Leadership I Defence I **Representation**

Beyond Convenience

Protecting Patients:

The Case Against Liberalisation of the Sale of P Medicines

2025

Pharmacists' Defence Association

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Executive Summary

The renewed debate over the self-selection of Pharmacy (P) medicines in pharmacies highlights the complex balance between accessibility, patient safety and the pharmacist's role.

Evidence from a Pharmacists' Defence Association (PDA) survey highlights the overwhelming opposition to making P medicines available on open display for self-selection, primarily due to concerns over patient safety, inappropriate use, and the increased risk of harm. The results underscore the importance of maintaining current policies, ensuring that P medicines are not on open display or available for self-selection and only available under the supervision of pharmacists.

Pharmacists play a crucial role in protecting patients by providing expert advice, ensuring the appropriate use of medicines, and preventing potential drug interactions. Any changes in how the public obtains their P medicines from a pharmacy must be made after full consultation with pharmacists and other healthcare professionals, as their insight and experience are critical to safeguarding public health.

The risks of allowing unsupervised access or facilitated access with little control to these medicines far outweigh the potential benefits, as shown by the PDA's evidence and the growing concerns about misuse and adverse drug reactions (ADRs). Considering this, patient safety and not consumer convenience must remain the priority in all regulatory decisions.

PDA Policy Position on P Medicines

This report outlines the PDA's policy position on regulating and the sale of P medicines in the UK and why self-selection of P medicines cannot be supported. It evaluates proposed changes, including self-selection models, and presents key risks, findings, and recommended actions to safeguard patient safety and uphold professional pharmacy standards.

The PDA strongly opposes any move towards the self-selection of P medicines, arguing that such a change undermines pharmacist oversight and increases patient safety risks. The current framework, which mandates pharmacist supervision, is essential to facilitate appropriate use, prevent misuse, and provide necessary professional advice. The PDA asserts that thorough consultation with the pharmacy profession and key stakeholders should precede policy modifications.

Key Arguments and Recommendations

Regulatory and Safety Considerations

P medicines contain active ingredients that require careful supervision to prevent misuse, addiction, interactions and ADRs. Regulatory bodies, including the Medicines and Healthcare Products Regulatory Agency (MHRA) and General Pharmaceutical Council (GPhC), have historically mandated restricted access to P medicines and pharmacist involvement in the sale thereof.

Risks of any Form of Self-Selection

The misuse of medicines could pose significant health risks, as patients may use unreliable sources of information and misdiagnose conditions, misuse medications or unknowingly combine them with contraindicated substances without the pharmacist having the opportunity to intervene and provide guidance. This can lead to an increased risk of ADRs, particularly among elderly patients managing multiple medications (polypharmacy) or co-morbidities.

Additionally, the open display of medicines raises concerns about theft and illicit use, especially for drugs with potential for abuse, such as pseudoephedrine and codeine-containing preparations. Without mandatory pharmacist involvement and restricted access, commercial pressures may prioritise financial incentives over patient safety, potentially compromising appropriate oversight and use of medicine.

Stakeholder Concerns

The Royal Pharmaceutical Society (RPS) facilitated discussions with the General Pharmaceutical Council (GPhC) and a representative from Boots UK Ltd on the self-selection of P medicines without prior engagement with the wider profession, leading to pharmacists questioning their motives and significant opposition.

The PDA conducted a snapshot member survey in July 2024, with 1,323 pharmacists completing the survey. The results revealed that 93% of respondents opposed the concept of self-selection. They cited difficulty in supervision (94%), concerns about inappropriate selection (96%), and potential for disputes or violence (87%) as their main concerns.

Lessons from Historical Changes

Past regulatory interventions (e.g., MHRA restrictions on children's cough syrups) demonstrate the importance of pharmacist oversight in mitigating risks. They play a crucial role in supervising P medicine sales, as shown by sales restrictions of pseudoephedrine and ephedrine in April 2008 and the rapid withdrawal in March 2023 of pholcodine-containing products from over-the-counter sales.

Proposed Actions

It is essential to maintain and strengthen existing policy positions and regulations by retaining the requirement for restricted access and pharmacist supervision of P medicine sales to ensure appropriate use and patient safety. Engaging with the industry and regulatory bodies is crucial. The GPhC and MHRA must conduct formal consultations with pharmacists and the wider pharmacy sector before making any changes that expand public access to P medicines.

Additionally, improving public awareness and health literacy through educational initiatives will help patients understand the risks associated with selecting medicines themselves, with little or no oversight from a pharmacist. Finally, more vigorous enforcement measures should be introduced to prevent the misuse, theft, and abuse of high-risk medicines, helping to reduce unintended health consequences.

Conclusion

The PDA reaffirms its commitment to protecting patient safety and professional pharmacy practice. It urges regulatory bodies to prioritise robust consultation and uphold restricted access and pharmacist supervision in P medicine sales. Any deviation from the current model risks undermining public trust and healthcare outcomes.

The PDA welcomes stakeholder engagement to ensure a coordinated policy approach that ensures pharmacists remain at the forefront of medicine supply and patient consultation.

Section 1: Introduction and Context

Overview of Pharmacy (P) Medicines

Medicines are the most common type of therapeutic intervention in healthcare and are generally patients' preferred treatment approach because of their effectiveness, acceptability, and convenience.

The current UK regulatory framework governing the sale and supply of medicines is a well-established system designed to be flexible and responsive to changing clinical practice, healthcare delivery, and society's constant evolution. At its heart is maintaining patient and public safety while enabling individuals, wherever possible, to take greater responsibility for managing their health.

The Medicines Act 1968, which was introduced to control the supply of medicines after problems with the off-label use of thalidomide, categorises medicines into three types:[1]

- **Prescription-only medicines (POM):** These medicines must be prescribed by a doctor or other authorised health professional and dispensed from a pharmacy or other specifically licensed premises.
- **General sales list medicines (GSL):** These medicines may be purchased without the supervision of a pharmacist and are available in retail outlets, such as a newsagent, a supermarket, or a vending machine in a shop.
- **Pharmacy medicines (P):** Pharmacy or P medicines are medicinal products that can be sold only from registered pharmacy premises or registered online pharmacy by a pharmacist or a person acting under the supervision of a pharmacist. Currently, they must not be accessible to the public by self-selection.

Current P medicines include those with active ingredients which could become addictive or be harmful in the long term if used inappropriately or incorrectly in conjunction with other treatments.

The licensing authority for UK medicines, the MHRA, describes a P medicine as being:

> *'…generally for short term treatment of medical conditions that can be readily identified and are not likely to persist, although they may sometimes be available for the management of long-term conditions. Pharmacy medicines need to be used more carefully than medicines sold in other retail outlets and people may require special advice on treatment.'*

In community pharmacies, regulated by the GPhC, the storage conditions for P medicines must ensure that medicines are kept safe, effective, and fit for use.

A key requirement includes secure storage:

- P medicines must be stored typically behind the pharmacy counter or in a place inaccessible to the public and 'are not usually displayed on open shelves.'[2]
- Only pharmacists or authorised staff should have access to them.

[1] Medicines: reclassify your product - GOV.UK
[2] Medicines: reclassify your product - GOV.UK

The PDA's Role in Pharmacy Practice and Policy Development

The PDA is the largest pharmacist membership and leadership organisation in the UK, representing individual pharmacists' professional and workplace interests. The PDA defends pharmacists against external pressures that could compromise their professional judgment, ensuring they can practice with the highest clinical and ethical standards. The association actively engages in policy discussions, advocating for regulations prioritising patient safety and pharmacists' role in healthcare.

As a key stakeholder in pharmacy policy, the PDA provides its members with leadership, legal, regulatory, and professional support. It ensures that pharmacists' voices are heard in government consultations, influencing decisions that impact pharmacy practice and medicine safety. The PDA has historically opposed policies that undermine pharmacist oversight, such as the self-selection of P medicines, and remains committed to maintaining the profession's role in safeguarding patients and public health.

The PDA also conducts research, gathers evidence, and surveys pharmacists to ensure that regulatory changes align with real-world pharmacy practice. It defends pharmacists in over 5,000 cases each year where their professional practice is challenged. This extensive experience provides invaluable insight into the root causes of patient harm, allowing us to identify systemic issues and drive meaningful improvements in pharmacy practice, preserving patient safety. The mission includes preventing commercial pressures from overriding clinical judgment, thereby protecting pharmacists and their patients. By highlighting risks associated with reduced pharmacist intervention, the PDA continues to champion the essential role of pharmacists in healthcare.

The Evolving Debate on Self-Selection of P Medicines

When using the term 'self-selection' or 'facilitated self-selection' concerning P medicines in this report, we are doing so in the context of the risk associated with any liberalisation of the current restrictions around the sale of this category of medicines.

Before implementing changes to the present framework governing current professional practice, it is appropriate to consider the significant existing and proposed future contributions that P medicines may make to the health and well-being of patients and the wider National Health Service (NHS).

With their unique patient accessibility, linked to the critical requirement for pharmacist supervision, P medicines are a key component of care policy development and delivery. Under the existing framework of pharmacist supervision, their availability helps ensure that the partnership between the pharmacist and patient is maintained for self-initiated treatment and that appropriate professional support and information are provided at the point of decision-making to enable optimum care outcomes.

A primary objective of shared decision-making[3] is for patients to be empowered and take greater ownership (wherever possible) of their own care. Any shift toward self-selection that reduces pharmacists' opportunities or ability to provide effective professional input into patient care and public health, particularly regarding the supply of P medicines, could undermine the rationale for expanding their role in care delivery and public confidence in that expansion.

In 2023, The Supervision in Community Pharmacy – Supervision Practice Group (SPG) was established to review and provide recommendations on the future of supervision in community pharmacy. Its remit was far-reaching, similar to the P medicines debate. It included defining supervision in a modern pharmacy setting, ensuring clarity around legal and professional

[3] Shared decision making | NICE guidelines | NICE guidance | Our programmes | What we do | About | NICE

accountability and exploring changes to the regulatory framework to enable more flexible, safe, and efficient pharmacy operations. It was recognised that any changes relating to supervision in community pharmacy would impact the sale and supply of P medicines. The Supervision in Community Pharmacy Recommendations from the SPG report states:[4]

> *'In relation to the supply of P medicines, the group agreed that further work would need to be undertaken in consultation with the Medicines and Healthcare Products Regulatory Authority (MHRA). This was discussed as a large and wide-ranging subject area that required in-depth discussion and debate to consider the ramifications for various future scenarios.'*

Changes to the rules around P medicines could have far-reaching effects and unintended consequences, making thorough consultation crucial to protecting patient safety and preserving the role of professional oversight. Any discussion on the sale and supply of P medicines must involve a diverse and representative group of stakeholders, similar to the SPG, to ensure a well-rounded and informed perspective. Engaging the full spectrum of pharmacy professionals, regulators, and patient safety experts in a transparent process is vital for maintaining confidence in regulatory decisions and safeguarding public health.

Therefore, the conversation regarding the self-selection of P medicines at the RPS's Cross Board Open Business Meeting on 18 June 2024[5] should not have proceeded in isolation with only the GPhC and a large multiple pharmacy commercial organisation involved.

Soon afterwards, the GPhC attempted to clarify its position by introducing a new term, 'facilitated self-selection,' in a frequently asked questions (FAQs) document. They believe the term is helpful because it 'emphasises the crucial roles of the pharmacy team in facilitating the supply of the medicine to the person and of the pharmacist in supervising the supply.[6] Furthermore, the GPhC intends to continue using the term, subject to ongoing review and feedback. However, since its introduction, the PDA has been unaware of any formal or informal review process undertaken by the GPhC.

In contrast, the RPS's professional standards clearly state: 'Pharmacy medicines must not be accessible to the public by self-selection.'[7] This firm stance directly contradicts the implications of 'facilitated self-selection' and reinforces the need for pharmacist oversight in medicine supply. The discrepancy between these two positions creates confusion within the profession and among the public.

