



**A Guide to
General Pharmaceutical Council
Investigations and Fitness to Practise
Proceedings**

Contents

Introduction	3
What is the GPhC's role?	4
How does the GPhC investigate concerns?	5
Stage 1 – Raising concerns	6
Stage 2 – Investigation	7
Stage 3 – Conclusion of investigation	8
Stage 4 – The Investigating Committee	9
Stage 5 – The Fitness to Practise Committee	10
The 3 stages of a Fitness to Practise Committee hearing	11
What does the hearing room look like?	12
What sanctions can the Fitness to Practise Committee impose?	13
Conclusion	14

Introduction

For a pharmacist any complaint or concern which is raised by the General Pharmaceutical Council (GPhC) can be confusing and stressful, particularly because the outcome may have an impact on your ability to earn a living. It is therefore crucial that you take specialist legal advice at an early stage in order to put you in the best possible position to respond to the allegation and to help you to navigate your way through the various stages of the process.

I have been advising and representing professionals who are subject to fitness to practise proceedings for over 18 years. My particular expertise in this area means that I am not only able to assist in relation to proceedings brought by the GPhC, but I am also able to advise regarding associated issues which may also be ongoing at the same time, such as corresponding fitness to practise steps being taken by NHS England; helping to protect your business as well as you.

This guide is intended as an overview of the GPhC's fitness to practise process and I hope that it will be of use to any pharmacy professional who is concerned about fitness to practise proceedings, or who wants to know more about how the GPhC regulates. It deals with the most common questions that my clients ask me when they are facing an investigation.

The figures in this guide are taken from the GPhC's Annual Report 2021/2022.



Noel Wardle | Partner

T. +44 (0) 117 325 0039

M. +44 (0) 7594 649135

Temple Bright | templebright.com

29 Great George Street | Bristol BS1 5QT

What is the GPhC's role?

The GPhC is the body responsible for registering and regulating pharmacists, pharmacy technicians and pharmacy premises in Great Britain. In 2021/22, 61,137 pharmacists, 24,928 pharmacy technicians and 13,844 pharmacy premises were registered with the GPhC.

Its main function is

“to set and promote standards for the safe and effective practice of pharmacy by registrants at registered pharmacies”

From time to time, the GPhC may have concerns regarding whether a pharmacist or technician is practising safely and effectively. If it does, it may carry out a ‘fitness to practise’ investigation. The GPhC may also have concerns about a pharmacy premises registration and has the power to enforce premises standards against the pharmacy premises registration. This Guide only looks at fitness to practise investigations relating to registered pharmacy professionals.

The GPhC may start a fitness to practise investigation because of issues identified during an inspection, or because a complaint has been made by someone else, such as a patient or another healthcare professional.

Many pharmacists will never have to face a fitness to practise investigation, but investigations by the GPhC are not uncommon and are increasing year-on-year. This is probably due to a greater awareness amongst the public of the role of the GPhC, combined with the ease with which the public can now raise concerns.

In 2021/22, the GPhC considered 3,080 fitness to practise concerns.

