ROYAL PHARMACEUTICAL SOCIETY

Call for evidence: Restrictions on the Self Selection of Pharmacy Medicines

07.2024

Executive summary

Under the Medicines Act (1968) a pharmacy medicine (P medicine), is a medicinal product that can be sold from registered pharmacy premises by a pharmacist or a person acting under the supervision of a pharmacist. (Part III, Section 52). However, the legislation does not prohibit self-selection of these medications, leaving that to the regulator.

Following changes brought by the pharmacy regulator (the General Pharmaceutical Council) implementing an outcomes approach to standards, there are pharmacies that are now adopting a more flexible interpretation to the open display and self-selection of P medicines. The national pharmacy boards of the Royal Pharmaceutical Society (RPS) were asked to consider current policy position at a meeting on 19 June 2024, resulting in the current call for evidence.

This call for evidence will inform the programme of work exploring the current position of the Royal Pharmaceutical Society (RPS) that *"Pharmacy medicines must not be accessible to the public by self-selection"*.

The call for evidence is led by the Science & Research Team at the RPS under the leadership of its Chief Scientist. The Science & Research Team will also undertake a review of the published evidence by accessing academic databases. The current 'call for evidence', is in recognition of the possibility that some formal data (qualitative or quantitative), evaluations, and assessments pertinent to the review may not be published and in the public domain but held internally within organisations, or by individuals and other stakeholders. To help inform our review, we welcome such evidence to be submitted to us, in particular by:

- Regulators
- Pharmacy employers, including small independents to large multiples
- Pharmacy representative bodies
- Patient representative bodies
- Individual pharmacists, pharmacy technicians, and pharmacy team members

- Academics
- Thinktanks
- Researchers
- International pharmacy organisations

Please respond on behalf of an organisation or as an individual by contacting us as indicated below (see How to respond).

Context

Under the Medicines Act (1968) a pharmacy medicine, (P medicine) is a medicinal product that can be sold from registered pharmacy premises by a pharmacist or a person acting under the supervision of a pharmacist. (Part III, Section 52)

> (a) that person is, in respect of that business, a person lawfully conducting a retail pharmacy business;
>
> (b) the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy; and
>
> (c) that person, or, if the transaction is carried out on his behalf by another person, then that other person, is, or acts under the supervision of, a pharmacist.

The Medicines Ethics and Practice guide of the Royal Pharmaceutical Society (RPS) currently states that pharmacy medicines "*must not be accessible to the public by self-selection".*

Background

There is a long history of tension regarding the self-selection of P medicines.

The law was tested by Boots in 1951, when self-service in shops was new. Boots allowed patients to select P medicines, put them in wire baskets and take them to the till. Since a pharmacist was in attendance at the till, the high court and the court of appeal held that sale of P medicines had lawfully been made under supervision.

However, the Royal Pharmaceutical Society of Great Britain (RPSGB) as the regulator brought in the provision that "Pharmacy medicines must not be accessible to the public by self-selection", preventing this practice from continuing. This was generally understood to mean that medicines are not available for self-selection and must be out of reach to the public, behind the medicines counter or in locked cabinets.

This was followed over the years by several cases where organisations sought to change the self-selection to P medicines, using empty boxes on display and other approaches to help drive consumer awareness of P medicines.

Most recently this came to a head in September 2012 when the General Pharmaceutical Council (GPhC), who had recently formed as the independent regulator, launched a consultation on premises standards which moved regulation towards an outcome-based approach. In these standards they removed the explicit standard on the self-selection of P-medicines.

During this consultation process, the RPS (and other pharmacy organisations) objected to this change and raised strong concerns with the GPhC.

The GPhC stated that the prohibition of the sale of P medicines from open display should no longer apply within the standards. Instead, a decision on whether or not P medicines should be on self-selection should be made locally by owners or superintendents.

The GPhC stated that there were to be three pre-conditions:

- Pharmacies would need to notify the GPhC of their intention to allow P medicines on self-selection.
- Guidance on compliance for pharmacies would need to be developed and communicated in advance.
- The current arrangements (no P medicines on self-selection) would remain in place until new enforcement rules came into effect).

The GPhC have since gained those enforcement powers and as such there are no specific barriers that prevent owners from allowing P medicines on open display. The GPhC require owners and superintendents to make a full assessment of their pharmacies before allowing P medicines on open display – looking at potential risks, training and staff views.

