ROYAL PHARMACEUTICAL SOCIETY

Private (non-NHS) prescribing: call for evidence document

Royal Pharmaceutical Society response

About you

In what capacity are you responding to this survey?

- On behalf of an organisation
- As a healthcare professional sharing my personal views and experiences
- As a member of the public sharing my personal views and experiences

Questions for organisations

What is the name of your organisation? (Optional)

Royal Pharmaceutical Society

Questions for both organisations and healthcare professionals

Which of these prescribing or dispensing services do you provide? Select all that apply.

- In person
- Online
- Telephone
- Other, please specify
- None of the above

Do you provide NHS or private services?

- NHS only
- Private only
- Both NHS and private
- Not applicable

Where do you work? Select all that apply.

If you offer international services or work internationally, please select 'other' and provide details.

- England
- Northern Ireland

- Scotland
- Wales
- Other, please specify
- Prefer not to say

Section 1: oversight and regulation

This section of the call for evidence is focused on the effectiveness of existing mechanisms to oversee and regulate private prescribing.

To what extent do you agree or disagree that existing mechanisms enable the effective oversight and regulation (including enforcement) of UK registered private prescribers? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

To what extent do you agree or disagree that existing mechanisms enable the effective oversight and regulation (including enforcement) of EEA registered prescribers (with medicines dispensed in the UK)? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

To what extent do you agree or disagree that existing mechanisms enable the effective oversight and regulation (including enforcement) of medicines supplied under private PGDs? (Optional)

- **Strongly agree**

- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

What are the strengths of the current regulatory regime for medicines accessed through private providers? (Optional, maximum 500 words)

The UK has a multi-layered framework that combines product regulation (MHRA), professional regulation (GPhC, GMC, PSNI and other professional bodies) and provider regulation (CQC/HIS/HIW/RQIA). This structure offers clear responsibilities and enforcement levers across the medicine's lifecycle and care settings. Recent strengthening of safeguards for distance-selling pharmacies has clarified expectations for high-risk medicines and placed greater emphasis on verification beyond questionnaires. Cross-professional principles for remote consultations and prescribing set an expectation that assessment quality, documentation and follow-up match in-person care. The legal framework for patient group directions (PGDs) remains well-defined, supporting protocol-driven, population-level supply when governance is robust. Taken together, these elements provide a coherent basis for safe access via private routes when they are applied consistently and enforced proportionately.

The existing mechanisms work in the majority of cases and if regulations are tightened this could have unintended consequences, for example, it could make it more difficult for people to access travel vaccinations.

Patients can choose to access medicines without it being part of their shared care record. This provides reassurance in some cases that nobody else will know what medicines they are taking, for example medicines that may have stigma attached to them. In addition, some medicines are unavailable via the NHS, or only available if a person meets certain criteria, and an individual may be content to pay privately to obtain that medicine, for example weight loss medicines, thereby reducing the burden on the NHS. And sometimes there may be a delay to accessing medicine via the NHS route so an individual will decide to access it privately, for example, medicines to treat ADHD or cancer. Some people are also time poor, so being able to more easily access a medicine privately can help them. Being able to access medicines privately also enables an individual to take control of their health.

EEA prescribers sit outside of UK regulations and do not have to comply with the practice standards of a UK regulatory body. EEA-registered prescribers may not be subject to the same standards and expectations as either NHS or UK-registered private

prescribers and may be employed by a UK business or overseas online provider that is registered by the relevant regulatory body.

What are the limitations of the current regulatory regime for medicines accessed through private providers? (Optional, maximum 500 words)

Gaps remain in cross-border contexts: EEA-registered prescribers who generate prescriptions dispensed in the UK largely sit outside UK professional standards and appraisal systems, complicating quality improvement and sanctions. Information-sharing between independent online services and NHS care is inconsistent, which weakens medicines reconciliation and ongoing monitoring. Digital enforcement can be slow to keep pace with rapid re-branding or domain changes. In private PGD settings, governance is variable and can drift towards individual diagnosis rather than protocolised supply. Historic inspection findings on independent online care illustrate that, without strong governance, services can deviate from safe practice; progress has been made, but variation persists. The continued presence of illicit online supply also risks confusing patients about legitimate private routes.

As clinicians we would like to see all of the medicines a person is taking, or has been prescribed, in one place. However, from a patient perspective, they may wish to have certain medicines prescribed privately so that they are not part of the shared record, particularly where there is stigma attached to taking a certain type of medicine, for example mental health medicines.

Some individuals may access information online and make a decision that they require a certain medicine which they are unable to obtain on the NHS due to certain criteria being in place. They therefore obtain the medicine privately and there is the risk that it may not be best suited to them.

There are instances when a person goes to a private prescriber, but because the private prescriber does not have access to all of the information about the patient, the patient is then referred back into the NHS for an assessment and prescription. NHS prescribers could be receiving additional workload when private prescribers write to either inform them of medicines they have prescribed or ask that patient records are checked to ensure suitability. There is an issue not just of workload but of clinical responsibility then added to that. There is a need to keep workload and responsibility entirely with the private prescriber and ensure that systems are better set up to share information.

As data around private prescribing is not shared and seems difficult to obtain, then it sometimes doesn't feel like safe practice. However, often the prescriber is also a clinician that works for the NHS and so their practice will be guided by the same principles, and they are not suddenly going to practice in an unsafe manner.

How could the current regulatory regime for medicines accessed through private providers be strengthened? (Optional, maximum 500 words)

RPS recommends:

1. Interoperable identity and activity flags linking professionals, corporate entities and platforms to reduce regulatory arbitrage.
2. A minimum clinical-assessment standard for prescription-only medicines in private/online models, explicitly prohibiting questionnaire-only pathways for higher-risk conditions/classes.
3. Clear corporate-level duties for online providers (alongside individual professional accountability), aligned with platform-level enforcement for illegal promotion.
4. A private-PGD minimum governance standard: named clinical lead, periodic audit, incident review and red-flag escalation.
5. Consent-based, bidirectional information-sharing with the core NHS record (or a robust, auditable reconciliation alternative).
6. A proportionate outcomes/harms surveillance mechanism for private routes, including EEA-origin prescriptions dispensed in the UK.