Pharmacists now face this juxtaposition between the GPhC's terminology and the RPS's long-standing professional standards. This lack of coherence undermines the pharmacists' role and risks weakening established safeguards, ensuring patient safety remains central to regulations and professional standards.

Notwithstanding, taking a sector-wide approach to key considerations and developments in pharmacy practice ensures alignment amongst all stakeholders and professionals. It promotes consistency in policy and practice and prevents fragmented interpretations of key themes, safeguarding patient safety and protecting pharmacists' professional responsibilities.

[4] Supervision-in-community-pharmacy-FINAL-APPROVED.pdf
[5] June 2024 EPB indexed OPEN BUSINESS Combined papers for website.pdf
[6] Statement on self-selection of pharmacy medicines | General Pharmaceutical Council
[7] 3.1.2 Pharmacy (P) medicines

Section 2: Self-Selection vs Facilitated Self-Selection

When selecting P medicines, both self-selection and facilitated self-selection introduce significant risks that require careful consideration. The PDA has conducted research by visiting pharmacies with these models and has undertaken a literature review.

Self-Selection

Table 1: Definition, key features and risks of self-selection

Self-selection allows patients to pick P medicines directly from open shelves without mandatory interaction with a pharmacist or pharmacy staff.	
Key features	**Risks**
• Medicines are displayed alongside other retail products, allowing all customers unrestricted access. • Patients rely on packaging information or personal knowledge to determine which and whether a medicine is appropriate for them. • Pharmacists and staff may be available for advice, but their involvement in the purchasing decision is not required.	• Inappropriate use Patients may misdiagnose their condition or misunderstand dosage instructions without professional guidance, leading to improper use. This can delay necessary medical intervention(s) and increase the risk of adverse reactions or dangerous drug interactions.[8] • Health literacy challenges Many adults struggle to interpret health information, particularly when it involves dosing and contraindications. This increases the likelihood of misinterpretation and incorrect administration.[9] • ADRs People taking multiple medications face a higher risk of harmful drug interactions if they select medicines without consulting a pharmacist. Without oversight, they may overlook essential contraindications or safety warnings.[10] • Theft and misuse Open access to P medicines raises concerns about theft, particularly of medicines prone to abuse. Pharmacies must assess security risks and implement measures to prevent unauthorised access.[11] • Disputes with patients

[8] Risks of self-medication practices - PubMed
[9] Risks of self-medication practices - PubMed
[10] Self-medication: A current challenge - PMC
[11] FAQ: self-selection and open display of Pharmacy medicines | General Pharmaceutical Council

	If a pharmacist later advises against a purchase, patients may become resistant or even confrontational, feeling that they have already made the decision. This can create challenges in enforcing safe supply practices.[12]

Facilitated Self-Selection

Table 2: Definition, key features and risks of facilitated self-selection

Facilitated self-selection allows patients to browse and select P medicines but requires intervention from a pharmacist or appropriately trained pharmacy staff before the purchase is completed.	
Key Features	**Risks**
• Medicines are displayed openly, but patients must engage with a pharmacist or trained staff before purchasing. • The pharmacist provides oversight, verifying the suitability of the medicine before finalising the sale. • This model aims to balance accessibility with professional guidance.	• Operational strain Requiring pharmacist involvement for every facilitated self-selection could put additional pressure on pharmacy teams, especially during busy periods. Ensuring effective supervision while managing other responsibilities may be challenging.[13] • Commercial pressures In pharmacies where sales targets are a factor, there is a risk that commercial interests could influence decisions, potentially compromising patient safety. Pharmacists may face pressure to approve sales rather than prioritise clinical judgment.[14] • Limited oversight in high-traffic settings or busy environments In busy pharmacies, staff may not always be able to intervene effectively, increasing the risk that inappropriate purchases go unchecked. If pharmacists are stretched too thin, facilitated self-selection may not provide the safeguards intended.[15] • Resistance from patients Even with facilitated self-selection, patients may react negatively if advised against purchasing a medicine they have already chosen. Managing these situations requires

[12] GPhC Sanctions Self-Selection Of P Medicines Amid Controversy
[13] Statement on self-selection of pharmacy medicines | General Pharmaceutical Council
[14] GPhC Sanctions Self-Selection Of P Medicines Amid Controversy
[15] RPS statement on the self-selection of P medicines

	clear communication and firm professional guidance.[16]

Operational challenges, resource limitations and potential conflicts between safety standards and commercial interests exacerbate all the risks outlined above for both selection models. Therefore, it is prudent to maintain rigorous controls and prioritise caution in selecting and dispensing P medicines. Even the GPhC themselves identified issues surrounding innovative models of selling P medicines after they 'ruled that the luxury pharmacy, which held the Royal Warrant as a pharmacist to Queen Elizabeth II, has not met its inspection standard on 'governance'[17] after they found P medicines in the 'retail area.'[18]

Table 3: Key differences between self-selection and facilitated self-selection

Aspect	Self-Selection	Facilitated Self-Selection
Access	Open and unrestricted	Open but controlled, by requiring staff approval
Safety Controls	Limited to packaging instructions	Pharmacist intervention influences safety but is not guaranteed
Patient Autonomy	High but often uninformed	Moderate, guided by professional advice
Professional Role	Minimal intervention	Active engagement to ensure suitability and mitigate risks, though supervision gaps exist
Risk Level	High (misuse, theft, ADRs)	High, if operational challenges prevent effective oversight or effective implementation and/or management

Advancing Technology in Retail Environments and Settings

The increasing use of technology in retail environments, including community pharmacies, has seen the widespread introduction of automated check-outs and other self-service solutions. While these advancements can improve efficiency and customer convenience, without proper safeguards, they raise important questions about patient safety, regulatory compliance and pharmacist oversight.

Given the ongoing discussions about how patients obtain their P medicines, it is appropriate to consider the impact of automation on the supply of P medicines as part of this report. If liberalisation of the sale of P medicines is ever permitted in some form, automated sales of P medicines should be strictly controlled to prevent harm to patients and public health.

[16] The fight is on — can proposals for self selection of P medicines be defeated? - The Pharmaceutical Journal
[17] John Bell & Croyden fails inspection standard over P-meds in 'retail area'
[18] Improvement action plan | John Bell & Croyden | GPhC

The risks of automated check-outs and other self-service solutions:

- Lack of pharmacist and pharmacy team oversight.
- Theft of high-risk medicines is more likely in an automated environment.
- Patients may purchase duplicate medicines, leading to risks of overdose.
- Difficulty in enforcing age restrictions on certain pharmacy medicines.
- Automated systems may not flag contraindications or interactions.
- Patients may obscure P medicines as part of the scanning process to avoid any interventions from nearby staff.
- If P medicines are refused in some manner, they may be abandoned nearby or in different areas of the retail area without adequate control and safe storage restrictions.

Section 3: Regulatory and Legal Framework

Foundations of Current Regulations

The Medicines Act 1968[19] defines three legal categories of medicines:

- Pharmacy Medicines (P)
- General Sale Medicines (GSL)
- Prescription Only Medicines (POM).

Regulation 220 in the Human Medicines Regulations 2012 describes the requirements for the sale or supply of medicinal products under the supervision of a pharmacist.[20] However, it is essential to understand that this is not a recent requirement – certain medicines have always been required to be sold under the supervision of a pharmacist.

There is a long-standing professional requirement for the sale of P medicines under the supervision of a pharmacist:

> *'A pharmacy medicine is a medicinal product that can be sold from a registered pharmacy premises by a pharmacist or a person acting under the supervision of a pharmacist. Pharmacy medicines must not be accessible to the public by self-selection.'*[21]

While the professional guidance above is clear that P medicines can be purchased by a member of the public only from a registered pharmacy and only when that purchase is made under the supervision of a pharmacist and never by way of self-selection, the recent FAQs[22] from the GPhC

[19] Medicines Act 1968
[20] The Human Medicines Regulations 2012
[21] 3.1.2 Pharmacy (P) medicines
[22] FAQ: self-selection and open display of Pharmacy medicines | General Pharmaceutical Council

introduces ambiguity and is juxtaposed against the RPS's professional standards, which is a critical safeguard embedded in professional practice.

Periodically, this requirement or the interpretation of how supervision by the pharmacist is discharged comes under challenge.

Response to the PDA survey included the following comments:

'People ask for OTC medication without realising it affects other drugs they already have prescribed. safety concerns here.'

'No supervision of these sales, the P category would need to be abolished, and items just be GSL or POM.'

Historical Precedents and Background

Pharmaceutical Society of Great Britain v Boots Cash Chemists (Southern) Ltd (1951)

The legal foundation underpinning the supervision of P medicines within pharmacies dates back to a seminal Court of Appeal judgment in 1953, which followed an initial case in 1951. This ruling remains a reference point in pharmacy law, particularly about whether P medicines can be displayed for self-selection within a pharmacy. The case primarily considered a pharmacist's ability to intervene – practically exercising supervision and preventing a member of the public from purchasing an inappropriate medicine.

However, this case focused mainly on the technical question of when a sale is deemed completed and the point at which a pharmacist can exercise their duty of supervision. The Court transcript describes the pharmacist's opportunity to intervene in the transaction as follows:

> *'The pharmacist was stationed near the poisons section, where his certificate of registration was conspicuously displayed, and was in view of the cash desks. In every case involving the sale of a drug the pharmacist supervised that part of the transaction which took place at the cash desk and was authorised by the defendants to prevent at that stage of the transaction, if he thought fit, any customer from removing any drug from the premises.*[23]

While this case established a precedent, it is crucial to consider the broader societal and professional context of that time: Pharmacists in the 1950s operated within a society that showed greater deference to them (and other healthcare professionals in general), and most pharmacists were also business owners rather than employees. The dynamic between pharmacists and patients was markedly different from today; if a pharmacist refused to sell a medicine to a patient, they were more likely to accept the decision with gratitude and respect. By contrast, in the modern era,

[23] Contract—Offer and acceptance—Sale of goods—Self-service—Time of sale. *Pharmaceutical Society of Great Britain v Boots Cash Chemists (Southern) Ltd (1951)*

pharmacists frequently encounter verbal abuse and, in some cases, physical threats[24] when upholding their professional responsibilities.

The PDA's annual Safer Pharmacies Charter (SPC) highlights the stark reality that violence and abuse directed at pharmacists and pharmacy teams has become an all-too-common occurrence.[25] This changing landscape further reinforces the need for robust regulatory protections that preserve pharmacist-led supervision over P medicines and prevent self-selection from becoming a norm.

Despite the 1953 case ruling, successive Governments and regulators have upheld the principle that P medicines must not be displayed in a way that allows for self-selection. This enduring professional standard reflects a continued commitment to patient safety, ensuring that pharmacists retain the ability to assess, advise, and intervene appropriately in the sale of medicines.

Response to the PDA survey included the following comment:

> ***'It's concerns about refusal of a sale when a patient has already selected and held the medicine (put in their basket), so they have 'psychologically bought' the medicine. I don't mind empty boxes being on display to allow for patients to see information, but this is very different. In the current climate, patients are more likely to become aggressive/violent when the sale is refused.'***

Regulatory Evolution and Policy Development

As part of the modernisation of healthcare regulation following recommendations made after the Shipman Inquiry[26], the Government mandated that healthcare regulation should be provided by an organisation separate and distinct from the healthcare professional body. In the case of pharmacy in Great Britain, the combined professional body and regulator was the Royal Pharmaceutical Society of Great Britain (RPSGB), founded in 1841 as The Pharmaceutical Society of Great Britain and subsequently receiving a Royal Charter of Incorporation in 1843.

