The Pharmacists' Defence Association's Response to the General Pharmaceutical Council's Consultation on Guidance for Pharmacist Prescribers

June 2019

| representing **your** interests | | defending **your** reputation |

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, pre-registration pharmacists and pharmacy students and, when necessary, defend their reputation. It currently has more than 28,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The PDA is the largest pharmacist membership organisation and the PDA Union is the only independent Trade Union exclusively for Pharmacists, in the UK.

The primary aims of the PDA are to:

- Support pharmacists, pre-registration pharmacists and pharmacy students 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
- Arrange insurance cover for individual pharmacists, pre-registration pharmacists and pharmacy students to safeguard and defend their reputation.

Summary

The General Pharmaceutical Council is consulting from 29 March 2019 to 21 June 2019 on new guidance for pharmacist prescribers.

Foreword

The PDA has long campaigned for enhanced roles for pharmacists which make use of their unique skills and expertise. We are pleased that an ever-increasing number of pharmacists are becoming independent prescribers and that the roles are developing in different settings and across the four countries of the UK (though, we may take issue with the details or the direction of travel). For the profession, prescribing by pharmacists was first introduced in the form of supplementary prescribing in 2003, but should still be viewed as a relatively new and emerging role for the profession, particularly since its prevalence has started to increase markedly only within the past few years. [1] Given the importance of these developments, and that the profession is at a critical stage in its history, it is important that pharmacists have access to a regulatory guidance document that is:

a) fit for purpose, as a guide for pharmacists to help them protect patients and the public

b) reflects the profession's unique skills and role as experts in medicines and

c) encapsulates the profession's ambitions for the future, and the cutting-edge practice currently taking place.

Our view is that this proposed guidance does not achieve any of these things, and needs substantial review. Our rationale for this view is explained in response to the consultation questions.

Questions

1. **Have we identified all the necessary areas for ensuring safe and effective care is provided?**

No

The PDA is broadly supportive of the areas covered by the draft guidance. This includes, for example, important concepts such as prescribing within the level of competence and maintaining appropriate clinical knowledge.

However, our view is that the document overall is vague, ambiguous and unsuitable for professional use. Too much of the content is based on statements of principle such as *"To minimise patient risk and improve patient safety, pharmacist prescribers must make sure prescribing is evidence-based, safe and appropriate"* which in essence reiterate requirements and expectations that already apply to pharmacists. "Guidance" ought to be helpful to its audience. A person reading the Highway Code would not expect to be told that they merely need to "drive safely and appropriately". Ultimately, this guidance does not provide the necessary detail to help pharmacists keep patients safe.

Recommendation

This guidance needs a significant overhaul to make it fit for purpose; ultimately, in our view, a substantially different document is required. The GPhC should not publish a guidance document based on this consultation. It should consider the responses to this consultation and put forward a further consultation at a later date on a revised document.

Recommendation

A guidance document for pharmacist prescribers must be more prescriptive than that which has been proposed. It must support pharmacists to work to a process / framework / system in their prescribing. The approach which has been taken in the proposed guidance, which appears to rely heavily on stating outcomes and statements of broad principle, is not appropriate.

Pharmacist prescribers work in different settings, each of which presents its own challenges. This includes in GP practices, hospitals, community pharmacies, care homes, online pharmacies and residential settings. In addition, pharmacists engage in specific activities which are ideally suited to their roles as experts in medicines. The guidance takes a generic approach to pharmacist prescribing across all settings, without dealing with the nuances of each.

Recommendation

The guidance document for pharmacist prescribers should address the nuances of prescribing in different settings, and the specific activities to which pharmacists' roles are suited, providing specific tailored guidance relevant to each. This may include, for example, guidance around repeat prescribing, working alongside GP colleagues to discuss cases and jointly agree individual patient plans and dealing with secondary care letters and discharge recommendations.