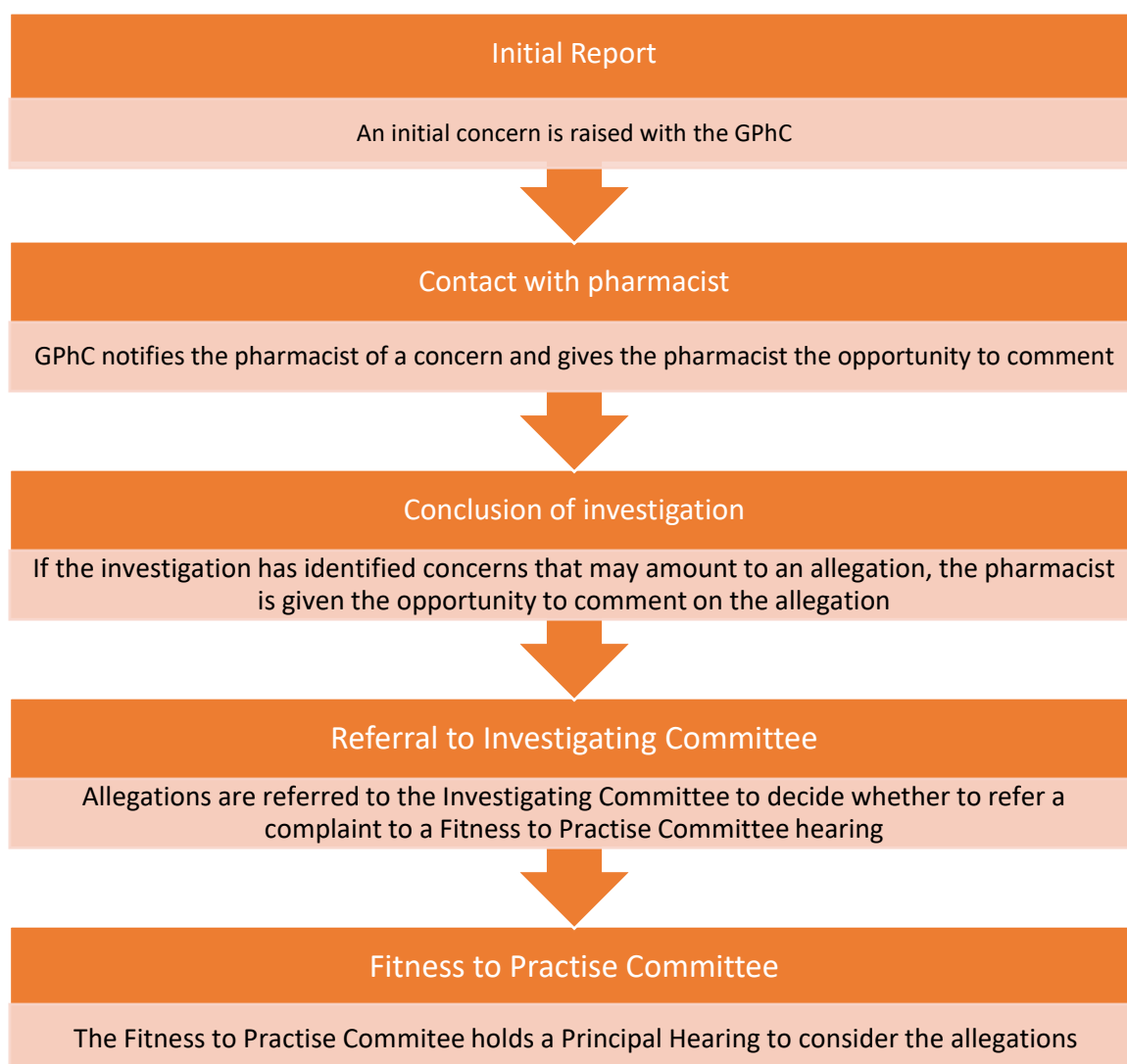
The GPhC says that it aims to complete its investigation within six months from receipt of a concern, although it will often take much longer depending on the seriousness and complexity of the case.

How does the GPhC investigate concerns?

The GPhC may investigate a concern using its own inspectors, through its in-house case workers, or using external solicitors.

There are several stages to a fitness to practise investigation, and an investigation may conclude and be closed at any one of these stages – just because a concern has been raised does not mean that the concern will end up being considered at a Fitness to Practise Committee hearing.

I have set out the main stages of an investigation in the flow chart below and will then look at each stage in more detail.



Stage 1 – Raising concerns

As well as its role in registering and regulating pharmacists, the GPhC must register and regulate pharmacy premises.

As part of its duty to regulate pharmacy premises, the GPhC conducts inspections of pharmacy premises using its team of inspectors, who are all registered pharmacy professionals.

If the inspectors identify concerns whilst carrying out premises inspections, or as part of other routine duties, the inspectors may pass those concerns to the GPhC concerns team to investigate further.

