another prescribed person or the Protected Disclosures Commissioner for assessment, and the discloser will be notified in writing.

    b. If having carried out such an initial assessment, the designated persons decide that there is not sufficient evidence that a relevant wrongdoing may have occurred, they will notify you as soon as practicable of that decision and the reasons for it and the procedure will be closed.

    c. If, during the initial assessment, it appears that the disclosure or issues related to the disclosure have already been investigated by the PSI, the designated person may need to review these findings before determining if further steps need to be taken under this policy.

d. If, having carried out such an initial assessment, it is decided that there is sufficient evidence that a relevant wrongdoing may have occurred, the PSI may need to investigate further and will, in any event, take appropriate action to address the relevant wrongdoing, having regard to the nature and seriousness of the matter concerned and the available information.

3. The designated person may, as necessary, arrange a further meeting or meetings with you to discuss your concern.

4. Where there is sufficient evidence that a relevant wrongdoing may have occurred, the information received will be brought to the attention of the relevant inspection/investigation team for effective follow-up, in line with PSI's regulatory remit. In some cases, we may appoint an independent investigator with relevant investigative experience or specialist knowledge of the subject matter.

5. We will provide feedback to you within a reasonable period and no longer than three months from the date of acknowledgement of your disclosure. Further feedback will, as necessary, be provided at intervals of three months until the procedure is closed.

Disclosures may, in light of the seriousness of the allegations, be referred to the appropriate authorities or such prescribed person under legislation as may be appropriate. Where a report of a disclosure concerns a breach of EU law, as provided for in the Act, the prescribed person must send the information to the relevant EU body as soon as is practicable, where this is provided for under EU or Irish law.

In circumstances where an investigation does not conclude that any relevant wrongdoing has taken place or where the person making the disclosure is mistaken or unaware of all the facts surrounding the issues raised, the designated person will explain that the concerns are unfounded.

Sometimes, the need for confidentiality may prevent us from giving you specific details of the investigation and/or any outcome or disciplinary action taken as a result. You should treat any information about the investigation as confidential.

If you make a report in accordance with this policy, but the information or allegation is subsequently not confirmed by the investigation, no action will be taken against you. You will be fully protected from any less favourable treatment, penalisation or victimisation under the Protected Disclosure Acts.