

# Registered pharmacies enforcement policy

Effective from March 2019

## 1. Introduction

### What this policy is about

- 1.1 We have an important role in providing assurance to people that the pharmacy services they and their families use will be safe and effective. We also want to drive continuous improvement in the quality of care that people receive when using pharmacy services.
- 1.2 We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register. We have a range of enforcement options that we use to achieve these objectives, including statutory enforcement powers set out in the Pharmacy Order 2010 and the Medicines Act 1968.
- 1.3 The effective use of these enforcement options in regulation is important to secure compliance with our **standards for registered pharmacies** and, where necessary, to ensure that pharmacy owners who have not complied may be held to account. This policy:
  - sets out the approach and principles we follow when using our enforcement options
  - summarises the range of enforcement options available to us
  - outlines the criteria we take into account when making decisions about which enforcement option, or combination of options, to use
  - supports consistent decision-making about when to use our enforcement options
  - aligns with our wider strategic approach to regulation.

### Who this policy is for

- 1.4 This policy is primarily aimed at pharmacy owners, who are responsible for ensuring the safe and effective provision of pharmacy services at or from a registered pharmacy, and are accountable for making sure that the standards for registered pharmacies are met. However, this policy is also useful to anyone who is interested in how we regulate registered pharmacies including the public, defence organisations, other regulatory bodies, including the Professional Standards Authority (PSA) and the Courts.
- 1.5 Registered pharmacies may have different ownership structures. Throughout this policy we use the term 'pharmacy owner'. This includes registered pharmacies owned by an individual pharmacist, partnership or body corporate. This policy applies equally to all types of pharmacy owners.

- 1.6 This policy also applies to all registered pharmacies regardless of whether the pharmacy provides services face to face in a traditional way or over the internet.

### What falls outside this policy

- 1.7 This policy focuses on registered pharmacies and the enforcement action that we may take against pharmacy owners. In some cases, we may identify concerns or issues about individual pharmacy professionals that require further investigation through our fitness to practise processes. These will be considered in line with our published guidance and procedures. You can **find out more about fitness to practise processes for individual pharmacy professionals** on our website.
- 1.8 This enforcement policy cannot substitute for judgement in individual cases. There will be occasions when, depending on the facts of an individual case, it will not be appropriate to follow the exact steps described in this policy. It should be read as a general guide to good practice when carrying out, or considering, enforcement action.

## 2. Our approach to enforcement

- 2.1. Our overall approach is to support and encourage pharmacy owners to meet the standards for registered pharmacies. We are committed to using the minimum regulatory intervention required to achieve the desired result, known as 'right-touch' regulation<sup>1</sup>. This means we will use the minimum regulatory action required to ensure that pharmacy owners are meeting our standards.
- 2.2. We encourage pharmacy owners to meet our standards through a range of different activities. This includes promoting the standards and supporting guidance through our website and other channels such as our online newsletter. We also ask pharmacy owners for evidence that they are continuing to meet the standards through our inspections, and we publish inspection reports. We share insights from our inspection activities across the wider pharmacy sector, to encourage learning and drive improvements.
- 2.3. Where possible we try to secure the safe and effective practice of pharmacy at or from a registered pharmacy through open communication and dialogue with the pharmacy owner.
- 2.4. We have a number of different enforcement options available to us to secure compliance with our standards. These range from improvement action plans to statutory enforcement powers including improvement notices and conditions on registered pharmacy premises. We use our statutory enforcement powers in situations when a pharmacy owner does not complete an improvement action plan and carry out the necessary changes to make sure our standards are met, or in situations when there is a serious risk to patient safety. We define statutory enforcement action as any use by the GPhC of the range of statutory enforcement powers set out in the Pharmacy Order 2010 and the Medicines Act 1968.
- 2.5. We make decisions about when to use our enforcement powers consistently and proportionately, so that we take only the steps we need to take to make sure a pharmacy meets the standards and to safeguard the public. We act swiftly, robustly and fairly, with a clear focus on safety.
- 2.6. We work collaboratively with other regulators and agencies to ensure that the most appropriate organisation manages the concerns. If the GPhC is not the appropriate enforcement authority we

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<sup>1</sup> Right Touch Regulation (Revised) -

<https://www.professionalstandards.org.uk/publications/detail/right-touch-regulation-2015>

will notify the relevant organisation and assist them where appropriate and necessary. When doing so, we follow the provisions of the General Data Protection Regulation and other relevant legislation.

