

Consultation on Pharmacist Supplementary and Independent Prescribers Regulations 2017

A consultation document

14 November 2016 – 9 January 2017

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About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our primary purpose is to ensure that practising pharmacists are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

1. Setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register;
2. Maintaining a publicly accessible Register of pharmacists, and pharmacy premises;
3. Handling concerns about the fitness to practise of registrants, acting as a complaints portal and taking action to protect the public; and
4. Ensuring high standards of education and training for pharmacists in Northern Ireland.

The Pharmacy (Northern Ireland) Order 1976 requires that the organisation ensures the provision of professional leadership – the Council has established a Pharmacy Forum for this purpose.

Why are we consulting?

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

In 2004 Article 5(1) of the 1976 Order was amended by the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2004 ("the 2004 Order") inserting a new sub-paragraph (ff), permitting the Council to make Regulations with respect to:

"(ff) annotation of the register of pharmaceutical chemists to indicate particular qualifications, specialist areas of practice and status"

In addition, the 2004 Order inserted the following new paragraph (5) into Article 8 of the 1976 Order):

*"(5) Where a person—
(a) gives to the registrar such reasonable proof as may be prescribed that he satisfies the prescribed requirements for a particular annotation to be recorded against his name in the register of pharmaceutical chemists in accordance with regulations under Article 5(1)(ff); and*

*(b) pays the prescribed fee to the Society,
he shall be entitled to have that annotation recorded against his name in that register."*

In 2012 much of the Medicines Act 1968 was transposed into The Human Medicines Regulations and a new form of wording was created in relation to pharmacist prescribers.

The Pharmaceutical Society NI, having reviewed the current legislative provisions, has established that unlike the arrangements for Pharmacist Supplementary Prescribers, no specific Regulations were made to reflect the introduction of Pharmacist Independent Prescribers in 2007.

Whilst it is accepted that the policy intent in 2007 was that Pharmacists should be able to act as Independent Prescribers and that with the right credentials, namely completion of an approved course, being on a relevant register for a minimum time period and operating within their own competencies, they should have had their entry on the Register annotated and thereby be authorised to act as Pharmacist Independent Prescribers. The specific Regulations have not been made and we are seeking to do so now.

A letter has been sent to all Pharmacist Independent Prescribers informing them of the situation and the Council's proposed approach. A copy of this letter can be found here: <http://www.psni.org.uk/wp-content/uploads/2013/02/Dear-Independent-Prescriber-FINAL-12092016-1.pdf>

The Pharmaceutical Society NI is now consulting all stakeholders on proposals for amendment to the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994, in respect of "Independent Prescriber" annotations. At the same time we are seeking to amend the Regulations in regard to Pharmacist Supplementary Prescribers to ensure consistency in approach.

In addition, the Council of the Pharmaceutical Society NI is taking this opportunity to bring the Principal Regulations into line with obligations under the EU's general system of recognition, which enables workers to have their professional qualification recognised in a relevant European state, in relation to both Pharmacist Supplementary and Independent Prescribers, by clarifying the "relevant" registers for the purposes of qualification.

Once this consultation has been completed, the responses considered and a proposal is made and passed by Council, it will make the necessary Regulations for approval by the Department of Health. The Regulations will then be subject to the negative resolution procedure in the Northern Ireland Assembly.

How to respond to this consultation

We welcome your response to this consultation and have listed some questions to assist you. In order to help us analyse responses, we would strongly encourage you to complete the response template provided.

Responses should be sent by post, fax or email to:

“IP” Annotation Consultation 2017
Pharmaceutical Society of Northern Ireland
73 University Street
Belfast, BT7 1HL

Tel: 028 9026 7935
Fax: 028 9043 9919

Email: Mark Neale, consultation coordinator consultations@psni.org.uk

Accessibility of information

If you are having difficulties accessing the documentation or you need us to make adjustments in order to be able to respond to this consultation, please contact us and we will do our best to address the issue.

The Pharmaceutical Society NI will publish a summary of responses following the completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. We can only withhold information in exceptional circumstances. We will only consider withholding information in cases where the respondent has indicated, at the time of submission, that the information is to be withheld, and only where a legitimate reason has been provided. If you wish your response to remain confidential, please provide your reasons in writing, setting out why you believe the information should remain confidential. It should be noted that such reasons must be capable of being justified to the information Commissioner as we are subject to the Freedom of Information Act 2000.