It appears that insufficient consideration has been given to the use of language in the document. An example of this is the use of the word "person" instead of "patient", which contributes to the ambiguity, vagueness and non-professional nature of the document. This includes, for example *"pharmacist prescribers should…. act in the person's best interests…"*. "Patient" and "person" are used interchangeably in the same sentence, paragraph or chart in the guidance, ostensibly in reference to the same individual(s).

The GPhC has said it will send the document to “patients’ representative bodies” to get feedback from them. If “person” were an appropriate term for a patient, those bodies would refer to themselves as “person representative bodies”, and so would the GPhC – but that is not the case. The use of the term “person” instead of patient does not acknowledge that the individual is a recipient of healthcare and may be perceived as a means of healthcare professionals absolving themselves of responsibility for that care. ”Patient” embraces the ethos and attitude that the pharmacy sector has, and should continue to have, towards recipients of its services. It is certainly important for pharmacists to treat patients and their representatives appropriately – as people would expect to be treated – but that does not mean that the word “patients” or the term “patients and their representatives” should be replaced with “people” in policy, standards or guidance for pharmacists.

Recommendation

To avoid ambiguity and make the guidance suitable for an audience of pharmacists, the GPhC must change all references to “person” and “people” within the document to refer instead to patients, where the reference is intended to be to the recipient or prospective recipient of healthcare. If the reference to “person” or “people” is intended to encompass both patients and others, then it should be changed to say “patients and others they interact with in the course of their work”, for example.

2. For each of the nine key areas, do you agree or disagree with the guidance we have proposed?

1. **Taking responsibility for prescribing safely - DISAGREE**
2. **Keeping up to date and prescribing within your level of competence - DISAGREE**
3. **Working in partnership with other healthcare professionals and people seeking care - DISAGREE**
4. **Prescribing in certain circumstances - DISAGREE**

5. **Prescribing non-surgical cosmetic medicinal products - DISAGREE**
6. **Remote prescribing - AGREE**
7. **Safeguards for the remote prescribing of certain medicines - AGREE**
8. **Raising concerns - DISAGREE**
9. **Information for pharmacy owners and employers of pharmacist prescribers - AGREE**

3. Please explain your responses to the two questions above. (You will be asked questions later in the consultation about what pharmacist prescribers must do in order to prescribe safely, and to carry out both prescribing and supplying; and about the safeguards for remote prescribing.)

The explanation for our response to question 1 has been provided in response to question 1. The points we have made in response to question 1 relate to all of the nine key areas of guidance. We have made further recommendations relating to specific sections, below.

Recommendation

Under "Taking responsibility for prescribing safely", the sentence "*Pharmacist prescribers must manage incentives or targets*" must be expanded upon. The guidance should include that pharmacist prescribers must not agree to any incentives or targets which would be likely to compromise their professional judgement and should raise concerns about any attempt by another person to impose such incentives or targets upon them. Similarly, the GPhC must take steps to ensure that no such incentives or targets are imposed in the first place; this may need to be done not only through its premises standards, but through its working relationship with other regulators, since the GPhC does not have premises jurisdiction in certain settings where pharmacists prescribe.

Prescribing is an activity which poses particular risks to patients. It is important that pharmacists work within the boundaries of their competence, in order to protect patients.

The GPhC has said, “*Pharmacist prescribers must regularly check that they are covered by their professional indemnity insurer for any additional or different prescribing roles they undertake, and review their cover as appropriate.*” This might foster a mindset among some prescribers of “If I’m covered for it, I can do it.” The PDA has encountered that mindset; instead, the mindset ought to be “Am I competent to do it, and if so and I will be doing it, I must make sure that my indemnity insurance covers that activity.”

Recommendation

Under “Keeping up to date and prescribing within your level of competence”, the sentence “*Pharmacist prescribers must regularly check that they are covered by their professional indemnity insurer for any additional or different prescribing roles they undertake, and review their cover as appropriate”* must be changed to “*Pharmacist prescribers must, having first ensured that they are competent to undertake a particular activity before doing so, check that they are covered by their professional indemnity insurer for the activities they undertake, and review their cover as appropriate. This includes in respect of any additional or different prescribing roles they undertake.”*

Recommendation

The GPhC should produce a standard template scope of competence document with guidance around how to demonstrate competence in prescribing. This would assist pharmacist prescribers to ensure that they only practice within their competence and provide a tool to review and develop competence over time.

