



August to October 2016

## **Pharmacists' Defence Association Response to the Department of Health's Consultation on Proposed Changes to the Pharmaceutical Services Regulations (NI) 1997**

| representing **your** interests |

# Contents

**About the Pharmacists Defence Association ..... 03**

**Executive Summary ..... 04**

**Consultation Response ..... 05**

**References..... 08**

## 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 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 Pharmaceutical Services Regulations (NI) 1997 regulate the provision of community pharmacy services.

### The Department of Health is consulting on two separate matters:

01. Changes to the UK-wide Human Medicines Regulations 2012 have created two new groups of prescribers and provide for registered therapeutic radiographers to independently prescribe medicines, while registered dieticians are able to enter into supplementary prescribing arrangements. For pharmacists to be able to dispense prescriptions issued by these new prescribers, the Pharmaceutical Services Regulations (NI) 1997 would need to be amended.
02. The Department of Health is proposing to amend the terms of service to clarify that community pharmacy contractors will not be in breach of the terms of service if they refuse to provide pharmaceutical services to a person who is violent, threatens violence, commits or threatens to commit a criminal offence. Similarly, it is proposed that contractors be permitted to refuse to provide pharmaceutical services if anyone accompanying the person seeking the service behaves in this manner.

### The PDA's recommendations are:

- If changes to legislation are made which permit pharmacists to supply prescriptions written by therapeutic radiographers (as independent prescribers) or dieticians (as supplementary prescribers), the Department of Health must:
  - Communicate to pharmacists both information about the changes to the law and how to go about checking the details of the prescribing status of individuals in those groups
  - Provide pharmacists with an understanding of the nature and scope of each role, so that if they are presented with a prescription for a medicine which may have been prescribed outside the competence of a therapeutic radiographer or dietician, they may potentially be able to identify it as such. This will enable pharmacists to exercise their duty of care in advising the prescriber and/or the patient accordingly.

- Changes to legislation must be made and written clearly to ensure that all pharmacy services may be refused in the circumstances described in 23(a) and 23(b) of the draft Statutory Rules.
- Changes to the legislation must be written so as to ensure that both pharmacists and pharmacy contractors may refuse to provide pharmaceutical services in the circumstances described in 23(a) and 23(b) of the draft Statutory Rules.
- The proposed paragraph 23(b) in the draft Statutory Rules must be amended (subject to the Department of Health obtaining legal advice on the matter to ensure the desired effect is achieved) to the effect that pharmacy services may be refused where *"the chemist reasonably believes that the person seeking pharmaceutical services, or any other person accompanying that person, is committing or threatening to commit a criminal offence."*

## 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.<sup>1,2,3,4</sup> This may mean that the responses obtained will not truly represent respondents' views.

# Consultation Response

**1. Following the changes to the Human Medicines Regulations 2012, do you agree with the Department’s proposal to amend the General Pharmaceutical Services Regulations (NI) 1997 to recognise registered therapeutic radiographers as independent prescribers and registered dieticians as supplementary prescribers. This will ensure community pharmacy contractors can dispense prescriptions issued by these new prescribers.**

Yes  No

The consultation document states that ‘the UK wide Human Medicines Regulations 2012 has created two new groups of prescribers and provides for registered therapeutic radiographers to independently prescribe medicines while registered dieticians are able to enter into supplementary prescribing arrangements.’ For the prescribing status of therapeutic radiographers and dieticians to be given full effect in Northern Ireland, it would be necessary for the General Pharmaceutical Services Regulations (NI) 1997 to be amended to allow community pharmacists to supply prescriptions from those prescribers. However, it does not necessarily follow that the PDA would agree with the provisions in the Human Medicines Regulations 2012, which could confer prescribing status on those two groups, in the first place.

The ‘Yes’ and ‘No’ boxes above have been left intentionally blank.

In order for the PDA to have submitted an informed position on this matter, the organisation would have wanted to understand fully, amongst other things, the nature of the training undertaken by the two groups, how they are each regulated and the nature of their work including the associated risks. Such matters are beyond the scope of the PDA’s role.

The PDA submits that, if the proposed changes are made, meaning that pharmacists are able to supply prescriptions from either of these two groups, the Department of Health must communicate to pharmacists both information about the changes to the law and how to go about checking the details of the prescribing status of both therapeutic

radiographers and registered dieticians. The Health and Care Professions Council advised the PDA that the register on its website (<http://www.hcpc-uk.org/check/>) will include annotations of prescribing status for registered therapeutic radiographers and dieticians that have it; we ask that the Department of Health verify this and communicate this to all pharmacists. The PDA also asks the Department of Health to provide pharmacists with an understanding of the nature of each role, so that if they are presented with a prescription for a medicine which may have been prescribed outside the competence of a therapeutic radiographer or dietician, they may potentially be able to identify it as such. This will enable pharmacists to exercise their duty of care in advising the prescriber and/or the patient accordingly.

