

Royal Pharmaceutical Society

The Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 [draft]

The health and sport committee will shortly be examining the order mentioned above: The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 which will give the pharmacy regulator more extensive powers over registered pharmacy premises.

As the professional body representing individual pharmacists working in all sectors of the profession we contributed to the original consultation around the new standards and we are in regular dialogue with the General Pharmaceutical Council around the implementation of the new powers in the new inspection model, feeding back our members views on the initial pilots which have been taking place.

In principle we are supportive of the changes in legislation outlined in the order and hope that the regulator will use the new powers to encourage a model of continual improvement, ensuring that pharmacy premises will be suitable for the new and emerging clinical roles in our communities and that any variation in standards across the profession is minimised.

This order will affect many of our members in their professional practice and should you have any further questions we would be happy to be of assistance.

Dr. John McAnaw MRPharmS
Chair
Scottish Pharmacy Board
Royal Pharmaceutical Society

General Pharmaceutical Council

The Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 [draft]

About the General Pharmaceutical Council

1. The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. Our main job is to protect, promote and maintain the health and safety of people who need or use services from pharmacists or pharmacy technicians, or services provided at a registered pharmacy.
2. Our role and functions are set out in the Pharmacy Order 2010. Our principal functions include:
 - setting standards for registered pharmacies which require them to provide a safe and effective service to patients
 - inspecting registered pharmacies to check if they are meeting our standards
 - setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
 - maintaining a register of pharmacists, pharmacy technicians and pharmacies
 - setting the standards of conduct and performance, and continuing professional development, that pharmacy professionals have to meet throughout their careers
 - investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public.

Overview

3. The GPhC is a member of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board and we support and contribute actively to the work of the Board which advises ministers in the four countries of the UK on the rebalancing of pharmacy legislation and regulation.
4. The changes to legislation proposed by ministers in this Section 60 order will enable us to improve the way in which we regulate registered pharmacies and help to ensure that patients and the public receive safe and effective pharmacy services.
5. Since we came into operation in 2010 we have developed a new approach to inspecting pharmacies and implemented standards for registered pharmacies. Our approach to regulating pharmacies has been informed by feedback from those we regulate and patients and the users of pharmacy services in Scotland and the other countries in

which we regulate. A [recent evaluation](#) of the new approach commissioned by the GPhC found that there is consensus among pharmacy professionals that our inspections of pharmacies in Great Britain are helping to improve patient safety and the services pharmacies offer to patients and the public.

6. This s60 order would give us powers to implement a number of key measures originally set out in the legislation to establish the GPhC, The Pharmacy Order 2010, as well as planned improvements to the current model for regulating pharmacies. This includes powers to publish reports of our inspections of pharmacies and further powers to take proportionate enforcement action against pharmacies where necessary.
7. As a proportionate regulator that only uses the intervention that is needed, we welcome the range of regulatory tools that the s60 order will provide us to regulate registered pharmacies. This will ensure that any regulatory intervention is appropriate and necessary to help ensure patients and the public receive safe and effective pharmacy services.
8. We believe these changes will help to support the quality strategy for healthcare in Scotland. For example, through publishing inspection reports we can share information about which pharmacies are and are not meeting our standards. The inspection reports will help to support shared learning about good practice across pharmacy and therefore promote improvement. Publishing reports will also give patients access to information they can use when making decisions about their care.

Removing the obligation to set standards in rules

9. The s60 order would change the current legislation so that the GPhC would no longer be required to set standards for registered pharmacies in rules.
10. When the GPhC developed the standards, we took full account of the approach developed by the Better Regulation Executive and taken forward by Sir Philip Hampton. As such we have consciously moved away from a model which looks at enforcement to one where we work with those we regulate to encourage and enable them to focus on outcomes; the things that matter to patients. This in turn makes them much easier to understand, both by those we regulate, as well as patients and the public in whose interest we work.
11. Placing standards in rules would mean that the standards would have to be prescriptive and inflexible. This runs the risk of a bureaucratic and disproportionate approach. Additionally, registered pharmacies are found in a variety of settings, from large supermarkets to smaller pharmacies located in rural areas. A rules-based approach to standards would stifle innovation and be restrictive to pharmacies in different settings.