There needs to be better sharing of data between private providers and the NHS (and vice versa) to enable all the information about the medicines a patient is taking, to be seen and available in one place. This will improve patient safety and continuity of care. There needs to be transparency at both an individual patient level as well as a population health level so there is a better understanding of healthcare and medicines that are being prescribed across the system.

Online private providers are becoming more commonplace and additional regulatory regimes may be needed for these providers. There particularly needs to be more consistency around the provision of online services, including prescribing.

There is some confusion as to how private providers are regulated, who regulates each service, and who has governance responsibilities in terms of the clinical appropriateness of the medicines. This should be made clearer.

If you are aware of any data captured on medicines accessed through private providers, please provide details on the source of the data and how it is currently used. (Optional, maximum 500 words)

Available sources include regulator guidance and communications, inspection / enforcement outputs for independent online providers, patient-safety investigations focused on remote care risks and information-sharing, and criminal enforcement

activity against illicit online supply. While useful, these sources do not constitute a comprehensive outcomes dataset across private routes; linkage to NHS incidents, admissions and mortality is limited.

In NHS Lanarkshire they gathered data on the number of Mounjaro private prescriptions that were processed through their hubs, to estimate the associated workload for the primary care team. They accounted for approximately 20-25% of all correspondence.

To what extent do you agree or disagree that this data is sufficient to appropriately monitor this activity? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**
- **Not applicable**

Private prescribing of medicines may have an impact on medicines shortages at a local and / or national level. As the data around private prescribing does not appear to be readily available it is difficult to assess this impact on the medicines supply chain.

There is little to no data sharing between private providers and the NHS so data on private prescribing is difficult to obtain. There is also little data on incidents following the private prescribing of medicines.

To what extent do you agree or disagree that medicines advertising in the UK is effectively regulated? (Optional). Please consider both digital advertising (for example, websites and social media) and traditional advertising (for example, leaflets and print advertisements).

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

The legislative framework for tackling illegal and harmful online content has strengthened, but practical, cross-border enforcement against dynamic promotion of prescription-only medicines remains challenging and requires sustained, coordinated action

We believe that medicines advertising is generally effectively regulated, however it is incredibly challenging to keep abreast of all the modes of advertising, especially online weight loss clinics. There seems to be a level of inconsistency on what is allowed to be advertised in terms of online services, including prescribing of individual medicines. Social media platforms seem to be difficult to regulate.

Please share any additional evidence you would like to contribute regarding the effectiveness of existing mechanisms to oversee and regulate private prescribing. (Optional, maximum 750 words)

Recent uplifted safeguards for distance-selling pharmacies have tightened governance around high-risk medicines and emphasised independent verification. Professional principles for remote consultations and prescribing reaffirm that remote care must meet the same standard as in-person care, including identity checks, adequate history and examination where appropriate, clear documentation and safety-netting. Ongoing patient-safety investigation work highlights gaps in interoperability and data-sharing between independent online services and NHS care. Earlier inspection evidence demonstrates how weak governance can lead to unsafe practice, underlining the need for corporate accountability as well as individual professional duties. Finally, continued enforcement activity against illicit online markets shows the need for platform-level and multi-agency action to reduce patient exposure.

Section 2: patient safety and access to medicines

This section of the call for evidence seeks to understand the impact of private prescribing on patient safety and access to medicines.

What do you understand to be the main reasons for patients to access medicines from private providers? (Optional, maximum 500 words)

Patients are motivated by timeliness, convenience (out-of-hours and remote options), privacy and targeted access to therapies perceived as difficult to obtain via the NHS. Digital channels can reduce travel and time costs and broaden choice, especially for lower-acuity presentations. However, reliance on limited clinical information increases the risk of incomplete medicines reconciliation and suboptimal monitoring unless mitigated.

In the case of gender incongruence patients access medication from private prescribers due to long waiting times for care on the NHS. Private providers may also prescribe in

situations where the NHS would not. Diagnosis guidelines may be different and the medications and doses available may also be less restricted.

In the case of ADHD clinics, often patients access private providers for faster diagnosis and treatment as the NHS waiting lists are so long. There is anecdotal evidence that once diagnosed and treated initially, these patients then get faster access to NHS clinics for medicines titration as they already have a diagnosis and only require treatment review and titration. They effectively "jump the queue" thereby creating greater health inequality and access.

In terms of other medicines, patients may access them privately as they do not reach the NHS criteria to be prescribed the medicine, they may be time poor and accessing a medicine privately is quicker and more convenient or the medicine may not be available via the NHS, such as travel vaccinations.

What do you understand to be the main reasons for patients to access medicines from healthcare professionals under private PGDs? (Optional, maximum 500 words)

Private PGDs can provide rapid, protocol-driven access for defined cohorts (for example, vaccinations and travel health) without a prescriber consultation, where eligibility criteria are met and governance is strong. Their value is speed and consistency. Risks arise if PGDs are stretched towards individual diagnosis or used without adequate audit, clinical leadership or escalation routes, contrary to national guidance that frames PGDs as population-level mechanisms.

Convenience e.g. travel vaccines. These may not be available on NHS services therefore can only be accessed privately.

To what extent do you agree or disagree that patients can safely access medicines from UK private providers? This includes access under private PGDs. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

We disagree that is 100% safe. Private providers do not have access to the patient record and rely on the patient providing a complete and accurate history of medical conditions and medication. Often private providers contact NHS services asking them

to “check if their patient is suitable” which is neither safe nor appropriate. Who then has overall responsibility for the care of the patient?

Also, private prescribing allows individuals to play the system as there is more flexibility and information on what is prescribed is not shared on a patient record. This could mean some patients get several doses of a medicine.

To what extent do you agree or disagree that patients can safely access medicines from EEA providers? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don’t know**

There are significant concerns around patients accessing medicines via EEA prescribers as they sit outside of UK regulations. There has been a suggestion to ban EEA prescriptions being dispensed, although we are aware this would cause significant cross border issues. However, these could be overcome by putting special arrangements with Ireland in place.