Recommendation

Under "Keeping up to date and prescribing within your level of competence", the GPhC must define what is meant by the terms, 'specialist' and 'generalist'.

Under the section *"Working in partnership with other healthcare professionals and people seeking care"* the GPhC has said:

"Pharmacist prescribers must decide whether they can prescribe safely when:

- *they do not have access to the person's medical records*
- *the person refuses to give consent to contact their prescriber for more information*

…"

Prescribing pharmacists have advised us that there are circumstances when a pharmacist has prescribed an ordinarily innocuous item for a patient, having been refused access to their medical records. The pharmacist wrote to the GP practice advising of what they had prescribed and it became apparent to the practice pharmacist that the lack of access to the patient's records had led to the delayed diagnosis of a serious underlying condition, for which the medicine was not appropriate. However, the practice pharmacist was unable to let the prescribing pharmacist know about it since the prescriber did not have permission to access the records. The lack of access to information carries risks.

Recommendation

Under "Working in partnership with other healthcare professionals and people seeking care", the GPhC should advise pharmacist prescribers to ensure they have access to all the information about the patient, including medical history, that they need to make prescribing decisions - and avoid prescribing where that is not the case. If they can't obtain sufficient information, and a patient refuses to allow access to their medical records, where these would otherwise be available to the pharmacist and would provide that information, such patients should be signposted appropriately to a prescriber with access to the required information.

In addition, if the patient refuses to allow communication about the prescribing with their GP or regular prescriber, and the pharmacist believes that certain information is or may be essential for the GP or regular prescriber to have, the patient should be referred back to that prescriber. The GPhC should state this in the guidance.

Recommendation

Under "Working in partnership with other healthcare professionals and people seeking care", the GPhC should advise pharmacists to ensure they have access to the appropriate support and clinical supervision required to perform their roles safely, collaborating with other healthcare professionals as necessary. This should include a requirement to undertake a competency assessment to prescribe in the circumstances, and avoid putting themselves in a position where they do not have the required support.

The results of a study on prescribing by dispensing doctors were recently published. The study said, "*Approximately one in eight practices in primary care in England are 'dispensing practices' with an in-house dispensary providing medication directly to patients. These*

practices can generate additional income by negotiating lower prices on higher cost drugs, while being reimbursed at a standard rate. They, therefore, have a potential financial conflict of interest around prescribing choices." It concluded *that "Doctors in dispensing practices are more likely to prescribe higher cost drugs."* [2]

The conflicts of interest are similar where pharmacists prescribe and supply themselves, or prescribe and supply from a pharmacy where they work.

Recommendation

Under "Prescribing in certain circumstances", the GPhC must outline potential conflicts of interest in more detail. This should include advice on offers of gifts and hospitality, the management of employers' interests in pharmacist prescribing and ensuring pharmacist prescribers undertake training from independent providers.

Recommendation

Under "Prescribing in certain circumstances", the GPhC has said, *"If a pharmacist prescriber both prescribes and supplies a prescription it must be within their scope of practice, and the pharmacist prescriber should have robust governance arrangements in place."* The GPhC must be more prescriptive about what it means by "robust governance arrangements" and what these arrangements will achieve.

The involvement of pharmacists in the management of repeat prescribing generally is a huge opportunity for pharmacists that has not yet been fully realised. Pharmacists providing this service can take a much more detailed look at the clinical and medicines-related rationale for prescribing. In so doing, they can deliver added benefits to patient safety, clinical effectiveness, concordance and pharmaceutical care generally. Additionally, they contribute to waste reduction and management of over-ordering. However, we are concerned to ensure

pharmacists do not inherit the common practice where prescriptions are simply signed with little or no scrutiny of appropriateness.

