Developing guidance to support the safe and effective supply of ‘Pharmacy (P)’ medicines

About this document

The purpose of this discussion document is to outline a framework of the guidance we intend to produce on the supply of Pharmacy (P) medicines. We are publishing this document as a starting point for further discussion with stakeholders, including patients and the public, to obtain views on, and identify, the key areas that must be adequately addressed by owners and superintendents that operate registered pharmacies and supply P medicines.

We will use this document to elicit the views of our stakeholders on the proposed content of the guidance and in particular, on the main areas that we have initially identified for inclusion.
The General Pharmaceutical Council (GPhC) published standards for registered pharmacies in September 2012. Responsibility for meeting these standards lies with the pharmacy owners and superintendent pharmacists, and requires them to ensure that they create and maintain the right environment for the safe and effective practice of pharmacy, where risk is managed and medicines are supplied safely.

We committed to support the standards by developing and publishing guidance in a number of important areas. One of those areas being the sale and supply of Pharmacy (P) medicines – that is those medicines that can only be sold from a registered pharmacy, under the supervision of a pharmacist.

This document describes the key issues we think might warrant further guidance in relation to the safe and effective supply of P medicines. It sets out the areas we believe pharmacy owners and superintendent pharmacists need to consider further as part of the framework to ensure the safe and effective supply of P medicines. This will enable patients to benefit from the expertise of suitably trained staff through their advice and support.

The guidance will also set out clearly the important role of local risk assessment and supervision in the safe supply of P medicines.

**Our standards for registered pharmacies state:**

“The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.”

It is this outcome that our guidance on the supply of P medicines is seeking to reinforce. Our focus is looking at how the legal requirement for pharmacist supervision is met in a way which best supports patient outcomes, whilst promoting open communication with pharmacy staff, and utilising their skills.
About pharmacy (P) medicines

The Medicines Act 1968 and the Human Medicines Regulations 2012 control the sale and supply of medicines. The legal status of medicinal products is part of the marketing authorisation (MA) process and products are classified in the UK as either:

- Prescription Only Medicines (POMs), (where the supply must be made against a prescription, except in a small number of prescribed circumstances)
- Pharmacy (P) medicines, (where the supply is made in a pharmacy without prescription, under the supervision of a pharmacist)
- General Sale List (GSL) medicines (which can be sold in general retail outlets and do not need the supervision of a pharmacist)

The requirement for all P medicines to be sold under the supervision of a pharmacist in a registered pharmacy is a legal requirement within medicines legislation and is not affected by this guidance.

Any issues relating to medicines classification are not a matter for the GPhC, but for Government and the Medicines and Healthcare products Regulatory Agency (MHRA). Further information about medicines categorisation and the role of the MHRA can be found on the MHRA website at www.mhra.gov.uk
Current requirements regarding pharmacy (P) medicines

Both the legal framework and our regulatory policies reflect the fact that medicines are not ordinary items of commerce. All the arrangements for displaying, marketing and selling medicines in a pharmacy, including P medicines, must reflect that fact.

The legal requirement for the sale and supply of a P medicine to take place from a registered pharmacy and be supervised by a pharmacist remains in place and is unaltered. Where P medicines are displayed in a registered pharmacy is not set out in law.

Open display of P medicines will not be allowed unless a number of specific additional measures are in place. These are:

1. Guidance on the supply of P medicines, of the sort considered in this paper, is published.
2. We have our full range of powers to enforce the standards for registered pharmacies in place.
3. Owners and superintendents will have to notify us in advance of their intention to allow the open display of P medicines. And they may be asked to describe what arrangements they are introducing to meet the legal requirements and deliver our standards.

Our view is that having access to appropriate advice from trained staff, whether it be the pharmacist, pharmacy technician or other staff operating under the supervision of the pharmacist, is more important than the physical location of P medicines.

Pharmacy owners and superintendent pharmacists in collaboration with pharmacy professionals are well placed to exercise their professional judgement and decide which, if any, medicines are made available for open display in their pharmacies. In making these decisions, the primary objective must be to ensure the safe and effective supply of medicines with an appropriate level of advice and effective supervision.
The Guidance

We intend to produce guidance on the supply of P medicines to identify the key areas that must be adequately addressed by owners and superintendents that operate registered pharmacies and supply P medicines. The guidance will need to be read and used alongside the standards for registered pharmacies.

We welcome the views of our stakeholders on the proposed guidance and in particular:

- The areas we have identified for inclusion in the guidance
- The proposed content for each area

Proposed topics for inclusion in guidance
The guidance will cover the following areas:

1. Professional decision making and accountability
2. Managing risk
3. Staff
4. Involving patients in decision making and communicating effectively

1. Professional decision making and accountability

As the pharmacy regulator we seek to hold people accountable for what they are actually responsible for. In the case of individual pharmacy professionals it is their conduct, behaviours and professional practice; in the case of owners and superintendents it is the culture and environment, both physical and organisational, they create in their pharmacies.

The guidance will detail where the responsibility and accountability for meeting our standards for registered pharmacies lies – that is the pharmacy owner and where this is a body corporate, the superintendent pharmacist too.