What are the risks of patients accessing medicines through private providers? This includes access through online platforms. (Optional, maximum 500 words)

Key risks include questionnaire-only pathways for prescription-only medicines; weak identity/age verification; poor information-sharing with NHS services (impairing monitoring and follow-up); variable control of high-risk and controlled drugs; and exposure to illicit online suppliers masquerading as legitimate providers. Cross-border prescribing complicates verification and accountability.

- Variation in diagnosis criteria and treatment guidelines followed
- Variation in safety monitoring e.g. monitoring for side effects
- Variation in follow up
- Discontinuation of care or treatment interruption if patient can no longer afford to pay for care

What are the benefits of patients accessing medicines through private providers? This includes access through online platforms. (Optional, maximum 500 words)

When well governed, private routes can deliver faster initiation, convenience and wider channel choice. Properly implemented PGDs can streamline care for clearly defined scenarios and reduce bottlenecks, provided escalation pathways and audit are in place.

- Patients with conditions which have long waiting times for care can access treatment more quickly.
- Patients who wish to access medication not available on the NHS can access these medications.
- Patients who do not meet strict NHS criteria for a particular medicine can access it and benefit from this
- Patients who wish to have anonymity around a particular medicine can do this
- For some patients this is in fact a very positive experience if they engage with a reputable private provider. Many patients may find private care a very good option to access the care they needed while on NHS waiting lists.

How can the risks to patients from accessing medicines through private providers be mitigated? (Optional, maximum 500 words)

RPS recommends: prohibiting questionnaire-only prescribing for higher-risk indications/classes; consent-based access to the core NHS record (or a robust, auditable reconciliation alternative) before initiation/renewal; strong identity and age verification; routine GP notification (with recorded consent) and explicit follow-up/stop criteria; targeted audit for high-risk classes and systematic incident reporting; and a private-PGD minimum governance standard (named clinical lead, audit cadence, and red-flag escalation).

All private providers are currently regulated via CQC in England, HIW in Wales and HIS in Scotland. There might be a way of assessing private providers and making this assessment available to the public in an easy-to-understand format, so that it is clear which private providers have been assessed and what standards they are working to.

To what extent do you agree or disagree that sufficient safeguards are in place to prevent harm caused by medicines accessed through private providers? (Optional). Please consider medicines accessed for their licensed indication (what they have been approved to treat), medicines accessed off-label (prescribed in a different way than that stated in its licence), controlled drugs (medicines that are closely regulated due to their potential to be abused or cause addiction) and medicines accessed that are not authorised for use in the UK.

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**

- **Disagree**
- **Strongly disagree**
- **Don’t know**

In terms of private prescribing or private PGDs, very little is known around incidents or near misses as this data is not collected.

In Scotland, in 2006, a circular from SG was distributed around tighter controls for private CD prescribing, using controlled stationary (PPCD1) and an obligation on Health Boards to authenticate information, approve applications, register private prescribers with the Board, administer the process of ordering and obtaining a prescription pad from NHS NSS, deal with any reported loss or theft of stationary etc. The advice was that Boards would invoice the private prescriber for this cost. However, since 2006 there has been a large increase in private provision, particularly use of CDs in private ADHD clinics, resulting in a large increase in workload administratively and around the governance.

To what extent do you agree or disagree that appropriate safeguards are in place to protect patients against counterfeit (fake) medicines? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don’t know**

How easy or difficult is it for dispensers (pharmacists) and other healthcare professionals to verify the authenticity of prescriptions from UK private prescribers? (Optional)

- **Very easy**
- **Easy**
- **Neither easy nor difficult**
- **Difficult**
- **Very difficult**
- **Don’t know**

It is fairly difficult unless the prescriber is already known to the pharmacist. It is relatively easy to check the registration of the doctor or other prescriber on the various regulators' registers.

It is more difficult to verify that the prescription genuinely comes from that prescriber unless the pharmacist is already familiar with the doctor's signature. This would involve confirming details directly with the prescriber or clinic. The advice in the MEP 3.3.4 Forged prescription is to *Use contact details for the prescriber that are obtained from a source other than the suspicious prescription (e.g. directory enquiries).*

How easy or difficult is it for dispensers (pharmacists) and other healthcare professionals to verify the authenticity of prescriptions from EEA prescribers? (Optional)

- **Very easy**
- **Easy**
- **Neither easy nor difficult**
- **Difficult**
- **Very difficult**
- **Don't know**

Speaking to our members it is more difficult to undertake due diligence when a prescription is written by an EEA prescriber.

This is more difficult because it is more challenging to confirm the registration status of the prescribers. The GMC website does have links to the website for the equivalent registration bodies in EEA member states. However, members report difficulties with certain countries because

- Some of the websites are difficult to navigate and members are not familiar with using these sites
- There is a language barrier making it more difficult to find and understand the information
- Some member report being unable to find an online register for some countries

At RPS, we get enquiries about the requirements for electronic signatures for electronic prescriptions from EEA countries (regulation 219A) and advanced electronic signatures for UK prescriptions (regulation 219). Members are asking if the prescription they have been sent meets the legal requirements. The definitions of an advanced electronic signature and electronic signatures are not easy to find in the legislation.

What are the risks associated with prescriptions received electronically from private providers, compared to on paper? (Optional, maximum 500 words)

Secure, standards-based e-prescribing with identity assurance can reduce transcription errors and improve auditability. However, ad-hoc electronic formats (e.g., emailed PDFs) may obscure prescriber authenticity, especially cross-border. Paper prescriptions allow traditional checks (e.g., signatures) but are forgery-prone and lack structured data. A secure, standards-based electronic approach for private routes, with identity assurance, is preferable.

An electronic prescription has to be marked as dispensed so it cannot be dispensed more than once. However, there are issues around invalid electronic signatures. When paper prescriptions are presented there have been incidences where a patient has tried to change the quantity on the prescription, this cannot happen if the prescription is sent electronically.