Following legal advice during a consultation in 2007, the RPSGB conducted a public and professional review of the prohibition on self-selection of P medicines. Notably, the RPSGB Governing Council at the time included a small number of Privy Council appointees, while the majority were elected pharmacist registrants. Many of these elected members had direct patient-facing roles and practical experience in professional practice. The result of the consultation was clear:

> *'91% of respondents agreed that the Society should place professional restrictions on the way in which Pharmacy medicines are displayed and made accessible to the public and 64% of respondents believed that there should be a complete prohibition on the self-selection of Pharmacy medicines.*

[24] Pharmacy bodies call on Government to protect pharmacy teams from violence at work - Community Pharmacy England
[25] Safer Pharmacies Charter | The Pharmacists' Defence Association
[26] Learning from tragedy, keeping patients safe - Overview of the Government's action programme in reponse to the recommendations of the Shipman Inquiry CM 7014

The reasons for these views centred on patient safety issues and the importance of ensuring that a Pharmacy medicine is appropriate for the patient concerned and that necessary advice on the safe and effective use of the medicine is given.'[27]

However, in 2010, professional regulation was removed from the RPSGB, and a new pharmacy regulator with a government-appointed Council was established, the GPhC, to regulate pharmacists, pharmacy technicians, and pharmacy premises in Great Britain. The remaining professional body was renamed in 2010, following an amendment to the supplemental Royal Charter of 2004, the Royal Pharmaceutical Society (RPS).

The GPhC's Governing Council was fully appointed (as opposed to elected) with a majority of lay members and led by an appointed lay Chair. In 2012, the newly created GPhC revised the long-standing standards inherited from the RPSGB in 2010. This led to a further challenge to allow for the self-selection of P medicines, which came during the revision to the standards for pharmacy premises undertaken by this newly constituted regulatory authority in 2012.

Within these existing standards, there was a well-established and explicit prohibition:

'4.12 Ensure procedures for sales of over-the-counter medicines enable intervention and professional advice to be given whenever this can assist the safe and effective use of medicines. Pharmacy medicines must not be accessible to the public by self-selection.'[28]

In 2012, the GPhC proposed revised standards that underwent a public consultation. Despite serious concerns and grave reservations from the two pharmacist membership bodies representing pharmacists, the GPhC removed this explicit prohibition on self-selection.

As a result, the PDA and other organisations successfully fought to reject proposals which would have allowed P medicines to be available for self-selection from open displays in community pharmacies, alongside GSL medicines and even non-medicinal items.

Concerns at the time included:

- Reducing the opportunity to prevent improper sales, placing the public, pharmacists and staff at greater risk.
- Causing even greater tension between commercial and patient safety considerations in community pharmacy.
- Damaging the ability of the pharmacist to ensure that the right P Medicine is taken for any condition.
- Increasing the number of medicines in circulation increases the risk of harm to the public.
- Creating confusion amongst the public in an area with too much confusion.
- Damaging the control that supports the safe de-regulation of medicines from POM to P.
- Allowing owners and their business managers to decide whether P medicines should be sold by self-selection undermines the pharmacists' responsibility for selling medicines and ensuring the pharmacy's safe and effective operation.
- Harming operational practices that improve patient safety.

A GPhC paper from April 2013 notes the concerns from the two largest membership organisations for pharmacists:

[27] Outcomes of the RPSGB consultation on the self-selection of pharmacy medicines
[28] General Pharmaceutical Council: Standards for pharmacy owners and superintendent pharmacists of retail pharmacy businesses - September 2010

'... stakeholders holding a range of views on detailed topics, including those with continuing concerns about the absence from the registered pharmacies standards of a blanket prohibition on the open display of Pharmacy medicines. For example, we have met at senior levels with the Royal Pharmaceutical Society and the Pharmacists Defence Association to discuss their concerns about this subject and the Council's regulatory approach.

We have been asked in recent discussions whether the Council would consider holding a further consultation specifically on this topic. We have shared our view that this appeared to be an unlikely course for the Council ...'[29]

In the summer of 2013, the RPS issued an updated policy statement on the prohibition of self-selection of P medicines. It maintained that no new evidence supports changing its policy position. Having P medicines openly accessible could hinder pharmacists' ability to provide safe and effective medication to patients and the public, and the RPS considered it a potential risk to public safety.[30]

At the RPS Annual Conference in September 2013, the then Chief Pharmaceutical Officers (CPhOs) for England, Wales, and Scotland discussed the GPhC's plans to allow self-selection of P medicines.

Professor Bill Scott (then CPhO – Scotland) was reported as saying[31] that the GPhC should look to the RPS for professional advice and would be foolish to dismiss its opinion, stating:

'If [a medicine] can be self-selected… then it shouldn't be a P medicine, it should be general sales list (GSL)'

Professor Roger Walker (then CPhO – Wales) was reported as saying[32] that self-selection might hamper the drive to reclassify more prescription-only medicines (POMs) to P status. He also warned that P medicines should not become perceived as 'freely available' [to the public].

Response to the PDA survey included the following comment:

'The pharmacists are the ones who deal with patients day in and day out. They know what the risks are to their patients. They should not be bypassed on decision making on things that concern them.'

Professor Scott's statement that medicines suitable for self-selection should not be classified as P medicines remains critical. Medicines must be classified based on clinical need and the necessity of pharmacist intervention.

Similarly, Professor Walker's warning that self-selection could hinder the reclassification of POMs to P medicines is still pertinent. If the public perceives P medicines as freely available, the ability to justify their controlled supply and pharmacist supervision could be undermined.

[29] General Pharmaceutical Council meeting 11 April 2013: Paper 04.13/C/04 - Public business - Registered pharmacies project
[30] The fight is on — can proposals for self selection of P medicines be defeated? - The Pharmaceutical Journal
[31] Pharmaceutical Journal (PJ), 15 September 2013: 291, p234
[32] Pharmaceutical Journal (PJ), 15 September 2013: 291, p234

Although these individuals are no longer in position, their concerns highlight fundamental issues amid recent developments. Their perspectives must not be ignored, as they provide insight into the long-term consequences of self-selection policies and reinforce the importance of maintaining appropriate safeguards.

On 12th July 2013, a GPhC news item stated:

> *'The General Pharmaceutical Council (GPhC) has set out clearly what it has decided about the open display of pharmacy medicines or self-selection.*
>
> 1. *self-selection is not allowed at this time in Great Britain*
> 2. *the law says that the sale of pharmacy medicines must be supervised by a pharmacist and the law has not changed in this regard*
> 3. *self-selection will not be allowed in Great Britain until key safeguards are in place. No date has been set for that yet'*[33]

In November 2013, following significant concern expressed by pharmacists, the GPhC published a background paper around developing guidance to support the safe and effective supply of all pharmacy P medicines. The paper stated:

> *'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.'*[34]

The PDA is unaware that the GPhC is publishing such guidance or the outcome of any engagement it may have undertaken with stakeholders. It remains unclear when the GPhC approved a start date for the self-selection of P medicines or whether any new evidence that the GPhC holds could warrant a change.

Alignment and Conflict of Self-Selection Policies with Existing Frameworks

The table below summarises alignment with and conflicts against existing regulatory and legal frameworks governing the sale and supervision of P medicines.

Table 4: Alignment with and conflicts against existing regulatory and legal frameworks

Alignment with existing frameworks	Conflicts with existing frameworks
Encouraging patient autonomy and self-care The NHS has increasingly promoted self-care and community-based healthcare models to	**Non-compliance with the Medicines Act 1968 and Human Medicines Regulations 2012**

[33] Open display of pharmacy medicines: what the GPhC says - 12 July 2013

[34] The General Pharmaceutical Council (GPhC) - Background paper: November 2013: Developing guidance to support the safe and effective supply of 'Pharmacy (P)' medicines

reduce pressure on GP services and hospitals. Self-selection aligns with this shift by making P medicines more accessible to patients who may wish to manage minor ailments independently. **Integration with digital health initiatives** The NHS is embracing digital solutions such as patient passports and self-monitoring apps. Self-selection could complement these tools by enabling patients to access medicines with minimal intervention, assuming proper safeguards are in place. **Alignment with retail and customer trends** The broader retail sector has embraced self-service models through automated check-outs and digital health consultations. Self-selection policies could follow this trend, provided that pharmacist intervention remains an integral component.	The current legal framework requires pharmacist oversight in the sale of P medicines. Allowing self-selection without mandatory pharmacist interaction contradicts these legal provisions. **Undermining pharmacist supervision** The regulatory structure emphasises the pharmacist's role in assessing patient needs, screening for contraindications, and providing tailored advice. Self-selection would reduce the frequency and necessity of these critical interventions, increasing the risk of inappropriate medicine use. **Increased risks of ADRs** Pharmacists are key in advising patients on potential ADRs and interactions with existing medications. Without pharmacist supervision, patients may unknowingly take medicines that could cause harm, leading to increased hospital admissions and regulatory concerns. **Impact on medicine classification** The principle that a medicine requiring pharmacist supervision is categorised as a P medicine could be undermined. If medicines can be selected without consultation, it raises the question of whether they should be reclassified as general sales list (GSL) products, reducing professional control over their supply. **Regulatory challenges for the GPhC and MHRA** Implementing self-selection would require significant changes to existing regulations, extensive consultation, and reassessment of medicine classifications, security measures, and patient safety protocols. **Professional standards** RPS's professional standards clearly state that P medicines must not be accessible to the public by self-selection.

Given these conflicts, any change in policy and liberalisation of the current restrictions around the sale of this category of medicines require thorough evaluation to ensure they do not compromise patient safety, the integrity of pharmacy practice or existing legal frameworks.

The Risks Involved in Emerging Policies and Legislation

Recent policy shifts, including legislative developments relating to the supervision requirements in community pharmacies[35], the NHS Long-Term Workforce Plan's[36] proposals to expand the role of other pharmacy team members and pave the way with technological advances could significantly disrupt the current model of safe medicine supply, including the safe supply of P medicines.

Whilst technological advances, evolving policies, regulatory guidance, and legislation could benefit operational aspects, they should not pave the way to replace the pharmacist's expertise in medicine safety, patient consultation and clinical interactions. Pharmacists' oversight is critical in acute and episodic care, where patients seek immediate relief for infections, pain and allergies. Additionally, they ensure the safe and effective use of P medicines in long-term care, preventing ADRs with treatments for long-term conditions. Their role is pivotal, identifying potential drug interactions, assessing the suitability of P medicines in complex cases and providing tailored guidance – expertise that cannot be replicated by other roles or technology.

This issue is further exacerbated by the financial strain on the NHS, which has pushed healthcare providers to deliver 'more for less.'[37,38] This phenomenon is not unique to NHS settings and includes community pharmacies contracted to deliver NHS services.[39,40] As cost-saving initiatives prioritise efficiency, a further risk arises from the unintended consequence of multiple policy and legislative changes converging, risking pharmacists further away from patients with medicine-related queries and reducing their ability to prevent medicine-related harm. This shift places additional burdens on an already overwhelmed healthcare system.

Instead of reaching their full potential as frontline, patient-facing pharmacists, they may be diverted into overseeing dispensing processes while other pharmacy team members handle ad-hoc patient consultations. Alternatively, they could be confined to a consultation room, focused on prescribing activities, leaving them unable to intervene in potentially unsafe sales of P medicines.

Section 4: The Role of Pharmacists in Safeguarding Patient Safety

Pharmacists as the Gatekeepers of Medicines

Pharmacists are the gatekeepers of medicines, and their interventions ensure medicines are supplied appropriately, reducing risks from incorrect self-diagnosis and misuse. This is valid for all categories of medicines, including P medicines.

Pharmacists train for a four-year level seven master's degree with substantial content focussing on how the human body responds to medicine and what effect the medicine has on the human body. All graduates then must complete a further one year of foundation training.

[35] The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2024
[36] NHS Long Term Workforce Plan
[37] Latest figures show general practice is delivering 'more for less' | NHS Confederation
[38] Is there really an NHS productivity crisis? | Institute for Fiscal Studies
[39] 'Complete turmoil' for pharmacies with loss on prescriptions - BBC News
[40] Labour pledges to 'go further' than current community pharmacy proposals - The Pharmacist

At the end of that year, they must pass an independent exam set by the GPhC before they can be entered into the register of pharmacists.