Legally speaking, the sale and supply of a P medicine must take place on registered pharmacy premises under the supervision of a pharmacist. The GPhC have confirmed that this must continue to be the case, and that appropriate measures should be in place to ensure that supervision continues. They believe that the wider GPhC premises standards provide for this[1].

However, the GPhC have confirmed that they work to an outcome-based approach to the standards and no-longer explicitly prohibit self-selection. As a result of this, some

[1]GPhC (2018) Standard for Registered Pharmacies.
https://assets.pharmacyregulation.org/files/document/standards_for_registered_pharmacies_june_2018_0.pdf

pharmacies have begun to consider the open sale of P medicines in their pharmacies, with others already piloting this by re-designing pharmacy shelving, allowing patients access to what was traditionally considered the "back wall".[2] [The linked website (Reference 2) shows photo and images of the pharmacy setup].

Their view is that the blunt instrument of "no self-selection" doesn't consider the various ways in which pharmacies could support access to medicines creatively and has publicly stated they believe the rules are outdated [3].

The RPS Policy Position

In July 2013 the RPS formally adopted all policy from the RPSGB, until such a time that the RPSGB policy is repealed and superseded. Therefore, the 2009 RPSGB Code of Practice came into force for RPS policy, which explicitly called out the prohibition of self-selection of P medicines.

In 2013 the RPS argued that on professional and patient safety grounds that all community pharmacists should continue to keep their P medicines in the safe environment of the pharmacy counter and not out on self-selection. The RPS published an interim statement of professional standard on the supply of Over-the-Counter Medicines [4]

This re-iterates the RPS Position "*Pharmacy medicines must not be accessible to the public by self-selection*".

This position has persisted in the Medicines, Ethics, Practice (MEP) publication and continues to be the main policy position of the RPS.

In 2013, when the GPhC were consulting on changes to the open sale of P medicines the RPS objected strongly. At the time the RPS believed that self-selection would take control away from the pharmacist regardless of the planned safeguards and it voiced fears that the GPhC would pay little attention to the objections. The RPS expressed concern that the nature of the consultation is likely to change from one where patients are guided to the medication that is most beneficial for them to a conversation where a pharmacist is required to try and retrieve an unsuitable drug from the hands of a patient.

The RPS continues to support the wide use of OTC medicines, and has long campaigned for the wider access to self-care treatment working closely with the Self-care Forum to help drive a self-care agenda in government. The RPS recognise the huge value that self-care

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[2] Boots (2024) Pharmacy Medicines. https://www.boots.com/health-pharmacy/pharmacy-medicines
[3] C&D (2013) GPhC brands P meds rules anachronistic. https://www.chemistanddruggist.co.uk/CD016154/GPhC-brands-P-med-rules-anachronistic-in-defence-of-self-selection
[4] RPS (2016) Interim statement on supply of OTC Medicines. https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/interim-statement-of-professional-standard-supply-of-otc-medicines.pdf?ver=2016-10-10-102722-000].

and treatment can provide to patients and the public, and support patients having greater access and information to self-care treatments.

The Arguments for Change

On one hand:

- The self-selection of P medicines could be seen as supporting the interests of consumers and patients as it allows them to access a medication in order to consider a potential purchase - and still gives pharmacists an opportunity to refuse a sale if it would not be appropriate.
- Open selection allows patients to read the information that is provided by manufacturers on the packaging and exposes patients to a wider range of medications, enhancing their choice and understanding. Advocates of this approach suggest that this provides greater patient empowerment.
- This approach makes healthcare more transparent and accessible in line with current government initiatives. This arguably leads to a more informed public and helps people make better choices and provides wider access to a range of treatments.
- Keeping medications in this way perpetuates the paternalistic nature of healthcare that has been criticised by patient groups.

On the other hand:

- P medicines have been classified in this way in order to protect the public. They have been deemed by the MHRA to require an additional level of protection because they have the potential for harm (large packs of paracetamol for example), or might be dangerous in other ways (side-effects, interactions etc.)
- Putting them onto open display and into the hands of patients may make the decision not to sell, more challenging.
- Open sale may present an increased risk of shop lifting and diversion of some of these products.
- The opportunity to prevent the sale of P medicines, with the potential to harm, would be diminished, if they were on open display, thus making it easier for patients to abuse or cause accidental harm.
- There may be confusion among the general public by allowing pharmacy owners or Superintendent Pharmacists to decide whether the self-selection of P medicines is

permitted or not. One pharmacy may allow self-selection and another not, leading to confrontation with pharmacy staff.

- The more commercially minded owners may dilute the reputation of pharmacies as being guardians of healthcare and ensuring the safe use of medication.