In your experience, what medicines are patients seeking to access through alternative legal routes (non-NHS), and why? (Optional, maximum 500 words)

Demand is frequently reported for weight-management agents, dermatology treatments, travel health and sexual health medicines, and some ADHD/psychotropic therapies which often driven by convenience, privacy, or perceived NHS access thresholds. These areas warrant enhanced verification and monitoring.

- Weight loss medicines as they may not meet the current NHS criteria
- Medicines to treat mental health conditions as they may not want others to know they need these medicines
- Medicines for conditions where there is a long waiting list to be seen

In your experience, what is the impact on patient safety of medicines supplied under private PGDs? (Optional, maximum 500 words)

When used as intended PGDs can be safe and efficient such protocolised supply for defined cohorts, delivered by trained staff under audit and with clear escalation. Safety concerns arise when eligibility checks are superficial, escalation is unclear or PGDs are used as a substitute for individual clinical assessment.

The use of private PGDs support pharmacies to provide effective services. This question seems to suggest there is an issue with private PGDs and if that is the case, this should be made clear.

It would be useful to have a list of the companies that develop and sell the private PGDs and that these are in some way quality assured. In particular, there needs to be assurance that the private PGDs are following the most recent NICE guidelines.

Guidance on governance and accountability in these circumstances should be developed.

To what extent do you agree or disagree that private prescribing improves medicines access for people with protected characteristics within the meaning of the Equality Act 2010? (Optional). The protected characteristics under the act are age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

In the case of gender reassignment private prescribing does improve medication access for those who can afford it as waiting times for NHS care are so long.

For certain areas we believe private prescribing can widen health inequalities, in particular, access to medicines for ADHD. This widens health inequalities for those from more deprived backgrounds.

Please describe any benefits or barriers related to inequalities you've observed that have been caused by private prescribing. (Optional, maximum 500 words)

Private routes may benefit people with mobility or time constraints but may disadvantage the digitally excluded or those requiring safeguarding. Variability in language support, affordability and digital literacy risks widening inequalities unless specific mitigations are in place. Overall, impacts are mixed.

If a number of people are accessing a medicine privately, such as a weight loss medicine, and stock levels become low, this means that those patients who are being prescribed the medicine on the NHS, for example for diabetes, are at risk of not getting the medicine they need for their long term condition.

In addition, we are aware of incidences where an individual pays to go privately but expects the medicine to be covered by the NHS and can then not afford to pay for the private prescription.

To what extent do you agree or disagree that sufficient training and education on private prescribing is available to healthcare professionals? (Optional)

- **Strongly agree**

- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

Provision exists but is uneven and not uniformly mapped to online-specific risks such as identity assurance, data-sharing and remote red-flag assessment

We believe that much more work is required in this area. It is an ever-expanding market, and more training and education should be available. The standard of training is also very variable.

Training for PGDs is not always provided or even signposted to.

Please share any additional evidence you would like to contribute regarding the impact of private prescribing on patient safety and access to medicines. (Optional, maximum 750 words)

There is momentum towards safer practice: strengthened safeguards for distance-selling and clear professional principles for remote care offer a stronger baseline. Nonetheless, information-sharing and identity assurance remain key weaknesses in independent online pathways. Continued enforcement against illicit online supply underscores the need for coordinated platform-level approaches. RPS supports proportionate governance that preserves timely access while ensuring consistent clinical standards, auditability and accountability.

Questions about recent restrictions on the sale and supply of puberty-suppressing hormones

In 2025, following 3 temporary emergency orders, the government introduced indefinite legislation placing restrictions on the sale and supply of puberty-suppressing hormones for under 18s with gender incongruence and/or gender dysphoria through private prescriptions, and for any indication for under 18s through EEA prescriptions. This followed in the wake of findings from the Cass Review about the safety of these medicines and advice from the Commission on Human Medicines about the current prescribing environment.

We are seeking evidence to understand the impact of this change.

Do you wish to answer questions regarding placing restrictions on the sale and supply of puberty-suppressing hormones?

If you select 'no' you will go straight to section 3 which is focused on quality of care.

- **Yes**
- **No**

To what extent do you agree or disagree with the following statements?

Restrictions on the sale and supply of puberty-suppressing hormones to under 18s for gender incongruence and/or gender dysphoria have been effective in limiting prescribing by UK private prescribers. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

Restrictions on the sale and supply of puberty-suppressing hormones to under 18s for gender incongruence and/or gender dysphoria have been effective in limiting prescribing by EEA registered prescribers. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

The prescribing of cross-sex hormones to under 18s for gender incongruence and/or gender dysphoria is undertaken in accordance with NHS guidelines (offered with extreme caution and with a clear clinical rationale) by UK private prescribers. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**

- **Strongly disagree**
- **Don’t know**

The legislation is widely published making it unlikely that reputable private prescribers or pharmacies would be involved in supply. Patient groups have also made it clear that patients could be prosecuted for having these drugs for gender reassignment. However, these drugs are available from online pharmacies for other conditions so it is unclear how diversion to use as puberty blockers would be prevented.

There is wide variation in the standards of care offered in private practice. This means that in some practices care is offered in accordance with NHS guidelines but not in all. To put this into perspective in some adult gender centres accept diagnosis of gender incongruence made by some private prescribers but not all. It is also worth considering that a lot of private prescribers will not see patients under the age of 18 but this patient group may access hormone treatments from other sources for example online purchase, unregulated sellers. In gender care there are three sources of treatment, NHS, Private Gender clinics and unregulated sources and unfortunately the third source is very common due to long waiting lists and restrictions to NHS access.

The prescribing of cross-sex hormones to under 18s for gender incongruence and/or gender dysphoria is undertaken in accordance with NHS guidelines (offered with extreme caution and with a clear clinical rationale) by EEA registered prescribers. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don’t know**

Government and NHS guidance on the sale and supply of medicines for gender incongruence and/or gender dysphoria to under 18s (puberty-suppressing hormones and cross-sex hormones) is sufficiently clear for frontline practitioners. (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**

- **Strongly disagree**
- **Don't know**

The guidance on Puberty blockers is clear and has been well published. However, the guidance on cross sex hormone prescribing is perhaps not so clear. At one point there was some debate around prescribing guidance for 17 year olds as some guides seemed to refer to 16 and under and others to under 18y years,for example.