Consultation period

The consultation will run for eight weeks from 14 November 2016 until 12 noon on 9 January 2017.

When the consultation closes, we will analyse the responses we receive which will be considered by the Council of the Pharmaceutical Society NI before making a final decision on any amendments.

Consultation questions

We would welcome any views you may wish to submit on the questions outlined below. It is important that you provide reasons for your comments, where possible, in order for the Council of the Pharmaceutical Society NI to consider the rationale for your views. We have provided a response template to complete, which is available on the website: <http://www.psn.org.uk/publications/consultations/>

Preliminary questions -

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

Substantive questions –

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?
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?
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?
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?

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

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

What is this consultation about?

The Pharmacy (Northern Ireland) Order 1976 (“the 1976 Order”) is the principal legislation providing the basis for the regulation of Pharmacists in Northern Ireland.

In 2004 Article 5(1) of the 1976 Order was amended by the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2004 (“the 2004 Order”) inserting a new sub-paragraph (ff), permitting the Council to make Regulations with respect to:

“(ff) annotation of the register of pharmaceutical chemists to indicate particular qualifications, specialist areas of practice and status”

In addition, the 2004 Order inserted the following new paragraph (5) into Article 8 of the 1976 Order):

*“(5) Where a person—
(a) gives to the registrar such reasonable proof as may be prescribed that he satisfies the prescribed requirements for a particular annotation to be recorded against his name in the register of pharmaceutical chemists in accordance with regulations under Article 5(1)(ff); and
(b) pays the prescribed fee to the Society,
he shall be entitled to have that annotation recorded against his name in that register.”*

Following from these amendments, the General Regulations were changed via Pharmaceutical Society of Northern Ireland (General) (Amendment) Regulations 2004/236 to provide a new Regulation relating to annotations in the Register for Supplementary Prescribers¹ by inserting paragraph (3) into Regulation 9:

*“(3) Where a person—
(a) has been registered as a pharmaceutical chemist for a period of two years or more;
(b) gives to the registrar a certificate stating that he has satisfactorily completed a training programme accredited by the Society for the annotation “SP” (Supplementary Prescriber) to be recorded against his name; and
(c) pays a fee of £25 to the Society,
he shall be entitled to have that annotation recorded against his name by the registrar in that register.”*

¹ A Pharmacist Supplementary Prescriber is able to provide prescriptions to a named patient, within a care plan, under the direction of a prescriber

This amendment allowed Pharmacists in Northern Ireland, who complied with these Regulations, to act as Pharmacist Supplementary Prescribers.

In 2006 the concept of an Independent Prescriber was introduced across a number of professions including pharmacy. These proposals were made by the then Department of Health, Social Services and Public Safety (DHSSPS), however, no specific corresponding provision in the General Regulations, or elsewhere, for Pharmacist Independent Prescribers was made.

In 2009 the DHSSPS introduced;

The Pharmaceutical Services Regulations (Northern Ireland) 1997 (as amended by 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;" (our emphasis)*

In addition, in 2012 the Human Medicines 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;" (our emphasis)*

In this consultation the Council of the Pharmaceutical Society NI will seek to address both the issue of no specific Regulations being made to prescribe Pharmacist Independent Prescriber requirements and to update the wording in Regulations to reflect changes made by the introduction of the Human Medicines Regulations 2012.

Additionally, the Council of the Pharmaceutical Society NI is taking this opportunity to bring the Principal Regulations in line with the General Systems Regulations.

This consultation is seeking views of stakeholders in respect of the Council of the Pharmaceutical Society NI's proposals to regularise this matter.

Current annotations to the Register

In 2004, when Pharmacist Supplementary Prescribers were introduced, the Pharmacy (Northern Ireland) Order 1976 was amended to reflect these changes, at the same time specific Regulations were made to enable such annotations to be made on the Register of pharmaceutical chemists.

