A guide to voluntary agreements: what they are for and when they may apply
Introduction

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

What this document is about

1. This document tells you:
   • what a voluntary agreement is
   • its purpose
   • when we will consider entering into an agreement with a pharmacy professional.
   It will be regularly reviewed to ensure it remains fit for purpose and aligns with our general approach to managing concerns.

Who this document is for

2. This guidance aims to help pharmacy professionals understand what a voluntary agreement is and when we will consider making one. It may also help people who are involved in investigating cases, and in monitoring pharmacy professionals who have an agreement in place. This includes:
   • pharmacy professionals who have had a concern raised about them, are considering making a self-declaration or already have an agreement in place
   • representative bodies providing support or advice for pharmacy professionals
   • GPhC staff members who are responsible for assessing cases and considering the use of an agreement
   • employers thinking about making a referral or have a staff member subject to an agreement
   3. It may also be useful to anyone who is interested in the fitness to practise process.

Equality and diversity

4. The GPhC is committed to promoting equality, diversity and inclusion in all we do. We value diversity and individuality in our staff, in the pharmacy profession and in our governing Council. Our aim is to make sure that our processes are fair, objective, transparent and free from discrimination, and that all stakeholders receive a high level of service. We keep to the principles set out in the Equality Act 2010 and have developed an equality, diversity and inclusion scheme.

5. All GPhC staff are expected to demonstrate our values and to work towards these aims throughout the fitness to practise process. The GPhC will act in accordance with the rights set out in the European Convention on Human Rights (ECHR) as incorporated into domestic law by the Human Rights Act 1998.
About voluntary agreements

6. Throughout our decision-making process we want to act in a proportionate, efficient and effective way. Our priority is patient safety and, where possible, we prefer to put arrangements in place that protect the public through mutual co-operation and partnership.

7. If we receive a concern and believe that working in partnership with a pharmacy professional to protect the public is an appropriate outcome, we may offer a pharmacy professional the opportunity to enter into an agreement with the GPhC. This guidance explains when we may make such an offer and what it involves.

8. These agreements are different from ‘undertakings’, which are statutory arrangements that may be agreed at an Investigating Committee. Voluntary agreements are not statutory. They will usually apply to health or performance matters and will not be appropriate for any misconduct that presents a risk to patient safety.

9. You can find out more about our fitness to practise process on our website.

What is a voluntary agreement?

10. A voluntary agreement is an arrangement between the GPhC and a pharmacy professional. It is a commitment the pharmacy professional makes about their future practice. It takes place after we have finished our enquiries about a concern (when we have gathered information on which we can make a decision) and before the formal committee stage (an Investigation Committee).

11. The aim of the agreement is to allow the pharmacy professional to continue to practise, but with some agreed requirements in place to make sure they remain safe to practise, and that any health condition is properly managed. The agreement is entirely voluntary and is designed to provide support for a professional.

12. An agreement can help minimise the stress for everyone involved in the case and enable us to conclude the process fairly and promptly quickly. Pharmacy professionals may want to contact their defence organisation or legal representative before deciding to enter into an agreement.

When we will consider offering voluntary agreements

13. We can offer an agreement once we conclude our enquiries, for example, after we have made preliminary enquiries and received any relevant health assessment reports, or once we have concluded an investigation.

14. We will only consider an agreement where it is adequate to assure patient safety and is an appropriate and proportionate outcome. We will only make an agreement when it is possible to draft an appropriate and practical arrangement that can be effectively monitored. We will only recommend an agreement if we are satisfied that the pharmacy professional can benefit from it.

15. When deciding whether to offer an agreement to a pharmacy professional, we will consider if:
   - we are satisfied that patients and the public will be protected
   - an agreement is an effective and proportionate way of dealing with the concerns about the pharmacy professional
• there is evidence of a pharmacy professional’s willingness to respond positively to restrictions and oversight, and to work with the GPhC
• a risk or potential risk to patient safety remains, if the condition is not appropriately managed
• the pharmacy professional has sufficient insight into any health problems or conduct
• there is evidence that the pharmacy professional has been open and honest
• the pharmacy professional, although not currently impaired, requires some support to enable them to practise safely and effectively
• the agreement is a fair and a proportionate response to the risk that exists
• the absence of an agreement could lead to a risk developing in future

We will also consider any relevant information about the pharmacy professional’s health. This is not a full list and there may be other factors which are relevant to individual cases.

