October 2017

Pharmacists' Defence Association Response to the General Pharmaceutical Council's Consultation on Guidance to Ensure a Safe and Effective Pharmacy Team

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pda
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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 26,000 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 pharmacistt

Summary of GPhC proposals

The GPhC is consulting from 20 July to 11 October 2017 on proposed guidance for pharmacy owners on creating suitable working environments which enable pharmacy staff to operate safely and effectively. The guidance is intended to support the GPhC's Standards for Registered Pharmacies and covers a broad range of topics, including governance, education and training, working environments and management and leadership.

The GPhC is also proposing to cease setting training requirements and assessing and approving training courses for dispensing and medicines counter assistants. It plans instead to provide guidance for employers on what that training might involve.

The PDA's recommendations are:

- Requirements of pharmacy owners must be set out to include minimum staffing levels, the requirement to act upon whistleblowing concerns and the training of pharmacy staff. These must be clear, unambiguous and set out in an enforceable form (i.e. not in guidance). The wording must be such that public protection, and not commercial benefit, is prioritized.

- The GPhC must also specify how its inspection process will change to ensure these requirements are met and enforced and must set out threshold criteria, an investigation process and indicative sanctions for breaches.

- The GPhC must use its powers to hold pharmacy owners and superintendents to account for meeting the Standards for Registered Pharmacies by issuing improvement notices and using other sanctions when necessary.

- The GPhC must define, by creating a list of which individual(s) in a partnership or body corporate would be held accountable for a failure to comply with the Standards for Registered Pharmacies.

- The GPhC should introduce a test for superintendent pharmacists, pharmacy owners and those in positions of responsibility in pharmacy such as senior managers, to assess whether or not they are (and remain) fit and proper persons to hold their positions of responsibility. It should create a register of such persons to facilitate this.

- The respective responsibilities of pharmacists and pharmacy owners must be clarified in a way which underpins the professionalism of the pharmacist.

- The areas covered in the proposed guidance – including governance, education and training, working environments and management and leadership – are each of sufficient importance to public safety and care to warrant separate guidance documents. Each should have its own.

- The format of GPhC guidance documents should include explanations of the impact of the matter in question on patients, a summary of the applicable law and regulatory standards, references to case studies or relevant public inquiries which have drawn important conclusions (such as the Francis inquiry in to the Mid-Staffordshire Hospitals NHS Foundation Trust) and further sources of information / advice, as appropriate.[4] The wording of such guidance must be clear and unambiguous.

- The GPhC must continue to set the training requirements for pharmacy support staff, including dispensing and medicines counter assistants, in an enforceable form (not in guidance). It must also continue to approve and quality assure training courses for these staff.

- The requirement for medicines counter staff and dispensing assistants to complete the training course within three years must be retained.

These recommendations are also repeated in the relevant section of this document.

Foreword

Professor of Pharmacy Law and Ethics, Joy Wingfield, is a highly respected academic with extensive knowledge of healthcare regulation and pharmacy law, particularly in the context of corporate pharmacy. She said in July 2017 that the GPhC' appears to have 'pious hopes' that this proposed guidance will be followed by employers, not least since the sanctions available are 'practically worthless'.[1]

Considering that the guidance is unenforceable, the absence of any attempt by the GPhC to set enforceable standards for registered pharmacies and the approach taken by some pharmacy employers to the conditions in their pharmacies, some may wonder whether the GPhC *does* have any hope that it will be followed.

Consultation Response

The new framework will make it clear that the pharmacy owner is accountable for making sure unregistered pharmacy staff are competent for their roles

1. Do you agree with the proposed approach?

NO

Enforceability, Monitoring and Sanctions

Guidance may be regarded as advice which can be optionally followed, whereas GPhC *standards* set enforceable obligations. By its nature, the guidance cannot be enforced.

In setting out important expectations in relation to staffing levels, staff training and whistleblowing in guidance, the GPhC has chosen not to be able to *enforce* those expectations. It will defer to the judgement of employers on the extent to which they see fit to follow the guidance. They may even decide not to follow it at all, because there are no regulatory consequences for non-compliance. The GPhC will be unable to provide any meaningful assurance to the public that the matters set out in this guidance are being adhered to.

Wording

We would not have expected such proposals from a healthcare regulator, whose role is to protect the public. Its hallmarks include deregulation, vague corporate wording and a shift in the balance of power in the employer/pharmacist relationship, towards the employer. Many of the points belong properly in enforceable standards; however, even if they were written in such standards, the wording must be made sufficiently prescriptive to avoid allowing too much flexibility in interpretation.