Concerns may also be raised by members of the public, other pharmacists, other regulators or other healthcare professionals. Concerns can be communicated to the Council by the completion of the 'raising concerns' form on the Council's website. Just over half of fitness to practise concerns raised with the GPhC in 2021/2022 came from members of the public.

The GPhC will conduct an initial review of the concern to consider whether it should investigate further or whether the concern should be closed at this initial triage stage. For example, a concern may be raised which falls outside the scope of the GPhC's role.

If the GPhC considers that the complaint is outside its remit or does not meet the threshold criteria for investigation, it will close its file at the triage stage without further action. In 2021/22, 2,577 complaints were closed at the triage stage; that was over 9 in 10 (91%) of the total number of concerns that were concluded in that year.

If the concern does raise matters which fall within the GPhC's statutory functions, it will proceed to investigate the concern.

Investigation

The first you may hear of a GPhC investigation might be when you receive a letter from a GPhC case investigator informing you that an issue has been brought to their attention. That letter might not give much information about the concern and may simply state that the GPhC is investigating a concern and will write to you again when it has investigated further.

Any pharmacist who receives a letter from the GPhC will naturally be worried, but remember many cases do not progress further than the initial investigation.

Often the initial letter will state that you are not being invited to comment at that stage, but you may comment or provide documentation if you wish. You should seek legal advice before commenting or providing documentation at this stage, because you are unlikely to know the full picture, and anything you say at this early stage may have an impact on the case as it progresses.

The GPhC's investigation may be wide-ranging and take some time. The GPhC may obtain statements from the complainant and witnesses and obtain documents such as prescriptions, PMR data, standard operating procedures or pharmacy registers. Depending on your role in the pharmacy, the GPhC may ask you to provide those documents or they might ask someone else to provide them (for example the superintendent pharmacist).

As part of the investigation, the case investigator may also ask you to answer questions. This is usually done in correspondence. Again, you should seek legal advice before answering any questions. Whilst the case investigator may explain that pharmacists have a duty to co-operate with fitness to practise investigations, careful thought must be given to replies.

Stage 3 – Conclusion of investigation

When the case investigator considers that they have completed their investigation, they will consider whether any of the concerns raised give rise to an allegation against the pharmacist.

An allegation may arise in many different circumstances, for example following a criminal conviction or caution, or a failure to comply with the GPhC's Standards or guidance.

At that stage, the case investigator will usually write to you and give you the opportunity to comment on the allegations arising out of the investigation and the evidence obtained by the GPhC.

Even though the GPhC may have taken many months to conclude its investigation, you will often be given only a short time to respond.

At this stage you will have to consider whether to respond and, if so, what you should say. Care must be taken with any response you give because any response may form part of the bundle of evidence should the case progress further.

The GPhC will then consider the allegations and all the evidence – including your response – and decide what action to take.

In 2021/22, 72% of investigations that progressed beyond the initial triage stage concluded with either no action being taken or with the pharmacist receiving a letter of advice at this stage. If the GPhC believes that an allegation is more serious, it may either refer the allegation directly to the Fitness to Practise Committee (usually for the most serious types of cases where an interim order may be necessary, or cases which arise out of a criminal conviction or caution) or they may refer the allegation to the Investigating Committee.

At this stage you may also need to consider whether steps should be taken to protect your business, especially if it is not owned by a limited company.

Stage 4 – The Investigating Committee

The Investigating Committee is a screening committee. It cannot decide disputes of fact. Its role is to consider the allegations which have been made against the pharmacist and to decide whether they are sufficiently serious to be referred to the Fitness to Practise Committee for a hearing, or whether the allegations can be disposed of in another way, such as by giving a letter of advice, or a warning.

In 2021/22, 34 cases (or 13% of the total number of concerns that progressed beyond the initial investigations stage) were concluded by the Investigating Committee.

The Committee meets in private. Witnesses do not give evidence in-person and it does not hear live evidence from any person but, instead, the Committee considers the allegations by reference to documents and statements. You will not be able to attend the meeting at which your case is considered. However, you will be given the opportunity to submit a written response to the allegations which have been made against you, and this response will be provided to the Committee in advance of the meeting, together with the GPhC's documents.

