

Outcome of consultation on Draft Guidance 'Professional indemnity insurance for pharmacists in Northern Ireland'

Summary of responses and our response

June 2014

Contents

Purpose of report	3
Background	3
Who did we hear from?	3
Summary: Our comments and our response.....	4
Responses to the consultation	7
Q1. Do you think the guidance contains the right level of detail?.....	7
Q2. Is the guidance clear and easy to understand?.....	8
Q3. Can you suggest any improvements that would be helpful for us to include in our guidance?.....	9
Additional comments	11

Purpose of report

This report provides a summary of the responses to the consultation on Draft Guidance 'Professional indemnity arrangements for pharmacists in Northern Ireland' held between 5 February 2014 and 2 April 2014.

The report provides background to the consultation, a breakdown of the respondents to the consultation and a commentary on the responses to the proposed draft guidance.

Background

The statutory requirement for registrants to have appropriate professional indemnity cover as a condition of their registration with the Pharmaceutical Society NI was 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 2013.¹ 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.

The statutory obligation requiring practising pharmacists to have indemnity arrangements in place applies from the date of the coming into operation of the 2013 Amendment Order.

Following a DHSSPS consultation², enabling regulations to support the introduction of this statutory requirement were laid at the NI Assembly on 1 May 2014 and came into operation on 1 June 2014.

The Guidance produced for consultation outlines how these regulations will be implemented in practice and what this means for our registrants.

Who did we hear from?

We received nine responses.

Three individual pharmacists and six organisations responded to the consultation.

CPNI	Pharmacy representative body
Pharmacy Forum	Pharmacy representative body
National Pharmacy Association (NPA)	Pharmacy representative body
Boots UK	Pharmacy
Randalstown pharmacies ltd	Pharmacy
Professional Standards Authority (PSA)	Oversight UK healthcare regulation body

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>

Summary: Our comments and our response

As a result of the feedback from consultees, we have made some changes to our Guidance. The following section is a summary of the key themes to emerge from the consultation and our response and decisions.

Frequently asked questions

We have produced a FAQs document alongside the Guidance in response to consultation feedback which has been helpful in identifying areas that require further clarity. This is a live document that will be updated as we implement the statutory requirement.

What we heard: Appropriate cover

Several consultees suggested further clarification should be provided in relation to appropriate cover. Consultees asked what is deemed appropriate cover given the range of practice areas and diverse roles undertaken by pharmacy; how this will be assessed and the form and format of evidence required of indemnity cover.

Some consultees called for a special exemption from the indemnity cover requirement for pharmacists with non-public facing roles.

Some consultees said it would be helpful if the Guidance contained more information on recommended providers and an offer to approve providers chosen by the registrant.

Our response

We have produced a FAQ document and added a section on appropriate cover which addresses this. (See page 6 of the FAQ document '*What is adequate and appropriate cover?*')

The requirement of the EU Directive³ is to ensure that a system of professional indemnity or insurance is in place for all healthcare delivered in the UK.

In the Guidance and FAQ document it is emphasised that the requirement to have a professional indemnity arrangement in place applies to **all** individual registrants and it is their personal responsibility to ensure that they have cover and that it is appropriate to their area of practice. It will be for individual registrants to assure themselves that appropriate cover is in place. We cannot offer advice on what type and level of indemnity cover is appropriate.

In the FAQ document we include a section '*I am a registered pharmacist in Northern Ireland but I work as a lecturer, not in direct healthcare. How does this affect me?*' (See page 4 of the FAQ document)

³ European Directive 2011/24/EU

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

(See also page 7 of the FAQ document *'How will we judge adequacy and appropriateness?'* Page 8 of the FAQ document, *'Where can I find guidance or support to help me choose an appropriate provider?'* See also page 3 and 9 of the Guidance)

Disclosure of information to insurer

We have also amended the Guidance to make clear to registrants that they must disclose all material information which would influence an insurer's decision on whether or not to provide them with cover. We have amended the Guidance to include the following:

'Utmost good faith is a key principle of insurance. This means that in relation to dealings with insurers and insurance providers you must at all times act in good faith, making a full declaration of all in the insurance proposal which would influence an insurer's decision on whether or not to provide you with cover and the terms of that cover.' (Page 8 of the Guidance)

What we heard: Non-compliance

Fitness to practise process

The PSA take the view that concerns about non-compliance with indemnity insurance requirements should be dealt with under the fitness to practise process as an administrative removal process would not, in their view, protect the public and maintain public confidence in pharmacy profession and its regulation.