Excerpts which illustrate this include:

- ***"Staff numbers and roles are appropriate for the services provided and are systematically reviewed in line with changing services and workloads"***
  - Employers could interpret the word 'appropriate' as they see fit. They may reason, for example, that staffing numbers are *appropriate* for the services provided, even where there exists an avoidable risk to patient safety. Employers may choose, inappropriately, to factor in unrelated financial objectives in determining whether staff numbers are *'appropriate'*. Patient safety must be protected irrespective of these things.
  - To meet this expectation, staff numbers need not be sufficient to meet the workload and service expectations; they would merely need to be reviewed when services and workloads change.

- ***"There are appropriate staffing plans in place to cover absence"***
  - Employers will decide what constitutes *'appropriate'*.
  - In the absence of any stipulation from the GPhC, it is unclear whether 'absence' covers all forms such as annual leave and times when people are not present during the pharmacy's working hours, or is restricted to the types commonly referred to as absence, such as sickness absence.
  - If workload during a staff member's absence remains the same as it would if he/she was present, 'covering' it should involve the like-for-like replacement of the absent member of staff with another. However, an employer may choose to interpret 'cover' as meaning 'in relation to'. The plans may involve not replacing or 'backfilling' the absence at all.

- ***"[Pharmacy owners] should make sure they have considered whether they can make protected time available for training"***
  - The guideline is that owners should *consider* whether they can make protected time available for training, but need not make it available.
  - As with the other bulleted guidelines, the use of the term 'pharmacy owners should' means this is not a mandatory requirement, so owners need do nothing at all.

- ***"Unregistered pharmacy staff who are involved in dispensing and supplying medicines must have the knowledge and skills of the relevant units of a nationally recognised Level 2 qualification, or are training towards this"***

  – It is unclear what is meant by "relevant units", to which "Level 2" qualification it is referring and whether "Level 2" relates to the UK Qualifications and Credit Framework.

- ***"Training covers a common set of skills and abilities including professionalism, good communication skills, and effective working in multi-professional teams"***

  – This guideline lacks detail and as such is effectively meaningless.

- ***"There are appropriate processes for assessing that managers have the competence, skills and experience needed, to carry out their role"***

  – 'Appropriate' has not been defined and nor have the competencies, skills and experience that the GPhC expects.

  – An employer may take the view that the skills required support commercialism rather than professionalism.

- ***"A role-specific induction is carried out for all new members of the pharmacy team"***

  – This does not specify what the induction should include. Without further detail, it may range from a manager saying "here is the dispensary" to a detailed three-month rotation learning about different aspects of the pharmacy.

Recommendation

Requirements of pharmacy owners must be set out to include minimum staffing levels, the requirement to act upon whistleblowing concerns and the training of pharmacy staff. These must be clear, unambiguous and set out in an enforceable form (i.e. not in guidance). The wording must be such that public protection, and not commercial benefit, is prioritized.

The GPhC must also specify how its inspection process will change to ensure these requirements are met and enforced and must set out threshold criteria, an investigation process and indicative sanctions for breaches.

The GPhC was established in 2010. In September 2017, through a freedom of information request, we obtained details of the GPhC's regulatory activities relating to pharmacy premises and pharmacy owners. The GPhC has never:

- Fulfilled its legal obligation to set Standards for Registered Pharmacies in rules (which then have to be laid before parliament)

- Issued an improvement notice to a pharmacy owner*

- Brought a fitness to practise case against a registrant for a failure to comply with the Standards for Registered Pharmacies. It confirmed that its focus, as far as individual registrants and standards are concerned, is on the Standards for Pharmacy Professionals

- Established a category in its fitness to practice database for recording allegations which relate to compliance with the Standards for Registered Pharmacies

- Disqualified, removed, or sought to disqualify or remove, a pharmacy premises from the register (article 14 of the Pharmacy Order 2010)

- Sought or obtained a conviction against a pharmacy owner under articles 12 or 14 of the Pharmacy Order 2010 (failing to assist or obstructing an inspector, providing false or misleading information to an inspector, failing to produce a document or record to an inspector when requested to do so or failure to comply with an improvement notice)

* The GPhC has the power to issue improvement notices either for:
  - a failure to meet its Standards for Registered Pharmacies OR
  - a failure to meet the conditions of the pharmacy's registration with the GPhC. See section 13 the Pharmacy Order 2010

Recommendation

The GPhC must use its powers to hold pharmacy owners and superintendents to account for meeting the Standards for Registered Pharmacies by issuing improvement notices and using other sanctions when necessary.