In 2006 Independent Prescribers were introduced, principally through the changes made to who can prescribe to patients under the Medicines Act 1968, and the related Regulations. At this point no specific Regulations were made to prescribe the requirements for the annotation of “IP” to the Register. However, the general principle as applied to Pharmacist Supplementary Prescribers was used to grant accreditations, namely that Pharmacist Independent Prescriber applicants attend an accredited Pharmacist Independent Prescribers Course, gain an appropriate certificate, provide the Registrar of proof of the same, along with evidence of a minimum period on the Register and pay a fee of £25.

At its Council meeting of 15 February 2007, the Council agreed to accredit a Qualification from Queen’s University Belfast in regard to Pharmacist Independent Prescribers and since then has assessed applications against this requirement and the parallel requirement in Pharmacist Supplementary Prescriber annotations of length of time on the Register.

In 2009 and again in 2013, the Pharmaceutical Society NI consulted on and published Standards and Guidance for Pharmacist Prescribers, further minor amendments 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 reviewing its legislative framework and having sought legal opinion, the Council of the Pharmaceutical Society NI has concluded that going forward having specific Regulations in regards to the requirements for Pharmacist Independent Prescribers’ annotation on the Register would be preferable and it is now seeking to have these draft Regulations made. The Department of Health has confirmed that its view is that specific Regulations are required.

Proposals

The Council, in proposing these draft Regulations, is seeking to mirror the Regulations for Pharmacist Supplementary Prescribers as introduced in 2004, modified to reflect changes in the Human Medicines Regulations 2012. The draft Regulations attached at the end of this consultation set out our proposals.

The draft Regulations will enable the Registrar to annotate entries in the Register of

Pharmaceutical Chemists once three criteria have been met, namely:

- a. having been registered as a pharmaceutical chemist for a period of two years or more on a relevant register
- b. giving the Registrar a certificate stating that he has satisfactorily completed an accredited training programme for the annotation “IP” (Independent Prescriber) to be recorded against his name
- c. Paying a fee of £25 to the Society

To undertake any specialist area of practice, health professionals including pharmacists must be adequately trained and only work within their competencies. Principle 5 of the Code, published in February 2016, at 5.1 states registrants must “practise only when you are competent and fit to do so”.

The Council proposes that to be a Pharmacist Independent Prescriber, as with a Pharmacist Supplementary Prescriber, a pharmacist must be registered for a period of at least two years. This enables a pharmacist to build on their post qualification skills and it is accepted that during this two year period the appropriate Independent Prescribing course can be completed.

In a proposed change to the 2004 Regulations regarding Pharmacist Supplementary Prescribers and ensuring consistency between the Pharmacist Independent Prescriber annotation proposal and the extant Regulations for Pharmacist Supplementary Prescriber annotation, the Pharmaceutical Society NI is proposing an additional phrase which clarifies that it will recognise two years registration with all competent authorities as described in General Systems Regulations:

“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;”

In a similar manner and for consistency with the Human Medicines Regulations 2012 it is proposed that the Regulations for both Pharmacist Supplementary Prescribers and Pharmacist Independent Prescribers are expanded to include the activities that a prescriber is qualified to undertake. These proposals are reflected in the wording of Regulation 9 as below:

For Pharmacist Supplementary Prescribers: *“thereby noting in that register that he is qualified to order drugs medicines and appliances as a pharmacist supplementary prescriber.”*

And for Pharmacist Independent Prescribers: *“thereby noting in that register that he is qualified to order drugs medicines and appliances as a pharmacist independent prescriber.”*

Finally the Council is seeking to recover the costs associated with annotation including accreditation, the production of guidance and application administration. The proposed £25 is a one-off payment designed to offset the above costs.

Annex 1

This consultation is a public consultation which will be published on the Pharmaceutical Society NI website.

It is recognised that the subject matter is of particular relevance to certain groups and individuals these are:

1. Individuals on the Register of the Pharmaceutical Society NI
2. Students on the Student Register of the Pharmaceutical Society NI
3. The Ulster Chemists Association
4. The Guild of Healthcare Pharmacists
5. Community Pharmacy NI
6. The Pharmacy Forum
7. Individual Pharmacy Superintendents
8. Department of Health.