Timeframe for evidence

There were a few comments on the timescale to allow registrants to provide information/evidence to the Registrar when requested. Comments included that a short timescale is applied whilst another consultee called for a reasonable timeframe in order to give the registrant time to respond to the request.

Our response

We have added the following section to the Guidance (see page 8 *1.6 Indemnity cover and fitness to practise arrangements*)

In this section we describe instances where we will consider taking fitness to practise action if we believe a registrant makes a false declaration that they have professional indemnity cover in place while practising; cancels their indemnity cover and fails to put alternative cover in place; or has professional indemnity cover which is inappropriate for their practice.

What we heard: Style and format

The PSA considers the final document should be written in present tense rather than the future tense so as to 'future proof the guidance.'

Our response

The document is written in the future tense.

What we heard: Questions at registration/renewal to assess the need for cover

Two consultees suggested that a series of questions are asked on indemnity insurance at registration/renewal to enable pharmacists to quickly identify if they need indemnity cover and if their current arrangement meets the requirements.

Our response

The declaration that registrants are required to sign at the time of annual retention is sufficient and sets out the arrangements which allow a registrant to remain on the register.

We ask registrants to confirm that they have cover in place appropriate to their area of practice and can provide evidence of this cover. If they are not practising we ask them to confirm that they will have an arrangement in place when they begin to practise.

Responses to the consultation

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

About right	Not detailed enough
4	3

** It should be noted that not all respondents answered all of the questions directly but provided comments which are included below in each instance.

What we heard

Appropriate cover

Several consultees suggested further clarification is provided in relation to appropriate cover; how this will be assessed and the form and format of the evidence required of indemnity cover.

It was felt that this needs to be considered with a greater level of detail in the Guidance, particularly as the range of practice areas and diverse roles undertaken by pharmacists means that the levels and types of liability cover required will vary from pharmacist to pharmacist and will be appropriate to their duties, scope of practice and the extent of risk.

It was suggested that the Guidance set out how pharmacists decide if they need insurance and what appropriate cover would be necessary, commensurate with their roles and area of practice. This would be particularly helpful for those working in 'non-traditional' roles and 'non-patient facing' roles.

One consultee stated that 'appropriateness' can only be tested in retrospect as the actual level of 'cover' will depend on individual circumstances relating to any incident that might lead to indemnities being called upon.

Exemption for pharmacists in non-public facing roles

A couple of respondents called for a special exemption from the indemnity cover requirement for pharmacists with non-public facing roles.

Non practising pharmacists

Clarity was sought around what the requirement meant for registrants who were not in practice. One respondent felt that a registered pharmacist if not practicing for a period and remain on the register should not be required to have an indemnity arrangement in place as a condition of their registration.

Timeframe for the provision of evidence

Two respondents commented on the timeframe for the provision of evidence of indemnity cover, if requested by the Registrar. A professional body called for a reasonable timeframe to be given in order to give the registrant time to respond to this request. The PSA said that they would expect a short timescale to be applied.

Employer/employee responsibilities

One consultee felt that the Guidance needs to be clearer about the balance of responsibility between employers and employees. They suggest that it should be a responsibility for employers to notify employee pharmacists whether they are indemnified by the company and for what activities, and whether this is extended to cover temporary staff.

If final responsibility is deemed to lie with the employee pharmacist consideration should be given to how this could actually be managed in reality especially for the larger employers.

Another consultee suggested that the Guidance should include the advice that pharmacists should discuss the level of cover required with their employer and/or indemnifier in order to ensure they have the correct level of cover.

Q2. Is the guidance clear and easy to understand?

Yes	No
5	2

What we heard

Application of guidance to locums

Further clarity was sought on the application of the Guidance for locums and the checks they need to complete with the employer prior to undertaking employment.

Notify when cover ceases

One consultee felt that it wasn't clear, what was required of registrants when they have to inform the Registrar when appropriate indemnity cover ceases e.g. do registrants have to let the regulator know if an annual policy held by an employer has expired. Reservations were expressed that employee pharmacists would be privy to this information.