Additional Considerations

There are an increasing number of providers that sell and supply P medicines online through pharmacies. These P medicines are sold through websites that allow consumers to select a product and add it to a virtual basket. As a result, the patient is effectively "self-selecting" the product. By having a barrier in physical premises that is not in place in digital structures may act as an impediment to brick-and-mortar pharmacies. The RPS, in consultation responses, has previously called out concerns about "product led" websites, instead calling for such approach to focus on the condition and consultation.

It is worth noting that the current regulations specify the sale must be under the supervision of a pharmacist. There is a closed consultation on legislative changes to supervision regulations that is underway. These may allow for the sale of P medicines under the supervision of a pharmacy technician operating with delegated authority. Therefore there may be implications of such legislative changes on the current topic.

The current practice of community pharmacy is evolving and changing to include innovations. There is therefore also a need to consider such innovations in the practice of pharmacy and whether these are being supported and delivered.

Our approach

At the RPS Board meeting 19th June 2024, a discussion took place in the Open Business section of the agenda on the self-selection of P medicines[5].

Enabled by the GPhC, the RPS understands that hundreds of pharmacies, from large multiples to small independents, have been approved by the regulator to enable patients to self-select certain P medicines. In each case, the sale of the P medicine is still required to take place within registered premises and under the supervision of a pharmacist.

RPS was deeply disappointed to learn of this monumental change in practice without wider communication from the regulator to the profession, patients, and the public. This change was identified by the RPS as a potential risk to patients and out of step with the policy and professional guidance offered to RPS members and the profession.

[5] https://www.rpharms.com/about-us/news/details/rps-statement-on-the-self-selection-of-p-medicines-

As a result, the RPS invited the GPhC and a pharmacy contractor to inform the three National Pharmacy Boards and describe the patient safety assurances that have enabled the regulator to approve this change.

GPhC have stated that ‘self-selection of P medicines would not be compatible with our regulatory standards without key safeguards being in place’. RPS sought to understand in more detail what these safeguards were and how they operated. As a result of these changes implemented by the regulator, the facilitated sale of P medicines is allowed legally and accepted by GPhC pharmacy inspectors.

The Boards were provided with information about the processes, staff training and safeguarding approaches that the GPhC inspectors considered in allowing greater access to P medicines by the public, including the safeguards to ensure certain medications, such as codeine containing products, Emergency Hormonal Contraception (EHC) and Sildenafil, are excluded from self-selection.

As pharmacies adopt changes to practice, including around direct access to P-medicines, they must ensure that patient safety is at the forefront of consideration and that pharmacists are empowered to use their own professional judgement.

The RPS is committed to patient safety and the safe development of innovative practice to meet the needs of patients now and for the future. As new evidence emerges, professional bodies need to ensure that their guidance and advice meet the need of the profession and are reflective of evolving practice, without compromising patient safety.

The RPS is continuing to consider its current position, which is now clearly at odds with the regulator, and the practice taking place in a significant number of pharmacies and is hereby issuing a call for evidence to ensure any potential forthcoming changes to its professional guidance are truly evidence based.

Scope

In considering its current position of “Pharmacy medicines must not be accessible to the public by self-selection” and whether this is still a valid position to hold and maintain, the RPS wants to be informed by a wide array of evidence, rooted in science. The evidence-base will support the RPS to carefully consider the appropriateness of the current position for now and the future.

The current call for evidence is focussed on the evidence of benefit and harm of a “facilitated self-selection” model for Pharmacy medicines in relation to patient care. We are particularly interested in the evidence relating to the following themes:

Patient behaviours around P medicines supplies

There are a number of potential concerns around the behaviour of patients when Pharmacy (P) medicines are available for self-selection. For example, patients might be more likely to resist decisions not to sell that could in theory result in confrontations with pharmacy staff, or patients might be more likely to select and go on to purchase medicines that can be abused or cause accidental harm. On the other hand, patients might be more likely to access appropriate medicines for treating their minor ailment or make better decisions around which medicines to choose from a range of suitable treatments, thus be better empowered.

Pharmacist and pharmacy team experiences of P medicines supplies

There are a number of potential concerns for pharmacists and pharmacy teams when Pharmacy (P) medicines are available for self-selection. For example, staff might have a greater degree of concern about misuse, abuse and diversion of self-selected P medicines based on their experiences, or they may encounter logistical and practical challenges at the point of sale. On the other hand, staff might have more positive experiences when being consulted about self-selected P medicines or find the practice improves efficiency or patient care.