The healthcare reform plan, announced by Wes Streeting in 2024 as part of the current Labour government, emphasises a shift from hospital-based care to community settings, a transition from analogue to digital systems, and a focus on prevention over treatment.[41] These priorities align directly with pharmacists' critical role in public health services and self-care, including the sales and supervision of P medicines.

- **Community-based care:** By moving care out of hospitals and into community settings, pharmacists will have an expanded role in patient health management, reinforcing the necessity of pharmacist-led supervision of P medicine sales.
- **Digital integration:** Introducing digital tools such as patient passports will enable pharmacists to access and update patient medical records, ensuring that P medicine recommendations are based on a complete clinical picture.
- **Preventative health focus:** As the NHS shifts toward prevention, pharmacists will be essential in guiding self-care, ensuring that P medicines are used appropriately, and intervening when professional advice is needed.

However, the thinking is not new, as demonstrated by a report from the RPS in November 2013.[42]

'Each year, 84% of adults in England visit a pharmacy at least once, 78% of these attendances being for health-related reasons.'

The report emphasised the essential role of pharmacists delivering patient-centred care, particularly in medicine management and supervision. It advocated for greater recognition of pharmacists as healthcare providers rather than just dispensers of medicine. The report stated that enabling self-selection of P medicines without pharmacist oversight would undermine this objective, creating risks around inappropriate medicine use and reducing clinical advice during patient interactions.

The report's recommendations remain highly relevant in today's healthcare landscape, particularly as pharmacy services evolve in response to increasing demand and healthcare reforms. Ensuring pharmacist involvement in the sale and supply of P medicines aligns with the broader vision of pharmacy as a key pillar of patient care rather than a retail-driven supply-and-demand model.

A survey by Ipsos[43] for NHS England in 2023 found that 29% of respondents had contacted or visited a community pharmacy, either for themselves or on behalf of someone else, in the previous week. More recent statistics emphasise the role and importance of pharmacists, and according to the Office for National Statistics September 2024 report[44], nearly 60% of adults reported using NHS services from a pharmacy in the preceding 28 days.

Announcing the evolution of the NHS landscape in 2024 underscores the necessity of professional supervision in pharmacy settings. To achieve this process, patients and the wider public need to take greater responsibility for maintaining and improving their health. This reinforces that P medicines should remain under the direct guidance of pharmacists as part of a clinically assessed approach to patient care.

Existing practice ensures that patients need to interact with pharmacy staff during the preliminary process of deciding whether a P medicine might or might not be an available or a suitable option for

[41] Government issues rallying cry to the nation to help fix NHS - GOV.UK
[42] Now or never: Shaping pharmacy for the future | RPS
[43] Public Perceptions of Community Pharmacy 2023 Report - Ipsos UK Knowledge Panel
[44] Experiences of NHS healthcare services in England - Office for National Statistics

their condition. As this conversation develops, pharmacists can (and do) provide professional input appropriate to the patient's situation to enable a joint decision.

Such decision-supporting pharmacist input includes:

- confirm any preliminary choice of P medicine as being appropriate,
- advise that another P medicine would be more appropriate,
- advise that another type of care intervention would be more appropriate,
- advise that no intervention at this stage would be most appropriate,
- recommend referral to another healthcare professional, or
- provide wider health-related information and/or advice and support.

However, any self-selection process means that patients will usually have already 'made up their minds' about what should happen next or whether a particular medicine is right for them when presenting at a counter in the pharmacy with the chosen product(s). Their choice may be based on a previous transaction, another person's recommendation (who may not be appropriately trained), advertising campaigns, etc. The drive to purchase a medicine must be met with a 'gatekeeper' who establishes the reasons, evaluates the risks and then recommends the appropriate action.

In these scenarios, the dynamic of a patient and pharmacist interaction could be based on questionable circumstances and fundamentally change from *'I have a problem, can you suggest something that might help'* to *'I need to buy this because…' or* '*Someone suggested getting…*' Pharmacists have genuine concerns that, in such circumstances, a patient's receptiveness to 'consultation' questions, plus any subsequent discussion and professional advice would be significantly reduced.

Accordingly, the opportunity could be lost to consider, discuss and agree whether jointly:

- the patient has made a correct self-diagnosis,
- the presenting condition requires consultation with another more appropriate healthcare professional or in another healthcare setting,
- the presenting condition is treatable with an available P medicine,
- the patient's GP can be informed of the use of the relevant P medicine where necessary to ensure integrated and optimised care can be maintained,
- the P medicine may
    - impact adversely on other existing medical conditions,
    - interact with any medicines already being taken for other conditions,
    - have potential side effects or ADRs that need to be watched out for and what action to take if developing,
    - have to be taken in a specific way for optimum outcomes to be achieved (e.g. for a set period, before or after food, etc.),
    - have to be stored in a specific way to maintain efficacy or
    - not be (fully) effective for that patient and, in which case, what to do next.

Any diminished ability of pharmacists to elicit relevant clinical or other factors and then provide professional input potentially pertinent to a patients safe and effective treatment with P medicines can potentially decrease patient safety and worsen care outcomes.

The Vital Role of Community Pharmacies as Healthcare Settings

Image generated using AI

Community pharmacies are the most accessible healthcare settings across the UK. Research from Ipsos for NHS England and NHS Improvement on public perceptions of community pharmacies[45] found that nearly one in every five people visit a pharmacy once a month. With a growing number of clinical services commissioned by the NHS in community pharmacies and other parts of the NHS being able to refer patients to pharmacies for advice and treatment, the frequency and number of visits to local pharmacies will only continue to increase.

Community pharmacies are increasingly considered as a healthcare setting where patients can access clinical services, commissioned by the NHS and local authorities, alongside provide healthcare provision, including the sale of P medicines. Although there is a shift towards prevention, often when someone presents at a community pharmacy, they are generally unwell or in need of care or medication. Pharmacists focusses on prioritising patient safety, professional oversight and advising on the appropriate use of medicines in these circumstances.

In comparison, individuals will visit a non-healthcare setting (retail shop) when they feel generally well and often elated in the pursue of buying a product or item. Research indicates that offering a wide range and level of products, aiming to meet the diverse needs of customers and results in higher sales and therefore profit.[46] Organisations therefore focus on convenience and often provide a broad range of products for customers to choose from, driving their own commercial interests.

It is therefore important to consider the terms '*patient*' against the use of '*customer*' and/or '*consumer*.' These terms must be used appropriately to reflect the primary concern in the different settings as it carries significant implications for the nature and type of interaction and the prioritisation of vulnerability and safety juxtaposed against convenience and profit.

> *'Customers are generally well people who enjoy elevated status by virtue of their potential to purchase goods or services. Patients, on the other hand, are (by current definition), not well. Their status is greatly reduced by illness or injury that renders them vulnerable, frightened, often in pain, medicated, exhausted and confused...'*[47]
>
> *…The 'goods' they are purchasing are a return to health and the 'services' they seek often require an unspeakable level of trust in their 'service provider'. It makes little sense to relate to patients as traditional 'customers…'*

This distinction is particularly important in community pharmacies, where access and the sale of P medicines are restricted to safeguard against misuse and potential adverse reactions. This is supported by a study, published in the Patient Experience Journal[48] highlighting that patients often experience illness or injury and requires careful attention to prevent adverse outcomes.

[45] IPSOS: Public Perceptions of Community Pharmacy
[46] The Effect of Product Variety and Inventory Levels on Retail Sales: A Longitudinal Study
[47] Customer service vs. Patient care
[48] Customer service vs. Patient care

By recognising pharmacies as healthcare settings rather than retail shops ensures that individuals receive the advice, guidance and care they need and should be referred to as patients; compared to non-healthcare settings referring to individuals as customers or consumers associated with convenience and ultimately the organisation's commercial interests.[49]

In England, data shows that pharmacies are even more accessible in deprived areas where health inequalities exist. In these locations, substantially more services are provided than pharmacies in less deprived areas.[50] The situation regarding access to GPs in primary care is the opposite, with the Health Foundation highlighting that general practice is underfunded and 'under-doctored' in areas of high deprivation.[51,52]

NHS England introduced Pharmacy First (PF) in 2024.[53] It enables the treatment and supply of medicines for seven common clinical conditions following a consultation with a pharmacist. By the end of June 2024, around 1.8 million PF consultations were conducted, with around 700,000 relating to a consultation on one of the seven clinical pathways.[54]

Graphic 1: Frequency of use of pharmacy services

In England, prescription charges apply to patients accessing PF who are not exempt from prescription charges. However, due to the devolved nature of NHS healthcare, there are circumstances where medication may be provided free of charge as part of specific schemes in one UK nation but not another. For example, in Scotland, patients can receive some medicines as part of the national NHS Minor Ailment Service.[55]

The NHS is placing increasing emphasis on 'self-care' and directing patients to pharmacists. As a result, patients may visit a pharmacy instead of their GP for advice on managing their condition or

[49] Customer service vs. Patient care
[50] 'Catastrophic implications': the pharmacy closures widening health inequalities
[51] 'Levelling up' general practice in England - What should government prioritise?
[52] Health inequalities
[53] NHS England » Pharmacy First
[54] Chief Pharmaceutical Officer's presentation at the Pharmacy Show, 15 October 2024
[55] The NHS Minor Ailment Service at your local pharmacy

symptoms, which could include a pharmacist's recommendation to purchase an appropriate medicine.[56,57]

Further, the range of conditions considered 'common' or 'minor' or 'low acuity' conditions has expanded, many of which can be managed using medicines from a registered pharmacy without a prescription. Nevertheless, many P medicines have highly detailed exclusion criteria, warnings of significant interactions, and detailed usage instructions.

Many conditions can be safely managed or treated with P medicines, but only if the medicine is appropriate for that patient, considering their health condition, existing medication regime, and medical history. This is why these medicines are only sold in registered pharmacies under the supervision of a pharmacist and not in grocery stores, petrol stations, or other retail outlets.

Pharmacy First – Opportunities for a Complete Patient Medical Record

The recent introduction of the PF service in England[58] has led to pharmacy patient medication records and labelling software providers having to create a facility for a digital consultation record. Digital records must include detailed consultation information from each patient interaction, recorded within the pharmacy's dedicated PF IT system on the same day, adhering to standard record-keeping practices, and ensuring the patient's medical record is updated with the pharmacy consultation details.[59]

This has been especially important as many consultations result in the supply of a POM via a clinical pathway and Patient Group Direction. The record of the consultation and supply is sent to the GP practice, and they can accept the pharmacy notification into the patient record. This is a paradigm shift in how pharmacies communicate with GP practices about patients, meaning that the doctor may now have a complete record of the consultation and any medication supplied.

With this precedent in place, it should be possible in the future, with the patient's consent, to upload the sale of P medicines to the patient's record at the GP Practice. The NHS needs to consider the benefits of recording the purchase of certain medicines from a pharmacy in the patient's GP record. Given the significant and deliberate misuse of certain products, there is a clear case for this to be considered.

However, allowing medicines to be on self-selection reduces the opportunity for engagement with patients and obtaining their consent to share any purchase information with their GP. It also introduces the concept of thinking that medicines are nothing more than normal items of commerce.

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[56] What does 'self-care' mean and how can it help?
[57] Policy guidance: conditions for which over the counter items should not be routinely prescribed in primary care
[58] NHS England » Pharmacy First
[59] GP Connect: Update Record - NHS England Digital

Learning From Self-Selection of Children's Cough Medicines

The risks associated with self-selection can be demonstrated by the withdrawal of many children's cough syrups from open sale around 17 years ago.

