



14 November 2016 to 9 January 2017

Pharmacists' Defence Association Response to the Pharmaceutical Society of Northern Ireland's Consultation on Pharmacist Supplementary and Independent Prescribers Regulations 2017

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About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 26,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist
- **e-mail:** enquiries@the-pda.org

Executive Summary

The Pharmaceutical Society of Northern Ireland (PSNI) is consulting on legal changes in relation to the annotation of the register of pharmacists who are qualified as independent prescribers, and corresponding changes for supplementary prescribers to ensure a consistent legislative approach to the two groups.

The PDA, for the most part, agrees with the proposed changes. However, we do make a number of recommendations, which are summarized below.

- The PSNI must ensure that the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202) are made accessible from the legislation.gov.uk website.
- The PSNI must consider how it would approach the decision as to whether to annotate the register for an individual where the requirement of a two-year period of registration as a pharmacist was met but this included a period of formal suspension from practice, either in the UK or another EU state, where without that period of suspension, the two-year minimum would not have been met. It must also decide on the appropriate way to deal with this in respect of the proposed legislation.
- The PSNI must verify that the use of the term 'to order drugs' in the proposed amendment to regulation 9 of the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202), will have the effect, in the context of that particular legislation, of enabling pharmacist independent prescribers to prescribe prescription-only medicines.

Historical background

The Pharmacy (Northern Ireland) Order 1976 ("the 1976 Order") is the principal legislation providing the basis for the regulation of pharmacists in Northern Ireland.

Article 5(1) of the 1976 Order was amended by the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2004 ("the 2004 Order") to permit the PSNI Council to make regulations with respect to annotation of the register of pharmacists, in order to indicate particular qualifications, specialist areas of practice and status. The 2004 Order also amended the 1976 Order to the effect that a person could have an annotation made where he or she provided the required proof of entitlement to a particular annotation and paid the required fee.

Following from these amendments, the *Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994* ("the 1994 Regulations" / S.R. 1994/202) were changed via the *Pharmaceutical Society of Northern Ireland (General) (Amendment) Regulations 2004/236* to provide a new regulation relating to annotations in the register of pharmacists, for supplementary prescribers. A paragraph was inserted into the 1994 Regulations to the effect that where a pharmacist had been registered as such for two years or more and provided a certificate of completion of an accredited supplementary prescriber training programme, and paid a fee of £25 to the PSNI, it would entitle the pharmacist to have the "SP" annotation recorded against his/her name. This amendment allowed pharmacists in Northern Ireland, who complied with these regulations, to act as pharmacist supplementary prescribers.

In 2006, the concept of independent prescribing was introduced across a number of professions, including pharmacy, principally through the changes made to who can prescribe to patients under the Medicines Act 1968, and the related regulations. The then DHSSPS, working with the PSNI and other bodies, developed a pharmacist independent prescriber (IP) qualification. That qualification was accredited by the PSNI in early 2007 and re-accredited when required.

However, whilst the 1994 Regulations had been amended in 2004 in respect of supplementary prescribers, no specific corresponding provision was made in the 1994 Regulations or elsewhere for pharmacist independent prescribers, to establish the legal requirements for the annotation of "IP" in the register of pharmacists.

Since 2007, the general principle, as applied to pharmacist supplementary prescribers, was used before granting accreditations, namely that pharmacist independent prescriber applicants attend an accredited pharmacist independent prescribers course, gain an appropriate certificate, provide the registrar with proof of the same, along with evidence of a minimum period on the register and pay a fee of £25.

The DHSSPS amended *The Pharmaceutical Services Regulations (Northern Ireland) 1997* ("the 1997 Regulations") through the *Pharmaceutical Services and Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2009*. The 1997 Regulations define a pharmacist independent prescriber as a person:

- a) *who is registered in the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976...; and*
- b) *against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber.*

In 2009 and again in 2013, the Pharmaceutical Society NI consulted on and published 'Standards and Guidance for Pharmacist Prescribers'. Further minor amendments to these standards were made in 2016 to reflect the new code of professional standards of conduct, ethics and performance for pharmacists in Northern Ireland.

These standards set out how pharmacists are to operate, when acting as pharmacist prescribers.

In 2012 much of the Medicines Act 1968 was transposed into the Human Medicines Regulations. These regulations created new provisions in relation to the definition and annotation of pharmacist independent prescribers, specifically, changing the requirement from an annotation to a "note" in the register thus:

Regulation 8

- a) *is a pharmacist; and*
- b) *is noted in the relevant register as qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;*

The PSNI, having reviewed the current legislative provisions, has established that unlike the arrangements for pharmacist supplementary prescribers, no specific amendments were made to the 1994 Regulations or elsewhere to reflect the introduction of pharmacist independent prescribers in 2007.

The PDA has provided assurances to the PSNI that this situation would not invalidate any current indemnity arrangements provided by the PDA. The Department of Health has also confirmed that it does not intend to seek to invalidate any accreditations currently in place in the absence of specific regulations.

In relation to fees, the PSNI has noted that a fee of £25 was charged in the absence of a specific power to do so, and does not propose to refund any fees previously paid, having obtained legal advice, in particular because the costs of course development and accreditation, and the costs of administration and any CPD or fitness to practise matters arising out of annotated registration, should properly be met by those annotated.

