

# Guide to sanctioning



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AN RIALTÓIR CÓGAISÍOCHTA  
THE PHARMACY REGULATOR

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## 1. Background

Where, following an inquiry by either the Professional Conduct Committee or the Health Committee, a complaint against a pharmacist or pharmacy owner has been upheld, section 48 of the Pharmacy Act 2007 (the Act) requires the Council to impose one or more of the following sanctions:

- a. Admonish or censure the pharmacist or pharmacy owner
- b. Attach conditions to the registration of the pharmacist or retail pharmacy business
- c. Suspend the registration of the pharmacist or retail pharmacy business for a specified period
- d. Cancel the pharmacist's registration or that of the registered retail pharmacy business
- e. Prohibit the pharmacist or pharmacy owner from applying to restore their name to the Register for a specified period

In deciding what sanction to impose the Council will consider submissions made by pharmacist/pharmacy owner and from the Registrar in relation to the appropriate sanction to impose in the circumstances of the particular case. High Court approval is required for the sanctions listed at (b) through (e) above.

The purpose of this document is to provide information regarding:

- (1) Council's general approach to sanctioning following inquiry
- (2) the factors the Council will take into account in determining what sanction is appropriate
- (3) examples of conduct that will indicate that a person is not fit to be registered as a pharmacist or pharmacy owner <sup>1</sup>

The document will assist:

- (a) the Council in determining appropriate sanctions in cases where complaints have been substantiated
- (b) the Professional Conduct Committee and the Health Committee in deciding what sanctions it will recommend to Council and in determining whether it is appropriate to request undertaking from a pharmacist or pharmacy owner<sup>2</sup>
- (c) parties appearing before the Council and/or their representatives when sanction is being considered. Fairness requires that a pharmacist/pharmacy owner appearing before the Council knows prior to any decision being made (a) what sanctions are available to the Council and (b) the matters that the Council will take into account when coming to a decision
- (d) members of the public in understanding the sanctions imposed by Council and the standards expected of pharmacists/ pharmacy owners
- (e) pharmacists and pharmacy owners in their understanding of how this aspect of regulation works in practice

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<sup>1</sup> for the purposes of section 14 and section 36 of the Pharmacy Act 2007

<sup>2</sup> under section 46 of the Pharmacy Act

This document provides a framework for its decision making. A range of activities can give rise to sanctions and there is necessarily a degree of overlap as to what sanction may be appropriate in a given set of circumstances. This document gives an indication of the approach that will be taken by Council in determining the appropriate sanction.

This document is not legally binding and is not legal advice. In each case where the Council is considering sanction it will have the assistance of a legal adviser and the registrants concerned and the Registrar will have the opportunity to make representations as to the appropriate sanction. This guidance cannot operate to alter or displace what is the law. Pharmacists and pharmacy owners are advised to take independent legal advice if they are the subject of a complaint to the PSI.

This document will be updated and revised as the need arises.

## 2. Application for Registration or Continued Registration

As noted above, the principles set out in this document are also relevant for the Council in deciding whether a pharmacist is fit to be registered.<sup>3</sup> In determining whether a person is fit to be registered the Council will have regard to whether the person has-

- a) been prohibited from practising as a pharmacist in another State
- b) been prohibited from providing health or social care/services in this or in another State
- c) been convicted of an offence in another state which has a bearing on their fitness to practise

In addition where a person has committed conduct that would warrant cancellation or suspension of registration (see below) this is conduct that is likely to result in the person being regarded as not fit to practise for the purposes of section 14 of the Act.

These principles are relevant in determining whether there are grounds for complaint against a pharmacy owner. Section 36 of the Pharmacy Act provides that one of the grounds for making a complaint against a pharmacy owner is that the owner has been convicted of an offence or has committed misconduct and the nature of that offence or misconduct is such that, were the person applying for registration as a pharmacist, the Council would be likely to refuse to register the person. Any conduct that would render a pharmacist unfit to remain on the register would, if committed by a pharmacy owner, also render a pharmacy owner unfit to operate a retail pharmacy business.

The circumstances which may warrant a suspension or cancellation of registration (set out later in this document) are also the circumstances that may indicate that a person is not fit to be registered for the purposes of section 14 or section 36 of the Act.

## 3. Purpose of sanctions

The purposes of imposing sanctions are public protection, the declaring and upholding of professional standards, the maintenance of public confidence in the profession and the maintenance of public confidence in regulation. The primary aim of a sanction is the protection of the public and not the punishment of the practitioner.

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<sup>3</sup> Section 14(1) of the Act provides that the Council must be satisfied that an applicant for registration as a pharmacist is fit to be registered.