16. We will not normally consider an agreement if the pharmacy professional has previously broken any previous agreement, or breached undertakings or conditions imposed by an Investigating Committee (IC) or Fitness to Practise Committee (FtPC). An agreement will not be appropriate if:
• the concern is one that should be referred to the IC
• the pharmacy professional has not demonstrated insight
• there is any risk to public protection even if an agreement is made

17. In offering an agreement, we will make it clear that it is an entirely voluntary initiative and that its purpose is to support the pharmacy professional making it to continue to practise. It must be agreed in partnership or it will not work. We will follow the process below to make, review and conclude the agreement.

Deciding on the appropriate agreement

18. Making an agreement does not mean that the pharmacy professional has admitted their practice is impaired. It is a partnership approach to make sure any potential risk to patient safety is mitigated and managed, and to provide assurance to the GPhC without having to delay resolution of the matter.
19. The agreement should always take account of the specific circumstances of each case and be drafted to reflect them. It should deal with the perceived risks in a proportionate way.

20. The aims of the agreement with the pharmacy professional should be made clear. This is so that when a review takes place, we are able to decide whether the aims have been achieved.

21. An agreement may include the following:
   - assurances that relevant individuals such as employers, contractors, primary care trusts, superintendents, Responsible Pharmacists and pharmacy staff are informed of the agreement and are willing to support the pharmacy professional if required by the agreement
   - regular updates by way of a report from suitable third parties that the pharmacy professional is complying with workplace or medical related agreements and that there are no new concerns about their fitness to practise, performance or health
   - permission to contact and share information with relevant third parties

22. Agreements are for a set period only and should not usually be recommended for more than six months. Towards the end of that period the we will discuss with the professional whether the agreement should be extended or whether it should finish.

23. When considering the period for which the agreement should continue, we will consider the time that is likely to be needed before the matter is resolved, for example, the time needed to complete any recommended treatment plan.

Making sure the agreement works for the pharmacy professional

24. An agreement depends on co-operation to be effective. We will work in partnership with the pharmacy professional to understand how effective an agreement is. We will review any supervision reports and any other relevant information sent in by the pharmacy professional during the period that the agreement is in place. We will assess information and monitor the agreement to decide whether:
   - the pharmacy professional is able to continue to meet the terms of the agreement
   - there are any new concerns that need to be acted on
   - there has been a deterioration in health or performance

25. If we receive evidence that a pharmacy professional is unable to continue with the agreement, we will consider whether we need more information to be able to confirm that this is the case. If it is confirmed, we will:
   - write to the pharmacy professional reminding them of the importance of meeting the agreement, and work with them to ensure the agreement remains workable, or
   - refer the case to the Investigating Committee (IC) if there is a risk to patient safety

26. If we receive information that suggests the agreements are not working, the agreement may end, or the case may be considered for referral to the IC. For example, this may be where there has been an additional concern raised, or where a health or performance matter to which the agreement relates now presents a risk to patient safety.
Reviewing the agreement

27. We will undertake a review of the agreement after six months or once the agreed term has come to an end if this is sooner. We will take into account the information received throughout the monitoring period and decide whether the agreement should be concluded or extended, or if the concern should be referred to the IC.

28. If we receive information that suggests that the agreement is no longer benefiting the pharmacy professional or it is no longer appropriate, for example if the pharmacy professional’s health or performance has deteriorated and there is a risk to the public or to themselves, we may then refer the case to the IC. The agreement may be extended for a maximum of six months if it is appropriate to do so. If the matter is not resolved at the end of this second period, we may consider alternative action. We may also decide the matter has been resolved and end the agreement.

Concluding the agreement

29. We may conclude the agreement at any time if we receive information that suggests it is no longer needed. We will end the agreement if:
   - the pharmacy professional has improved during the term of the agreement, and
   - the period of the agreement passes with no new concerns or deterioration in health or performance
   - the pharmacy professional’s health or performance has improved and there is no risk to the public
   - a risk assessment, including any relevant test results, does not highlight any issues

30. A pharmacy professional may discuss concluding the agreement with the GPhC if:
   - they are no longer able to meet the terms of the agreement
   - they believe the agreement is no longer needed and have evidence to support this
   - they believe the agreement is no longer appropriate and that a new, different, agreement should be put in place.

Publication and disclosure

31. The details of the agreement will not be published on the online register of pharmacy professionals. But we will notify the person that raised the concern of the outcome and may disclose details to an employer, or other relevant third party. This would depend on the nature of the agreement and if it is in the public interest to do so. You can find more information on what we publish and disclose and what informs our decision making in our publication and disclosure policy.

Support and advice

32. If you have any questions about the voluntary agreement process, you should contact the individual staff member responsible for managing your case. They will be able to answer your questions about how the process works. You can find more information on advice and support for those involved in the fitness to practise process is available in the fitness to practise section of our website.