

# Responding to complaints and concerns

Guidance Note: September 2010

# Guidance Note: Responding to Complaints and Concerns

The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales.

## **About this guidance**

This document provides guidance on dealing with complaints and concerns raised by patients, the public and other healthcare professionals.

## **Why we are providing this guidance**

We are providing this guidance to assist pharmacy professionals on how to best meet the responsibilities that a pharmacy owner or pharmacy professional has in relation to handling and managing complaints and concerns.

As dispensing errors are frequently the basis for complaints, we will also provide guidance on:

- How to minimise the risk of a dispensing error occurring
- What to do in the event of a dispensing error
- How to review dispensing errors

This Guidance Note has been published by the Standards Advisory Team. If you have questions about its content, please contact us on 020 3365 3640 or via email at [standards@pharmacyregulation.org](mailto:standards@pharmacyregulation.org).

This Guidance Note will next be reviewed in October 2011

## Introduction

The Standards of Conduct, Ethics and Performance must be followed by pharmacists and registered pharmacy technicians. Principle 1 of these Standards is to “make patients your first concern”. A requirement under this principle is to “organise regular reviews, audits and risk assessments to protect patient and public safety and to improve your professional service”.

The standards also require you to have standard operating procedures (SOPs) in place which must be followed at all times.

The Standards for Pharmacy Owners and Superintendent Pharmacists of Retail Pharmacy Businesses require pharmacy owners and superintendent pharmacists to ensure the safe and effective running of the pharmacy. To allow this there must be appropriate policies, procedures and records in place that are maintained and reviewed regularly. There must also be an appropriate mechanism in place to respond to and investigate all complaints and concerns raised.

The standards referred to above can be found at [www.pharmacyregulation.org](http://www.pharmacyregulation.org).

## Why complaints arise

There are numerous reasons for why a complaint or concern may arise. The majority of complaints or concerns are due to:

- Human error
- System failure, for example when a pharmacy doesn't have adequate SOPs in place
- How a complaint or concern is handled in the pharmacy

The way in which a complaint or concern is handled in the pharmacy can determine whether or not it is then referred to an independent body such as the General Pharmaceutical Council (GPhC) or the Primary Care Organisation (PCO).

## How to deal with a complaint or concern that has been raised

When something goes wrong or someone reports a concern to you, you should make sure you deal with it appropriately.

There should be an effective complaints procedure where you work and you must follow it at all times.

You should make a record of the complaint, concern or incident and the action taken. You should review your records and findings and audit them regularly.

## Dispensing Errors

The investigating committee considered 732 cases between April 2009 and March 2010. Approximately 32% of these cases concerned dispensing errors. The Disciplinary Committee considered 396 cases during the same period of which 15% concerned dispensing errors.

## How to minimise the risk of making a dispensing error

Dispensary layout:

- The dispensary should be organised to keep distractions to a minimum.
- The atmosphere of the dispensary should encourage good concentration.
- Alert staff to the dangers of stock being placed in the wrong location. Dispensary stock should only be put away by a competent member of staff.
- Keep a segregated area of the dispensary workbench for the dispensing process.
- Segregate prescriptions on the workbench to avoid patients receiving someone else's medicines. You may use baskets / trays if appropriate.

Dispensing process:

- Produce dispensing labels before any product is selected from the shelf.
- Do not select stock using dispensing labels or patient medication records (PMR). Refer to the prescription when selecting stock for dispensing.
- Dispense items from the prescription and not the generated label.
- You should have systems in place to identify who was involved in the dispensing and checking process of each prescription item (e.g. dispensed by / checked by boxes).
- Two people should be involved in the dispensing process where this is possible. A second competent person should carry out an accuracy check and ideally should not have been involved in the assembly process.
- If you are a pharmacist working alone, once you have assembled the medicines, try to create a short mental break between the assembly and final check to avoid carrying over any recollection of preconceived errors from the assembly process.
- All accuracy checks should be made against the original prescription re-reading the prescription first.
- Dispense balances of medication owed by reference only to the original prescription or a good quality copy. Do not rely solely on the information in the PMR or an owing note or

label. This will prevent you making the same error that may have previously been made by another pharmacist.