The High Court in *Medical Council v Murphy* (1984) set out the considerations relevant when deciding on sanction:

- (a) To make clear to the practitioner the serious view taken of the extent and nature of the misconduct so as to deter him from being likely on resuming practise to be guilty of like or similar conduct
- (b) To point out to other members of the profession the gravity of the offence of professional misconduct
- (c) Protection of the public
- (d) There is an obligation to assist the medical practitioner with as much leniency as possible in the circumstances

The Council will consider whether a registrant poses a risk to patients using their services and if so to determine what level of public protection is required.

### 4. Principles in determining sanction

The Council will examine the findings made by the committee of inquiry and the circumstances that gave rise to those findings and consider what sanction is appropriate. The Council will then consider whether aggravating or mitigating circumstances exist. For example where a pharmacist has addressed any shortcomings since the event that gave rise to the complaint this should be considered as a mitigating factor.

#### A. Proportionality

The Council will exercise its discretion having regard to principles of fairness, proportionality and reasonableness. It will weigh the interests of the public with those of the practitioner. Council will consider sanctions available starting with the least restrictive bearing in mind that protection of patients and wider public interest is always their primary concern.<sup>4</sup>

Council will consider:

- (a) Is the proposed sanction a suitable means of attaining the degree of public protection identified by the Council as necessary
- (b) Is it the least restrictive means of attaining that degree of public protection

#### B. Leniency

The Council will treat a pharmacist or pharmacy owner against whom a complaint has been substantiated with as much leniency as possible in the circumstances of the case.

#### C. Aggravating and mitigating factors

The Council will consider whether there are any aggravating and mitigating factors that may influence its decision regarding sanction. These factors should be relevant to the allegations proven at the inquiry. The factors set out below are not exhaustive nor will they be relevant in every case.

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<sup>4</sup> "the application of the doctrine of proportionality is to ensure that a measure imposes no greater restriction upon a Convention right that is absolutely necessary to achieve its objectives" (*Chaudry v GMC* [2002] UKPC 41 at 21)

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### Mitigating factors:

- a. Evidence of insight and understanding. This is of particular significance in assessing risk of recurrence. It is important that the registrant understands the seriousness of the events giving rise to the inquiry and that, where applicable, they accept the need for conditions.
- b. Attempts to address the problem. Eg admission, apologies, efforts to prevent recurrence
- c. Evidence of overall adherence to principles of good practice
- d. Personal mitigation, for example, stress, illness, inexperience, lapse of time<sup>5</sup>, lack of adequate supervision. However personal mitigation is generally regarded as more relevant in punishment but less relevant in regulation. Sanctions may have a punitive effect but that is not their purpose. Care needs to be taken in financial circumstances being used in mitigation. Public protection will take precedence over likely hardship to the practitioner.
- e. Respondent is one of a number of registrants involved in event but the only one the subject of a complaint
- f. Single isolated incident in unblemished career
- g. Open and full admissions at an early stage

As noted above the Council will apply the mitigating factors where it is of the view that it is appropriate to do so. They will not be applied in every case. For example, if a practitioner presents an ongoing risk to the public they should not be allowed to practise. Where mitigating factors have been suggested to the Council and the Council does not consider that they are valid or they are outweighed by other considerations the Council should give reasons why those factors did not in fact act in mitigation of their decision on sanction.

The Council will take care in relation to references or testimonials. The Council needs to be satisfied that they are genuine and can be relied upon. In particular it will consider whether the author was aware of the allegations and whether a professional referee is qualified to comment. However, no adverse inference should be drawn from fact that no reference or testimonial has been provided.

### Aggravating factors (some could also be specific allegations):

As noted above in relation to mitigating factors, they should be relevant to the allegations proven at the inquiry. Again note that the factors set out below are not exhaustive nor will they be relevant in every case.

- a. Prior conduct:
  - (i) Previous findings by PSI or other regulator in this or another jurisdiction
  - (ii) Previous convictions in Ireland or in another jurisdiction
  - (iii) Disregard of previous warnings or advice from Registrar/ Authorised Officers
  - (iv) Pattern of misconduct over period of time
  - (v) Poor compliance history

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<sup>5</sup> Although note that lapse of time of itself is not necessarily a mitigating factor. While it might be relevant to risk of recurrence it is not the same as mitigation.

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- (vi) Failure to comply with or disregard of previous sanctions imposed or undertakings given

Where relevant the Council will have access to information that was not available to the inquiry committee (for example, because it was prejudicial in determining whether allegations proven) but which is relevant in determining likelihood of recurrence or establishing a pattern of behaviour. Such information includes previous sanctions, undertakings, warnings and advices given to a registrant.