The Investigating Committee has a wide range of options for the disposal of cases, including:

- Direct further investigations.
- Take no further action.
- Provide a letter of advice.
- Give a warning (usually only if the pharmacist consents).
- Accept undertakings.
- Refer to the Fitness to Practise Committee for a hearing.

In 2021/2022, of the 34 cases concluded by the Investigating Committee, 28 registrants received a warning and 5 received a letter of advice.

You will be notified of the Committee's decision in writing. It usually takes a week or two to receive the decision.

Stage 5 – The Fitness to Practise Committee

Sometimes the GPhC may decide that it is necessary for interim steps to be taken against the pharmacist's ability to practise before the final fitness to practise hearing. In these circumstances, the GPhC will make a formal application to the Fitness to Practise Committee for an interim order to be made. Typically, an interim order will involve a pharmacist being suspended from practice or conditions being imposed on their registration until the final hearing has ended. If you receive a notification from the GPhC that they are going to apply for an interim order you need to take urgent legal advice as you may only receive a few days' notice before the application is heard.

Before the final hearing takes place, formal allegations and documentary evidence will be sent to you by the GPhC or its lawyers. If you are going to give evidence you will have to send a written statement to the GPhC together with the statements of any other witness on whose evidence you intend to rely at the hearing. There are time limits and formalities that apply to these procedures.

Careful thought must be given to the preparation of your evidence because it may have a significant impact on the outcome.

From the date when the case is referred to the Fitness to Practise Committee, it may take a year or more until the final hearing.

The Fitness to Practise Committee secretary will give formal notice of the date and time of the final hearing. Depending on the complexity of the case, the hearing may last several days. The hearing may take place in-person (at the GPhC's hearing centre in Canary Wharf) or remotely by video link.

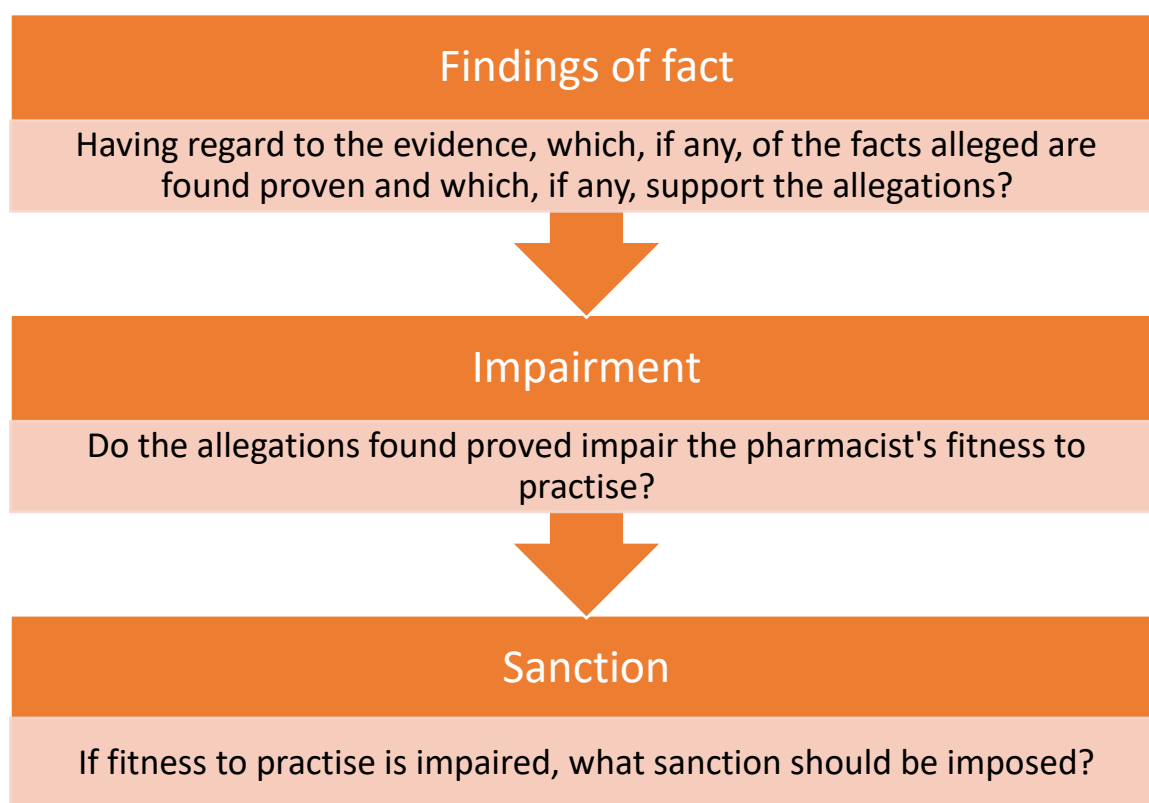
When the hearing takes place, the Fitness to Practise Committee will consider the allegations. You will have the opportunity to attend the hearing, ask questions of the GPhC's witnesses, give evidence, and address the Committee. Whilst it is possible to attend a fitness to practise hearing without a lawyer, an experienced lawyer who understands community pharmacy will know what questions to ask, what points should be drawn to the Committee's attention and the best way to present your case.