Is there anything else you would like to tell us about the recent restrictions on the sale and supply of puberty-suppressing hormones? (Optional, maximum 500 words)

Section 3: quality of care

This section of the call for evidence seeks to understand the impact of private prescribing on quality of care.

In your experience, what impact does patient access to UK private prescribers typically have on the quality of care received? (Optional)

- **Positive**
- **Negative**
- **No impact**
- **Don't know**

The quality of care offered by private providers appears to be variable. However, in some cases, for example gender patients being able to access care privately has been a lifeline allowing them sooner access to the care they needed without having to wait years or access to treatment which would not have been available on the NHS. Many report a very positive experience with private prescribers. There are also incidences of poor monitoring and prescribing of medicines with poor evidence base in private practice too.

In your experience, what impact does patient access to healthcare professionals operating under private PGDs typically have on the quality of care received? (Optional)

- **Positive**
- **Negative**
- **No impact**
- **Don't know**

In your experience, what impact does patient access to EEA registered prescribers have on the quality of care received? (Optional)

- **Positive**
- **Negative**
- **No impact**
- **Don't know**

How can the quality of patient care received from private providers be strengthened? (Optional, maximum 500 words)

Set minimum expectations for private/online models: verified identity; structured history and co-morbidities; medicines reconciliation; explicit red-flag checks; documentation equivalent to face-to-face care; monitoring plans and safety-netting; and routine GP notification (with consent recorded). For private PGDs, require a named clinical lead, training and competency assurance, periodic audit and incident review, and clear escalation pathways. Enable consent-based access to the core NHS record or a defined, auditable alternative. For higher-risk medicines, mandate enhanced checks and scheduled follow-up.

- Better regulation, potentially by a government organisation, would improve patient care.
- A rating system that patients could easily understand to make an informed choice of provider.
- More information to guide patients on what to look for when choosing a private provider
- Ability to share prescribing (and other) information between private and NHS providers

To what extent do you agree or disagree that patients receive appropriate consultation and clinical advice when prescribed or supplied medicines by private providers? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

This is very variable among providers there are some that are very thorough and others that are not, so it is difficult to generalise. However, many of the clinicians who are prescribing privately are also prescribing in NHS roles so it is likely that the quality of care would be the same.

To what extent do you agree or disagree that patients are routinely monitored by an authorised healthcare professional when prescribed or supplied medicines by private providers? (Optional)

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**
- **Don't know**

This is very variable among providers there are some that are very thorough and others that are not, so it is difficult to generalise.

If there is anything else you would like to tell us about patient consultation and monitoring when accessing medicines through private providers, please include it here. (Optional, maximum 500 words)

In your experience, what patient medical information is relied upon when prescribing privately? (Optional)

Select all that apply.

- Patient supplied
- NHS GP supplied
- Core NHS record
- Private provider's own records
- Other, please specify

How effectively is patient medical information shared between NHS and private prescribers, and vice versa? (Optional, maximum 500 words)

Information-sharing is inconsistent. Many independent online providers lack access to core NHS records and depend on patient-reported histories, which can be incomplete. Routine, consent-based notifications to NHS GPs are not universal, creating gaps in monitoring and potential duplication or conflict in therapy. A standards-based,

consented exchange for medication and diagnosis summaries would materially improve safety and continuity.

From our understanding there is little sharing of information between private providers and the NHS, which may be one of the reasons that patients choose to go privately. Even amongst NHS providers it is difficult to share information due to interoperability issues.

If there is anything else you would like to tell us about private prescribing data, please include it here. (Optional, maximum 500 words)

There is no comprehensive outcomes dataset for private prescribing across the UK. RPS supports a proportionate national mechanism which was developed with regulators and patient-safety bodies to capture harm signals, near misses and outcomes from private services, including EEA-origin prescriptions dispensed in the UK.

What impacts does private prescribing have on the wider healthcare system? (Optional, maximum 500 words)

Private access can reduce waiting times for lower-acuity care and provide convenience, but risks record fragmentation, duplication and unwarranted variation in assessment and monitoring—work that may rebound to NHS services when complications occur. Interoperability, standardised discharge communication and targeted audit can help realise benefits while containing system risk.

We need to consider the impact when patients move from private to NHS care either because they want to move as they have become eligible for NHS care, have come to the top of a waiting list to be seen or they have to move from private care because they can no longer afford it. This can lead to conflict as the patient may have been stabilised on a treatment not supported by NHS guidelines or they may be left without treatment while waiting to move from private to NHS care. It can also sometimes be difficult to get previous treatment and monitoring information, making safe prescribing difficult. There also needs to be a way of capturing any resulting conflict when the expectations to move to NHS prescribing are not met.

If patients are taking medicines outside of NHS guidelines, they are at increased risk of side effects, and this may impact the wider healthcare system by seeking care for these side effects. Example in gender care would be patients on high dose injectable oestrogen who have a blood clot and need to access care for this.

Private prescribing can have both a positive and negative impact on the wider healthcare system However, the overall lack of visibility of private prescribing and the potential lack of access to patient information when making prescribing medicines are issues that need to be resolved.

There are concerns about the potential additional workload on NHS prescribers when private prescribers write to either inform them of medicines prescribed or ask that records are checked to ensure suitability. There is an issue not just of workload but of clinical responsibility. There is a need to keep workload and responsibility entirely with the private prescriber and ensure that systems are better set up to share information.