### Recommendation

*If changes to legislation are made which permit pharmacists to supply prescriptions written by therapeutic radiographers (as independent prescribers) or dieticians (as supplementary prescribers), the Department of Health must:*

- *Communicate to pharmacists both information about the changes to the law and how to go about checking the details of the prescribing status of individuals in those groups*
- *Provide pharmacists with an understanding of the nature and scope of each role, so that if they are presented with a prescription for a medicine which may have been prescribed outside the competence of a therapeutic radiographer or dietician, they may potentially be able to identify it as such. This will enable pharmacists to exercise their duty of care in advising the prescriber and/or the patient accordingly.*

**2. Do you agree with the Department’s proposals to amend the terms of service for community pharmacy contractors so that they will not be in breach of their terms of service if they refuse to supply drugs or appliances to a patient if they (or a person accompanying them) are violent, threaten violence, commit or threaten to commit a criminal offence?**

Yes  No

The PDA wholeheartedly agrees that violence or the threat of violence (and other criminal acts) is a problem for pharmacists and would welcome the ability for pharmacists to refuse to provide pharmaceutical services on the basis outlined in the consultation document, subject to our comments below.

The proposed changes – to allow the refusal to supply drugs or appliances to a patient if he or she (or a person accompanying him or her) is violent, threatens violence, commits or threaten to commit a criminal offence – should not be given effect only through community pharmacy contractors, as this question imputes. It must also be possible for employee pharmacists and self-employed pharmacists to make the refusal. Pharmacy contractors will not always be present on the pharmacy premises, whereas a pharmacist will always be present or contactable and able to return with reasonable promptness during the operating hours of the pharmacy. If the legislative changes were made as suggested in this question, in the case of large multiples, a decision from the business owner (contractor) as to whether to make the refusal could take too long. The decision from the contractor could also place the pharmacist in a difficult position if it was different to that which the pharmacist would make as a professional.

In fact, a pharmacy contractor would have a conflict of interest in making a decision to refuse to provide pharmaceutical services, since the business would lose money as a result; it must therefore be possible for employee and self-employed pharmacists to make the decision.

It must be possible for part-time pharmacists to refuse to provide pharmaceutical services. The contractor should then be able to make the same decision to ensure a blanket refusal to provide services from the premises if necessary.

We note that the changes in the draft statutory rules (SRs) appear to have a different effect to that imputed in the above question; the possibility of which was the reason we asked to see a copy of the draft SRs and for them to be published alongside the consultation documents on the Department of Health’s website. We would not have been able to comment on the following issues in the same detail had we not received a copy of the SRs. We note and are grateful that the draft SRs were circulated among invited respondents but that they were not published on the website for all potential respondents to see.

The range of pharmacy services which could be refused should be broader than that described in this question. The PDA believes that it should be possible to refuse to provide any pharmacy service (not just the supply of drugs or appliances) if a patient (or a person accompanying him or her) is violent, threatens violence, commits or threaten to commit a criminal offence.

The draft SRs include the paragraph:

*“(23) Refusal to supply drugs or appliances*

*A chemist may refuse to provide pharmaceutical services where –*

- (a) the chemist or another person is subjected to or threatened with violence by the person seeking pharmaceutical services, or by any person accompanying that person; or*
- (b) the person seeking pharmaceutical services, or any other person accompanying that person, commits or threatens to commit a criminal offence.”*

The heading to the paragraph “Refusal to supply drugs or appliances” may suggest that the range of services which can be refused is limited, whilst the text which follows it (“a chemist may refuse to provide pharmaceutical services where...”) may suggest that all ‘pharmaceutical services’ (to the extent that the definition within the regulations permits) may be refused.

**Recommendation**

*Changes to legislation must be made and written clearly to ensure that all pharmacy services may be refused in the circumstances described in 23(a) and 23(b) of the draft Statutory Rules.*

In addition, the phrase ‘a chemist may refuse to provide pharmaceutical services where...’ may suggest, in accordance with the interpretations in Part I (2) of the Pharmaceutical Services Regulations (NI) 1997, that *pharmacists* as well as *pharmacy contractors* and suppliers of appliances could refuse to provide pharmaceutical services. We ask that the Department of Health seek legal advice to ensure that that is indeed the effect of this provision (as described above).

Further, the proposed paragraph 23(b) includes the wording: *“the person seeking pharmaceutical services, or any other person accompanying that person, commits or threatens to commit a criminal offence.”* Whether the person has committed a criminal offence would be for a court to decide; a pharmacist or contractor might *reasonably believe* that a criminal offence is being committed but may not in the moment *know* that a criminal offence is being committed. We suggest that the proposed paragraph 23(b) be amended (subject to the Department of Health obtaining legal advice on the matter to ensure the desired effect is achieved) to the effect that pharmacy services may be refused where *“the chemist reasonably believes that the person seeking pharmaceutical services, or any other person accompanying that person, is committing or threatening to commit a criminal offence.”*

**Recommendation**

*The proposed paragraph 23(b) in the draft Statutory Rules must be amended (subject to the Department of Health obtaining legal advice on the matter to ensure the desired effect is achieved) to the effect that pharmacy services may be refused where **“the chemist reasonably believes that the person seeking pharmaceutical services, or any other person accompanying that person, is committing or threatening to commit a criminal offence.”***

**Any other comments**

The organisation’s comments have been provided in response to the questions asked.

## References

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