- 2.7. We also make full use of the intelligence and data that we collect in order to support and inform our decision-making. This includes information gathered through our inspections; from our work with other regulators; from concerns raised by individuals or organisations; and, from the wider public. Making full use of our intelligence and data enables us to focus our efforts on proactively anticipating and responding to issues, and tailoring our regulatory responses to achieve the desired results in the best and quickest way.

### 3. Principles that guide our use of enforcement

- 3.2 We use our enforcement options to meet our statutory objective of protecting, promoting and maintaining the health, safety and well-being of patients and the public, including people who use pharmacy services. The following principles guide our decision-making:

#### Proportionality

- 3.3 Proportionality is about responding appropriately and taking the right action to secure compliance. This will generally involve taking account of the degree of the risk caused by non-compliance. Sometimes, however, we will need to take enforcement action even though the risks may be uncertain.
- a) We take action that we consider to be proportionate. This means that our response, including the use of enforcement options, must be assessed by us to be proportionate in the circumstances of an individual case.
  - b) Where appropriate, if the pharmacy owner is able to improve the service on their own and the risks to people who use services are not immediate, we will generally work with them to meet our standards rather than taking enforcement action.
  - c) We take enforcement action when people are at risk of harm or registered pharmacies are repeatedly or seriously failing to meet our standards.

#### Consistency

- 3.4 Consistency means taking a similar approach in similar cases to achieve similar outcomes within which a degree of discretion is available. We aim to be consistent in applying our enforcement options by, as far as possible, dealing with similar cases in a similar manner. However, it is important to note that:
- consistency does not mean that we use the same enforcement option every time our standards are not met
  - the facts in one case are rarely replicated exactly in another case: even though we aim to achieve broad consistency, we will take different decisions in cases where the facts are not the same
  - decisions about specific enforcement action rely on individual professional judgement and each case is evaluated on its own facts and circumstances and the assessed risks

- we train and support our inspectors and others involved in the decision-making processes to promote consistency in our approach and we have a range of oversight and quality assurance processes: all staff who make decisions about regulatory action will be required to follow this policy
- we collaborate with other regulators where appropriate, to promote consistent approaches

## Transparency

- 3.5 Transparency is about helping pharmacy owners to understand what is required of them at the outset and setting out what they may expect from us in return. It also involves making clear what remedial action is required and providing details of any rights of appeal.
- a) We are open and transparent about our approach to enforcement, consistent with how we carry out our regulatory functions.
  - b) We are clear about what we expect and how we approach cases where registered pharmacies are not meeting our standards.
  - c) We publish relevant information including the factors that we take into account when making decisions and the processes for appeals and making representations against our decisions.
  - d) We also publish information about the enforcement action we have taken, when this is appropriate and allowed by law.
  - e) We share learnings from our enforcement activity wherever possible so that it can be used by pharmacy owners and the sector more widely.

## Targeting

- 3.6 Targeting of enforcement action means prioritising and directing our regulatory efforts effectively. We use strategic and operational risk assessment to focus our resources where we believe they are most needed.
- a) We concentrate on the activities which create the most serious risk, either because the nature of the activity is inherently high-risk or because of a lack of appropriate controls or appropriate response in other less high-risk activities.
  - b) This involves identifying and focusing on those responsible for the risk.

## Accountability

- 3.7 Our enforcement activities will be open to public scrutiny, with clear and accessible policies, and fair and efficient complaints procedures.
- a) We are accountable to the public and our enforcement actions can be judged against the principles and approach set out in this policy.
  - b) Pharmacy owners need to know what to expect when our inspectors visit and how to raise any complaints they may have.
- 3.8 These principles apply to both the enforcement of individual cases and the management of our enforcement activities as a whole. They are not applied in isolation and are informed by an understanding of the pharmacy sector and the environment in which registered pharmacies are operating.

