

Policy on use of powers for temporary registration of persons under the Pharmacy (NI) Order 1976, as modified by the Coronavirus Act 2020

Introduction

1. Under Article 8E(1) of Pharmacy (NI) Order 1976, the registrar may register a person or a group of persons, in the register of pharmaceutical chemists if certain conditions are satisfied.¹
2. Those conditions are: (a) that that Department of Health (NI) has advised the registrar that an emergency has occurred, is occurring or is about to occur and that the registrar should consider acting under this provision² and; (b) the registrar considers that the “emergency registration requirement” is met in relation to the person or group of persons.³
3. The “emergency registration requirement” is met, in relation to a person, if the person is a fit, proper and suitably experienced person to be registered as a pharmaceutical chemist with regard to the emergency.⁴
4. In relation to a group of persons, the requirement is met if the group is comprised of persons who are of a type who may reasonably be considered fit, proper and suitably experienced persons to be registered as pharmaceutical chemists with regard to the emergency.⁵
5. The usual requirements regarding CPD, fees and fitness to practise do not apply to persons temporarily registered under Article 8E.⁶
6. It is important to note that the registrar cannot require people who are temporarily registered to return to practise and it is acknowledged that people would be doing so on a voluntary basis to help their community, having considered their own experience and health.
7. Registration under these provisions may be subject to any conditions imposed by the registrar and the registrar may vary, revoke or add new conditions at any time.⁷ A person temporarily registered as a member of a specified group may

¹ The relevant modifications to the Pharmacy (Northern Ireland) Order 1976 are made by section 5 and Schedule 4 to the Coronavirus Act 2020.

² The registrar was advised by the Department on 26 March 2020 that an emergency is occurring and he was asked to take appropriate steps to use his new powers “to facilitate the rapid temporary registration and/or annotation of pharmacists to support a flexible and strengthened pharmacy workforce during the Covid-19 emergency.”

³ Art 8E(2).

⁴ Art 8E(3)(a).

⁵ Art 8E(3)(b). All of the persons comprising a specified group of persons may be registered without first identifying each person in the group: Art 8E(4).

⁶ Art 8E(9) and (10). Paras 1 to 3 of Schedule 3 to the 1976 Order, however, continue to apply to temporary registrants.

⁷ Art 8E(5).

(but need not) be subject to the same conditions as other members of that group.⁸ Breaches of any condition attached to temporary registration is to be treated as not being done by a registered person.⁹

8. Registration under these provisions ends if revoked by the registrar. The registrar must revoke registration if the Department advises the registrar that there is no longer an emergency.¹⁰ The registrar may also revoke registration “for any other reason, including where the registrar has grounds for suspecting that the person’s fitness to practise may be impaired.”¹¹
9. There is no appeal to Council from a decision of the registrar to temporarily register or refuse to temporarily register a person or group of persons under Article 8E, to impose, vary or revoke conditions in relation to a person or group of persons’ temporary registration or to revoke a person’s temporary registration.¹²

Policy intention and purpose

10. This policy is intended to facilitate the speedy registration of as many fit, proper and suitably experienced persons as are required by the current emergency while minimising risks to patient safety.¹³ This policy includes and elaborates on the policy regarding Phase 1 of temporary registration approved by Council in March 2020.
11. In order to ensure that fair, consistent and transparent decisions are taken, the purpose of this policy is to set out how the registrar will make decisions concerning:
 - i. the temporary registration of fit, proper and suitably experienced persons during the emergency;
 - ii. the conditions, if any, to be imposed on such persons and how such conditions will be varied, revoked or added to;
 - iii. the revocation of temporary registration.

Temporary registration

12. In an emergency situation, the registrar will use his powers to temporarily register as many persons as are needed who have demonstrated that they have the required skills and knowledge and who have recent experience of pharmacy practice. Such persons must also be of good standing, that is fit to practise.

⁸ Art 8E(6).

⁹ Art 8E(12).

¹⁰ Art 8E(7)(a).

¹¹ Art 8E(7)(b). See also Art 8E(8) which states that a person’s registration as a member of a specified group may be revoked: (a) without revoking the registration of the other members of the group; or (b) as a result of a decision to revoke the registration of all the members of the group.

¹² Art 11(3)(a) to (d).

¹³ This policy was informed by relevant GPhC policies which were helpfully shared with the Society.