Recommendation

Under "Prescribing in certain circumstances", the GPhC should include a robust repeat prescribing protocol. We suggest that it should include:

- Confirming the diagnosis for which the medicine has been prescribed and ensuring that the clinical indication of the medicine is appropriate
- Ensuring all required monitoring of medicines has taken place
- Ensuring that where monitoring has taken place, results are being used to guide treatment
- Ensuring that prescriptions are not issued beyond allocated review dates without a more in-depth review
- Using the clinical record for guiding the issue of repeat prescriptions
- Consideration of communications following transfers of care (for example discharge from hospital)
- Contacting the patient if this would assist with the prescribing decision
- Reviewing drug interactions and any evidence of adverse drug reactions on the patient's history (and ensuring appropriate follow-up)

The guidance should also ensure pharmacists are clear that they have legal responsibility for the medicines they prescribe.

Recommendation

Under "Prescribing non-surgical cosmetic medicinal products", the GPhC should set an explicit requirement that pharmacist prescribers have appropriate training to identify patients with mental health conditions such as body dysmorphia, low self-esteem and other vulnerabilities. This should help ensure prescribing of cosmetic products is appropriate. Pharmacist prescribers should identify other treatment options for those patients, where necessary.

Recommendation

Under "Raising concerns", the GPhC has conflated the two distinct and different concepts of whistleblowing and the duty of candour (e.g. reporting and learning from mistakes). The PDA has previously pointed out to the GPhC that this conflation by it is unhelpful and diminishes both concepts. [3] Both concepts are important in their own right for public care and safety. The GPhC must treat the two concepts differently and put them under different sections in the guidance.

Recommendation

The section "Information for pharmacy owners and employers of pharmacist prescribers" appears to specifically relate to pharmacy owners, yet most pharmacist prescribers will not currently be working solely in a registered pharmacy. A further section should be added to the guidance which sets out the responsibilities of GP practices, care home owners and hospital trusts, for example, in relation to pharmacist prescribers. The GPhC must set out how it works with the CQC and other regulators to ensure the regulation of such premises and relevant healthcare professionals takes the activities of pharmacist prescribers in to consideration.

Prescribing safely

In section 3.1 of our proposals we say that having all the relevant medical information about a person and their medicines is vital to ensure safe prescribing. This may be obtained by communicating with the person's regular prescriber or by having access to the person's medical records. We provide guidance on what pharmacist prescribers must do in order to prescribe safely, including:

• asking for consent from their regular prescriber to access a person's medical records

• giving the person receiving care clear information so they can make an informed decision, and

• discussing other available options when it is not appropriate to prescribe

We also describe circumstances where pharmacist prescribers must decide whether they can prescribe safely, such as when:

• they do not have access to the person's medical records

• the person refuses to give consent to contact their prescriber for more information

• the person has not been referred to the pharmacist prescriber by their own prescriber, or

• the person does not have a regular prescriber (such as a GP)

4. Do you agree or disagree that these are circumstances when a pharmacist prescriber must decide whether they can prescribe safely for a person?

Disagree

Pharmacist prescribers must decide in all circumstances where they are about to prescribe, whether they can do so safely for a patient, and not only in the circumstances listed above.

5. Are there any other circumstances when a pharmacist prescriber must decide whether they can prescribe safely for a person?

Yes

Please refer to our responses to question 4. Pharmacist prescribers must make this decision in all cases when they are considering prescribing.

6. Please explain your responses to the two questions above and describe any additional circumstances that should be considered.

Please refer to our responses to the two questions above.

Prescribing and supplying

In section 4.2 of our proposals we say pharmacist prescribers should usually keep the initial prescribing separate from the supply of medicines prescribed, to protect the person's safety. We describe exceptional circumstances when it may be necessary to prescribe and supply, and have also identified certain circumstances when a pharmacist prescriber may prescribe and supply on a regular basis – for example, when administering travel vaccines.

