

Consultation on Draft Guidance

**‘Professional indemnity insurance
for pharmacists in Northern Ireland’**

A consultation document

5 February 2014 to 2 April 2014

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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 in Northern Ireland 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:

- setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register;
- maintaining a publicly accessible Register of pharmacists, and pharmacy premises;
- handling concerns about the fitness to practise of registrants, acting as a complaints portal and taking action to protect the public; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

Consultation summary

This consultation seeks the views of stakeholders on the draft Guidance: Professional indemnity insurance for pharmacists in Northern Ireland.

This statutory requirement for registrants to have appropriate professional indemnity cover as a condition of their registration with the Pharmaceutical Society NI has been introduced by the Northern Ireland Assembly via the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 (referred to in the remainder of this document as 'the Amendment Order').

The Amendment Order came into operation on 7 November 2013¹. This was necessary in order to comply with the requirements of Article 4(2) (d) of EU Directive 2011/24/EU on Patients' Rights in Cross Border Healthcare.

At the time of launching this consultation, the Department of Health, Social Services and Public Safety (DHSSPS) consultation on the draft subordinate regulations to support the statutory requirement is underway and the finalised regulations are yet to be laid before the Assembly.²

We are consulting in preparation for the introduction of this statutory requirement, subject to NI Assembly approval of the regulations.

This consultation document explains the statutory requirement and the draft guidance, outlines how we plan to implement it and what this means for our registrants.

This consultation will be of particular interest to professional bodies; registrants who are affected by these proposals and employers.

¹ <http://www.legislation.gov.uk/nisr/2013/258/introduction/made>

² DHSSPS 'Consultation on the Council of the Pharmaceutical Society of Northern Ireland (Indemnity arrangements) draft regulations (Northern Ireland) 2014'
<http://www.dhsspsni.gov.uk/showconsultations?txtid=66411>

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.

For ease of reference, the draft guidance and the relevant questions are presented together in this document.

Responses should be sent by post, fax or e-mail to:

Consultation on Draft Guidance: Professional indemnity insurance for pharmacists in Northern Ireland

Pharmaceutical Society of Northern Ireland
73 University Street
Belfast, BT7 1HL

Tel: 028 9026 7933
Fax: 028 9043 9919

E-mail: Michelle McCorry, consultation coordinator michelle.mccorry@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.

If you wish your response to remain confidential, the Pharmaceutical Society NI will generally respect that request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000.

Consultation period

The consultation will run for 8 weeks from 5 February 2014 to **2 April 2014**.

When the consultation closes, we will analyse the responses we receive which will be taken into account by Council of the Pharmaceutical Society NI when making its decisions on the final guidance.

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 that the Council of the Pharmaceutical Society NI can consider the rationale for your views.

We have provided a response template at Annex A to complete, which is available on the website <http://www.psni.org.uk/publications/consultations/>

Q1. Do you think the guidance contains the right level of detail?

Too detailed
About right
Not detailed enough

Please provide reasons for your answer

Q2. Is the guidance clear and easy to understand?

Yes
No
Unsure

If you answered no, which parts of the guidance are not clear?

Q3. Can you suggest any improvements that would be helpful for us to include in our guidance?

Yes
No
Unsure

Q4. Do you have any further comments on the guidance?

Yes
No

Further comments

1. About professional indemnity cover and registration

1.1 Why is a statutory requirement being introduced?

The Department of Health, Social Services and Public Safety Northern Ireland has recently brought into effect the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 (the Amendment Order), to comply with and implement the European Directive 2011/24/EU on the application of patient rights in cross-border healthcare.³

The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 came into operation on 7 November 2013.⁴

The Amendment Order introduced the statutory requirement for practising pharmacists to have appropriate cover under an indemnity arrangement in respect of liabilities which may be incurred in practising as a pharmaceutical chemist. This means that it will be a statutory requirement for pharmacists in Northern Ireland to have appropriate professional indemnity cover as a condition of registration.

The DHSSPS is currently consulting⁵ on regulations in support of this requirement.

The Department of Health London in 2013 consulted⁶ on this requirement on behalf of the four UK Health Departments. The consultation gave the following reasons for introducing this requirement.

Inconsistency between healthcare regulators: some healthcare regulators have a statutory requirement for professionals to have professional indemnity cover in place and others do not. The Pharmaceutical Society NI had a professional requirement for registrants to have in place cover but did not have any statutory powers in this area prior to the approval of the Amendment Order.

Individuals should be able to make a compensation claim where they suffer harm through the negligence of a registered pharmacist. There are concerns about pharmacists who practise without any cover or without sufficient cover in place and how they would meet the cost of litigation and any successful claim for compensation.

