



January 2016

## **Pharmacists' Defence Association Response to GPhC Consultation on Draft Amendments to Rules:**

The GPhC (Registration) Rules 2010,  
The GPhC (Fitness to Practise and Disqualification etc.) Rules 2010 and  
The GPhC (Statutory Committees and their Advisers) Rules 2010

# Contents

About the Pharmacists Defence Association .....03

Executive Summary .....04

Questions .....05

References .....09

## 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 25,000 individual pharmacist 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

## Executive Summary

The GPhC is consulting on proposed changes to its rules. The purpose of the changes, set out in the consultation document, is to:

- implement the statutory requirements for a registrant to have an appropriate indemnity arrangement in force and to have the knowledge of English necessary for safe and effective practice, as conditions of their registration
- introduce measures to avoid conflicts of interest arising from common membership of Appeals Committee and Fitness to Practise Committee panels

At the time of writing, the PDA has more than 25,000 members to whom we provide professional indemnity insurance cover. The proposed changes are an opportunity to enhance the protection of the public through a more robust regulatory approach. However, there are a number of factors to consider which affect the ability of pharmacists to comply with the proposed GPhC requirements and which relate to the ultimate suitability of the PI insurance cover from different providers.

### Our recommendations are:

- A requirement should be placed upon employers to provide their employees with sight of the respective PI insurance certificate. A requirement could then be placed upon registrants to seek copies of their employer's insurance certificates and retain them indefinitely. This would also help registrants to make an informed assessment about the suitability of their PI insurance.
- The Council must provide guidance to employees and employers (using its powers under Schedule 1 Part 6 of the Pharmacy Order 2010) about the suitability and minimum acceptable specification of indemnity insurance cover. The guidance should address the Council's expectations and highlight potential issues for registrants and employers to consider. The Council must ensure that all employer-provided PI insurance schemes are fully transparent and that the relevant conditions are explained in detail by employers to employees.

### The Consultation Document

As a general principle, we recommend that questions in a consultation such as this should be asked in an entirely neutral manner. Commencing questions with 'do you agree' could lead to acquiescence bias<sup>(1)(2)</sup>. This may mean that the responses obtained will not truly represent respondents' views.

## Questions

1. ***Do you agree with the proposal to prevent common membership of Fitness to Practise and Appeals Committee panels where this could give rise to a conflict of interest?***

**YES**

2. ***Do you agree with the proposed duty for registrants to provide information about their indemnity arrangements?***

**YES – HOWEVER, WE BELIEVE THAT A WIDER CAUTIONARY VIEW NEEDS TO BE TAKEN.**

Whilst we are not opposed to the majority of the proposed changes, there are omissions as well as practical considerations which necessitate revisions to the proposals.

### **Timing issue**

Draft rule 8A<sup>(2)</sup> requires registrants to produce evidence of indemnity insurance cover that was in place 'in respect of any period specified in the notice'. This would in practice mean that registrants and indemnity insurance providers would have to retain historical proof of indemnity insurance cover indefinitely. There are a range of indemnity insurance providers; some provide insurance for large numbers of registrants and others provide insurance for small numbers only. Records retention policies among insurers may vary, since the FCA has issued guidance that it is for each insurer and not their regulator to determine how long records are kept<sup>(3)</sup>. So, upon ceasing cover with a particular insurer, a registrant's records may ultimately be deleted by the insurer in accordance with the data protection principle that 'personal information must be kept for no longer than is necessary'.

Professional indemnity is secured, broadly, by two different routes; that provided by an employer and that sourced by the registrant privately and held in their own name. Whilst those pharmacists who rely upon their own individual PI insurance scheme should be able to readily comply with the newly proposed GPhC requirement and the GPhC will be able to relatively easily assure the public that such registrants do indeed practice with the benefit of PI insurance, this may become much more difficult for those registrants that rely upon their employer for their PI insurance.