In 2008, the MHRA imposed restrictions on some of these medicines. A report at the time highlighted:

> *'The measure comes after the MHRA found some parents were unwittingly overdosing children. 'It's a precautionary measure,' said Sarah Coakley, a spokeswoman for the MHRA. 'Nobody should panic.'*
>
> *There's nothing wrong with these medicines, it was the way that they had been given. If you are giving them the right dose, don't worry. Make sure you follow the correct dosage." She said the remedies could be dangerous if a child had more than the recommended dose or was given other products at the same time.*
>
> *A spokeswoman for Boots said: 'There are currently some medicines available that, under this new guidance, are now only recommended for use in children aged two years and above.'*
>
> *'In the interests of our customers, these will only be sold under the supervision of a pharmacist until the packaging is changed to reflect this.'*[60]

In hindsight, it is inconceivable that parents and/or guardians knowingly and willingly gave their children the wrong medicines or doses. However, many parents could not interpret or understand what was written on the box or the enclosed leaflet, may have been unaware of the risks, and may have been reluctant to ask for advice.

In 2009, the MHRA reclassified these medicines as P medicines:

> *'Products currently authorised with General Sales List (GSL) legal status may continue to be sold on open shelves and remain available through other retail outlets, such as supermarkets, until the new packaging reflecting Pharmacy (P) legal status becomes available. We expect the change to be complete by March 2010.'* [61]

This example illustrates the issue of health literacy when considering aspects involving numeracy (dose, frequency, etc.) and the inadvertent use of differently branded products that contain the same or similar ingredients, potentially leading to overdosing.

Response to the PDA survey included the following comment:

> ***'I've also seen adults requesting adult medication for children. Self-selection would make it easier for adults administering unsuitable medication to children which could increase harm.'***

[60] Child cough syrups taken off shelves
[61] Over-the-counter cough and cold medicines for children

Section 5: Public Health and Safety Implications

Public and Population Health Considerations

Medicines are potent products with significant therapeutic benefits but can also have serious adverse side effects. Health literacy is crucial in ensuring that patients understand medicines' therapeutic benefits and potential risks.

While patients generally grasp the dichotomy between POM and P medicines, blurring lines between these products could undermine that understanding. P medicines could carry significant risks if misused or underestimated by patients. Placing these on open display for self-selection diminishes the careful distinction between P medicines and other over-the-counter products like GSL medicines. This change could lead to a dangerous shift in public perception, where P medicines are seen as no different from less regulated commodities, potentially resulting in many unintended consequences.

Aggressive marketing campaigns could further reinforce such perceptions, undermining the safeguards associated with P medicines and leading to detrimental health and care outcomes. Without adequate health literacy to understand these risks, the proposed changes could have serious consequences for public health.

The Complexities of Literacy and Health Literacy

The divergence around access to a pharmacy and doctors in primary care in health-deprived areas has already been noted. Health deprivation is one of the seven criteria for determining an 'index of multiple deprivation.'[62] One of the other six factors is education. Research highlights that three in five adults (61%) cannot use everyday health information (for example, that would be contained in a patient information leaflet relating to a medicinal product) when it involves numeracy.

Research commissioned by NHS England in 2015 shows the level of adult health literacy as follows:

> *'…42% of working-age adults (aged 16-65 years) are unable to understand or make use of everyday health information, rising to 61% when numeracy skills are also required for comprehension.'*[63]

In addition, a multi-agency report in 2023 highlighted research which showed:

> *'... people with lower health literacy are more likely than those with higher health literacy to use television, social media, blogs or celebrity webpages for health information; at the same time lower health literacy is associated with lower odds of using medical websites for health information.'*[64]

In this context, the pharmacist's role is vital, as appropriate clinical assessments are made through questions asked, and appropriate advice is given when patients require information about a health concern and medicines.

[62] Deprivation - What is deprivation health? - The index of multiple deprivation
[63] Local action on health inequalities - Improving health literacy to reduce health inequalities
[64] A State of the Nation Report reviewing findings from patient and healthcare professional engagement

Further, research indicates that many patients feel embarrassed or ashamed to disclose their difficulties understanding health information. For instance, a study found that 40% of patients with low health literacy felt ashamed and hid their inability to read.[65] NHS England itself recognises the importance of making every contact count.[66]

This is why the long-standing professional guidance issued by the RPS regarding the prohibition of making certain medicines available for self-selection still holds firm. It is probably more relevant than ever before that every opportunity must be taken for a suitably trained healthcare professional to ensure that medicines are used appropriately and to support patients' use.

Response to the PDA survey included the following comments:

'A patient who had limited prior knowledge regarding a HRT treatment but had heard about it via social media was wanting to buy it to treat her symptoms (hot flushes, headaches). After some further questions, I realised that she was ineligible for the sale and needed to see a GP for further investigation. She was initially angry and demanded why and stated that she would just buy it at another pharmacy.'

'(Self-selection/open display) May encourage embarrassed patients to choose products they want/need without having to ask.'

Polypharmacy and the Risk of Inadvertent Harm

The number of patients taking five or more medicines (polypharmacy) is increasing with an ageing population. While patients often need to take many medicines for their medical conditions, this may not always be the most appropriate or best option.

'Age UK estimates that almost two million people over 65 are likely to be taking at least seven prescribed medicines. This number doubles to approaching four million for those taking at least five medicines….

…. Adverse drug reactions can have severe consequences for older people and cause nearly 6 per cent of unplanned hospital admissions. Between 2008 and 2015, the number of emergency hospital admissions caused by adverse drug reactions increased by 53 percent. In 1 in 50 cases that reaction proved to be fatal.'[67]

[65] Shame, health literacy and consent - PMC
[66] Making Every Contact Count (MECC): Consensus statement
[67] Age UK calls for a more considered approach to prescribing medicines for older people

Therefore, when an older patient goes to a pharmacy and self-selects a medicine that potentially interacts with their other, quite likely multiple medications, there is significant cause for concern.

A research paper published in the BMJ Open in 2022[68] highlighted the significant scale of the issue and found that a substantial proportion of hospital admissions were directly caused or contributed to by ADRs, placing a significant burden on patients and healthcare systems. This study also emphasised the connection between polypharmacy and increased ADR risks and found that 16.5% of hospital admissions were directly caused or contributed to ADRs. Further, patients with polypharmacy and multimorbidity (multiple chronic conditions) were more likely to experience ADRs.

The study estimated a significant financial burden on the healthcare system due to ADR-related hospital admissions. While acknowledging that this data is for all ADRs leading to hospitalisation, the data in the research paper include many products that can be purchased as P medicines. Allowing the self-selection of P medicines will likely increase the risk of avoidable ADRs and, therefore, add additional burden to an already strained NHS system.

'Factors associated with an ADR on logistic regression included age, number of medications and liver impairment. The data suggest ADRs place a significant and increasing burden on patients and healthcare services with associated financial implications.

Using patient-level cost data, the projected annual cost of ADR admissions to the NHS in England is £2.21 billion. With 39.4% of these ADRs identified as avoidable or potentially avoidable, future efforts should be directed to reduce this burden.'[69]

Response to the PDA survey included the following comment:

> ***'Polypharmacy concerns. Drug interactions. Poor patient management of their health without guidance from a pharmacist.'***

Quantity of Medicines in Circulation

Previous exploratory pilot experience examined the potential impact of self-selection of P medicines, which indicated that sales could increase by more than 50% above baseline.[70] If the GPhC's previously proposed change was implemented and the pilots' experience replicated nationally, the number of medicines in wider circulation would increase significantly and, therefore, so would the inherent potential dangers to the patient, their immediate family and friends, or the wider population. These include:

[68] Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions - PMC
[69] Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions - PMC
[70] Self-selection of P medicines – not in the public interest! | The Pharmacists' Defence Association

- accidental ingestion (especially by children),
- uninformed or unsuitable therapeutic use,
- intentional overdose and/or self-harm, and
- these medicines going out of date, with the inherent risks of loss of potency or unwanted iatrogenic effects.

Medicines Waste

Increased quantities of medicines in wider circulation can also significantly increase the number of unused and unwanted medicines that must be discarded or destroyed. Not only is this outcome a preventable expense for patients who buy P medicines unnecessarily due to reduced professional support, but it also raises the critical wider environmental and public health issue of ongoing safe disposal of waste medicines.

Waste disposal of medicines is now a highly regulated process which requires considerable pharmacist time, administration and resources, including the provision of:[71]

- professional information and advice to patients on why and how medicines should be disposed of in an appropriate, controlled manner (both at initial supply and on subsequent request) and
- funded and managed local collection and disposal procedures and systems.

Notwithstanding, if patients are unaware of the safe disposal of unwanted medicines by community pharmacies, there is a risk of unwanted or unused medicines being discarded in water and sewage systems, adding to pollution and public health risks.[72,73]

Section 6: Safety and Other Considerations

The Increase of Crime in Community Pharmacies

Concerns about how people may obtain harmful medicines through theft are also a significant consideration, given the substantial increase in shoplifting in the retail sector.


Image generated using AI

PDA members report a significant increase in shoplifting from pharmacies, which is reinforced by recent figures from the Office for National Statistics (ONS) annual crime survey for England and Wales,[74] which shows that shoplifting has continued to increase (up 30% annually) and remains at its highest level in 20 years. Recently, it was announced that 'shoplifters [are] out of control and becoming more brazen'[75] – something that P medicines

[71] Disposal of unwanted medicines - Community Pharmacy England
[72] New study reveals pharmaceuticals are polluting England's National Parks - News and events, University of York
[73] UK rivers contain cocktail of chemicals, pharmaceuticals and stimulants | Imperial News | Imperial College London
[74] Crime in England and Wales - Office for National Statistics
[75] UK shoplifting on the rise and more brazen, new survey says - BBC News

will not be protected against with any change in current practice.

The British Retail Consortium's (BRC) crime survey of 2024[76] echoes this trend, highlighting an increase in customer theft incidents from eight million to 16.7 million.

The BRC report also highlights that:

'Theft is also linked to violence and abuse in store. One of the key triggers of violence and abuse is when colleagues challenge customers they believe to be committing theft...'

The National Pharmacy Association (NPA) recently shared a member poll with The Mail on Sunday. The poll has led to a campaign from NPA members for a crackdown on prolific shoplifters to 'End the Shoplifting Epidemic.' The poll found that nine in ten sites have suffered an increase in thefts over the past year. The Mail on Sunday article[77] states that among many incidents reported, a thief threatened to stab an employee when she tried to prevent him from stealing, and 'two thugs' cleared cosmetics from a chemist in Kent in what police called a 'bulk theft.'

Unfortunately, pharmacists and pharmacy teams have increasingly been experiencing threatening behaviour and/or violence from the public.[78] Arguably, an increased likelihood of violence and abuse towards pharmacists and pharmacy teams is likely if they were to try to stop a sale or prevent the theft of some potentially harmful P medicines.

Opportunities to obtain strong and potent medicines open to misuse now openly available on shelves would make the theft of P medicines far more likely, as they are currently mainly inaccessible to opportunistic theft. Consequently, there could also be an increase in the illegal and illicit market, increasing the risk of misuse and harm.

Response to the PDA survey included the following comment:

'Inappropriate selection and potentially unnecessary confrontation, theft, difficulty in supervising/policing.'

The Risk of P Medicines Falling into the Wrong Hands

Should P medicines be made available on open display for self-selection, there are limited opportunities for pharmacists and pharmacy staff to supervise the purchase or intervene in the product's suitability.

Risks would increase further when a medicine needed to be taken to a general retail checkout point, leaving people with the option to change their minds and abandon the medication on a shelf in another part of the pharmacy (or in a supermarket) or at the checkout, leaving an opportunity for someone else to pick it up.

[76] BRC Crime Survey Report 2024
[77] Pharmacists introduce security measures amid violent shoplifting epidemic with some enforcing a 'one in, one out' policy in a bid to curb crime spree spreading across Britain | Daily Mail Online
[78] Statement from the GPhC on ongoing violent disorder and its impact on pharmacy services | General Pharmaceutical Council

Misusing medicines that can be purchased without a prescription is a significant issue. One research paper found that around 20 per cent (one in five) of UK adults may have misused a purchased medicine.