13. Temporary registration will be implemented in phases based on the scale of the emergency and the needs of the health system. In terms of recent experience, Phase 1 has begun by automatically registering all persons removed from the register¹⁴ in the last three years, who are in good standing, unless they elect to opt out. Such persons were written to and given the opportunity to opt out of temporary registration before their names were published on the temporary register.
14. Phase 2: It is anticipated, that in addition to the former registrants invited back onto the register in Phase 1, persons who can demonstrate that they are registered or were registered within the last 3 years with other pharmacy regulators (e.g. the General Pharmaceutical Council or the Pharmaceutical Society of Ireland) and who express a desire to join the temporary register can also be registered at this time. Such persons will be required to demonstrate that they have been, or are, in good standing with a UK or European pharmacy regulator and to make the normal declarations on health and character.
15. Depending on the scale of the emergency, it may be necessary to temporarily register further categories of persons, Phase 3,4,5 etc. This may mean including in the temporary register those persons who have demonstrated many, but not all, of the required knowledge and skills or who have less recent experience of pharmacy practice. Later phases may, for example, increase the number of years the person has been off the register or consider temporarily registering persons who have not fully completed their pre-registration training. These decisions will be taken after consultation with Government having considered the scale of the emergency and an assessment of any risks to patient safety.
16. As previously noted, there is no appeal to Council from a decision of the registrar to temporarily register or refuse to temporarily register a person or group of persons under Article 8E.¹⁵

Conditions on temporary registration

17. Conditions may be attached to temporary registration and the registrar may vary, revoke or add new conditions at any time.¹⁶ Persons temporarily registered as a member of a group may, but need not, be subject to the same conditions as other members of that group.¹⁷
18. When considering the imposition, variation or revocation of conditions on temporary registration, the registrar will consider any risks to patients or the public and the scale of the current emergency and whether any risks identified can be managed or eliminated by the imposition of conditions. In order to manage any risks posed by the temporary registration of a person or group of

¹⁴ Persons voluntarily removed and those removed for non-payment of fees.

¹⁵ Art 11(3)(a) and (b).

¹⁶ Art 8E(5).

¹⁷ Art 8E(6).

persons while facilitating such persons making a valuable contribution to the emergency, the registrar will only impose conditions which are:

- necessary to protect the public.
- otherwise in the public interest; or
- in the interests of the temporary registrant.

19. Further guidance on the imposition, variation or revocation of conditions on temporary registration can be found in the Appendix.
20. Conditions will only be placed on a registrant which are:
 - a. Proportionate;
 - b. Time bound;
 - c. The least necessary to assure the safe and effective practise of the registrant;
 - d. Subject to review.
21. If a decision is taken to impose, vary or revoke conditions on a person's temporary registration, the person and their employer will be informed of that decision. Any conditions will be visible on the temporary register. This will be aligned to our policy on disclosure.
22. There is no appeal to Council from a decision of the registrar to impose, vary or revoke conditions in relation to a person or group of persons' temporary registration.¹⁸

Revocation of temporary registration

23. In addition to the automatic revocation of temporary registration when the emergency ends,¹⁹ the registrar has the power to revoke registration "for any other reason, including where the registrar has grounds for suspecting that the person's fitness to practise may be impaired."²⁰
24. As with all other decisions in relation to the temporary register, the registrar must balance the need to protect patients and the public against the scale of the emergency and the need for sufficient numbers of pharmacists to respond to that emergency.
25. Concerns regarding pharmacists are usually managed through the Society's [fitness to practise processes](#). Temporary registrants are not subject to the normal fitness to practise processes.²¹ It is important, however, that the public is protected and that a proportionate and fair approach is taken to the management of concerns about temporary registrants.

¹⁸ Art 11(3)(c).

¹⁹ Art 8E(7)(a).

²⁰ Art 8E(7)(b). See also Art 8E(8) which states that a person's registration as a member of a specified group may be revoked: (a) without revoking the registration of the other members of the group; or (b) as a result of a decision to revoke the registration of all the members of the group.

²¹ Art 8E(10): Article 20 and Schedule 3 to the 1976 Order (other than paras 1 to 3) do not apply to temporary registrants.

26. Where a concern is raised about a temporary registrant, it will be considered on the specific facts of the case, taking into account the environment in which the person is working and the risk to patient and public safety. Consideration will also be given to any relevant information about resources, guidelines or protocols in place at the time. A detailed and speedy review of the available evidence will be carried out in order to understand the seriousness of the concern and if there is a real risk to patients. Consideration will also be given to whether the temporary registrant is able to carry out their role safely and effectively or whether allowing them to remain on the temporary register would undermine trust and confidence in the profession.
27. Having considered all of the evidence, including a submission by the registrant where possible, the registrar will remove a person from the temporary register only if the evidence suggests that removal is:
 - necessary to protect the public;
 - otherwise in the public interest; or
 - in the interests of the temporary registrant.
28. Further guidance on the imposition, variation or revocation of conditions on temporary registration can be found in the Appendix.
29. Other (non-fitness to practise) reasons for removing a person from the temporary register may include:
 - A person asking to be removed from the temporary register;
 - The discovery of errors or new information which indicate that the person should not have been placed on the temporary register.
30. If a decision is taken to remove a person from the temporary register, the person, their employer and any complainant will be informed of that decision. Decisions to revoke registration will not be published on the Society's website but information about temporary registration, including a decision to revoke registration, will be shared with any other regulator with whom the registrant is currently registered and any other health and social care regulator, on request.
31. A person removed by the registrar can no longer practise as a pharmacist in Northern Ireland.
32. The decision to revoke a person's temporary registration cannot be appealed to Council.²² In the case of a member of a group, it does not matter whether the registrar also decides to revoke the registration of any or all of the other members of the group.²³

²² Art 11(3)(d).