In 2021/22, the Fitness to Practise Committee held 40 final hearings.

The 3 stages of a Fitness to Practise Committee final hearing

The Fitness to Practise Committee will consider the allegations in three stages. These are set out below.

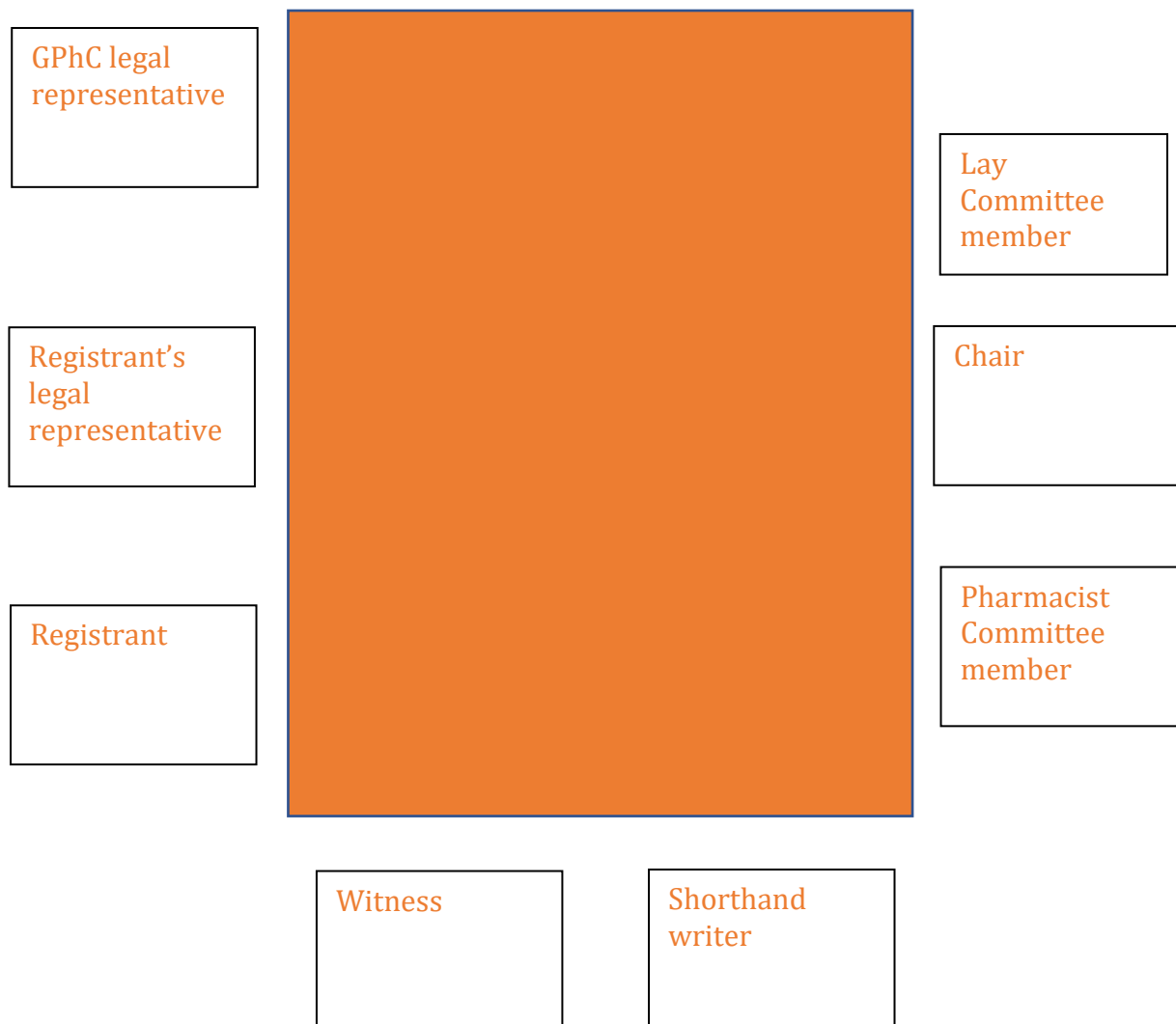
At each stage you will have the opportunity to address the Committee. It will then consider its decision in relation to each stage in private. It can take some time between stages for the Committee to make its decision.