'The most common reason for abusing an NPM [non prescribed medicine] was for sleep or relaxation purposes.' [79]

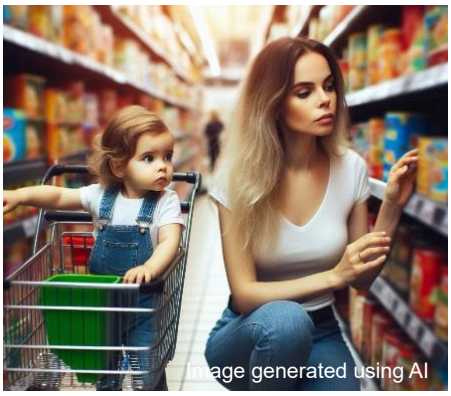
Unfortunately, even when pharmacists report potential problems with specific medicines, this is often downplayed, and there is a reluctance to take effective action.[80] Similarly, another paper reported on the misuse of prescription and OTC medicines to obtain illicit highs. It advocates:

'As more users turn from street drugs to prescription/OTC products, pharmacists must increase their vigilance when supplying medicines and be aware of medicines' potential to end up on the black market.' [81]

Pseudoephedrine and ephedrine, common decongestants found in many over-the-counter cold medications, have a legitimate therapeutic use but can also be used for illicit purposes if not adequately controlled or easier to obtain. The restrictions on sales of these medicines were introduced in April 2008 as a direct response to the risks posed by their misuse, particularly in the production of methamphetamine.[82] Authorities sought to prevent its abuse by imposing restrictions on its sale, emphasising the need for careful oversight in making certain medicines available to the public.

These restrictions highlighted the potential harm that can arise when certain medicines are too easily accessible to the public without proper controls. Similarly, the discussion surrounding the sale of P medicines revolves around the risks of such products falling into the wrong hands, leading to misuse or unintended harm. Any form of self-selection will not adequately protect the sales of these medicines, potentially leading to illicit uses and harm.

There is a real risk that a change in practice may not only encourage a different type of shoplifter to target pharmacies increasingly[83] (e.g. individuals addicted to substances), but it could also increase the risk to individual and public safety whilst putting pharmacy staff in greater personal danger if confronting such activities.



In supermarkets or larger stores, it is not uncommon to see previously selected items left by customers on any convenient shelf (but not the original stock location) or at the checkout if they change their mind about the purchase while completing their shopping. Moving to an open display for self-selection has raised the possibility of similar scenarios with P medicines in any store with multiple aisles or shelves containing a wide range of commodities and/or separate checkouts for those used for pharmacy items. A visit and evaluation of pharmacies by the PDA where a format of self-selection of P medicines was being piloted learned of just such a situation.

This scenario raises several issues, including the:

[79] Non-prescription medicine misuse, abuse and dependence: a cross-sectional survey of the UK general population
[80] Health - Pharmacist's painkiller warning
[81] Misuse of prescription and over-the-counter drugs to obtain illicit highs: how pharmacists can prevent abuse
[82] Pseudoephedrine and ephedrine: update on managing risk of misuse - GOV.UK
[83] Drugs stolen after four pharmacies raided by burglars in five nights | York Press

- safety risk to customers – especially younger children if, for example, the discarded selection is left on the confectionery shelves or children's areas,
- reduced opportunities for effective professional supervision and input,
- increased opportunities for shoplifting,
- exposure of medicines to potentially inappropriate storage conditions (e.g. freezer or heated counters) and
- professional regulatory or inspection issues whereby P medicines are located in parts of a shop, outside the pharmacy footprint registered with the GPhC.[84]

Section 7: Ethical and Professional Considerations

Insights from Online Pharmacy Growth

As technology advances, the internet is becoming an increasingly popular resource for people seeking health information and treatment. This has dramatically increased since the COVID-19 pandemic when access to in-person healthcare was restricted, and subsequently, as the NHS has struggled to recover and overcome demand increases.

With the growing desire to access healthcare online for convenience, speed of access, or to seek treatment anonymously for a condition that could be socially stigmatised, the popularity of online pharmacies has also expanded rapidly. However, the growth of this sector has also seen challenges in regulation and professional practice, which have yet to keep pace with the speed of innovation and increase in demand.

In August 2021, the Pharmaceutical Journal highlighted that since April 2019, the GPhC had taken enforcement action against over 40 pharmacies linked to their provision of online pharmacy services:[85]

'The majority of these pharmacies were working with online prescribing services that were prescribing medicines which are liable to abuse, misuse and overuse to people, on the basis of an online questionnaire'.

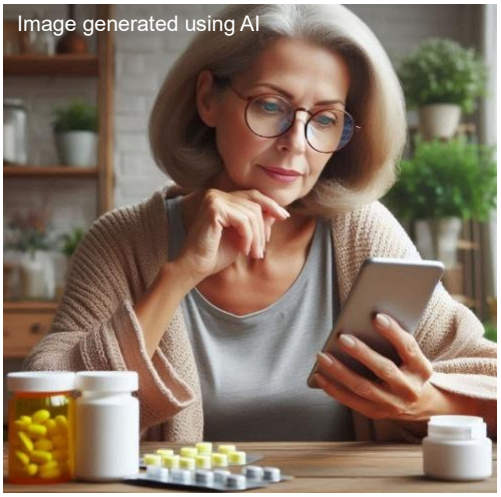


Image generated using AI

Medicines are not usual items of commerce, and therefore, placing certain products in a 'retail environment', be it physical premises or online, where a patient can select before a consultation or discussion with a healthcare professional, can present increased risk. There are significant examples of patient harm due to a lack of interaction between a patient and a prescriber.

[84] John Bell & Croyden fails inspection standard over P-meds in 'retail area'
[85] Enforcement action taken against 40 online pharmacies since April 2019, says pharmacy regulator - The Pharmaceutical Journal (pharmaceutical-journal.com)

The PDA has highlighted these concerns,[86] including the comments of a clinical expert whom the GPhC asked to consider whether online questionnaire-based (asynchronous) provision of weight loss medications, including Glucagon-like Peptide-1 Receptor Agonists, was appropriate.

The expert stated that in their opinion *'weight loss medications should not be prescribed from an online questionnaire.'*

The expert also said,*'…prescribing from a questionnaire without a face-to-face consultation is not and cannot be in a patient's best interests as the prescriber does not have a full and complete clinical picture of the patient, only self-reported information. Therefore, the prescriber cannot assess the patient clinically, assess their emotional and mental health, or have any kind of meaningful therapeutic dialogue with them.'*

There are significant lessons to be learned from the online pharmacy environment. In a similar way to asynchronous or questionnaire-based 'consultations,' P medicines being made available on open display for self-selection in a pharmacy premises limits the opportunity for consultation with a pharmacist, who is the expert in medicines, which presents genuine concerns about the increased risk of patient harm.

The challenges observed in online pharmacy services, where certain medicines require additional safeguards beyond a simple questionnaire, highlight caution in the open display of P medicines in physical settings. This resulted in the GPHC issuing Guidance for registered pharmacies providing pharmacy services at a distance, including on the Internet, in February 2025.[87]

> *'Some medicines are not suitable to be prescribed by a questionnaire model alone. Some medicines are not suitable to be supplied unless extra safeguards have been put in place to make sure they are clinically appropriate.'*[88]

The principles of safeguarding patient safety, ensuring clinical appropriateness and preventing harm apply equally to online and physical pharmacy environments. Just as online prescribing must ensure that medicines liable to misuse, those requiring monitoring, or those posing overdose risks are only supplied with appropriate checks, the open display of P medicines may inadvertently encourage misuse or inappropriate self-selection. Therefore, the GPhC must take a similar approach to the risks associated with the supply and sale of P medicines.

Professional Issues

Any changes to allow how P medicines are sold to patients may expose several professional implications, which could negatively impact patients, the public, pharmacy staff, and/or wider healthcare delivery.

Patient and Public Confusion

The GPhC stated that the prohibition of selling P medicines from open display should no longer apply within their standards. Instead, a decision on whether or not P medicines should be on self-

[86] PDA cannot support DiCE best practice guidance for online prescribing of GLP-1 receptor agonists for weight management in adults | The Pharmacists' Defence Association (the-pda.org)
[87] Online pharmacies to strengthen safeguards to prevent unsafe supply of medicines | General Pharmaceutical Council
[88] Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet

selection should be made locally by owners or superintendent pharmacists.[89] It requires owners and superintendents to fully assess their pharmacies before allowing P medicines on open display, looking at potential risks, training, and staff views.

Allowing locally defined owner/superintendent driven interpretations of open-display and self-selection of none, some, or all P medicines could create confusion for patients and the wider public because of the following:

- a blurring of current, important distinctions between available P medicines and GSL medicines (the latter not having any requirement for pharmacist supervision/intervention),
- the greater range of pack sizes for sale, from open pharmacy shelves, of certain medicines (e.g. analgesics) available in both P and GSL status products (the latter not having any requirement for pharmacist supervision/intervention),
- inconsistency about which medicines (if any) are made available for self-selection, both within a locality and more widely, due to different approaches taken by different pharmacies and
- Patients would be asked questions by pharmacy staff when purchasing some but not all items that can be self-selected from open-display shelves – something that currently does not happen.

The recent GPhC FAQs on self-selection[90] states:

> *'The Responsible Pharmacist (RP) has responsibility for all activity undertaken within a pharmacy that needs to be carried out under the supervision of a responsible pharmacist. This includes the sale of P-Medicines. The RP needs to be confident they are able to appropriately supervise sales of P-Medicines. Pharmacists have a professional duty to provide person-centred care, however if they are not satisfied that they can appropriately supervise sales of medicines, they may need to consider signposting patients to other providers.'*

However, the GPhC also states in an earlier document, focussing on monitoring the sale and supply of medicines subject to abuse or misuse[91], arguably including at least some P medicines that:

> *'Safeguards should be in place to make sure that sales and supplies of these medicines can be managed safely and appropriately, including having controls in place to stop repeat sales or to identify trends in requests.*
>
> *One example of a high-risk medicine is codeine linctus…we have taken enforcement action against 43 pharmacy premises and a pharmacy professional following intelligence-led inspections or investigations relating to unusually high sales of codeine linctus.'*

The Human Medicines Regulations 2012 (section 220) refers to sales of these medicines made by or under the supervision of a pharmacist. Although self-selection is not expressly excluded within the legislation, it is also not explicitly included. Therefore, the role of the RP is central to ensuring that the sale and supply of P medicines is conducted safely and in compliance with regulatory frameworks.

The GPhC acknowledges this responsibility in its recent FAQs on self-selection, which state that the RP must be confident in their ability to supervise sales of P medicines appropriately. Where

[89] Standards_for_registered_pharmacies_june_2018_0.pdf
[90] FAQ: self-selection and open display of Pharmacy medicines | General Pharmaceutical Council
[91] Focus on monitoring the sale and supply of medicines subject to abuse or misuse | General Pharmaceutical Council

supervision cannot be ensured to a satisfactory standard, the RP has a professional duty to prioritise patient safety, including refusing a sale or signposting the patient elsewhere.

Given these regulatory positions, the RP's authority and professional judgment must take priority in all cases. Suppose a conflict exists between self-selection policies and the RP's ability to supervise P medicine sales adequately. In that case, the RP must act in the best interests of patient safety and public health. They must ensure that sales remain within a controlled, monitored and professionally accountable framework – which may be difficult to maintain under any version of self-selection – or risk the GPhC potentially taking enforcement action against them.

Notwithstanding, in the event of a sudden change in staffing level in a pharmacy, it may not be possible for the RP to remove the sale of P medicines from open display and bring them back to a restricted area.

Balancing Commercial and Patient Safety Priorities

In a saturated market, where multiple medicines serve similar purposes, packaging becomes a key strategy for standing out and attracting attention. Therefore, it is understandable that manufacturers use colourful and eye-catching packaging effectively to make their products easily identifiable and recognised. Bright colours, bold designs and distinctive packaging can create a sense of urgency or appeal, drawing attention to a product amidst a crowded shelf.