- 3.9 Decisions about enforcement action are based on the information available to us at that time. We accept that there will be occasions when more facts emerge later in the process, or disputes of fact are resolved, and therefore enforcement action is no longer required. If we believe such a stage has been reached, we will cease enforcement, where appropriate.

## 4. Enforcement options

- 4.1 We have a number of different enforcement options available to us to secure compliance with our standards. These range from improvement action plans to statutory enforcement powers including improvement notices and conditions on registered pharmacy premises.
- 4.2 We choose the most appropriate enforcement option available in individual cases. This may involve using one or more of the following options set out below.
- 4.3 Our enforcement options can be used at any stage and are not sequential. In some cases, we may decide to use a combination of enforcement options.
- 4.4 We use these enforcement options flexibly, depending on the nature of the non-compliance and the desired outcome of the intervention. In deciding what level of enforcement action is appropriate, our inspectors exercise discretion and professional judgement according to the circumstances found.
- 4.5 Our inspectors are guided in this process by this policy, which provides a framework for consistent enforcement decision-making and takes account of the pharmacy context on a case by case basis.

### Range of enforcement options

- 4.6 This section outlines the range of the enforcement options (including statutory enforcement powers) that we have and how these work in practice.

#### Improvement action plans

Generally, we use improvement action plans as our first response to failures to meet our standards for registered pharmacies.

If one or more standards are not being met, and there is no immediate risk to the public or patients, we require pharmacy owners to develop an improvement action plan, setting out what they will do, within a set time, to put right the issues and meet the standards.

We follow up with these pharmacies to make sure they make the improvements needed and that the standards are fully met.

The use of an improvement action plan does not prevent further statutory enforcement action being taken in some cases where this is necessary. However, improvement action plans enable pharmacy owners to engage constructively with us about how to meet the standards and limit the impact of any non-compliance.

Where an action plan is not completed within the time given, or the pharmacy owner has made no attempt to comply with the action plan after repeated reminders, we consider other enforcement options, including the use of statutory enforcement powers.

## Conditions on registration

Registered pharmacies can have conditions attached to their registration. We have legal powers to impose conditions on specific pharmacy premises when this is necessary for the purpose of securing the safe and effective practice of pharmacy at those premises<sup>2</sup>. We can impose conditions on making the premises entry or subsequently (whether on renewal of the premises entry or otherwise).

Imposing, varying or revoking conditions of registration is a flexible enforcement process that we can use in a variety of different ways to ensure that pharmacy owners are meeting the standards and providing safe and effective care. We use conditions flexibly and in appropriate situations. Conditions may be used to restrict risky or unsafe activities or practices.

We give pharmacy owners reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition and of the date from which that condition, variation or revocation is to have effect. However, we also have legal powers to impose, vary or revoke conditions, with immediate effect, if we consider that giving reasonable notice would prejudice the health, safety and well-being of members of the public. In such cases, we still notify the pharmacy owner in writing.

Pharmacy owners may also apply for any of the conditions imposed to be varied or revoked<sup>3</sup>. There is more information about the process for applying to have conditions varied or revoked in our **Registration Rules**<sup>4</sup>.

A failure to comply with conditions relating to the standards can lead to an improvement notice being issued (see section below for more information).

## Improvement notices

We have legal powers to serve an improvement notice when our inspectors have reasonable grounds for believing there is a failure to meet the standards for registered pharmacies, or a failure to meet conditions relating to the standards<sup>5</sup>.

We will consider using an improvement notice if we decide that it is likely to result in the pharmacy owner addressing the matters of concern within an acceptable timescale. Where we use an improvement notice, we will explain clearly to the pharmacy owner why we consider there is a failure to comply and what they need to do to put it right.

Pharmacy owners are responsible for making sure that the work is carried out within the timeframe set out in the improvement notice. We will give pharmacy owners at least 28 days from the date the improvement notice is served. When we serve an improvement notice, the inspector will contact the pharmacy owner to discuss how they can comply.

When we are satisfied that the relevant action has been taken, the improvement notice will be withdrawn and the pharmacy owner will be notified in writing.