- b. The misconduct, poor performance or other breaches have been committed by a person in charge of the pharmacy premises (owner, superintendent, supervising pharmacist)
- c. Dishonesty
- d. Lack of insight
- e. Abuse of position of trust, for example by taking advantage of vulnerable person
- f. Direct or indirect patient harm<sup>6</sup>
- g. Failure to cooperate with investigation or during course of inquiry
- h. Breach of confidentiality
- i. Premeditated actions
- j. Abuse of position and dishonesty in context of drug abuse
- k. Concealment of wrongdoing
- l. Offences in relation to controlled drugs

### **D. Dishonesty**

Dishonesty on the part of a pharmacist or pharmacy owner is particularly serious as it undermines trust in the profession even where no patient harm has occurred. Examples include:

- (a) Defrauding employer, the Health Service Executive or patients
- (b) Providing false or misleading information on CV or providing false references
- (c) Falsifying patient records
- (d) Dishonesty in research is also serious because of the potential far reaching consequences

It is of particular concern where dishonesty is persistent and/or covered up. This is likely to result in erasure or refusal of registration.

### **E. Sexual misconduct**

This relates to conduct that may lead to a criminal conviction or is in some way abusive whether or not involving a criminal prosecution. It covers a wide range of conduct from assault to downloading child pornography. It is particularly serious for a Health Professional to have committed sexual misconduct. Sexual misconduct seriously undermines public trust in the profession.

Evidence of sexual misconduct is likely to result in the sanction of erasure. It is conduct that will usually render a person not fit to be registered for the purposes of sections 14 and 36 of the Act.

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<sup>6</sup> The primary concern of the disciplinary process is to address risk of harm

## F. Relevance of criminal convictions<sup>7</sup>

The purpose of disciplinary proceedings is to consider whether there is a need to restrict registration in order to protect the public and to maintain the high standards and public confidence in the profession. The fact that a practitioner has already paid a heavy price for their behaviour in prior criminal proceedings has little relevance in disciplinary proceedings. Likewise an acquittal on criminal charges will not prevent a subsequent inquiry into the events giving rise to the charges.

The purpose of the disciplinary hearing is not to punish for a second time. However, the fact that a sanction has a punitive effect does not make the sanction inappropriate. The Council is entitled to give greater weight to public interest and need to maintain confidence in profession than to the consequences for the registrant of the imposition of the penalty. The sanction or sentence previously imposed is not necessarily a definitive guide to the seriousness of the offence. The considerations that weigh in the courts when deciding on punishment are not necessarily relevant where the Council is deciding on sanction following a disciplinary inquiry. For example there may have been personal circumstances that led the court to be lenient.

Criminal convictions will also be relevant in determining whether a person is fit to be registered for the purposes of section 14 of the Act. Factors that will be taken into account where an applicant for registration has been convicted of a criminal offence include:

- (a) The seriousness of offences giving rise to the conviction
- (b) The relevance of the conviction to the practice of pharmacy
- (c) The relevance of the conviction to public confidence in the profession
- (d) When the conduct occurred
- (e) The applicant's age at the time when the acts in question were committed
- (f) The applicant's personal mitigation in respect of the conduct or behaviour concerned;
- (g) The applicant's efforts or lack of efforts to rehabilitate himself since the conduct or behaviour referable to the conviction was committed

When considering the seriousness of a conviction, the following aggravating factors will generally qualify the conviction as serious:-

- (a) Offence involving dishonesty, fraud or misrepresentation
- (b) Offence indicating drug or alcohol dependency
- (c) Offence involving violence exhibiting intentional or deliberate disregard of human life
- (d) Offence involving non-consensual sexual acts
- (e) Offence involving any sexual acts in relation to children including child pornography
- (f) Offence involving trafficking in or illegally manufacturing any controlled drug
- (g) Offence that poses a serious threat to public health, safety or welfare
- (h) Offence indicating a blatant disregard for the law or the system of registration

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<sup>7</sup> The Supreme Court in *Law Society v Malocco* (2005) noted that the purpose of the present proceedings is not punitive, but is one whereby a solicitor who might be unfit, due to misconduct, should, if so found, be prevented from continuing as a solicitor. No basis has been identified, nor could there be any logical argument to suggest, that where a professional person has been convicted of a criminal offence that the facts giving rise to such conviction could not be considered by a professional disciplinary body to ascertain whether or not the professional had committed professional misconduct.



