

# Managing concerns about the online sale and supply of habit-forming medicines and those liable to abuse or overuse

## Introduction

1. The number of online pharmacies in Britain has increased significantly in recent years and continues to grow. They can, in some cases, present a risk to patient and public safety through the supply of habit-forming medicines or those liable to abuse or overuse. For example, habit forming medicines such as controlled and Z drugs or others that can be abused and overused including weight-loss medicines.
2. Many online pharmacies deal with large volumes of routine and repeated sale and supply of habit forming pain-killers and z-drugs. The supply of these medicines is subject to checks and online pharmacies are expected to have sufficient checks in place. However, the quality of checks can vary with some online pharmacies. Examples of poor practice can include:
  - Prescribing decisions being made in a relatively transactional way, that is, using a questionnaire consultation, and minimal checking with a GP. Operating models may lack a real-time or face to face consultation between the patient and prescriber, or an adequate alternative. Checking of patient history or suitability with GPs can be absent or inadequate.
  - The sale and supply in some pharmacies can be streamlined with minimal levels of clinical checking with a commercial, rather than a clinical, focus
  - Poor or weak checking and monitoring of multiple or repeat supplies, despite dealing with habit forming medicines which are known for their potential to be abused, with evidence of more frequent or larger supplies than their policies allow
  - Patient reports of history and symptoms can be taken at face value without adequate verification or appropriate identification checks. For example, patient reports of a current diagnosis, such as to justify a particular medicine, being accepted as sufficient reason to prescribe.

3. Concerns about system failings<sup>1</sup> are referred to us under our enforcement framework and sometimes these concerns relate to the supply of habit-forming medicines. These concerns may also include pharmacy professionals whose fitness to practise may be impaired as a result of their role in any system failings. These concerns can often be complex.
4. It is therefore important to respond to these emerging issues by supporting those considering such concerns with guidance about the roles involved and the context within which these concerns can arise.
5. This guidance sets out information about the roles which might play a part in system failings. This includes high-level parameters for assessing the role of the Superintendent pharmacist (SI), Responsible Pharmacist (RP) and Pharmacist Independent Prescriber (PIP) when concerns about system failings have been identified. It also includes some information about the implications for a professional's fitness to practise when a pharmacy premises is subject to enforcement action.
6. This guidance will be of use to those assessing concerns of this nature throughout the entire fitness to practise process. It will also be of use to people working in an online setting and anyone with an interest in how we manage concerns. It should be read alongside additional resources available to understand online pharmacy, for example our *Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet* and *In practice: Guidance for pharmacist prescribers*.

### **Fitness to practise implications when a pharmacy is the subject of enforcement action**

7. Individual pharmacy professionals working in various roles and capacities such as SIs, RPs, or PIPs may have played a role in the system failings we have identified. They may be working routinely within these pharmacies and involved in implementing, maintaining, or having oversight of the activities of the pharmacy.
8. When a pharmacy fails to meet any of our pharmacy standards, we will in most cases agree an action plan with the pharmacy. This will be an agreed set of remedial actions taken by a pharmacy owner while the pharmacy continues to operate normally. An action plan is in most cases enough to address any patient risk. Action plans are used when standards are not met but any ongoing patient risk is considered to be manageable.
9. Where there is evidence of ongoing patient risk which requires more urgent action, an inspector can either serve an improvement notice or the Registrar can impose conditions on the pharmacy. A condition will usually restrict the pharmacy from providing a service which we believe puts patients at risk. An example of a condition would be to stop the sale and supply of certain medication or cease a particular service. An improvement notice will identify a specific failing, the risk it creates and what is needed to be done to address it. If a pharmacy does not meet the terms of an improvement notice, then GPhC will refer a pharmacy owner to the Fitness to Practise Committee (FtPC) for disqualification. Disqualification can lead to a pharmacy or pharmacies being removed from the Register.

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<sup>1</sup> By system failings we mean the processes, procedures and policies which have been identified as not meeting our pharmacy standards such that patients and members of the public have been put at risk of harm

10. If an improvement notice or conditions are required, it means that there is evidence of serious failings in the pharmacy system. The purpose of pharmacy enforcement is to secure the safe running of a pharmacy. If the safe running cannot be secured, the aim is to remove the pharmacy through disqualification proceedings.
11. However, this process cannot deal with the conduct of individual pharmacy professionals who are implicated in the system failures. So, where the GPhC has started enforcement action against the pharmacy and pharmacy owner, we will also, where appropriate, investigate the individual professionals involved to look into their potential failings as pharmacy professionals with a role in overseeing pharmacy services. For example, a pharmacy using an unsafe system of dispensing POMs could face disqualification. But if the unsafe dispensing system has come about through the acts or omissions of an SI to manage the dispensing system, then we will investigate the SI's conduct so that any appropriate action can be taken against the SI.
12. It would not be in the public interest to allow the pharmacy professional who has potentially played a key role in the unsafe system to continue in their practice without any restrictions just because we have dealt with the unsafe system. This is particularly important if the system failings are attributable to the acts or omissions of pharmacy professionals because they could potentially continue working in other settings making the same decisions leading to system failings in other settings.