The National Patient Safety Agency (NPSA) ([www.npsa.nhs.uk](http://www.npsa.nhs.uk)) has published a document entitled “A guide to the design of dispensed medicines”, which looks at the key aspects of labelling and presentation of a dispensed medicine.

Another publication, entitled “A guide to the design of dispensing environments”, provides guidance on how the design of a dispensary can improve patient safety. Whilst the physical design of the dispensary can inevitably improve the working environment and therefore patient safety other things should also be considered. For example, the workflow and how the dispensary area is utilised can improve the efficiency and improve safety.

## What to do in the event of a dispensing error

Pharmacists should carry out a root cause analysis in the event of a patient safety incident. This is a retrospective technique for looking for the underlying causes of a patient safety incident, behind the immediate and obvious cause. For example, one individual’s human error might be the immediate cause, but several factors could have contributed to the error such as fatigue, an inadequate checking system or poor standard operating procedures.

The NPSA is promoting root cause analysis and is encouraging organisations to identify the circumstances in which it should be used. This should take into account the severity of the incident and the scope for learning from it. Further information on root cause analysis can be found on the NPSA website at [www.npsa.nhs.uk](http://www.npsa.nhs.uk).

You may wish to consider all the points below when dealing with an error or handling a complaint. In addition, locum pharmacists may also wish to keep their own records in case they are contacted later.

When the patient first comes in or indicates that there has been an error:

- **Establish if the patient has taken any of the incorrect medicine.**

If the patient has taken any of the incorrect medicine, establish whether the patient has been harmed.

If they have been harmed, provide the complainant and the patient’s GP with the advice they need immediately. Contact the local drug information centre, if appropriate, for advice on the possible effects on the patient (giving details of concurrent medication).

Where no harm appears to have been caused, the GP should still be informed.

- **Ask to inspect the incorrect medicine.**

Make it clear that you do not wish to retain the medication, and that inspecting the medicine can give valuable clues about what went wrong. If the patient does not want to hand the medicine over to you, suggest that they retain it until they can hand it over to an appropriate representative of the GPhC or their local PCO. Incorrect medicines should not routinely be posted to these organisations.

If the patient does hand over and leave the incorrect medication with you retain it and keep it segregated from stock and other medicines to be supplied to patients.

Never dispose of any medicine unless the patient has given consent. Before doing so it should be retained carefully, for a reasonable period, in case of further developments.

- **Apologise**

In the case of a dispensing error, an apology should not be confused with an admission of liability.

- **Never try to minimise the seriousness of an error.**

A balance must be struck that reassures the patient, if no harm is likely, but without suggesting that the error is insignificant.

- **Make a supply of the correct medicine ordered on the prescription, if appropriate.**

You can lawfully make a supply of the correct medicine as this was authorised on the original prescription, even in the case of a controlled drug.

Where the patient has not taken any of the incorrect medication it is your professional judgment about whether the patient's GP needs to be informed.

- **Establish their expectations**

It is important to establish what the complainant would like you to do about their complaint.

- **Provide details of how to complain to an 'official body' if requested.**

Supply the complainant with the name and address of the Fitness to Practise Department of the GPhC if the complainant feels that the only way forward is to complain to an 'official body'. Explain that a Professional Standards Inspector from the GPhC may visit the pharmacy to undertake a review. You may also provide the details of the PCO so that the matter can be dealt with under the NHS complaints procedure.

- **Try and establish what happened and what went wrong.**

You may need to make your own inquiries into any possible causes of the alleged error for preventative purposes unless it is clear from the facts known to you, how the error is likely to have occurred.

You may need to speak to the person who presented or collected the prescription about the prevailing conditions in the pharmacy.

Contact the complainant and inform them of your findings.

- **Follow company procedures / SOPs for reporting errors or complaints.**

Where you are an employee pharmacist, you should follow the procedures laid down by your employer/Superintendent for who you should notify in the event of a dispensing error.

If you are working within a company, you may have to report any errors to your line manager and/or a Superintendent office. You must follow company procedures for such reporting and may wish to consult the superintendent pharmacist and other line managers for advice.