What does the hearing room look like?

The Fitness to Practise Committee usually has three members: a legally qualified Chair, a pharmacist member and a lay member. Sometimes the Chair is not legally qualified, in which case the Committee will sit with a legal assessor whose role is to advise the Committee on the correct law and legal procedure. The Committee will hear evidence and submissions in the hearing room. Hearings usually take place in public (unless the allegations are based on ill health) and may be reported.

The Committee room is usually set out like this:



What sanctions can the Fitness to Practise Committee impose?

The Committee has a range of sanctions available to it. When considering sanction, it must impose only the minimum sanction which is necessary to address the findings it has reached. It may:

- Take no further action. This was the outcome in a tenth of hearings in 2021/2022 and most commonly arises where the allegations have not been found proved.
- Give advice.
- Issue a warning. This was the outcome in just under 1 in 10 final hearings in 2021/2022.
- Impose conditions upon the pharmacist's registration. The conditions must be designed to address the failings that it has identified. Conditions must be for a fixed period and may be reviewed at the end of that period. The imposition of conditions happened in just under a tenth of hearings in 2021/22.
- Impose a period of suspension. The suspension must be for a fixed period of up to 12 months and will usually be reviewed at a hearing before the end of that period. The Fitness to Practise Committee directed that the pharmacist should be suspended from practice in around half of final hearings in 2021/2022.
- Removal from the register. A pharmacist who is removed from the register cannot apply to be restored for a period of at least five years. Removal was the eventual outcome in a fifth of final hearings in 2021/22.

In certain circumstances the Committee can order the GPhC to pay some or all of the pharmacist's legal costs, or it can order that the pharmacist pays some or all of the GPhC's legal costs. However, in practice, costs orders are rarely made.

There is a right of appeal against the Fitness to Practise Committee's decision. The appeal must be made within 28 days of the decision, so if you intend to appeal, you must act quickly.

The Committee may impose "interim measures" during the period of any appeal, restricting the pharmacist's ability to practise until the appeal period has ended and the sanction takes effect.

Conclusion

If there is anything raised in this Guide that you would like to discuss, or if you are currently the subject of an investigation and would like to discuss your case then please do not hesitate to contact me; I won't charge for the call.

I will usually give you a written estimate of fees in advance of doing any work for you. I would typically assist pharmacists with:



I can advise you during any of the above stages of the process, having many years of experience with investigations, and can offer time and cost-effective solutions.



Contact information

Noel Wardle

Partner
Risk, Compliance & Investigations

noel.wardle@templebright.com

T. +44 (0) 117 325 0039

M. +44 (0) 7594 649135

Temple Bright

29 Great George Street
Bristol
BS1 5QT