### **Issues regarding employer-provided PI insurance**

It may be impossible for a registrant to prove that they had indemnity insurance cover at a particular time if they were to rely on the employer to retain a copy. Under such circumstances, it would become necessary for a registrant to secure a copy of their employer's PI insurance certificate and keep it safely for an indeterminate period of time. Unless they did so, it may also prove difficult for registrants relying on their employer-provided indemnity insurance cover to obtain retrospective proof of that cover if they had since left employment.

### **Sight of an employer's insurance certificate**

A number of employers have assured their staff that they provide adequate indemnity cover for the staff members' professional duties. Often, they do this via staff newsletters or other forms of informal memo. However, if registrants are to be able to comply with the proposed regulatory requirement then they must have sight of their employer's professional indemnity certificate. Consequently, the onus needs to be placed upon employers to make copies of the insurance certificates and master policy documents readily available to the registrants employed in their pharmacies. This would allow registrants to make an informed assessment about the cover being provided. The PDA is aware of a number of instances where employers have told their employees that they have professional indemnity insurance in place, whereas instead they have public liability and employer's liability insurance in place – which is an entirely different type of insurance which would not satisfy the PI requirement and would not protect patients in the event of a dispensing or other error. PDA members working for many employers have reported difficulty gaining access to the master policy documents and/or PI insurance certificates. To date, the PDA is not aware of any registrant having been successful in doing so.

Ultimately, registrants, in relying upon their employer's professional indemnity insurance would also need to rely upon their employer having renewed their professional indemnity insurance policy at the time it had become due for renewal; this could not always be guaranteed.

### Employer-provided PI insurance being conditional

The public needs to be assured that employer-provided professional indemnity insurance would continue to provide protection to the public in the event of a claim against a registrant irrespective of whether the employer had identified a performance issue with the employee or not. As an example to illustrate this, guidance issued by one of the largest community pharmacy employers stipulates that the indemnity insurance cover applies to employee pharmacists and registered pharmacy technicians and that indemnity cover may be withdrawn if the employee does not follow the company's legal or other advice.

This appears to make the employer's PI insurance conditional. In instances where there is a conflict between the interests of the employee and the interests of the employer (and in claims for compensation this is often the case), this potentially leaves members of the public exposed to the possibility of the PI insurance being withdrawn.

Within the GPhC's Standards of Conduct, Ethics and Performance, standard 7.9 reads 'make sure that all your work, or work that you are responsible for, is covered by appropriate professional indemnity cover'. That work and those responsibilities are subject to all the other standards of conduct, ethics and performance. This means that professional indemnity cover must protect patients against breaches of all professional duties performed by registrants, which, due to the broad nature of roles in which registrants engage, is not limited to dispensing errors or clinical negligence. It must also extend, for example, to indemnifying against breaches of the duty of confidentiality or some other error or omission such as a failure to raise concerns which subsequently results in patient harm.

### Availability of insurance certificates

Professional indemnity insurance policies are variable in nature. Expiry dates, excesses and other terms and conditions of the policy vary. For registrants to effectively assess that appropriate professional indemnity cover is in place, the onus needs to be placed on employers providing professional indemnity cover to notify and make readily available to registrants the expiry dates, excesses and other terms and conditions of the policy.

The information must also be readily available to locum pharmacists, who may rely on a number of different employers providing professional indemnity cover. Therefore, in order to address these numerous issues, at a practical level, we make the following recommendation.

### Recommendation

*A requirement should be placed upon employers to provide their employees with sight of the respective PI insurance certificate. A requirement could then be placed upon registrants to seek copies of their employer's insurance certificates and retain them indefinitely. This would also help registrants to make an informed assessment about the suitability of their PI insurance.*

### Concerns over adequacy of the insurance schemes in meeting the GPhC requirements

The PDA is aware of a number of schemes purporting to provide professional indemnity cover and upon which registrants rely, but about which there are concerns as to whether they provide adequate safeguards to the public.