Please share any additional evidence you would like to contribute regarding the impact of private prescribing on quality of patient care. (Optional, maximum 750 words)

Quality hinges on clinical assessment, information-sharing and follow-up. Remote care should meet the same standards as in-person care. Embedding those standards, alongside clear PGD guardrails for protocolised use in defined cohorts, will reduce unwarranted variation. Aligning private online models with strengthened distance-selling safeguards and leveraging platform duties against illegal promotion will further protect patients. RPS also advocates corporate accountability in addition to individual professional accountability, hence that online service design, data flows and escalation pathways are safe by default**.**

Submitting further evidence

RPS submitted further evidence on:

- ***The efficacy of existing mechanisms for the oversight and regulation of private prescribing by UK and EEA registered healthcare professions, and supply and administration of medicines under private PGDs***
- ***The impact the existing arrangements for private prescribing and supply of medicines have on patient safety and access to medicines***
- ***How private prescribing by UK and EEA registered healthcare professions and the use of private PGDs affect the quality of care received by patients***

Royal Pharmaceutical Society

File A. Oversight and Regulation
DHSC Call for Evidence: Private non-NHS Prescribing
Date: 24 October 2025

Executive summary

The United Kingdom has a multi layered system that combines product regulation, professional regulation, and provider regulation. This provides a strong basis for safe access to medicines through private routes when requirements are applied consistently and enforced proportionately. Important gaps remain in cross border oversight, information sharing, and the governance of private patient group directions. The Royal Pharmaceutical Society recommends minimum clinical assessment standards for prescription only medicines in private and online models, clear corporate duties for online providers, a minimum governance standard for private patient group directions, improved information sharing with the National Health Service, and a proportionate national approach to surveillance of outcomes and harms. These recommendations build on recent regulator actions and national guidance [1–7, 9–12].

1. Current regulatory landscape

Products and enforcement

- The Medicines and Healthcare products Regulatory Agency regulates licensing, safety surveillance, and enforcement across the product life cycle [5].

Professionals

- The General Pharmaceutical Council sets standards and regulates pharmacists, pharmacy technicians and pharmacies in Great Britain [2].
- The Pharmaceutical Society of Northern Ireland regulates pharmacists in Northern Ireland.
- The General Medical Council sets standards for doctors and provides principles for safe remote consultations and prescribing that apply across settings [3, 10].
- Other professional regulators set standards for non medical prescribers.

Providers

- Independent providers are regulated by the Care Quality Commission in England and by the relevant bodies in the devolved nations, namely Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Regulation and Quality Improvement Authority [12].

Digital and advertising context

- The Online Safety Act creates duties for covered platforms to mitigate illegal content and to take down illegal material. Government and Ofcom materials describe the scope and initial enforcement approach [6, 14].

Patient group directions

- Patient group directions are written instructions that allow named and authorised registered professionals to supply and administer specified medicines to a defined cohort in planned circumstances. They are not a form of prescribing and national guidance sets out who can use them and the required governance [4, 11].

2. Strengths of the current regime

There are clear institutional roles for products, professionals, and providers, with inspection and enforcement powers across the system [2, 3, 5, 12]. Expectations for distance selling pharmacies were strengthened in February 2025, including additional safeguards for high-risk medicines and a stronger emphasis on independent verification beyond questionnaires [2]. Cross professional principles for remote consultations and prescribing set an expectation that assessment quality,

documentation and follow up should match in person care [3, 10]. Patient group directions are supported by national guidance that describes their scope, authorisation, training and governance requirements [4, 11]. Together these measures provide a coherent basis for safe private access when consistently implemented and proportionately enforced.

3. Limitations and risks

Cross border activity by prescribers registered in the European Economic Area who sit outside United Kingdom professional standards and routine appraisal makes consistent quality assurance and the application of sanctions more difficult where prescriptions are dispensed in the United Kingdom [1]. Information sharing between independent online services and the National Health Service is inconsistent which weakens medicines reconciliation, monitoring and safety netting. The patient safety investigation programme has highlighted the challenge of sharing information between independent online services and National Health Service care [7, 15]. Digital enforcement can lag behind rapid changes in online presence which reduces deterrence and requires coordinated platform level action under the Online Safety Act [6, 14]. Governance of private patient group directions varies and can drift toward individual diagnosis rather than protocol-based supply for defined cohorts if controls are weak [4, 11]. The continued presence of illicit online markets risks confusing the public about legitimate private routes and undermines trust, as shown by recent national and international enforcement activity under Operation Pangea [5, 13].

4. RPS recommendations

4.1 Identity, transparency and interoperability

Introduce interoperable identity and activity flags that link professional registration, corporate entities and platforms so that regulators can identify and act on risks quickly across settings. This should complement existing inspection and enforcement powers [2, 12].

4.2 Clinical assessment standard for prescription only medicines

Define a minimum standard for assessment in private and online models. Questionnaire only pathways should not be used for higher risk indications or for higher risk medicine classes. Required elements include verified identity, relevant history, medicines reconciliation, red flag checks, and documented decision making and safety netting, consistent with professional principles for remote care [2, 3, 10].

4.3 Corporate accountability for online providers

Set clear corporate level duties for online providers alongside individual professional accountability. Duties should cover service design, identity assurance, information flows, escalation pathways, audit, and cooperation with regulators. Enforcement should align with Online Safety Act provisions for illegal promotion or supply [6, 14].

4.4 Minimum governance for private patient group directions

Require a named clinical leader, defined eligibility criteria, version control and review dates, training and competency records, routine audit and incident review, and red flag escalation pathways. Patient group directions must not substitute for individual clinical diagnosis [4, 11].

4.5 Information sharing with the National Health Service

Enable consent based, bidirectional information sharing with the core National Health Service record, or a robust and auditable alternative where direct access is not feasible. Routine notification to the general practitioner should be the default with patient consent recorded [7, 15].

4.6 Outcomes and harms surveillance

Establish a proportionate national mechanism to capture outcomes, harm signals and near misses arising from private routes including prescriptions from European Economic Area prescribers that are

dispensed in the United Kingdom. This should align with existing patient safety bodies and avoid undue burden [1, 7, 15].

