



Advice note: Advance Clinical Checks

February 2023

Introduction

Following an increase in concerns from some members about what they are expected to do, the PDA has sought specialist legal opinion on the introduction of advance clinical checks for repeat medicines. This follows the development of new SOPs and PMR systems adopted by some pharmacy chains which removes the long-established professional practice of a pharmacist clinical check being required for each supply of a repeat prescription.

Keeping Patients Safe

Whilst technology and practice developments have an important role to play in enabling people to access advice, treatment, and routine medication, this should only be introduced and operated with an independent, risk-assessed, evidence-based approach. Innovation and technology related to the supply of medicines must be subject to UK regulation and safety standards. The advent of new systems provides an opportunity to further improve patient care and safety; however, the way that some of these systems are currently being developed and adopted appears to be based on efficiency gains and productivity benefits, rather than optimising care and reducing risk.

What is an “advance clinical check”?

In practice, pharmacists are being encouraged by their employer to perform a single initial clinical check on an NHS repeat prescription to cover multiple repeat supplies issued on future dates, in some cases for periods of up to 12 months. It is presently unclear who would be responsible for any errors or omissions that occur with an advance clinical check; each case would depend on the facts, but the actions of both the RP initiating the process and the RP(s) on duty at the time subsequent supplies are made, are likely to be scrutinised.

One pharmacy chain describes the advance clinical check as ***“a professional decision whether the clinical check for each patient may be reapplied to future prescriptions with the same items for a defined duration of time.”***

PDA members are concerned that although the repeat medicine remains the same, the patient’s health and other material factors may have changed and by removing the requirement for a pharmacist clinical check for each supply, this will lead to an increased risk of patient harm.

Members also raise concerns about the transparency of these processes for patients and the impact on prescribers who rely upon the pharmacist to act as a critical safety net when performing a clinical check on each repeat supply.

The legal opinion obtained by the PDA supports these member concerns and identifies two main areas of exposure:

- Personal Responsibility of Individual Pharmacists
- Corporate Responsibility

Personal Regulatory Responsibility

The GPhC publish Standards which must be met by all registered pharmacists and the PSNI produce a Code containing a similar set of mandatory principles.

The requirement for a pharmacist to undertake a clinical check is not explicitly set out in the GPhC Standards; however, several of the Standards and expected behaviours are engaged, including Standards 1, 2, 5 and 9, when considering whether a pharmacist should undertake a clinical assessment of each prescription before it is dispensed and supplied to a patient.

The GPhC Standards also refer pharmacists to guidance issued by the RPS as a professional leadership body. The RPS’s Medicines, Ethics and Practice explicitly refers to the clinical check, noting that this is *“One of the key skills of a pharmacist”* (section 2.6.5 of Edition 45).

For pharmacists registered with the PSNI, the position is clearer. PSNI has published its own Professional Standards and Guidance for the Sale and Supply of Medicines. The 1st March 2016 edition notes that *“The pharmacist must ensure that...a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient”*.

After carefully considering all the relevant regulatory standards and professional guidance, the legal opinion confirms:

“It would not be unreasonable to expect the Council to investigate a concern which related to a failure, by a pharmacist, to carry out a suitable and sufficient clinical assessment prior

to the supply of a medicinal product so as to ensure that that medicine is (or remains) appropriate for the patient.”

The opinion further states that pharmacy businesses which use an “advance clinical check” in their procedures gives rise to a fitness-to-practise risk for individual pharmacists who do not undertake a clinical check on each supply by reason of following such a protocol.

Exposure to Civil Liability for Pharmacists

The PDA is aware of significant patient safety incidents reported by members where repeat prescriptions not subject to a separate, fresh clinical check by a pharmacist, have been later identified as clinically inappropriate for the patient.

The obligations upon pharmacists as “gatekeepers” of medicinal products have been repeatedly confirmed in a series of high profile clinical negligence cases against individual pharmacists.

The legal opinion also confirms it would not be unreasonable for a court, when considering a civil claim against a pharmacist, to consider the extent to which the pharmacist undertook a sufficient and appropriate clinical check of the prescription prior to supply. Undertaking an advance clinical check gives rise to a risk of personal liability for a pharmacist who has not undertaken that clinical check by reason of such a protocol.