In many cases, patients may make a quick decision based on visual cues rather than an in-depth understanding of the medicine's specific benefits, and colourful packaging can be misleading. Vibrant packaging is a psychological tool whereby specific colours evoke feelings or associations. For example, blue can be linked with trust and calm, while red may signal urgency or energy.[92] This tactic is not limited to branding and taps into emotional responses and subconscious biases, which influence buying decisions. In the case of medicines, it contributes to the perception that a product is more effective or trustworthy simply because it stands out.

In some cases, colourful packaging can deliberately differentiate a product from its competitors, often making it more visually appealing compared to generic or less vibrant alternatives. While this strategy can help drive sales, it can also raise concerns, particularly when it comes to public health. Therefore, the UK has strict guidelines for advertising and promoting medicines to the public.[93]

Most medicines have colourful and, at times, recognisable characters on their packaging. This may lead to younger children innocently picking up 'interesting or colourful' products from open-display shelves in a way that means the accompanying adult is unaware of the action, adding a further dimension of child safety to the problems associated with self-selection.

Notwithstanding, some children (especially teenagers) may look older than their actual age, making it problematic for retail outlets' staff to decide whether they are old enough to buy certain legally controlled commodities. For example, in the UK, there is a complete ban on the open display of tobacco-containing products, which must be hidden from view behind counters or in covered containers. This was implemented through the Health Act 2009 and became effective for large shops in 2012 and all other stores in 2015.[94]

[92] Packaging Colour Psychology - How It Affects Your Success | GWP Group
[93] Advertise your medicines - GOV.UK
[94] One month until the end of tobacco displays - GOV.UK

In contrast, there is no direct legal or regulatory restriction on the sale of GSL or P medicines[95], and their exposure to children. Instead, control is expected to be exercised through appropriate professional supervision or pharmacist input. This process may be most suitable for displaying such medicines on shelves protected behind the pharmacy counter or other physical barriers.

Some children (who may look like adults) might decide to try to purchase a P medicine and present at the pharmacy counter with their chosen product. This scenario raises the general problem of engaging these patients in appropriate dialogue about their perceived condition. It requires staff to gauge and/or ascertain their actual age after the self-selection process. The pharmacist, therefore, may have an even more difficult task in deciding whether it is appropriate and professionally responsible to make the sale for certain P medicines.

There is already significant evidence within some pharmacy businesses of the prerequisite to stimulating higher P medicine sales by, for example, applying promotions linked with loyalty and own-brand products.[96] Unsurprisingly, many pharmacists are concerned that a primary influence on pharmacy owner decision-making about the sales of P medicines is linked to commercial strategies.

Suspensions of P Medicine Sales

Because P medicines are not currently on open display, their sale can be temporarily or permanently suspended and immediately, with little difficulty, if the pharmacist must leave the pharmacy premises for any reason.

For example, in March 2023, the MHRA withdrew pholcodine-containing cough and cold medicines from the UK market as a precautionary measure. This decision was based on a review that found the benefits of these medicines did not outweigh the increased risk of the very rare event of anaphylaxis to neuromuscular blocking agents used in general anaesthesia.[97]

The removal of pholcodine-containing medicines from pharmacy sales due to safety concerns highlights the importance of pharmacist supervision in selling P medicines. This case demonstrates pharmacists' critical role in identifying and mitigating risks associated with medicines, ensuring that only safe and appropriate treatments remain available to the public.

The withdrawal also underscores the effectiveness of regulatory safeguards in responding to emerging safety data, reinforcing why self-selection of P medicines without pharmacist oversight could compromise patient safety by allowing potentially harmful medicines to be accessed without professional intervention.

Continued Viability of the P Medicine Category

As demonstrated by recent NHS reform announcements, P medicines are now expected to help implement a range of national care policy imperatives.[98] However, support for and development of many of these policies is predicated on the knowledge that their current supply to patients and the public is effectively supervised and supported by pharmacists rather than being provided on prescription by a prescriber.[99]

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[95] Preventing_underage_sales_acs_assured_advice.pdf
[96] Savviest Boots Advantage Card members pocket £817 in savings
[97] Pholcodine-containing cough and cold medicines: withdrawal from UK market as a precautionary measure - GOV.UK
[98] Greater use of OTC drugs could save NHS £3.1bn per year, report claims
[99] Prescribing of over the counter medicines is changing

The existing regulatory process and practice allow appropriate professional safeguards to be maintained to help ensure patients' and public safety and optimise care outcomes from the supply of P medicines. Further, they enable the provision of additional professional advice, support, or information to promote public health and pharmaceutical care.

A policy change that allows the self-selection of P medicines and its potential (and possibly unintended) consequences could undermine confidence in the P medicine status and its important, yet underutilised, role as a policy catalyst. This shift may not only slow down or require a re-evaluation of national policy implementation and patient care redesign. Still, it could also raise concerns about the medium-term viability of the current P medicine category.

The principle of POM to P switches is well-established and policy-supporting, and recent MHRA guidance has further streamlined the process. [100] If Government endorsement and regulatory approval of more reclassifications is predicated on the knowledge that the current P medicine supply is effectively supervised to 'give pharmacists the tools they need to support patients in self-care' [101], then any perceived dilution of such professional input and safeguards could undermine continued backing for this policy.

It has already been noted that when the MHRA is considering reclassification of medicine from POM to P status. A detailed assessment of the benefit against the risk profile is undertaken, which would be expected to consider any direct or indirect impact on:

- individual patients,
- public health,
- access to care, and
- access to health information by the public.

Given the RPS welcoming a suggestion for more medicine reclassification applications from POM to P, recognising that it may 'improve opportunities for self-care and enable more timely and convenient access to medicines.'[102] It is essential to note that this is set against the backdrop of the current professional standards, which state that P medicines are not accessible by self-selection.

Therefore, should any policy position change to allow self-selection of P medicines, it can significantly affect any future 'benefit to risk' assessment of reclassification applications. Equally of concern is whether it might also impinge on some existing P medicines, where the original profile of 'benefit to risk' was already finely balanced (e.g. products containing pseudoephedrine).

Certain drug manufacturers position themselves as 'switching machine[s]'[103] focusing on reclassifying medicines to make them available without a prescription and bringing OTC medicines to market that are easy for pharmacists and their teams to recommend with just a few supervisory questions creates dangerous paths linked to commercial interest over patient safety.

Whilst a change to self-selection might make the prospect of POM to P switches more economically attractive for drug manufacturers due to its potential to increase sales and despite describing them to pharmacy owners as 'little profit rocket'[104] and routes to more profit, this impetus might be more than offset by increasing professional, regulatory and political concerns.

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[100] Final_reclassification_guidance_180324.pdf
[101] New opportunities to reclassify medicines: what you need to know – Department of Health and Social Care Media Centre
[102] RPS supports DH move for more POM to P reclassifications
[103] 'Switching machine': Maxwellia 'poised and ready' for more POM to P switches
[104] OTCs could be 'profit rockets' for pharmacies, says Maxwellia boss

Section 8: Stakeholder Perspectives and Survey Insights

The PDA's Current Position on Policy Development and Discussions

The PDA has raised serious concerns regarding a paper by the RPS on the 'Open Sale of P Medicines in Community Pharmacy.'[105] The RPS's Cross Board discussed the topic during an open business meeting held on 18 June 2024, with no prior warning to their membership, the wider profession or the pharmacy sector.

The paper considered significant changes regarding decisions about the self-selection of P medicines, expressing concern that these could compromise patient safety. For example, pharmacists could be pressured into allowing the sale of medicines without proper clinical assessment.

The RPS paper also argued that pharmacy owners and superintendents could make local decisions. However, any policy allowing local decisions to be made by pharmacy owners without the oversight of a pharmacist who may be working in the affected pharmacy could enable unsafe practices to flourish.

Such a policy position ignores that P medicines require careful clinical judgment, which commercial pressures could compromise. The PDA has observed this phenomenon several times, most recently involving PF.[106]

The paper also compared the sale of P medicines in physical pharmacies to online transactions, where medicines are selected without professional assessment. Allowing patients to choose medicines without the professional input of a pharmacist, akin to online transactions[107], could lead to serious risks, including misuse or dangerous interactions with other medications.

The PDA maintains that the RPS's historical position is the correct and safest approach and that the RPS should engage with the wider pharmacy profession and community pharmacy sector before reconsidering this policy position. Since the RPS issued its call for evidence on the self-selection of P medicines,[108] there has been a concerning lack of follow-up action. No further papers or updates have been published by the RPS, leaving the issue unresolved and the sector without clear guidance or direction.

Moreover, there has been no meaningful dialogue or collaboration with other pharmacy organisations to discuss the implications of the proposed policy changes – as proposed by the SPG, during deliberations on supervision in community pharmacy. This lack of progress has frustrated many within the profession, particularly those in community pharmacies. The absence of a comprehensive discussion or transparent process undermines the credibility of the RPS's approach. It raises questions about the extent to which pharmacists' views and concerns have been sought and genuinely considered.

Following the RPS's meeting in June 2024, the PDA has raised concerns about the GPhC's shift in terminology.[109] Specifically, the term 'facilitated self-selection', introduced by the GPhC in their

[105] PDA evaluates the renewed debate on the self-selection from open displays of Pharmacy (P) medicines in community pharmacies | The Pharmacists' Defence Association
[106] 'Immense pressure': Managers impose Pharmacy First targets
[107] PDA: GPhC consultation 'watering down' online pharmacy guidance
[108] Call for evidence
[109] Statement on self-selection of pharmacy medicines | General Pharmaceutical Council

FAQs,[110] has caused confusion and considerable alarm within the profession, as expressed in the PDA's survey results.

The PDA is concerned that this new approach diminishes the essential clinical oversight in P medicines' safe supply and sale. The concept introduced by the GPhC suggests that patients could make their own choices about P medicines. At the same time, a pharmacist merely facilitates the transaction, undermining the pharmacist's clinical responsibility and placing the patient at risk of inappropriate medicine use. The role of a pharmacist is not simply to facilitate transactions but to ensure the safe and appropriate use of medicines based on their professional expertise. Further, this ambiguity risks undermining patients' trust in pharmacists as healthcare professionals responsible for their safety and well-being.

The PDA believes that for any policy changes to be made, there must be a robust, open conversation that includes the voices of all relevant stakeholders, including community pharmacists, professional associations and regulatory bodies. The lack of meaningful engagement and the failure to publish further information since the call for evidence from the RPS signals a worrying disregard for the professional consensus needed to ensure patient safety and uphold the standards of pharmacy practice. Without such a conversation, any decisions on this issue will remain inadequate and potentially harmful to the profession and the public.

Response to the recent PDA survey included the following comment:

> ***'Consultations are often a formality after a decision has already been made. We must protest strongly about this to prevent it from happening. We need to always keep pharmacy as professional as possible and not allow access to P medicines without some sort of intervention/supervision.'***

A Temperature Check of PDA Members and Other Pharmacists

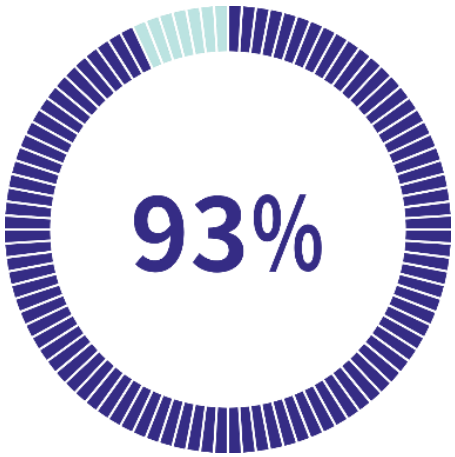
The PDA survey results provide a snapshot of pharmacists' perspectives on the self-selection of P medicines, offering valuable insights into their opinions, concerns, and the potential impact on patient safety and professional practice.

The self-selection of P medicines is of great concern to pharmacists in patient-facing roles. These pharmacists have first-hand experience with the complex process of patient consultations, especially in the busy setting of community pharmacies.