It was also requested that an explanation of the term 'temporary register' is included in the Guidance.

Advice to registrants on choice of cover

It was suggested that the Guidance include recommended providers and an offer to approve providers chosen by the registrant. It was also considered important to make clear that employee pharmacists who are covered by their employer will require separate indemnity insurance for activities outside of that employment.

One consultee suggested the inclusion of Guidance for health service employed pharmacists with particular reference to vicarious liability and how it applies to Northern Ireland, perhaps in a Q&A format.

Non-compliance

Further clarity was sought around the process of removal from the register administratively and referral to fitness to practise proceedings.

The PSA is of the view that concerns about non-compliance with indemnity insurance requirements should be dealt with under the fitness to practise process. This view is based on their scrutiny of regulators' fitness to practise decisions that practising without indemnity insurance calls into question a health professional's commitment to patient safety.

An administrative removal process would not, in their view, protect the public and maintain public confidence in pharmacy profession and its regulation. They point out that a non-compliant registrant could have been practising without appropriate cover for some months prior to detection.

The PSA believe that allowing a registrant to simply re-join the register as soon as they obtained appropriate cover this would seriously undermine the indemnity requirement and confidence in the profession and its regulator.

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

What we heard

Style and format

The PSA considers the final document should be written in present tense rather than the future tense so as to 'future proof' the Guidance.

Visible evidence of indemnity cover

One consultee suggested that the display of evidence of indemnity cover, such as a certificate would provide assurances to the public and patients and would facilitate the requirement for registrants to provide evidence of indemnity on request. They suggest this requirement could be included in the Premises Standards issued by the Pharmaceutical Society NI.

Explanation of ‘appropriate cover’

The effectiveness of the Guidance could be improved, it was suggested by adding an explanation of the requirement to hold ‘appropriate cover’ and what methods/standards the Registrar will apply when assessing whether cover is appropriate.

Several consultees suggested further clarification should be provided in relation to appropriate cover.

Advice to registrants on choice of cover

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Compliance – random checks

The PSA note point 2, section 1.4 of the Guidance which states that the Pharmaceutical Society NI ‘*will not routinely seek evidence of indemnity cover but may ask for evidence of indemnity cover in circumstances where a compliant has been made or there are concerns that appropriate indemnity cover may not be in place*’.

The PSA ask the Pharmaceutical Society NI to supplement this with a system of random checks on a proportion of registrants and suggest the application of a *Right-touch regulation*⁴ approach in the developing a system of random checks. Right-touch regulation means applying the minimum regulatory force required to achieve the desired result – in this instance the desired deterrent effect.

Questions at registration/renewal to assess the need for cover

Two pharmacy representative bodies suggest that when a pharmacist renews their registration, in addition to the current questions asked at registration, a further set of questions should be asked on indemnity insurance to enable pharmacists to quickly identify if they needed indemnity cover and if their current arrangement meets the requirements.

Questions suggested include whether the pharmacist works in a public facing role providing clinical services; if they are self employed or a locum and how they ensure they are covered by any employer's insurance.

⁴ CHRE, 2010. *Right-touch regulation*. Available at: <http://www.professionalstandards.org.uk/library/document-detail?id=a3ea5638-fadf-400e-8635-47bf4b028a1f>

Additional comments

Boots believe that self-declaration without a need to provide specific details of cover, is an appropriate way of ensuring that all pharmacists are operating within indemnity arrangements.

Boots have requested that the DHSSPS do not proceed with introducing these regulatory powers as they believe such arrangements would 'serve no practical purpose' and would merely be an exercise in bureaucracy leading to additional costs to be borne by registrants and/or their employers through higher fees.

The NPA believe that the current system works well. CPNI urge the Pharmaceutical Society NI to deal with indemnity assurance arrangements sensibly by using a similar approach to that currently in place, and if further regulatory changes are deemed necessary that these are measured and proportionate given the current context of:

- existing indemnity arrangements which are working well
- low level of complaints / claims
- low level of risk relative to other areas of the Health Service.

CPNI also strongly emphasise the importance of the Pharmaceutical Society NI retaining parity with the GPhC and adopt a similar approach on this issue.

For further information on this paper please contact:

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