Proposed Statutory Rule

STATUTORY RULES OF NORTHERN IRELAND

2016 No. XXX

PHARMACY

Pharmaceutical Society of Northern Ireland (General) (Amendment) Regulations (Northern Ireland) XXXX

Made

Coming into operation

The

Council of the Pharmaceutical Society of Northern Ireland, makes the following Regulations in exercise of the powers conferred on it by Article 5 (1) (ff) of the Pharmacy (Northern Ireland) Order 1976 ^(a). The Department of Health, ^(b) has approved these Regulations in accordance with Article 25A (2) of that Order ^(c)

Citation, commencement and interpretation

1. These Regulations may be cited as the Pharmaceutical Society of Northern Ireland (General) (Amendment) Regulations (Northern Ireland) XXXX and shall come into operation on XXXXXXXX

2. In these Regulations "the principal Regulations" means the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 ^(d).

Amendment of the principal Regulations

3. In Regulation 9 of the principal Regulation (Qualifications for registration)—

(1) for sub-paragraph (3)(a) substitute—

"(a) (i) has been registered as a pharmaceutical chemist for a period of two years or more; or
(ii) has evidence from a competent authority or competent authorities of a relevant European state of being lawfully established as a pharmacist for a period of two years or more;

(aa) is currently registered as a pharmaceutical chemist;"

(2) in paragraph (3), after "by the registrar in that register" add the following words -

“thereby noting in that register that he is qualified to order drugs medicines and appliances as a pharmacist supplementary prescriber.”

(3) after paragraph (3), add the following paragraph –

"(4) Where a person–

- (a) (i) has been registered as a pharmaceutical chemist for a period of two years or more; or
- (ii) has evidence from a competent authority or competent authorities of a relevant European state of being lawfully established as a pharmacist for a period of two years or more;

(aa) is currently registered as a pharmaceutical chemist;

(b) gives to the registrar a certificate stating that he has satisfactorily completed a training programme accredited by the Society for the annotation “IP” (Independent Prescriber) to be recorded against his name; and

(c) pays a fee of £25 to the Society,

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”

Sealed with the Common Seal of the Pharmaceutical Society of Northern Ireland on XX XXXX XXXX in the presence of

L.S.

The Department of Health, hereby approves the foregoing Regulations.

Sealed with the Official Seal of the Department of Health, on XX XXXX XXXX

A Senior Official of the Department of Health.

L.S.

Explanatory Note

(This note is not part of the Regulations)

These Regulations amend the Pharmaceutical Society of Northern Ireland (General) Regulations (Northern Ireland) 1994 (S.R. 1994 No. 202) (the principal Regulations) to enable the registrar to annotate the register of pharmaceutical chemists to indicate pharmacists who have particular qualifications, specialist areas of practice and status.

Regulation 9(3) of the principal Regulations is amended to confirm that a person with the annotation "SP" (Pharmacist Supplementary Prescriber) recorded against his name in the register of pharmaceutical chemists is qualified to order drugs medicines and appliances as a Pharmacist Supplementary Prescriber.

These Regulations also insert sub-paragraph (4) to Regulation 9 of the principal Regulations, to set out the requirements to enable a person's entry in the register to be annotated "IP" (Pharmacist Independent Prescriber). This annotation will confirm that he is qualified to order drugs medicines and appliances as a pharmacist independent prescriber.

The amendments to Regulation 9 of the principal Regulations also allow for professional experience from a relevant European State to be considered as part of the two year registration requirement for annotation as either an Pharmacist Independent Prescriber or a Pharmacist Supplementary Prescriber.

^a S.I. 1976/1213 (N.I. 22) the relevant amendments are 1981 c.55, S.I. 1994/429 (N.I. 2), S.R. 2004 No. 78, S.R. 2008 No. 192, S.R. 2012 No. 308, and S.I. 2015/ 806.

^b 2016 c.5. Section 1 (5)

^c Article 25A is inserted by Article 9 of S.R. 2012 No. 308.

^d S.R. 1994 No. 202 as amended by S.R. 1996 No. 187, S.R. 1999 No.217, S.R. 2002 No. 206, S.R. 2003 No. 356, S.R. 2004 No. 236, S.R. 2005 No. 63, S.R. 2006 Nos. 207 and 240, S.R. 2007 No. 287, S.R. 2008 No. 222, S.R. 2009 No. 166 and S.R. 2016 No. 170.