### Contingent Medical Malpractice

Contingent Medical Malpractice (CMM) insurance advertised by some of the unions relies on the employer providing the primary medical malpractice insurance and primary public liability cover and keeping it in place<sup>(4)</sup>. CMM cover is designed to protect against an employer's insurer's insurance scheme failure and consequent inability for the primary insurance scheme to pay costs, for example as a result of financial difficulties. If however, the employer simply chooses not have medical malpractice insurance in place in the first place, or fails to renew their cover in a timely manner then CMM cover will not operate and will not provide any protection to the public. This means that registrants, the public and the regulator would still be reliant upon and would need to be assured of the professional indemnity cover being provided by the employer. As such, an insurance certificate for CMM provided to the regulator as proof of PI insurance by a registrant does not provide the solid assurance that the GPhC would require to satisfy itself that patients are protected by professional indemnity insurance, for if the employer did not renew their insurance, then the CMM insurance would not operate.

### Employer-retained excesses on the PI insurance

Many community pharmacy employers provide professional indemnity insurance to their GPhC-registered staff by dint of their membership of the National Pharmacy Association, which provides professional indemnity as an automatic NPA member benefit. Many pharmacists have historically been told that if a pharmacy is in NPA membership, then they will always be automatically insured by the NPA insurance scheme. However, unbeknown to many employees and locums some of the largest employers have agreed an internal excess, below which it is the employer and not the NPA that is required to pay any claims for compensation – typically this excess is in the region of £100,000 per claim. This scenario raises a multitude of concerns. Under the insurance statutes and insurance regulatory requirements (Financial Conduct Authority), those providing insurance must have sufficient assets and funding to cover the value of their potential liabilities<sup>(6)(7)(8)(9)</sup>. Under the EU Solvency-II insurance directive, the value of ‘best estimate liability’ for insurance providers means any certain or potential obligation for payment now or in the future<sup>(5)</sup> and is therefore in part assessed on the total costs if all insured parties were to simultaneously require payment of a claim to the maximum value covered by each of their individual insurance policies. This is an important insurance regulatory and consumer protection law principle and serves to protect the interests of patients in the example of pharmacist PI insurance.

However, the effect of the financial arrangement between some insurers and the NPA (which is designed to keep insurance premiums paid to the NPA by the employer to a minimum) is that technically, unless the employer takes out additional insurance with another insurance provider to cover the excess limit, then the patients will not have the benefit of Professional Indemnity insurance in place (as described above) for any claims below the excess limit retained by the employer. In such a scenario, the NPA insurance only operates for claims above (for example) the £100,000 limit. As such, under such circumstances patients may not enjoy the automatic protection of an FCA-regulated insurance policy; instead they have to rely upon the preparedness and the financial ability of the employer to settle their compensation in the event that they make a claim.

In the example described, the community pharmacy employer cannot be an insurance provider directly as it is unlikely to be regulated as such, but unless it has made additional insurance arrangements then it is for all intents and purposes acting as the insurer for the first £100,000 of each claim. Even if it has made additional insurance arrangements, then it should be transparent about its arrangements and not simply tell its employees that they are covered by the NPA. For every 1000 GPhC-registered employees working for such an employer, if it were required to honour claims in respect of each of those employees simultaneously, requiring payment of £100,000 in each case, such an employer itself would need to be able to make compensation payments of £100 million, which it could not. This takes such insurance outside of the scope of the protections described in the solvency arrangements stipulated by the insurance regulations and creates an unsatisfactory and unacceptable risk to the public.

As far as registrants being able to comply with the GPhC requirement to work with the protection of PI insurance, it is felt that such arrangements may well mean that they will be unable to comply. More importantly, they are unlikely to ever be told, instead they are simply being told that their employer is a member of the NPA and therefore they are given a feeling of confidence in their insurance arrangements which is not entirely founded upon fact. They are not being told about the special financial arrangements which can have a significant impact upon both the pharmacists’ ability to comply with the GPhC requirement and potentially also the impact upon patients.