²³ Art 11(3)(d).

Status of temporary registrants

33. Pharmacists are playing a vital role in responding to the coronavirus emergency and the Society acknowledges the pressures on the profession at this time. The primary concern of pharmacists is the care of patients and people using pharmacy services. To deliver safe and effective care, pharmacists, working in partnership with other healthcare professionals and people using their services, should use their professional judgement to assess risk and ensure decision-making is informed by any relevant guidance and the values and principles set out in the *Code* (2016). The *Code* and related standards support pharmacists by highlighting the key principles which must be followed, including the need to work cooperatively with colleagues to keep people safe, to recognise and work within the limits of their competence, and to have appropriate indemnity arrangements relevant to their practice.
34. The registrar cannot require people who are temporarily registered to return to practise and it is acknowledged that people would be doing so on a voluntary basis to help their community. With this in mind, temporary registrants are reminded that:
- They should only return to practise if they are fit to do so. They should consider their health, skills, knowledge and personal circumstances when making this decision.
 - They must follow the standards for pharmacists set out in the *Code* (2016). They must work within the limits of their knowledge and skills and refer to others when needed.
 - They must make sure that their work is covered by appropriate indemnity insurance for their practice; their employer should help with this.

Employers

35. Employers and service providers remain responsible for carrying out appropriate checks before employing or deploying temporarily registered workers. This includes ensuring that adequate professional indemnity is in place and making sure that temporarily registered pharmacists are competent for any role they fulfil and are appropriately inducted, trained and supervised.

Measurement and evaluation

36. After the emergency, this policy including its implementation and outcomes will be reviewed. The policy will be evaluated on an annual basis to review if the persons and groups which were identified are still considered fit, proper and suitably experienced to be temporarily registered or annotated during an emergency.

Date of next review: April 2021 or sooner subject to new evidence from practise.

April 2020

Appendix: Supplementary guidance on imposition, variation and revocation of conditions on temporary registration and revocation of temporary registration for fitness to practise reasons

This guidance sets out some factors which may be relevant to the question of whether restrictions on practice (conditions or revocation of temporary registration) are:

- necessary to protect the public.
- otherwise in the public interest; or
- in the interests of the temporary registrant.

When is a restriction on practise necessary to protect the public?

Conditions or revocation of temporary registration is necessary to protect the public if there is information available which indicates that there is a risk to patients, colleagues or other members of the public if the pharmacist continues to practise without any restrictions.

The first step is to consider the nature and extent of the risk. There might be a risk to the safety of patients, for example, if there is evidence that the pharmacist:

- has made a large volume of dispensing errors in a short period;
- is experiencing an alcohol or drug dependence which has affected their ability to practise safely and effectively.

The second step is to consider what action needs to be taken to deal with the identified risk. If the risk of the pharmacist repeating their behaviour is low, or if the level of harm which might result is low, it might not be necessary to restrict the pharmacist's ability to practise. If the only way to properly deal with the identified risk is to restrict the pharmacist's practice with conditions, or to stop the pharmacist from practising, it is likely that restrictions are necessary to protect the public.

When is a restriction on practise in the public interest?

It is likely to be rare for restrictions to be imposed only on wider public interest grounds. Restrictions can be justified as being in the public interest if there would be serious damage to the reputation of the profession as a whole if a pharmacist was not restricted in their practice.

For example, a pharmacist is charged by the police with a serious criminal offence. Even if the Registrar considers there is no ongoing risk of harm to the public, he might consider that the public's confidence in the profession as a whole could be seriously damaged if there were no restrictions on the pharmacist's practise.

When is a restriction on practise in the interests of the pharmacist?

A restriction on practise may be in the interests of the pharmacist if, for example, they are addicted to a controlled drug. As a pharmacist, they will have privileged access to medication. It might be in the interests of the pharmacist's health for this access to be restricted or removed. In these circumstances, restrictions may also be necessary to protect the public.

Factors to consider and proportionality

In reaching a decision on whether to impose/ vary conditions or revoke registration, the Registrar will consider:

- the gravity of the concern;
- the nature of the evidence;
- the seriousness of the risk of harm to patients, including information about the likelihood of a further incident or incident being repeated;
- the seriousness of risk to members of the public if the pharmacist continues to practice unrestricted;
- whether public confidence in the pharmacy profession is likely to be seriously damaged if the pharmacist continues to practise without any restrictions;
- whether it is in the pharmacist's interests to hold unrestricted registration - for example, the pharmacist may clearly lack insight and need to be protected from him or herself;
- whether the pharmacist has any previous fitness to practise findings;
- In weighing up these factors, the Registrar must carefully consider the proportionality of his decision. He should consider if it is proportionate in terms of dealing with the risk to the public (including patient safety and public confidence) and in terms of the impact of any action on the pharmacist's own interests.

Conditions or revocation

If the Registrar decides that some restriction on practise is required, he must then consider whether conditions would be a sufficient and proportionate response to the risk he has identified. He should only revoke registration if conditions would not meet his concerns adequately.