Recommendation

The GPhC should introduce a test for superintendent pharmacists, pharmacy owners and those in positions of responsibility in pharmacy such as senior managers, to assess whether or not they are (and remain) fit and proper persons to hold their positions of responsibility. It should create a register of such persons to facilitate this.

In our view, the best way to protect patients is to underpin the professionalism of the pharmacist. It is important to have clarity in the respective responsibilities of pharmacists and pharmacy owners, in respect of various matters covered in the guidance. For example, if a pharmacist - who is responsible for the safe and effective running of the pharmacy - requested training for a member of staff, in our view it should then be incumbent on the pharmacy owner to provide such training to support that professional request.

2. *Does the proposed guidance adequately cover the key areas to ensure a safe and effective team?*

NO

The guidance cannot *ensure* that a team will work safely and effectively. However, adequate premises standards, inspection and enforcement, resulting in a good working environment, could *enable* them to do so. The proposed guidance will not achieve this in any case (please refer to our responses to other questions for our rationale).

3. *Is there anything else not covered in the guidance that you would find useful? Please give details.*

In 2016, the PDA called for the GPhC to set *standards* for pharmacy owners on staffing levels and targeting and to improve its inspection process to detect poor staffing levels and workplace pressures. We also called for the GPhC to issue guidance on staffing levels and managing organizational goals and targets, which could apply to both pharmacy owners, superintendents and pharmacists.[2]

Guidance on staffing levels, for example, could have included details of methods of establishing appropriate staffing, how to set up a staffing model, how to gather and use data to inform it, how to plan and monitor a rota and how to monitor whether patient safety incidents and care are related to staffing levels. We would like to see such guidance produced following the establishment of suitable regulatory standards and an improved inspection process.

Recommendation

The areas covered in the proposed guidance – including governance, education and training, working environments and management and leadership - are each of sufficient importance to public safety and care to warrant separate guidance documents. Each should have its own.

4. *Do you agree with the minimum level of competence for unregistered pharmacy staff who are involved in dispensing and supplying medicines?*

NO

Please explain your reasons for this.

The GPhC is proposing to cease setting training requirements and assessing and approving training courses for dispensing and medicines counter assistants. It said in the consultation document that its *"powers of accreditation are explicitly for courses leading to registration as a pharmacist or pharmacy technician"*. However, it has managed the situation since 2010 without apparent difficulty and to our knowledge, it has not publicly requested a change to those powers. In addition, it does have the ability to require registrants and pharmacy owners to comply with the standards it sets, which may include requirements around the training of support staff.

In our view, the proposals will mean that there will be no defined, common pharmacy roles other than 'pharmacist' and 'pharmacy technician'. We envision that, if introduced at this point in time, it would lead to a chaotic and inconsistent approach throughout Great Britain as to the quality of training [unregistered support staff] have and the transferability of their roles from one pharmacy to another. It also means that 'pharmacy technician' will become the least qualified role which is nationally recognised in pharmacy. Such a change in the pharmacy workforce would need a much wider discussion on the roles of pharmacists, pharmacy technicians and pharmacy support staff and should not arise simply from the deregulation of the training of other pharmacy support staff.

Guidance on role visibility

The proposed guideline *"[pharmacy owners should make sure] people who use pharmacy services can easily see who staff are and the role they are carrying out"* will be of little use if the GPhC's proposals are implemented. The name of the role will be meaningless to the public in terms of what they can expect of the person's skills and competence.

Support staff

The GPhC has stated that it sees the term 'support staff' as outdated, because it isn't consistent with 'approaches to quality governance and team work'. It has also portrayed dispensing and medicines counter assistant roles as nebulous concepts, stating that *"The terms 'medicines counter assistant' and 'dispensing assistant' do not represent precise roles. 'Dispensing assistant' in particular is an umbrella term for a variety of roles supplying medicines to the public."* Support staff clearly play an important role, but it is imperative that there remains demarcation between how the roles of pharmacists and other staff are referred to, in order to make it clear that pharmacists have supervisory responsibility for the operation of a pharmacy. Dispensing and medicines counter assistants have sufficiently well-defined roles for the title to be readily understood within pharmacy practice. If this were not the case, it would not have been possible for the GPhC to refer to them as such within the consultation document, nor to accredit training requirements for them as it does as present.

5. The guidance makes it clear that all unregistered pharmacy staff who need further education and training to meet the required competency level for their role should be enrolled on an appropriate training programme within three months of starting in their role.

Do you agree with our proposed approach?

NO

Please explain your reasons for this.