The PSNI is now consulting all stakeholders on proposals to amend the *Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994*, in respect of "independent prescriber" annotations, and to bring this in line with the legislation applicable to supplementary prescribers. Since the conditions for annotation will be that evidence of eligibility for annotation must be provided, a fee of £25 must be paid to the PSNI and that the pharmacist must have been registered as such for two years or more, it is proposing to set regulations to recognise two years' registration with competent authorities in European states for that purpose, in accordance with its obligations under the EU's general system of recognition.

The Consultation Document

As a general principle, the PDA recommends that questions in a consultation such as this should be asked in an entirely neutral manner. Commencing questions with leading wording such as 'do you agree' could lead to acquiescence bias.^{[1][2][3][4]} This may mean that the responses obtained will not truly represent respondents' views.

From a readability perspective, it would have been helpful to have had all the relevant legal background set out clearly on one occasion in chronological order, in the consultation document itself (some information was to be found in a letter sent by the PSNI to independent prescribers which was referenced, but not included, in the consultation document).

Consultation Response

- 1. Do you agree with the Council’s proposal to amend the 1994 General Regulations to the extent identified in this consultation paper and the attached draft amending Regulations?**

YES

The PDA takes the view that the amendment should establish legislation which corresponds with the approach proposed by the PSNI in relation to independent and supplementary prescribers (subject to any caveats set out in this response document) and which will ensure consistency of approach to the two groups.

- 2. Do you accept that we have provided adequate information to explain the proposed legislative amendments and the provisions provided?**

YES

The *Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202)* are unavailable in their full form on the legislation.gov.uk website. It is this legislation which is referenced in the amending regulations included in the consultation document, but we have been unable to access it.^[5]

Recommendation

The PSNI must ensure that the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202) are made accessible from the legislation.gov.uk website.

- 3. Do you agree with the requirement that to be eligible to have an annotation on the Register as a Pharmacist Independent Prescriber, a pharmacist should have been registered for a minimum period of two years?**

YES

The requirement of having practiced as a pharmacist in an appropriate patient-orientated role is set by Universities as an entry requirement to the independent prescribing course. The PDA supports this as an appropriate patient safety mechanism.

However, given that it is proposed the legislative requirement be written thus:

[a pharmaceutical chemist] “has been registered as a pharmaceutical chemist for a period of two years or more” we make the following recommendation.

Recommendation

The PSNI must consider how it would approach the decision as to whether to annotate the register for an individual where the requirement of a two-year period of registration as a pharmacist was met but this included a period of formal suspension from practice, either in the UK or another EU state, where without that period of suspension, the two-year minimum would not have been met. It must also decide on the appropriate way to deal with this in respect of the proposed legislation.

4. Do you agree with the proposed approach, to bring the regulations into line with the Human Medicines Regulations 2012, of adding “thereby noting in that register that he is qualified to order drugs medicines and appliances as a pharmacist independent / supplementary prescriber” to the relevant regulations respectively?

YES

However, since we were unable to access the *Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202)*,^[5] we could not determine whether the terminology of the following proposed addition to regulation 9 will be appropriate:

“he shall be entitled to have that annotation recorded against his name by the registrar, thereby noting in that register that he is qualified to order drugs medicines and appliances as a pharmacist independent prescriber”

In particular, the PDA asks that the PSNI verifies that the use of the term ‘to order drugs’ will have the effect, in the context of that particular legislation, of enabling pharmacist independent prescribers to prescribe prescription-only medicines.

Recommendation

*The PSNI must verify that the use of the term ‘to order drugs’ in the proposed amendment to regulation 9 of the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994/202), will have the effect, in the context of that particular legislation, of enabling pharmacist independent prescribers to **prescribe** prescription-only medicines.*

Further, we ask that the PSNI review the use of the terms ‘pharmacist’ and ‘pharmaceutical chemist’ in the proposed revisions to legislation. If it is possible, in the context of the legislation, to use just one term or the other consistently, this should be done. It is difficult to comment with certainty on this matter given that we are unable to access the regulations to which the amendment is proposed.

5. Do you agree with the proposed approach, to bring the regulations into line with the EU’s mutual recognition system, of adding “has evidence from a competent authority or competent authorities of a relevant European state of being lawfully established for a period of two years or more;” to the relevant regulations?

YES

However, the quote in the question above is not as it is set out in the amending regulations in the consultation document. The question above does not stipulate as to what thing must have been established (a person), nor as what they must have been established (a pharmacist).

6. Do you agree that the Pharmaceutical Society NI should be able to collect a nominal fee to cover the accreditation, production of guidance and admissions administration costs of making an annotation to the Register?

UNSURE

We understand that healthcare regulators are required to be financially independent and self-sustaining from the fees that they collect.^[6] We make no comment as to whether or not this is an appropriate funding mechanism for regulators. However, given that mechanism is established, it seems reasonable that additional fees would need to be collected in order to fund the costs of accreditation, production of guidance and admissions administration.

7. Do you agree that £25 is a reasonable fee?

UNSURE

Whilst this may be an affordable sum for most or all pharmacists, without any rationale having been provided in the consultation documents as to how the PSNI arrived at the proposed figure, we can neither agree nor disagree that it is reasonable.

8. Having considered these draft Regulations the Pharmaceutical Society NI has not identified any equality concerns regarding these proposals, do you agree?

YES

From the information provided in the consultation document, no such issues are apparent.

References

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