12. Removing the obligation to set standards in rules is an important and necessary change to the legislation, to make sure we have a flexible and proportionate framework that:
- is focused on improving outcomes for patients and the public using pharmacy services
 - enables us to recognise the local context in which the pharmacy services are delivered and update the standards when necessary to reflect changes in pharmacy provision in Scotland, England and Wales.
13. Taking the standards out of rules will also enable the GPhC to use powers within the Pharmacy Order 2010 to issue an improvement notice or disqualify a pharmacy from the register for a failure to meet the standards. We are not currently able to use these powers as they require standards to be set in rules.
14. The order includes an explicit requirement for the GPhC to consult Scottish Ministers, as well as UK and Welsh Ministers, on any proposed changes to standards and we would also continue to hold full public consultations with patients and the public, registrants and other key stakeholders in all three countries.

Breaches of standards for registered pharmacies

15. We currently have limited powers to take action when pharmacies are failing to provide safe and effective services to patients. We welcome the new powers that the s60 order will give us to take proportionate and timely action where necessary. This will improve our ability to protect patients and improve the quality of the pharmacy services they receive.
16. The s60 order makes a number of improvements to the current legislation, including:
- Our enforcement powers will apply equally to all registered pharmacy owners. At the moment our powers to disqualify a pharmacy owner only apply to bodies corporate and not to retail pharmacy businesses owned by a pharmacist or a partnership, which is unfair
 - Decisions about failure to meet standards and subsequent suspension or removal of a registered pharmacy from the register will be made by fitness to practise committees instead of the Registrar. This change will mean that decisions are made in an open and transparent way, and there is an opportunity for shared learning and improvement
 - Pharmacies can be suspended from the register pending a full hearing of the case against the owners of pharmacy premises or prior to a disqualification decision or removal decision taking effect.

There is currently no power to suspend a pharmacy from the register on an interim basis and so this change closes a potential gap in public protection.

We will use our regulatory levers proportionately and would only take action to suspend or remove a pharmacy from the register as a last resort when necessary to protect, promote and maintain the health, safety and wellbeing of members of the public.

Publication of reports from GPhC inspections of registered pharmacies

17. We strongly welcome the proposed changes to the Pharmacy Order that will give us the powers to publish inspection reports and outcomes. One of the core principles of good regulation is that we should be open and transparent; we believe that publishing reports and outcomes from our inspections is essential to achieving this. We also believe that patients and the public would rightly expect this information to be publicly available to them.

18. Publishing this information will also provide assurance to patients and the public that the pharmacy services they are using are safe and effective, and will help to promote improvement by sharing good practice widely across pharmacy. Evidence from other sectors also suggests that being able to see how your peers are performing can act as a positive stimulus to improve.

19. We are committed to working with all our stakeholders, including patients and users of pharmacy services, as well as those in pharmacy, to help us develop an approach to publication which is open, transparent, fair and accessible.

Changes to the GPhC's powers to obtain information from pharmacy owners

20. The s60 order also amends the provisions relating to information that the GPhC can require pharmacy owners to provide. This may include the details of the key people responsible for the business (e.g. directors and superintendent pharmacists of bodies corporate, and partners in partnerships), information about investigations of and offences committed by those key people (and in some cases by the business itself), business addresses, and details of the type or types of activities undertaken at registered pharmacy premises.

21. By collecting some core information at the point of registration, we will be able to act more proportionately, understand better the trends and issues within pharmacy, allocate our resources more proportionately and develop better our understanding of risk in pharmacy. This information will be critical in supporting more efficient and effective regulation as well as sharing wider understanding of the sector with pharmacy owners, pharmacy professionals and patients and the public.

Further information

22. Further information on the General Pharmaceutical Council is available from www.pharmacyregulation.org.