The current GPhC requirement is that: *"[Dispensing and medicines counter] assistants must be enrolled on a training programme within three months of commencing their role (or as soon as practical within local training arrangements) and the programme must be completed within a three-year time period."* [3]

If the proposed changes are accepted, a person who is not on any pharmacy training course would be able to work in a pharmacy indefinitely, performing any role that the employer desired, with GPhC *guidance* that after three months they *should* commence a training course. Pharmacy owners would not be obliged to ensure that dispensing and medicines counter staff start a training course, or to enforce its completion. For the public, this would mean that pharmacy staff could be entirely untrained, or in trainee status, indefinitely. It would also be unwise to believe that such staff would know *'how to assess and reduce risks for the tasks they carry out' or how to 'reflect on their performance'* to any useful degree as per the proposed guidance; such behaviours are typically learned through professional training.

The consultation document provides a reminder of pharmacists' responsibilities, which are set out in enforceable standards: *"This strengthened accountability for pharmacy owners does not change the important responsibility of individual pharmacists – particularly the responsible pharmacist – to delegate tasks only to people who are competent, or to those that are in training and under supervision."* It also states: *"Pharmacy professionals should be able to satisfy themselves that anyone they delegate a task to is competent and appropriately trained to carry out the task. They should make sure unregistered pharmacy staff understand what they cannot and must not do, and know when to refer to a pharmacy professional."* If the proposals are accepted, in the absence of consistent standards of training from pharmacy to pharmacy, it will be difficult for pharmacists – particularly the sizeable population of locums - to meet this standard, since they will be unaware of the level of competence of each member of support staff.

It is difficult to understand why the GPhC would propose to:

a) allow employers to determine their own standards for dispensing and medicines counter assistant training, when they would have a clear interest in making that training as inexpensive and quick to complete as possible (which may be expected to reduce its quality);

b) remove any requirement of employers to ensure that pharmacy staff other than pharmacists and pharmacy technicians have any training at all;

c) claim that it would provide assurance of the suitability of training, in part, by asking employers for their feedback on the situation (page 10 of the consultation document).

Recommendation

The GPhC must continue to set the training requirements for pharmacy support staff, including dispensing and medicines counter assistants, in an enforceable form (not in guidance). It must also continue to approve and quality assure training courses for these staff.

6. What impact do you think the proposals will have on pharmacy owners?

NO IMPACT

Since the guidance is unenforceable and poorly worded, our view is that it will be largely disregarded and have no impact on pharmacy owners which results in meaningful positive outcomes for patients. In some cases, the outcome may be a diminution of patient safety. The guidance does not meet the hopes and aspirations of the profession in improving patient care and safety. Our rationale for this view has been provided in response to other questions.

7. What impact do you think the proposals will have on pharmacy professionals?

MOSTLY NEGATIVE

In setting out important matters such as whistleblowing, staffing levels, governance, training, management and leadership and working environments in guidance, the GPhC has not only failed to ensure its expectations are enforceable, but has sent a message that these are matters which it considers of insufficient importance to do so. Employers will be able to argue that since the GPhC's stipulations are in guidance form and are worded in a manner which permits very liberal interpretation, there are no mandatory regulatory expectations and consequently, such matters must be of lesser importance than those covered in its standards. The guidance may give the appearance that the regulator has taken substantive action to protect public safety, when in fact it appears to have achieved the opposite.

8. What impact do you think the proposals will have on unregistered pharmacy staff?

MOSTLY NEGATIVE

The standards of training provided to unregistered pharmacy staff will be reduced, potentially resulting in an adverse effect on patient safety and care.

9. What impact do you think the proposals will have on people using pharmacy services?

MOSTLY NEGATIVE

If enacted, these may have an adverse effect on the public and introduce an unnecessary risk to patient safety. Our reasons for holding this view are implicit in our response to other questions and in our consultation responses, which can be found at www.the-pda.org. Unenforceable standards open to interpretation will give a false sense of security to the public.

References

1. "In practice: Guidance on raising concerns," May 2017. [Online]. Available: https://www.pharmacyregulation.org/sites/default/files/in_practice-_guidance_on_raising_concerns_may_2017.pdf.

2. Professor Joy Wingfield, The Pharmaceutical Journal, "Concerns about GPhC consultation on 'pharmacy team'," 3 August 2017. [Online]. Available: http://www.pharmaceutical-journal.com/20203339.fullarticle?utm_campaign=2483_PJ_weekly_roundup&utm_medium=email&utm_source=Pharmaceutical+Journal.

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.

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