7. Are there any other circumstances where you think a pharmacist prescriber should be able to prescribe and supply?

No

8. Please describe any additional circumstances that should be considered.

N/A

Safeguards for the remote prescribing of certain categories of medicines

In section 7 of our proposals we describe prescribing remotely, including online, for certain categories of medicines. We say that certain medicines are not suitable to be prescribed remotely unless further safeguards have been put in place to make sure they are clinically appropriate. In our recent discussion paper on our guidance for registered pharmacies providing pharmacy services at a distance, including on the internet, respondents agreed that before prescribing remotely, additional safeguards should be put in place to make sure the medicines are clinically appropriate for the person. We have proposed five safeguards for making sure certain categories of medicines are prescribed safely. These say that the prescriber must:

- have robust processes in place to check identities, to make sure the medicines prescribed go to the right person
- have asked the person for the contact details of their regular prescriber, such as their GP, and for their consent to contact them about the prescription
- proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- have systems in place so that the pharmacy team can clearly document the prescriber's decision to issue a prescription if the person does not have a regular prescriber, such as a GP, or if there is no consent to share information
- work within national prescribing guidelines for the UK and good practice guidance

9. Are there any other safeguards that should be put in place to make sure certain medicines are prescribed safely remotely?

Yes

10. Please describe any additional safeguards you think there should be.

Recommendation

Pharmacists prescribing remotely must follow all of the guidance set out in this document, which includes, for example, working within their competence. They must not make assumptions where they cannot see the patient face to face.

The prescriber must refer the patient onwards where necessary, for example where a face to face consultation would be beneficial.

11. What kind of impact do you think our proposals will have on patients and the public?

Negative impact

The guidance is not helpful in its current form and may potentially foster some ways of working which create risks to patients.

12. What kind of impact do you think our proposals will have on pharmacist prescribers?

Negative impact

As outlined above, the document is vague and ambiguous. It means the guidance will be unhelpful to both pharmacist prescribers and patients, providing little assistance as the prescribing role evolves.

13. What kind of impact do you think our proposals will have on other pharmacy professionals?

No impact

The guidance in its current form will not have any meaningful influence over what pharmacist prescribers do and, as a result will have no effect on other pharmacists either.

14. What kind of impact do you think our proposals will have on employers or pharmacy owners?

No impact

The guidance in its current form will have no meaningful effect on employers or pharmacy owners.

15. Please give comments explaining your responses to questions 11 to 14.

Any comments have been given in response to the individual questions to avoid ambiguity.

Equality impact

We want to understand whether our proposals may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. We also want to understand whether our proposals may benefit any of these individuals or groups.

16. Do you think our proposals will have a negative impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

Age

Disability

Gender reassignment

Marriage and civil partnership

Pregnancy and maternity

Race

Religion or belief

Sex

Sexual orientation

None of the above ✓

17. Do you think our proposals will have a positive impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

Age

Disability

Gender reassignment

Marriage and civil partnership

Pregnancy and maternity

Race

Religion or belief

Sex

Sexual orientation

None of the above ✓

18. Please describe the impact on each of the individuals or groups you have ticked in questions 16 and 17.

N/A

References

[1] J. Robinson, “The trials and triumphs of pharmacist independent prescribers,” The Pharmaceutical Journal, 1 March 2018. [Online]. Available: https://www.pharmaceutical-journal.com/news-and-analysis/features/the-trials-and-triumphs-of-pharmacist-independent-prescribers/20204489.article.

[2] B. Goldacre, C. Reynolds, A. Powell-Smith, A. J. Walker, T. A. Yates, R. Croker and L. Smeeth, “Do doctors in dispensing practices with a financial conflict of interest prescribe more expensive drugs? A cross-sectional analysis of English primary care prescribing data,” BMJ Open, 5 February 2019. [Online]. Available: https://bmjopen.bmj.com/content/9/2/e026886.

[3] “Pharmacists’ Defence Association Response to the General Pharmaceutical Council’s Consultation on Standards for Pharmacy Professionals,” June 2016. [Online]. Available: https://www.the-pda.org/wp-content/uploads/gphc_standards_response_201606.pdf.