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<sup>2</sup> Section 74D of the Medicines Act 1968

<sup>3</sup> Section 74E of the Medicines Act 1968

<sup>4</sup> Rule 23 of the General Pharmaceutical Council (Registration Rules) Order of Council 2010

<sup>5</sup> Article 13 of the Pharmacy Order 2010

If a pharmacy owner fails to comply with the improvement notice, the matter must be referred to the Fitness to Practise Committee for consideration as a disqualification case<sup>6</sup>. There is further information about disqualification proceedings below.

Any person on whom an improvement notice is served may appeal to a magistrates' court, or in Scotland, to the sheriff<sup>7</sup>. An appeal may be brought within 28 days beginning with the date on which the improvement notice was served. The Court may suspend an improvement notice pending the determination or abandonment of the appeal.

On appeal against an improvement notice, the Court may either cancel the notice or confirm it, with or without change.

## Other enforcement options

4.7 As part of our enforcement options, we can also:

- **disqualify a pharmacy owner for failing to meet the standards and remove all premises entries from the register<sup>8</sup>**

The legal test to apply this sanction, where registered pharmacy standards are not met, is whether the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively, so far as concerns the retail sale of medicinal products (whether they are on a general sale list or not) or the supply of such products in circumstances corresponding to retail sale. These decisions are made by the Fitness to Practise Committee.

- **remove one or more premises entries from the register**

We can do this if the Fitness to Practise Committee is satisfied that the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively. Again, the legal test to apply this sanction, where registered pharmacy standards are not met, is whether the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively, as set out above. These decisions are also made by the Fitness to Practise Committee.

- **suspend one or more premises entries**

We can do this pending a full hearing of a case against a pharmacy owner<sup>9</sup> or prior to a disqualification decision or removal direction taking effect (the decision will only take effect after the time for bringing an appeal has passed, or if an appeal is brought, until the appeal is heard)<sup>10</sup>. These powers are only exercisable where the Fitness to Practise Committee is satisfied that it is necessary for the protection of the public or otherwise in the public interest.

4.8 Disqualification and removal directions may be given for a limited period, meaning that premises entries will be restored at the end of that period. These decisions are also made by the Fitness to Practise Committee.

4.9 Pharmacy owners have the right to appeal against disqualification and removal directions to the High Court (or the Court of Session in Scotland) within three months beginning with the date on

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<sup>6</sup> Article 14 of the Pharmacy Order 2010

<sup>7</sup> Article 16 and 17 of the Pharmacy Order 2010

<sup>8</sup> Section 80 of the Medicines Act 1968

<sup>9</sup> Article 56(1)(A) of the Pharmacy Order 2010

<sup>10</sup> Section 82A of the Medicines Act 1968

which the direction is given<sup>11</sup>. Pharmacy owners also have the right to appeal to the High Court (or the Court of Session in Scotland) against interim suspension measures<sup>12</sup>.

- 4.10 A body corporate can also be subject to disqualification proceedings for matters other than failures to meet the standards for registered pharmacies<sup>13</sup>. This applies where a body corporate is convicted of an offence under relevant pharmacy and medicines legislation, or one of its board members, officers or employees has been convicted of an offence, or has been guilty of misconduct that would, if that person were a pharmacist, render them unfit.

## 5. Criteria for taking enforcement action

- 5.1 Decisions to use enforcement action are taken on a case by case basis. This will be proportionate and related to the level of risk to pharmacy users and the seriousness of any failure to comply with our standards.
- 5.2 There are a number of factors that we consider when deciding which enforcement option or combination of enforcement options to use. These factors include, but are not limited to:
- the seriousness of the concerns
  - the risk of harm to patients or the public
  - compliance with other regulatory or enforcement requirements
  - the willingness and ability of the pharmacy owner to meet the standards, including any steps already taken to do this
  - the impact or potential impact of non-compliance
  - evidence of repeated or multiple failures to meet our standards
  - the likely impact of the enforcement action on the registered pharmacy
  - the likely impact of the enforcement action on the wider patient community and public (for example, where a condition on premises registration is imposed that restricts the provision of a certain service)
  - the wider public interest
  - the potential for wider learning points for pharmacy owners may mean we will prioritise a single case, so that enforcement sends a broader message to a sector and encourages improvements in the sector
  - any other relevant considerations
- 5.3 The weight given to each and any of these factors will be dependent on all the circumstances of the particular case. In all cases we will take into account the wider public interest of any action, including effective use of our resources, and whether such action would align with our wider approach to regulation. Consideration of these factors may result in a change to the type or severity of the enforcement action we intend to take.