### Recommendation

*The Council must provide guidance to employees and employers (using its powers under Schedule 1 Part 6 of the Pharmacy Order 2010) about the suitability and minimum acceptable specification of indemnity insurance cover. The guidance should address the Council’s expectations and highlight potential issues for registrants and employers to consider. The Council must ensure that all employer-provided PI insurance schemes are fully transparent and that the relevant conditions are explained in detail by employers to employees.*



3. *Do you agree with the proposed changes on applications for entry in the register?*

YES

4. *Do you agree with the proposed changes on applications for renewal of an entry in the register?*

YES

5. *Do you agree with the proposed changes on applications for an annotation to an entry in the register?*

YES

6. *Do you agree with the proposed changes on applications for renewal of an annotation to an entry in the register?*

YES

7. *Do you agree with the proposed changes on applications for restoration of an entry in the register?*

YES

8. *Do you agree with the proposed changes on applications for restoration of an annotation to an entry in the register?*

YES

9. *Do you agree with the proposed changes to fitness to practise proceedings in cases where it is alleged that a pharmacy professional does not have the knowledge of English necessary for safe and effective practice?*

YES

10. *Do you have any other comments you want to make?*

NO



## References

1. Avoiding the Yes Bias by Dave Vannette  
**[www.qualtrics.com/blog/avoiding-the-yes-bias/](http://www.qualtrics.com/blog/avoiding-the-yes-bias/)**
2. Lean Analytics: Use Data to Build a Better Startup Faster by Alistair Croll, Benjamin Yoskovitz page 166
3. Insurance: Conduct of Business Handbook 2.4  
**[www.handbook.fca.org.uk/handbook/ICOBS/2/4.pdf](http://www.handbook.fca.org.uk/handbook/ICOBS/2/4.pdf)**
4. Guild of Healthcare Pharmacists – Contingent Medical Malpractice – GPhC Declaration on Professional Indemnity Arrangements  
**[www.ghp.org.uk/GPYUDN/BPELYN](http://www.ghp.org.uk/GPYUDN/BPELYN)**
5. CEA Insurers of Europe – Solvency II Glossary  
**[http://ec.europa.eu/internal\\_market/insurance/docs/solvency/impactassess/annex-c08d\\_en.pdf](http://ec.europa.eu/internal_market/insurance/docs/solvency/impactassess/annex-c08d_en.pdf)**
6. The Prudential Regulation of Insurers Under Solvency II – Bank of England Quarterly Statement 2015 Q2  
**[www.bankofengland.co.uk/publications/Documents/quarterlybulletin/2015/q2prerelease\\_2.pdf](http://www.bankofengland.co.uk/publications/Documents/quarterlybulletin/2015/q2prerelease_2.pdf)**
7. LLM1220 - Introduction to Lloyd's: Capital Structure: The Chain of Security: Solvency by HMRC  
**[www.hmrc.gov.uk/manuals/llmanual/llm1220.htm](http://www.hmrc.gov.uk/manuals/llmanual/llm1220.htm)**
8. Solvency II: A New Regime for Insurers, Bank of England Policy Statement PS2/15, March 2015  
**[www.bankofengland.co.uk/prd/Documents/publications/ps/2015/ps215.pdf](http://www.bankofengland.co.uk/prd/Documents/publications/ps/2015/ps215.pdf)**
9. Solvency II Association – The Solvency Capital Requirement (SCR)  
**[www.solvency-capital-requirement.com/](http://www.solvency-capital-requirement.com/)**

[www.the-pda.org](http://www.the-pda.org)

The Pharmacists' Defence Association  
The Old Fire Station  
69 Albion Street  
Birmingham  
B1 3EA

Contact information

General Enquiries: 0121 694 7000

Fax: 0121 694 7001

Web: [www.the-pda.org](http://www.the-pda.org)

Email: [enquiries@the-pda.org](mailto:enquiries@the-pda.org)