5. Implementation and measurement

Align inspection activity with strengthened expectations for distance selling and with remote care principles so that providers receive consistent signals across regulators [2, 3, 10, 12]. Use platform duties under the Online Safety Act alongside Medicines and Healthcare products Regulatory Agency enforcement to disrupt illegal promotion and supply [5, 6, 14]. Pilot secure and consent-based exchange of medication and diagnosis summaries using existing National Health Service infrastructure or trusted intermediaries [7, 15]. Define a concise set of metrics for private services, for example the proportion with general practitioner notification recorded, timeliness of follow up for higher risk medicines, and audit completion for patient group directions.

6. Evidence gaps and research priorities

There is no comprehensive outcomes dataset for private prescribing across the United Kingdom. Priority research needs include linkage of private service activity to National Health Service incidents and admissions, evaluation of identity assurance models in remote care, and evaluation of governance interventions for private patient group directions [1, 7, 11, 15].

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Royal Pharmaceutical Society

File B. Patient Safety and Access
DHSC Call for Evidence: Private non-NHS Prescribing
Date: 24 October 2025

Executive summary

Private routes can improve timeliness, convenience and choice for patients. The same routes also introduce specific risks that require consistent safeguards. The principal risk factors are questionnaire only pathways for prescription only medicines, weak identity and age verification, incomplete clinical information that impairs medicines reconciliation and monitoring, variable control of high risk and controlled medicines, and exposure to illicit online supply posing as legitimate services. These concerns are most visible in independent online models and in cross border activity [1, 4, 5, 6, 7].
The Royal Pharmaceutical Society recommends a practical package of safeguards. These include a clear prohibition of questionnaire only pathways for higher risk conditions and classes, consent based access to the core National Health Service record or a robust and auditable reconciliation alternative, strong identity and age verification, routine general practitioner notification with explicit follow up and stop criteria, targeted audit for high risk classes, systematic incident reporting, and minimum governance standards for private patient group directions [2, 3, 4, 5].

1. Why patients use private providers

Patients report timeliness, convenience through out of hours and remote access, privacy, and targeted access to therapies that are perceived as difficult to obtain through the National Health Service. Digital channels can reduce travel and time costs and widen choice for lower acuity presentations. These advantages are recognised in the Department of Health and Social Care call for evidence which seeks to ensure that safety and quality keep pace with access [1].
Private patient group directions add value where a protocolised model suits a defined cohort such as immunisation or travel health. They are not a substitute for individual clinical diagnosis and require clear governance [4].

2. Patient safety risks in private routes

Questionnaire only pathways

- Pathways that rely only on structured questionnaires for prescription only medicines carry a risk of incomplete assessment and of missing red flags. Recent regulator actions have strengthened expectations for distance selling pharmacies, including independent verification and additional safeguards for high-risk medicines such as glucagon like peptide one receptor agonists [2, 3].

Identity and age verification

- Weak identity checks increase the risk of impersonation and unsafe supply. Professional guidance for remote consultations and remote prescribing expects adequate verification and documentation that matches the standard of in person care [3].

Information sharing and monitoring

- Inconsistent information sharing between independent online providers and the National Health Service undermines medicines reconciliation and planned follow up. The patient safety investigation programme has identified information sharing with National Health Service services as a central problem in independent online prescribing [5].

Controlled and high-risk medicines

- Where governance is weak, the risk of inappropriate supply or inadequate monitoring increases. This risk is heightened for controlled drugs and for classes that require close follow up.

Illicit online supply

- Illicit sellers continue to operate and present as legitimate sources. National enforcement continues to identify significant volumes of illegal medicines and online listings, which increases the risk that patients confuse legal private routes with illegal sources [6].

Cross border complexity

- Prescriptions generated by prescribers outside the United Kingdom but dispensed in the United Kingdom add verification and accountability challenges. Historic inspection evidence shows that without strong governance online services can deviate from safe practice [7].

3. Benefits when governed well

When services meet professional standards and governance expectations, private access can enable faster initiation of appropriate therapy, reduce travel and time burden, and increase patient choice. Properly governed patient group directions provide standardised care for defined scenarios with clear eligibility and escalation routes [4].

4. Safeguards recommended by the Royal Pharmaceutical Society

4.1 Prohibit questionnaire only pathways for higher risk use cases

For higher risk indications and higher risk medicine classes, services should complete and document a clinical assessment that goes beyond a questionnaire. This should include verified identity, relevant medical history, medicines reconciliation, red flag checks and explicit safety netting, in line with professional principles for remote care [2, 3].

4.2 Ensure consent-based access to core National Health Service information or a robust alternative

Before initiation or renewal, providers should access the core National Health Service record with patient consent or follow a documented and auditable reconciliation pathway that achieves an equivalent standard where direct access is not feasible. Routine communication to the general practitioner should be the default with consent recorded [5].

4.3 Strengthen identity and age verification

Adopt multi factor verification appropriate to clinical risk, with repeat verification at renewal for higher risk medicines [3].

4.4 Mandate routine follow up and stop criteria

For higher risk medicines, define review intervals, monitoring parameters and clear stop rules at the point of prescribing and supply.

4.5 Targeted audit and incident reporting

Conduct focused audits for high-risk classes and integrate incident reporting with National Health Service patient safety systems to support learning [2, 5].

4.6 Minimum governance for private patient group directions

Require a named clinical leader, training and competency records, version control and expiry dates, periodic audit, incident review, and red flag escalation pathways. Patient group directions must not be used as a substitute for individual clinical diagnosis [4].

4.7 Platform and market controls

Use the Online Safety Act framework and Ofcom guidance alongside Medicines and Healthcare products Regulatory Agency enforcement to reduce exposure to illegal promotion and illegal online sellers [6, 8].

5. Electronic and paper prescriptions

Secure standards based electronic prescribing can reduce transcription error and improve auditability when coupled with strong identity assurance. Ad hoc electronic formats such as emailed images or portable document format files can obscure prescriber authenticity especially in cross border settings. Paper prescriptions allow traditional manual checks but are vulnerable to forgery and lack structured data. A secure standard based electronic approach with robust identity controls and data integrity is preferable for private routes [2, 3].