Corporate Responsibility

Pharmacy owners have their own professional and legal responsibilities to ensure the services provided by them are safe. Those responsibilities principally attach to the superintendent pharmacist and the owner through the premises standards.

The GPhC Standards for registered pharmacies oblige pharmacy owners (including directors and superintendent pharmacists) to ensure that staff work within recognised professional practice.

Standard 2.3 Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public.

NHS Terms of Service

NHS Contractors have an obligation to ensure that the pharmacist’s clinical check is undertaken in accordance with the “*standards generally accepted in the pharmaceutical profession*”.

The Royal Pharmaceutical Society’s Medicines, Ethics and Practice provides, in relation to the

roles and responsibilities of the responsible pharmacist, that a “*Professional check (clinical and legal check) of a prescription*” is “*required under the NHS pharmaceutical legislation*”.

Having regard to the detailed NHS Terms of Service the conclusion is:

- It is generally accepted by the pharmaceutical profession that a pharmacist should carry out a clinical check for each supply.
- Contractors therefore have an obligation to ensure, so far as they can, that a clinical check is carried out by reason of paragraph 29 of the Terms of Service.
- It is likely that each employee or locum pharmacist has a contractual obligation (either explicitly or impliedly) to ensure that they act in such a way that their employer/contractee provides its services in accordance with its legal and ethical obligations.
- In addition, certain of the Terms of Service requirements strongly imply that a clinical check must be undertaken before the supply of each prescription (including each batch of a repeatable prescription). This places an obligation upon a pharmacy contractor to ensure that medicines including repeats, are only supplied where clinically appropriate.

Next Steps

The PDA has expressed serious concerns to the GPhC about the removal of an important safety step in the supply of prescription medicines, and is awaiting their considered response. The PDA is also engaging with other stakeholders on this topic, including PSNI and the NHS regarding its expectations of pharmacy contractors providing NHS services.

The PDA calls upon the GPhC, PSNI and the RPS, to meaningfully engage with pharmacists to reiterate, enforce and where necessary strengthen the regulatory standards and professional guidance relating to the requirement that a pharmacist clinical check must be undertaken before the supply of each prescription including repeats, so that pharmacists can be confident they are practising in a way that maintains patient safety at all times and is in line with the standards generally accepted in the pharmaceutical profession.

PDA Advice

The Responsible Pharmacist (RP) is in charge of the registered pharmacy and the RP's statutory duty is to secure the safe and effective running of the registered pharmacy when it is operational.

The PDA reminds pharmacists there is no professional consensus on the concept of an “advance clinical check” and a pharmacist following such a procedure would be working outside the scope of established and accepted professional practice. Members believe that

there is no patient benefit for introducing advance clinical checks and this could lead to a diminution in patient safety; the process appears to be driven by commercial factors.

The decision to operate an advance clinical check is solely at the professional discretion of the pharmacist. The pharmacist is personally accountable for their actions and must critically appraise any systems and processes they work under, to ensure patients receive safe and effective care. This is particularly important where there are departures from accepted and established professional practice.

The PDA recognises that members will want to know if their indemnity insurance extends to such unorthodox processes being introduced by pharmacy owners. The PDA is a risk-based organisation and uses its extensive expertise to advise and alert members to foreseeable risks to patients and themselves, so that individual choices can be made on mitigating those risks.

Members who have in the past or are currently operating advance clinical checks or similar processes can rely upon the PDA and the associated indemnity insurance to defend and support them in the event of an error, claim or complaint, even if they are involved in the advance clinical check process. However, for the reasons outlined above, even benefiting from good legal defence in such a situation is no guarantee of a favourable outcome for the pharmacist in any potential proceedings.

The PDA urges pharmacists not to participate in processes where a single clinical check applies to future repeat supplies.

Pharmacists should continue to clinically check each supply of a medicine including repeats as such a procedure maintains patient safety and reduces the risk of exposure to liability for individual pharmacists.

Pharmacists are advised to raise any outstanding concerns with the Superintendent Pharmacist in the first instance. The PDA can assist should there be any dispute or attempted enforcement of the procedures against the responsible pharmacist's professional judgement.