- **Record, review and learn from errors made.**

See section on reviewing errors.

- **Notify the pharmacist who was on duty at the time, if it was not you.**

You may use the Responsible Pharmacist record to ascertain who was on duty at the time.

- **Inform your professional indemnity insurance provider.**

In all cases of dispensing errors, the over-riding responsibility is for the health and well-being of the patient. Whilst keeping this in mind, you should inform your professional indemnity insurers as soon as possible, in case a claim is later made against you.

## Reviewing errors

Make a written record of your findings when you carry out your review to establish what went wrong. You can record your findings using the mnemonic "CHAPS" to cover the various areas of the supply.

"CHAPS" covers the following points.

**C**                      **C**onditions in the pharmacy at the time.

This can be established from the:

- Complainant

- Records - Records would help to identify the name of the responsible pharmacist and whether they had been working without a break.
- Computer - Computer records may help to identify the number of prescriptions dispensed that day and the exact time the prescription was dispensed.

Interestingly most errors do not occur during busy periods of dispensing.

You may wish to review the layout of the dispensary and the availability of bench space. You may use baskets or similar to hold dispensed items before checking and handing to the patient with counseling. It has been reported that pharmacists who use this type of system help prevent medicines being crossed from one patient to another, and also to keep the bench space tidy.

**H**            **H**Health of the pharmacist and other members of the team.

Was the pharmacist or other person(s) involved in the dispensing process ill at the time?

**A**            **A**ssistance.

Was the pharmacist working alone or was s/he assisted? Identify the person who assisted. Make a judgment about the qualifications and competence of the assistant.

**P**            **P**rescription should be recovered from the file or get a copy of it from the relevant Prescription Pricing Authority.

- Was the error caused by the legibility of the prescription?
- Was the prescription hand written or computer generated?
- Check endorsements for what was supplied.

**S**            **S**ystems used for dispensing and checking must be reviewed.

Depending upon whether the pharmacist was working alone or with someone assisting, this covers every part of the dispensing process. The type of error may direct your attention to one area of dispensing practice. Usually errors fall into categories:-

- Misreading the prescription.
- Incorrect picking of the medicines.
- Transposing the label or labelling the medicine incorrectly.
- Giving the wrong prescription to the wrong patient (for example, where the error involves placing the medicine in the wrong bag or where the patient's address is not checked properly when handing out the dispensed medicine).
- Selection of the wrong strength (or wrong preparation) from the PMRs when using the Repeats facility, then checking the stock against the label, not the original prescription.
- Incorrect compounding.
- Supplying contaminated or out-of-date stock.
- Dispensing against an incorrectly written owing slip, rather than the prescription.

Whatever weaknesses there are in the system, the final accuracy check must overcome them. It is most important to review these critically.

The mnemonic "HELP" can be used when making the final check on the dispensed medicine, to ensure that all the necessary checks have been made. "Help" stands for the following:-

- H** "How much" has been dispensed. Open all unsealed cartons and sealed cartons, if appropriate, to check that the contents are correct and match the quantity requested on the prescription. Check that the correct patient information leaflet has been included.
- E** "Expiry date" check. Ensure this is sufficient to cover the treatment period.
- L** "Label" check. Check the patient's name, product name, form, strength and dose are the same as on the prescription. Check that the correct and appropriate warning(s) are included on the label.

- P** “Product” check. Check that the correct medication and strength which has been requested on the prescription has been supplied.

Handing out of dispensed medicines must be carried out by trained staff. To avoid handing medicines to the wrong person, prescription receipts may provide useful safeguards, although even these are not foolproof. The person collecting the dispensed medicine should be asked for the address or date of birth of the patient, which should be checked against the prescription.

When reviewing dispensing errors which have resulted in a serious patient safety incident, the NPSA incident decision tree helps to identify why individuals acted in a certain way, and this may be a very useful tool for pharmacists, managers and organisations to consider using. Information on the incident decision tree can be found at [www.npsa.nhs.uk](http://www.npsa.nhs.uk).