## **G. Relevance of patient outcome/ risk of harm**

Identical conduct can have entirely different outcomes. The Council in considering sanction will assess the risk posed to members of the public were the registrant's practice to be unrestricted. The fact that a patient ultimately came to no harm will be less relevant than the risk posed by the behaviour of the practitioner. The Council will take into account the potential consequences of a practitioner's actions. As noted above patient outcome may be taken into account as an aggravating/mitigating factor in determining sanction.

## **5. Sanctions that may be imposed by the Council**

A range of sanctions is available to the Council under Section 48 of the Act and the Council may impose one or more of these. For example, the Council may decide to censure a pharmacist and impose one or more conditions.

The sanction imposed must be based on the evidence and proven allegations. A matter cannot be criticised through sanction if it was not the subject of a proven allegation.

### **A. Admonishment/censure**

These sanctions are appropriate at the lower end of the spectrum of concern and can be used where the Council wants to mark that the behaviour complained of is unacceptable and should not happen again. They represent a sliding scale in marking the disapproval of the Council in relation to the behaviour. The Council will consider whether the sanction provides adequate protection as neither admonishment nor censure restricts practise rights. The Council must be confident that there is no risk to the public or patients that would require restriction. These sanctions do not require High Court confirmation.

These may be appropriate for slightly more serious cases where the lapse concerned is isolated, where there is a low risk of recurrence or where the registrant has shown insight and has taken remedial action. They are unlikely to be appropriate where the registrant lacks insight and in this case conditions, suspension or cancellation should be considered.

### **B. Attachment of conditions to registration**

Conditions may be imposed on a pharmacist's or pharmacy owner's registration where the Council is of the view that there is some risk to the public from the pharmacist's practice or from the manner in which the pharmacy was operated but where the Council is satisfied that the risk is appropriately dealt with through conditional registration. For example, where a finding of poor professional performance has been made against a pharmacist, it may be appropriate to attach a condition that they should undergo specified further training and/or participate in a mentorship programme.

Where conditions are imposed the registrant may continue to work but must do so in a way that is consistent with the conditions imposed. Conditions appear on the relevant public register maintained by the PSI and are most likely to restrict a registrant's practise. They provide a flexible means of addressing concerns. A combination of conditions can be imposed including formal education and training requirements.

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The Council needs to be satisfied that the conditions are sufficient to protect public interest. They are an appropriate sanction where the failure or deficiency is capable of being remedied and where the Council is satisfied that allowing the registrant to continue to practise, albeit subject to conditions, poses no risk of harm or future harm.

The conditions must be appropriate, relevant to the allegations proven and realistic. They must be capable of monitoring. The objectives of conditions must be clear and communicated clearly to the registrant together with reasons for them.

Conditions are likely to be appropriate where the concerns about the registrant's practice are such that a period of retraining and/or supervision is the most appropriate way of addressing them. They may also be used where there are concerns in relation to health, performance, a single clinical incident or where there is evidence of shortcomings in a particular area of practice.

Even with a monitoring regime, to a large extent the registrant will have to be trusted to comply with the condition(s) and so the Council will need to be confident that the registrant will adhere to those conditions.

Conditions are unlikely to be suitable where problems cannot be overcome such as serious overall failings, lack of insight, denial or matters involving dishonesty or abuse of patients.

Conditions need to be realistic. For example, where they require that a pharmacist cannot provide unsupervised care or care outside a particular setting or dispense certain medications, in reality this may result in the registrant being unable to practice. In these circumstances it may be necessary to suspend or cancel registration.

Conditions may be appropriate where there are/is:

- a. Identifiable areas of practise in need of assessment and/ or retraining
- b. No evidence of general incompetence
- c. Potential and willingness to respond positively to retraining
- d. Insight into health problems, where relevant, and prepared to agree to abide by conditions regarding treatment and supervision
- e. Conditions will protect patients and patients will not be put in danger either directly or indirectly as a result of conditional registration
- f. Where adverse health issues conditions should be imposed in relation to medical supervision and supervision at work

### **C. Suspension of registration**

This sanction may be appropriate where a lesser sanction would not adequately protect public interest or act as a sufficient deterrent for the registrant or wider profession.

Council may consider the extent of the departure from expected standards and the risk of harm arising from that departure. This sanction has a deterrent effect and can be used to send a signal to the pharmacist, profession and public about the Council's view of the complained of behaviour. It will be appropriate where misconduct is sufficiently serious that action is required to protect patients and maintain public confidence in the profession. It is appropriate where the conduct falls short of conduct or concerns that are incompatible with continued registration. For example, suspension may be appropriate in a case where, although the misconduct is very serious, there has been an acknowledgment of fault and the Council considers repetition unlikely.