An independent review of this area which reported in 2010⁷ concluded that making professional indemnity cover a condition of registration with a regulator would be the most cost-effective and proportionate way of making sure members of the public could make a compensation claim in cases of negligence.

³ European Directive 2011/24/EU

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

⁴ <http://www.legislation.gov.uk/nisr/2013/258/introduction/made>

⁵ DHSSPS Consultation on the Council of the Pharmaceutical Society of Northern Ireland (Indemnity arrangements) draft regulations (Northern Ireland) 2014

<http://www.dhsspsni.gov.uk/showconsultations?txtid=66411>

⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/143273/Indemnity-Consultation1.pdf

⁷ Department of Health "Professional insurance and indemnity for regulated healthcare professionals – policy review research" Price Waterhouse Coopers, June 2010.

1.2 When will this requirement affect registrants?

The primary legislation is already in place and we are anticipating that the enabling regulations will be in place by 1 June 2014.

From this date, there will be a statutory requirement for registrants to have appropriate professional indemnity cover in place.

1.3 What does the requirement mean for affected registrants?

Subject to Northern Ireland Assembly approval, from 1 June 2014 it will mean the following for a pharmacist:

- They will have a personal responsibility to ensure that they have professional indemnity cover in place; or, if they are not working, they will need to ensure that they will have appropriate cover in place before they begin to practise.
- They will need to ensure that the professional indemnity cover they have in place is appropriate for their practice.
- The requirement for appropriate professional indemnity could be met via an employer's arrangements for those who are employed; holding personal professional indemnity cover, or a combination of the two.

For most registrants, we anticipate that they will already meet this requirement.

Many will work in a managed environment where they are indemnified by their employer.

Others, including many who are self-employed or those whose practise comprises a combination of employed and self-employed roles will have their own professional indemnity insurance.

Applicants will have to confirm that they will have appropriate indemnity cover in place before they begin to practise.

1.4 How will we check that appropriate professional indemnity cover is in place?

The Council of the Pharmaceutical Society of Northern Ireland (Indemnity Arrangements) Regulations (Northern Ireland) 2014 shall, subject to Assembly approval, come into operation on 1 June 2014. These regulations specify the following:

1. A person seeking to be registered (including an application for restoration) or at the time of annual retention must declare in writing, at the time of application, that:
 - a. they have indemnity cover in place, and
 - b. they can provide evidence of this indemnity cover.

This means that they will be required to sign a declaration and to have available, if requested, evidence of cover. It is the personal responsibility of registrants to ensure that they have cover and that it is appropriate to their area of practice.

2. The Registrar may request a copy of the indemnity cover or such other information deemed necessary to determine that appropriate cover is in place.

We will not routinely seek evidence of indemnity cover but may ask for evidence of indemnity cover in circumstances where a complaint has been made or there are concerns that appropriate indemnity cover may not be in place.

3. The Registrar may seek confirmation from a third party in relation to a registrant or person seeking to be registered that appropriate indemnity cover is in place.

For example, we may seek confirmation from the employer of appropriate indemnity cover where a registrant has declared that they are relying upon their employer's cover.

4. A registrant must inform the Registrar when appropriate indemnity cover ceases, in accordance with Article 11A (1) of the Amendment Order, as stated in Article 6 of The Council of the Pharmaceutical Society of Northern Ireland (Indemnity Arrangements) Regulations (Northern Ireland) 2014.

To ensure compliance with the regulations registrants will be obliged to inform the regulator if indemnity cover has ceased to be in operation. It is likely that the regulator will seek assurances that the registrant will not practice until appropriate cover is restored.

5. A registrant must be able to provide information on their indemnity cover on request to any person wishing to access their services.

Failure to provide evidence could result in a complaint being made to the regulator. This provision applies to all practitioners including those on the temporary register.

1.5 What happens if appropriate indemnity cover is not in place?

1. The requirement for indemnity cover is linked to registration and in the majority of circumstances a failure to hold appropriate cover can be dealt with by administrative means as set out in Article 11 A (9a) of the Amendment Order.

This means that an individual who is unable to complete the required declarations or in some circumstances provide supporting evidence, as detailed above, would not have their registration renewed or would not be registered by us.

2. A registrant may be referred to our fitness to practise proceedings where we have concerns that indemnity cover is not appropriate or in place as set out in Article 11 A (9b) of the Amendment Order.

This means that the matter may be referred to the Scrutiny Committee or Statutory Committee as a misconduct issue.

1.6 Appeals

Where the Registrar intends to refuse an application for registration or retention on the register, or where he plans to remove a name, the registrant will have the right of appeal to the Statutory Committee in accordance with procedures set out in Article 9 (3) of The Council of the Pharmaceutical Society of Northern Ireland (Indemnity Arrangements) Regulations (Northern Ireland) 2014.