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<sup>11</sup> Section 82(3) of the Medicines Act 1968

<sup>12</sup> Article 56(8) of the Pharmacy Order 2010

<sup>13</sup> Section 80(1)(a) and (b) of the Medicines Act 1968



5.4 We also consider whether we have sufficient evidence to enable us to proceed to take enforcement action and that this has been recorded appropriately. We follow up on any enforcement action to ensure that improvements are achieved. This includes increasing our level of inspection, where appropriate to do so.

## 6. What pharmacy owners can expect from us

- 6.1 Where we require pharmacy owners to take action to remedy any failings, we will:
- clearly explain the nature of the non-compliance(s)
  - discuss what is required to achieve compliance, taking into account the specific circumstances
  - clearly explain any actions required or decisions that we have taken
  - give advance notice of our intention to take enforcement action except in cases where we may be required to use urgent procedures
  - agree, wherever possible, timescales that are acceptable to both the pharmacy owner and us, in relation to any actions required
  - provide in writing details of how to appeal against any advice provided, actions required or decisions taken, including any statutory rights to appeal
  - explain what will happen next
  - keep in touch with the pharmacy owner where required and until the matter is resolved
- 6.2 We welcome approaches from pharmacy owners for advice and clarification on compliance related issues. We will work with pharmacy owners to address any regulatory risk associated with non-compliance that are identified and will take account of the pharmacy owner's willingness to work with us when considering what action we should take.

## 7. Other relevant powers

- 7.1 We have legal powers under the Regulation of Investigatory Powers Act 2000 ('RIPA')<sup>14</sup>. These powers extend to regulated activities that we carry out in Scotland<sup>15</sup>. This legislation gives public authorities a clear legal framework to follow if they are conducting surveillance and regulates the way in which investigations are carried out. Its aim is to provide the right balance between protecting privacy and the proper use of data and surveillance to help carry out evidence gathering, in accordance with relevant human rights legislation.
- 7.2 An authorisation under RIPA, providing the relevant statutory tests are met, provides us with the lawful basis to carry out covert (directed) surveillance activity (for example, monitoring and observing movements or activities) in our investigations, where appropriate<sup>16</sup>. However, the legislation does not authorise the GPhC to use covert human intelligence sources

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<sup>14</sup> Please note that we will be publishing full information about how we will use these powers in due course.

<sup>15</sup> The Regulation of Investigatory Powers (Authorisations Extending to Scotland) Order 2007

<sup>16</sup> The Regulation of Investigatory Powers Act 2000, Schedule 1, Part II (Relevant Public Authorities)

(for example using an informant or someone acting undercover). We will only consider using these powers in very limited cases and where all relevant criteria have been met.

- 7.3 The use of directed surveillance for a specific investigation must be subject to prior authorisation by a relevant GPhC officer (Director), as specified in Regulations made under RIPA<sup>17</sup>. In all cases, we are required to ensure that any directed surveillance is proportionate, lawful, properly authorised and necessary, having considered relevant and practicable alternatives.
- 7.4 The use of our powers under RIPA is overseen by the independent Investigatory Powers Commissioners Office (ICPO). The Commissioner, and those that work under the authority of the Commissioner, ensure compliance with the law by inspecting public authorities and investigating any issue which they believe warrants further independent scrutiny. This means that the GPhC is subject to inspection by the ICPO in relation to the use of our powers.

## 8. Other resources

- 8.1 **Further information about our approach to regulating registered pharmacies** can be found on our website.

## 9. Monitoring and review

- 9.1 We will review how this policy is practically applied and the outcomes of any enforcement action in order to monitor compliance with this policy.

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<sup>17</sup> The Investigatory Powers (Codes of Practice and Miscellaneous Amendments) Order 2018