[110] FAQ: self-selection and open display of Pharmacy medicines | General Pharmaceutical Council

The PDA recently invited its members to complete a short snapshot survey focussing on the self-selection of P medicines.

The results reveal that around 93% of all respondents are **not** in favour of any change to allow the self-selection of P medicines. Over 1,300 pharmacists responded.



The three top reasons for not supporting a change were:

- It would be difficult to supervise - 94%*
- Concern that patients may select medicines inappropriately - 96%*
- Risk of argument/violence if a patient is refused a sale of a self-selected medicine - 87%*

*more than one option could be selected

General comments from PDA members responding to the July 2024 survey

'Patients can rely on expert advice from pharmacies on P medicines on when to use and when not to use and when to be referred to primary care. This ensures that more sinister symptoms are picked up in a timely way and more serious symptoms are investigated at the earliest point. This leads to safer and effective use as well as investigation and subsequent diagnosis of more serious conditions without undue delay.'

'There is a reason P meds exist, as some of the medications can be abused. And this will be very difficult to take the medicines off the patient's hand if they want it. This will create a lot of friction and tension between pharmacy professionals and the public, as well as even violent behaviour.'

> ***'The current legislation provides sufficient protection for patients and pharmacists, while also allowing good access to medications. It also provides an important distinction between retail outlets and pharmacists. Allowing self-selection of P medications would not only risk jeopardising patient safety but also risk lowering the status of community pharmacies.'***

> ***'Patients will not understand the law that we can still refuse the sale. Will be harder for the responsible pharmacist to monitor. Lately some counter assistant training is below par, and I have concerns they will permit the sale without referring to the pharmacist. It will be impossible to monitor while we are doing all our "extra" services e.g. vaccination and Pharmacy First and are not in ear shot.'***

PDA members who are in favour of a change to enable P medicines to be available for self-selection (5% of respondents) were asked about their reasons for this response:

- It will save staff time, and we will still be here to answer questions – 64%*
- Patients have an opportunity to read the box and ask questions if they need our assistance – 85%*
- May encourage embarrassed patients to choose products they want/need without having to ask – 64%*

*more than one option could be selected

> ***'It is imperative that the GPhC urgently undertakes a full consultation with the profession on this patient safety issue and provides evidence and for the basis on which it believes that it is safe and appropriate to allow for the self-selection of medicines.'***

77% of PDA members responding to the survey think decisions about making P medicines available on open display should be made following consultation with the wider profession.

> ***'It is the wider profession that has a greater collective knowledge and understanding of real life working daily. It is arrogant of the professional body to think that they know best.'***

Section 9: Recommendations

The PDA's policy recommendations and practical implementation measures aim to balance accessibility with safety, ensuring that P medicines remain under appropriate professional supervision. Regulatory bodies, professional organisations, pharmacy organisations, and pharmacists must work together to uphold patient safety while enhancing pharmacists' role in responsible medicine supply.

Recommendations for Regulators

Regulators must take decisive action to ensure P medicines' safe management, sale, and supply. The GPhC and MHRA can uphold the integrity of pharmacy practice, enhance patient safety, and ensure that the management, sale, and supply of P medicines remain firmly under the professional oversight of pharmacists.

Recommendations for the GPhC

1. Reinforce pharmacist supervision in P medicine transactions to prevent unsafe practices.
2. Provide clear guidance to pharmacy owners, explicitly prohibiting open display.
3. Implement mandatory training for pharmacists and pharmacy teams on P medicine risks and safe practices.
4. Strengthen compliance monitoring through regular inspections, mystery shopper exercises, and audits.
5. Conduct thorough and transparent consultations before any policy shifts relating to P medicine sales.
6. Establish a framework to prevent financial incentives from compromising professional judgment.
7. Explore mandatory in-store security or obscuring measures for medicines at high risk of misuse or theft.

Recommendations for the MHRA

8. Ensure stricter oversight when reclassifying medicines from POM to P status, requiring robust safety evidence and pharmacist oversight.
9. Enhance reporting and monitoring of side effects and ADRs related to P medicines.
10. Evaluate high-risk P medicines for potential tighter restrictions or additional pharmacist screening.

Joint Actions and Public Engagement

11. Develop public awareness campaigns highlighting pharmacists' role in medicine selection and patient safety.
12. Collaborate closely with professional pharmacy bodies to refine policies and align regulations with real-world practice.

Recommendations for Professional Bodies and Pharmacy Organisations

Advocacy and Policy Influence

1. Actively lobby against regulatory changes that could undermine the pharmacist's role in medicine safety.
2. Ensure policy shifts prioritise patient well-being and uphold professional standards.
3. Monitor and challenge policy shifts, holding regulators to account.
4. Advocate for evidence-based policies that keep patient safety at the core of pharmacy regulation.

Development of Best Practice Standards

5. Create and implement best practice guidelines for safe selling and supplying P medicines.
6. Provide clear professional standards to help pharmacists balance accessibility with safety.

Public Awareness and Education

7. Launch targeted campaigns to educate patients on the risks of P medicines.
8. Reinforce the benefits of a pharmacist-led approach to medicine safety.

Ongoing Professional Development

9. Establish continuous professional development programs for pharmacists and pharmacy teams.
10. Update training regularly to address evolving challenges in medicine supply and demand.

Implementation guidelines for pharmacists and pharmacies

Strengthening the Pharmacist's Role in P Medicine sales

1. Ensure pharmacists remain central to upholding patient safety while allowing safe access to P medicines.

Effective Patient Communication

2. Provide concise verbal and written guidance on medicine use, contraindications, and interactions.
3. Use private consultations for sensitive discussions, encouraging professional advice before purchase.

Ongoing Training and Pharmacy Staff Development

4. Prioritise continuous training incorporating real-world case studies and scenario-based learning.
5. Ensure all pharmacy staff understand the distinction between GSL and P medicines and the necessity of pharmacist oversight.

Security and Risk Mitigation

6. Restrict access to areas where P medicines are kept, preventing theft and unauthorised access.

7. Implement electronic monitoring and controlled access systems to track high-risk medicine transactions.
8. Introduce theft prevention measures, such as enhanced surveillance and purchase limits.

Digital Integration for Safety

9. Utilise patient records to monitor P medicine sales and identify usage patterns.
10. Integrate P medicine purchases into NHS electronic health records where feasible for better oversight and follow-up care.

Patient Education on Responsible Self-Care

11. Apply the 'Make Every Contact Count' [111] approach to educate patients on responsible medicine use.
12. Reinforce the role of pharmacists as the experts in medicine and patient care.

[111] Making Every Contact Count (MECC): Consensus statement

Conclusion

The issue of whether Pharmacy (P) medicines should be available for self-selection in community pharmacies raises profound questions about patient safety, public health, and the evolving role of pharmacists within the healthcare system. This report draws upon a wealth of evidence, historical precedents and professional insights to establish a clear position. **Any changes to the selection process of P medicines pose significant risks that outweigh potential benefits, making preserving the current policy and regulatory framework imperative.**

At the core of this debate is the pharmacist's role as a guardian of patient safety. Pharmacists are uniquely qualified to assess the suitability of medicines, considering factors such as medical history, drug interactions and potential adverse reactions. Their expertise and direct engagement with patients ensure that P medicines are used appropriately, safely and effectively. **This report strongly reinforces the view that self-selection of P medicines would significantly undermine pharmacist oversight, increasing risks of inappropriate medicine use, ADRs, potential for misuse and potentially severe health consequences.**

The regulatory and legal framework, including the Medicines Act 1968 and subsequent amendments, provides a robust structure that prioritises patient safety while allowing for the flexible use of P medicines under pharmacist supervision. These regulations have evolved in response to evidence and societal needs, ensuring that medicines with more significant risks remain accessible only through professional oversight. Historical cases, such as *Pharmaceutical Society of Great Britain v Boots Cash Chemists (Southern) Ltd (1951)*, further highlight the enduring importance of supervision in safeguarding public health.

Expanding access to medicines goes beyond convenience and must not come at the expense of safety. Past experiences, such as reclassifying children's cough syrups and limiting the number of pseudoephedrine tablets sold simultaneously, demonstrate the risks of relaxing regulations without sufficient professional safeguards. The pharmacist's role in ensuring P medicines' safe and effective use cannot be compromised, and any regulatory changes must prioritise patient welfare above commercial interests, driven by models of convenience.

Furthermore, evidence from recent PDA surveys shows overwhelming opposition among pharmacists to self-selection, citing increased risks of harm, diminished opportunities for professional consultation and challenges in balancing safety with commercial pressures. The economic and public health dimensions of this issue are also critical. Allowing self-selection could not only lead to increased rates of adverse drug reactions, misuse and waste but also place additional strain on an already burdened NHS.

The financial implications of inappropriate medicine use and the potential for increased emergency admissions underscore the importance of maintaining the pharmacist's role in supervising P medicines. Aligning this approach with broader healthcare initiatives, such as the PF programmes and the NHS's emphasis on integrated care, reinforces the need for pharmacist-led intervention.

Ethically, self-selection undermines the principles of informed consent and shared

decision-making fundamental to modern healthcare. Patients rely on pharmacists to provide tailored advice, clarify complex medical information and guide them toward safe and effective treatment**. In a self-selection model, critical health interactions may be diminished, compromising patient outcomes and the public's trust in pharmacy as a healthcare profession.**

As healthcare evolves, embracing innovations that enhance access and empower patients while maintaining robust safeguards is essential. A middle ground, such as facilitated self-selection with mandatory pharmacist engagement, may warrant conceptual exploration, but it must be recognised that it represents a diminution in patient safety. Any changes must be carefully evaluated through evidence-based consultation, ensuring they do not compromise patient safety or dilute professional standards. **Therefore, the PDA urges all stakeholders, including regulatory bodies, policymakers, and pharmacy leaders, to engage in meaningful consultation before considering any changes to the current framework**. A collaborative, evidence-based approach ensures that patient and public safety remains at the heart of all medicine supply decisions.

The PDA reaffirms its position that P medicines should remain under restricted access and under pharmacist supervision. This approach reflects the best principles of healthcare delivery: prioritising safety, enabling informed decision-making, and ensuring equitable access to expert advice.

Stakeholders must resist changes prioritising convenience or commercial gain over these fundamental values. By maintaining the current policy and regulatory framework and strengthening the pharmacist's role, we can uphold the highest standards of patient care, public health, and professional integrity in pharmacy practice.

About the PDA

The Pharmacists' Defence Association (PDA) is a pharmacist membership and leadership organisation that aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. The PDA is run by pharmacists it has over 39,000 members.

The primary objectives of the PDA are:

- to advance and protect good health by promoting proper standards and best practice in pharmacy
- to support the safe and effective practice of pharmacists at every stage of their education and career
- to provide leadership and representation for employed and self-employed pharmacists, and those in training
- to protect, defend, lobby for and support the interests and reputations of pharmacists
- to work with and support local, national and international organisations with similar objectives
- to facilitate professional indemnity insurance, arrange benefits and undertake any other activities that can support our wider objectives

Contact us directly:

For any further enquiries relating to this report or any other policy positions, get in touch with us via email, using policy@the-pda.org

For any media or press-related enquiries, get in touch with us via email, using press@the-pda.org

Appendices

Glossary of Terms and Acronyms

Acronym/Term	Detail
ADR	Adverse Drug Reaction
BRC	British Retail Consortium
CPhO	Chief Pharmaceutical Officers
FAQs	Frequently Asked Questions
GP	General Practitioner
GPhC	General Pharmaceutical Council
GSL	General Sales List (medicine)
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health System
NPA	National Pharmacy Association
ONS	Office for National Statistics
P medicines	Pharmacy Medicines
PDA	Pharmacists' Defence Association
POM	Prescription Only Medicine
RP	Responsible Pharmacist
RPS	Royal Pharmaceutical Society
RPSGB	Royal Pharmaceutical Society of Great Britain (former Pharmacy Regulator)