

Review of overall outcome of an inspection process

Introduction

It is important to note that an inspection provides a snapshot of the pharmacy's operations and practice on the day and the evidence recorded in the report will reflect what was found at that time.

We anticipate that we will be able to resolve most of the issues concerning inspection reports and our judgements without the need for a formal review. This is because there will be opportunities for both the Responsible Pharmacist and the pharmacy owner/superintendent to check the report before it is published.

The Responsible Pharmacist is asked to confirm that the evidence collected during the inspection is an accurate reflection of what was found at the end of the inspection. The pharmacy owner/superintendent pharmacist will be sent the draft report for a factual accuracy check before it is finalised.

However, we recognise that there may be, on the rare occasion, a disagreement with the overall outcome of an inspection. In line with our commitment to operate as an open and transparent regulator, we have introduced a process for pharmacy owners/superintendents to seek a formal review of the GPhC's overall outcome of an inspection judgement (standards met/standards not all met), where they consider that the evidence does not support the outcome.

Pharmacy owners/ superintendents cannot request reviews of individual findings at principle level where the overall outcome is 'standards met'.

The Review Process

This is a three-stage approach, which is also set out in the flowchart at the end of this document.

Stage 1 – Request for review

A request for a review of the overall outcome of an inspection must be made by the owner/superintendent in writing using the 'Request for review of the overall outcome of an inspection' form. (On click the form will attempt to download to your PC)

The proforma can only be submitted once the pharmacy owner/superintendent has received the final version of the report and **must be submitted within 5 working days of receipt of the final report**. On the form they must clearly set out:

- 1. why they are challenging the overall outcome of an inspection, and
- 2. how the overall outcome is inconsistent with the evidence agreed with the Responsible Pharmacist at the time of inspection, and
- 3. how the overall outcome is inconsistent with the Inspection decision-making framework (making reference to the specific parts of the framework they consider the outcome to be inconsistent with).

For the request to be accepted they will need to demonstrate why the overall outcome should be changed from 'standards not all met' to 'standards met'.

Further, the purpose of any review is not for the owner or superintendent to submit new evidence that was not part of, or available at the time of the inspection.

Where the Head of Inspection determines that a review is not justified as it does not meet the criteria above, the owner/ superintendent will be notified by a letter with the reasons for this decision.

Stage 2 – Independent review

Where the request for a review has been accepted the Head of Inspection will allocate an independent reviewer from a different region who has had no previous involvement in the inspection, to carry out the review. This could be another Regional Manager or Deputy Regional Manager. The Head of Inspection will agree the approach to be adopted for the review with the reviewer. This could include:

- a desk-top review of the report;
- a conversation/meeting with the inspector and/or a representative of the pharmacy;
- a further visit to the pharmacy depending upon the nature of the issues raised.

When the reviewer has completed the work for the review they will make a recommendation to the Head of Inspection about the proposed outcome. This will either be:

- No change to the overall outcome of the inspection or the inspection report.
- No change to the overall outcome of the inspection but amendments to the inspection report.
- Change in the overall outcome of the inspection and associated amendments to the report.

The reviewer's recommendation should generally be completed within 8 working days. This timescale may be extended, for example, where a further visit to the pharmacy is required.

Stage 3 – Notification of the review decision

The Head of Inspection will consider the independent reviewer's recommendation and where the report is amended the Head of Inspection will undertake a further quality review of this before it is finalised. The pharmacy owner/ superintendent will then be notified about the outcome of the review by letter. This will set out the reasons for the Head of Inspection's decision and include a copy of the final report.

This decision will be final and there will be no further opportunity for the owner/superintendent to make representations.

Complaints procedure

This decision review procedure does not prevent an individual from making a <u>complaint about the</u> <u>service provided by the GPhC</u>, for example in respect of how it carries out its work, at any time. However, this should not be considered as an appeal mechanism for this decision review procedure.

Review process flowchart