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A suspension can be imposed where admonishment, censure or conditions are not sufficient or are inappropriate to protect the public or where the allegations are serious but there is not a realistic risk of recurrence and therefore cancellation of registration not appropriate. If evidence suggests that the registrant is unable to resolve their failings a cancellation will be more appropriate.

Suspension may be appropriate in relation to conduct which, while not presenting a risk to patients, undermines confidence in the profession.

Suspension may have long term consequences for a pharmacist including dismissal from employment or an inability to secure employment in the future and this should be taken into account in determining the proportionality of the sanction.

Suspension must be for a specified period of time. Suspension may be accompanied with an admonishment or censure. It may also be accompanied by conditions which will come into effect at the conclusion of the period of suspension.

The following are examples of the circumstances where suspension may be appropriate:

- a. No conditions can be adequately framed to protect the public
- b. Single instance where lesser sanction not sufficient
- c. There is a serious falling short of the conduct expected of a pharmacist but the conduct is not fundamentally incompatible with continuing to be registered in that public interest can be satisfied by less severe sanction than cancellation
- d. The registrant has insight and does not pose a significant risk of repeating the behaviour
- e. There is evidence of a disposition towards non compliance
- f. It is required to send a message to the profession and the public that the conduct complained of is unacceptable and the public confidence in the profession and regulation demands no lesser sanction

Please note that the above factors and circumstances are not exhaustive and the Council will take into account the particular circumstances of each case.

### **D. Cancellation of registration**

This is a sanction of last resort for serious, deliberate or reckless acts, for example, involving abuse of trust (such as sexual abuse), dishonesty or persistent failures. It should be used where there is no other way to protect the public, for example, through lack of insight, continuing problems or denial. An inability or unwillingness to resolve matters will suggest that a lower sanction may not be appropriate. Clear reasons for cancellation should be given.

Cancellation may also be appropriate where the nature and gravity of the allegations are such that any lesser sanction would lack the deterrent effect or undermine confidence in the profession or in the regulatory process.<sup>8</sup>

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<sup>8</sup> Burke, Re [1999] IEHC257: the striking off of a solicitor can have a punitive element, it can have an element of protection for the public but it always has an element of protecting the good name of the solicitors' profession and the good name of the profession must be paramount

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Factors that may be considered in deciding whether cancellation is appropriate include:

- a. Is this the only sanction that will be sufficient to protect the public interest. Public interest will be considered in the broad sense including reducing risk of harm and maintaining public confidence in the profession and in its regulation
- b. Doing harm to others or behaving in a way that could foreseeably result in harm to others either deliberately, recklessly, or through repeated incompetence, particularly where there is a continuing risk to patients. Harm may include physical, emotional and financial harm. Council will consider the seriousness of the harm in coming to decision
- c. Abuse of position, abuse of trust or violation of the rights of patients
- d. Any serious misconduct of a sexual nature, including sexual abuse or involvement in child pornography
- e. Any violent conduct whether towards members of the public or patients where the conduct is such that that public interest can only be satisfied by removal of registration
- f. Fraud, theft or dishonesty, especially where persistent or covered up
- g. Persistent lack of insight into seriousness of actions or consequences or failure to respond to interventions
- h. Convictions or cautions involving any of the conduct or behaviour set out above.
- i. Particularly serious departure from Code of Conduct
- j. Registrant presents a continuing risk to patients or members of the public
- k. Lack of competence or ill health that cannot be addressed by attaching conditions to registration
- l. Reckless or wilfully unskilled practice; reckless or dangerous dispensing
- m. Concealing adverse incidents. For example, covering up a dispensing error
- n. Wilful failure to keep essential records
- o. Falsifying records
- p. Failing to act, knowing that a colleague or subordinate is improperly treating or abusing patients
- q. Repeated or serious breach of confidentiality
- r. Drug related offences or misconduct in relation to controlled drugs
- s. Persistent misuse of alcohol or drugs

Please note that the above factors and circumstances are not exhaustive and the Council will take into account the particular circumstances of each case.

The Council may impose a prohibition for a specified period on applying for restoration. This period will be determined based on the nature of the allegations proven and the circumstances surrounding the event.

## 6. Requirement to give reasons

As required by section 49(1)(b) the Council will give reasons for its decision regarding sanction in each case so that the pharmacist, pharmacy owner, the profession and the public can understand and can have confidence in the Council's decision. It is important that the Council provides clear reasons for imposing a particular sanction.