Internal reports or reviews of facilitated/open/self-selection P medicine models

Some pharmacy employers, whether small independents or larger organisations such as large multiples, may have undertaken trials and evaluations where P medicines have been placed on display for self-selection, in order to examine the impact of this practice on a range of indicators including or in addition to examples mentioned above. We imagine these evaluations would have examined patient safety indicators as well as patient benefit.

In addition, we imagine that the regulators would have received, collated and examined evidence that provides assurance around the self-selection of P medicines from a patient safety perspective, and which they hold on file.

It is also possible that pharmacy or patient representative bodies, academics, thinktanks, and other stakeholders and researchers have conducted formal assessments of the benefits and harms of P medicine self-selection, which are not available in the public sphere.

International models around the equivalent of P medicines

It is likely that similar models to self-selection of P medicines exist internationally. While a systematic search of databases is likely to unearth relevant publications, international pharmacy organisations might hold their own evaluations, which could inform the current assessment of evidence of benefits and harms of self-selection on patient care.

Evidence of harm, particularly actual harm or instances of near-miss

Finally, a range of regulators, or other official agencies or organisations may be in receipt of evidence of harm, particularly actual harm or instances of near-misses relating to the model of P medicine self-selection submitted to them via incident reports or other monitoring means.

How to respond

The call for evidence is open for 8 weeks until **6th September 2024**. Responses must be in the form of formal data (ideally analysed), for example detailing trials, assessments, reports or evaluations of the benefit and harm of a "facilitated self-selection" model for Pharmacy medicines in relation to patient care.

Additionally, if you believe it is not possible to provide specific evidence because no data to address a particular concern(s) is currently available, please provide an explanation of areas where further research is required.

Please submit your responses by using the Monday.com form on our Call for Evidence webpage.

If you would prefer to respond via post, please send your response to:

The Science & Research Team
Royal Pharmaceutical Society
66-68 East Smithfield
London, E1W 1AW

When responding, please indicate that you are responding to this consultation by using the following reference in your correspondence: **'Self-selection: 2024 call for evidence'**.

Please also indicate if you are responding as someone on behalf of a regulator, someone representing the views of a pharmacy business or representative body for pharmacy or for patients, an individual pharmacist or pharmacy technician, an academic, a thinktank, another stakeholder or research organisation, an international pharmacy body, or in another capacity (please specify).

The names of respondents to this call for evidence will be published (unless specifically requested otherwise), but their responses will not be publicly attributed to them.

Questions (for attention of those responding by post)

About you

1. Name

2. Contact email address

3. Please tell us in what capacity you are responding:

   - ☐ Regulator
   - ☐ Pharmacy employer
   - ☐ Pharmacy staff (e.g. counter staff)
   - ☐ Pharmacy representative body
   - ☐ Patient representative body
   - ☐ Pharmacist
   - ☐ Pharmacy technician
   - ☐ Academic
   - ☐ Thinktank
   - ☐ Researcher
   - ☐ International pharmacy organisation
   - ☐ Other

4. If you are responding on behalf of an organisation, what is its name?

5. If you are responding as a pharmacist, pharmacy technician, or a pharmacy team member, please tell us what setting you work in:

   - ☐ Community pharmacy
   - ☐ Primary care (e.g. integrated care board)
   - ☐ Secondary care

- ☐ Academia
- ☐ Other
- ☐ Not applicable

Self-selection of Pharmacy medicines

6. Do you have evidence of benefit and harm of a “facilitated self-selection” model for Pharmacy medicines in relation to patient care?
   - ☐ Yes
   - ☐ No

If yes, please submit the evidence in your response making clear the origin of it and further information that assures its provenance and credibility.

7. Do you believe there is an evidence gap in relation to particular concern(s) around the benefit and harm of a “facilitated self-selection” model for Pharmacy medicines in relation to patient care?
   - ☐ Yes
   - ☐ No

If yes, please provide an explanation of areas where further research is required.

8. We will be including a list of contributors' names when publishing the results of this call for evidence.
   If you would like to **opt out** of this list, keeping your contribution anonymous, please check the below box.
   - ☐ I would like to opt out & remain anonymous

Next steps

The evidence gathered through this exercise will inform a report written by the Science & Research Team at the RPS. That report will also consider the published evidence around the benefit and harm of a “facilitated self-selection” model for Pharmacy medicines in relation to patient care. The evidence-base will support the RPS to carefully consider

the appropriateness of the current position on facilitated self-selection of P medicines for now and the future.