In the context of the supply of P medicines, owners and superintendents are responsible – and will be held to account for the things that they control and the decisions that they make. For example the placement of medicines within the registered pharmacy and the offers or incentives that they may put in place.
Pharmacy professionals must exercise their professional judgement when the supply of P medicines are made and make sure that appropriate communication takes place with the patient during each sale of a P medicine. The pharmacy owner and superintendent pharmacist must empower professional staff to exercise their professional judgement in the interest of patients and the public.

This includes, most importantly, ensuring that pharmacists are empowered and enabled to exercise their professional judgement, and their professionalism, in the supervision of P medicines supplies. Staffing levels, the physical layout of the pharmacy, and sales procedures must all be designed with both legal and professional requirement in mind.

2. Managing risk

A risk assessment is a careful and thorough look at what, in your work, could cause harm to patients and what you need to do to prevent this and further harm. The supply of medicines is a core pharmacy service and as such a risk assessment would need to be undertaken to ensure safe outcomes for patients. Risk assessments should be specific to the individual pharmacy and the staff working in it. The guidance will set out the areas the risk assessment should cover to demonstrate that appropriate measures have been taken to ensure medicines are supplied safely to patients. Additional safeguards will be needed if open display is to be considered by the pharmacy owner and superintendent.

The proposed areas that need to form part of the risk assessment will include:

- Information about medicines which have been misused locally;
- Any reclassification of POM to P medicine status
- Any relevant information from the MHRA, UK government or devolved administrations about medicines which have been, or are likely to be, open to misuse from an individual pharmacy;
- Current information or guidance from bodies such as the MHRA or Department of Health (DH) on medicines that may present higher risks to health if bought without sufficient advice;
- Evidence that any particular issues concerning the pharmacy’s layout and any associated security issues have been considered as part of an assessment of risk and where medicines are stored and displayed; and,
- The experience and skills of staff
- Evidence that this guidance has been taken into account

In relation to the placement of P medicines in a registered pharmacy, the owner and superintendent pharmacist would need to undertake a specific risk assessment for each registered pharmacy where they decide that open display of P medicines is appropriate.

This means that an owner or superintendent may decide, on the basis of their risk assessment, that they do not wish to place any P medicines on open display. Alternatively, they may decide, it is appropriate for one of their pharmacies but inappropriate for another of their pharmacies, (if they have more than one). Or they may decide it is appropriate for some P medicines but not for others.
3. Staff

We propose that the guidance will set out the need for owners and superintendent pharmacists to give full consideration to staff, their training and skill mix when considering how to achieve the best outcomes for patients in relation to the sale and supply of P medicines.

Pharmacy staff are required to be fully involved in ensuring that our standards are met. Professional staff must be able and encouraged to use their professional judgement, irrespective of any management and commercial pressures, to ensure the best interests of patients.

There must be full and open communication with pharmacy staff, to discuss the effective supply of P medicines at individual pharmacies. We would expect that all members of staff involved in the sale of medicines to the public are suitably trained, (or undergoing relevant training), are instructed to ask appropriate questions of customers wishing to buy medicines, and are able to advise patients appropriately. And staff should be given procedures to follow, which will empower them to exercise their judgement and inform them when they need to refer to the pharmacist.

Where pharmacy staff are undergoing training, as an owner or superintendent pharmacist we would expect that these staff are supervised appropriately and only work within their capability, particularly where they have only recently begun training or are new to a role.

Trained staff must be aware that certain medicines need the pharmacist’s intervention and particular medicines, such as those newly reclassified as P medicines from POM, need extra care, support and advice when being requested.

Staff must be trained to manage inappropriate sales (and being alert to attempts to purchase medicines in order to misuse or abuse them). Consideration should be given as to whether additional training in communications skills is needed to support staff in managing difficult interactions. Owners and superintendents should be able to demonstrate how this training has been carried out and is being put into practice.

We also recognise that in addition to staff training, a key consideration for owners and superintendents must be the numbers of staff who work within a pharmacy. This skill mix is a key part of any decision about how best to supervise the sale of P medicines and provide appropriate advice to patients.
4. Involving patients in decision making and communicating effectively

The importance of involving patients in decisions about their care should be reinforced. Our view is that there is increasing amounts of research which highlights the benefits of this approach. Healthcare professionals, including pharmacists are rightly held in high esteem and are trusted by the public. So, in many cases, patients will simply wish to defer to the judgement of a healthcare professional such as a pharmacist, in others they may wish to discuss in more detail the recommended course of treatment. On occasion the patient may ultimately disagree with the advice of the pharmacy staff or is unwilling to take it. Whatever the outcome, the conversation should always be encouraged.

Pharmacists make the final decision as to whether to make a supply, using their professional judgement and discretion. Where a product is unsafe or unsuitable for a customer, in the judgement of the pharmacy staff, a supply should not be made and this decision should be communicated clearly to the patient. In some circumstances it may be appropriate to record decisions to refuse, either where the interaction is particularly difficult or to assist in identifying any patterns in medicines refused for sale.

Next steps

This document is intended to explain in more detail the GPhC’s approach to securing the safe and effective supply of P medicines. Improvements need to be made to the way in which P medicines are supplied to patients and the public. How that can be best strengthened elicits a diverse range of views, some very strong on issues such as open display of P medicines. We intend to use this document to support discussions with individuals and representative bodies in the coming months and will publish draft guidance in due course.