6. Equality and inclusion

Private routes can help patients who face time, travel or privacy barriers. At the same time people who are digitally excluded or who require safeguarding may be disadvantaged by online only models. Services should provide accessible formats and translation where needed and should make affordability and digital literacy considerations explicit [1, 16].

7. Data gaps and priorities

There is no comprehensive outcomes dataset for private prescribing across the United Kingdom. Current evidence is strongest for process and enforcement activity rather than measured clinical outcomes. Priority actions include a proportionate national mechanism for outcomes and harms surveillance, better linkage between private activity and National Health Service incidents and admissions, and transparency on adherence to identity verification, reconciliation and follow up standards [1, 5, 7].

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Royal Pharmaceutical Society

File C. Quality of Care and Private Patient Group Directions
DHSC Call for Evidence: Private non-NHS Prescribing
Date: 24 October 2025

Executive summary

Quality of care in private routes depends on the standard of clinical assessment, the appropriateness of the legal mechanism used, and the strength of governance and information sharing. Patient group directions are a legal mechanism for protocol-based supply and administration for a defined cohort. They are not a form of prescribing, and they must not replace individual clinical diagnosis [4, 5]. When used within their intended scope with strong governance and audit, private patient group directions can deliver timely and standardised care. Risks arise when eligibility criteria are weak, when escalation arrangements are unclear, and when information is not shared with the National Health Service to support continuity and monitoring [4–7]. The Royal Pharmaceutical Society recommends a clear minimum governance standard for private patient group directions, strengthened information sharing with National Health Service services, and alignment with professional expectations for remote care and with safety measures for distance selling [2–5, 8].

1. What good looks like for quality

High quality private care aligns with professional principles that require the same standard as in person care for assessment, documentation, and follow up [3, 8]. For services that prescribe, this includes verified identity, relevant history, medicines reconciliation, red flag checks, clear documentation, monitoring plans and safety netting. For services that use patient group directions, quality is expressed through strict adherence to protocol-based eligibility, trained and authorised staff, and auditable processes that demonstrate safe supply and administration [4, 5]. Where private and National Health Service care intersect, providers should share information with consent to support monitoring and continuity [6, 7].

2. Purpose and guardrails for private patient group directions

Patient group directions enable supply or administration of specified medicines to a pre-defined group of patients who meet explicit criteria. They are suitable for planned circumstances such as immunisation and travel health where a protocol can safely replace an individual prescription and where a diagnosis is not required at the point of supply [4, 5]. They must not be used to manage undifferentiated presentations or conditions that require individual clinical diagnosis. National guidance sets requirements for authorisation, governance, training and competency, review dates and version control, documentation standards, and audit [4, 5]. These requirements apply equally in private settings.

3. Governance model for private patient group directions

RPS recommends a minimum governance standard to secure quality and safety in private use.

Leadership and authorisation

- Name a clinical lead responsible for patient group direction design, authorisation and oversight. Ensure organisational approval and version control with explicit expiry dates [4, 5].

Eligibility and red flags

- Define inclusion and exclusion criteria that are specific, evidence based and testable at the point of supply. Include explicit red flag criteria and escalation routes to a prescriber or other appropriate clinician [4, 5].

Competency and training

- Maintain role specific competency frameworks, training records and periodic revalidation for all named and authorised professionals. Ensure access to clinical support when complex presentations arise [4, 5].

Documentation and information sharing

- Record the assessment against the criteria, the medicine supplied or administered, batch numbers and expiry for parenteral products, and the advice and safety netting provided. With consent, notify the general practitioner and update the care record through a secure channel so that reconciliation and follow up are possible [4–7].

Monitoring and audit

- Set an audit plan with indicators such as adherence to inclusion criteria, documentation completeness, incident rate, and timeliness of escalation. Review audit findings and incidents at a defined frequency and update the patient group direction and training as required [4, 5].

4. Interoperability and records

Information sharing between private services and the National Health Service remains inconsistent and is a recurrent patient safety concern in independent online models [6, 7]. For quality assurance in private use of patient group directions, providers should implement consent-based exchange of medication and diagnosis summaries, or a clearly documented and auditable alternative where direct access to National Health Service records is not available. Routine notification to the general practitioner should be the default and patients should be informed about how their information will be used [6, 7].

5. Integrating professional standards and distance selling safeguards

Professional guidance for remote consultations and remote prescribing requires that identity verification, assessment quality and documentation meet the same standard as in person care [3, 8]. Although a patient group direction is not prescribing, the same principles of safe assessment and documentation at the point of supply apply. Strengthened expectations for distance selling pharmacies introduced in February 2025 reinforce the need for independent verification and careful handling of higher risk medicines. Private providers that supply under a patient group direction should mirror those safety expectations where they are relevant to the medicine and context [2].

6. Quality measures and outcomes

A concise set of indicators can demonstrate quality and support improvement.

- Proportion of supplies that meet all inclusion and exclusion criteria as recorded on the patient group direction.
- Proportion of cases with documented safety netting and patient advice.
- Proportion of notifications sent to the general practitioner with recorded consent.
- Timeliness of escalation for presentations that meet red flag criteria.
- Audit completion rate and time to implement actions.
- Incident rate per one thousand supplies and distribution by contributory factor.

7. Implementation considerations

Introduce a standard template for private patient group directions that incorporates all mandatory fields from national guidance and adds RPS recommended sections for escalation and information sharing [4, 5]. Provide a role-based training package and competency assessment for all named professionals. Establish a secure route for routine communication with National Health Service services to support medicines reconciliation and follow up. Map responsibilities across corporate leadership and individual professionals so that accountability is clear. Consider the relevance of platform obligations and enforcement powers for online services that advertise or facilitate access to medicines so that illegal promotion is discouraged and enforcement is coordinated [2, 9].

8. Evidence gaps and priorities

There is limited outcomes level evidence for quality and safety of private patient group direction services at national scale. Priorities include linkage between private activity and National Health Service incidents and admissions, evaluation of different models of consent-based information sharing, and evaluation of governance interventions that improve adherence to criteria and escalation rules [1, 4–7].

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