### Pharmacy professional roles which might play a part in system failings

13. It is not possible to provide an exhaustive list of roles which might play a part of a system failings, nor would it be appropriate as each case is considered on its own facts. However, it is possible to look at the key roles in online pharmacy models and assess how each interacts with the system failings.
14. As the inspection process when it leads to enforcement action will have identified serious failings in the running of the pharmacy, the next step is to determine how the failings came about and whether they are attributable to the SI, RP or PIP. At the heart of our approach is the principle that all individual pharmacy professionals are accountable for their practice and conduct, whether in relation to care they provide directly or in the context of their management, governance and leadership practice.

### The Superintendent pharmacist and their legal obligation under the Medicines Act 1968

15. **Superintendent pharmacists** have a statutory role in that *“the retail pharmacy business, so far as concerns the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of a superintendent.”*<sup>2</sup> Although the obligation for meeting the pharmacy standards falls on the owner, the SI can also be held to account for failings in the management of any of the pharmacy services. This is because the Medicines Act 1968 has set a legal requirement for the SI to have under their management the keeping, preparing and dispensing of medicinal products, and this includes any system, processes and policies which cover these activities. Therefore, if there are system failings, then there can also be a question about the SI's management and oversight.

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<sup>2</sup> Section 71(1)(a) Medicines Act 1968

16. Where an inspection report has identified failings which put patients at risk, and where the failings have resulted in enforcement actions, the GPhC will assess the SI's role at that pharmacy. This will include:

- their involvement in putting in place a particular standard operating procedure (SOP), process or system
- their role in managing and overseeing the processes and system
- their involvement in the review of the safety and quality of the service or system being monitored
- their involvement in the development of risk assessments and actions to mitigate any identified risks
- the range and pattern of any failures in the processes and system
- the extent of their daily involvement in the management of the pharmacy
- their role and input in the clinical policies which should be in place to manage the prescribing and supplying decisions
- any omissions or failings in recognising and mitigating patient risks or safety concerns.

17. The fundamental question for any assessment of the SI is that if there have been system failings, is this attributable to any act or omission on their part as the SI and their statutory role.

### **The Responsible Pharmacist and their legal obligation under the Medicines Act 1968**

18. **Responsible pharmacists** also have a statutory role in the operation of a pharmacy and this includes the obligation to *“establish (if they are not already established), maintain and keep under review procedures designed to secure the safe effective running of the business.”*<sup>3</sup> This is a significant statutory obligation and it requires more than the RP acting as the most senior dispensing pharmacist.
19. The RP must ensure that the system used by a pharmacy is safe before dispensing can take place. It is not enough that a RP ensures SOPs or clinical policies are followed. The RP is also legally obliged to ensure that the SOPs and clinical policies are safe and effective enough to protect the health and well-being of patients and members of the public, and ensure that they are followed.
20. Where an inspection report identifies failings which put patients at risk it will be appropriate to assess the role and conduct of the RP who has worked within the pharmacy. Important factors to consider will be how they are employed and how frequently they work as the RP and the extent of their actual control.
21. For example, an RP employed full time and closely involved in the running of the pharmacy will be different from the occasional locum RP who has worked only a handful of shifts providing cover. As with the SI, the issue will not be whether they have complied with processes, SOPs or clinical guidance already in place. Rather, it will be to assess if they have carried out their role

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<sup>3</sup> Section 72A(3) Medicines Act 1968

and obligations as the RP in keeping under review the safe and effective running of the pharmacy business.

22. The respective roles of SI and RP in the context of the ownership structure of the pharmacy will also be taken into account when considering their fitness to practise. The more involved and implicated the SI or RP is in the ownership and control of the pharmacy, the more likely it is that the system failures also reflect professional failings amounting to impairment of fitness to practise.
23. In assessing the roles of the SI and RP the GPhC will usually consider key sources of evidence. Key sources of evidence will include inspection reports, inspector witness testimony, job descriptions, witness testimony from other members of staff, reviews of SOPs and clinical policies by expert witnesses and audits of patient care.
24. Audits of patient care are important evidence. They do not provide evidence of direct patient care failings on the part of the SI or RP. Audits can, however, provide evidence of system failings and demonstrate how poor a system is if the audit shows regular patterns of failings.

### **The role of the Pharmacist Independent Prescriber as a key part of the online prescribing and dispensing model**

25. Pharmacist independent prescribers are increasingly likely to play a pivotal role in these online pharmacy models. The GPhC published guidance for prescribers in February 2020<sup>4</sup>. The GMC in 2019 took robust action against two doctors who had routinely prescribed dihydrocodeine based on patients' self-reporting of symptoms through a questionnaire consultation, with no GP input and with no diagnosis being made to justify the prescription. Since then, our inspections intelligence suggests more online pharmacies are using PIPs. Poor prescribing practice is poor practice whether the prescriber is a medical practitioner or a pharmacist.
26. Where PIPs are prescribing high risk habit-forming medicines with the potential for abuse, every decision to prescribe must be clinically sound and robust. Such decisions will not be sound or robust simply by reference to whether they followed the pharmacy SOPs, processes or clinical policies which are in place at that particular pharmacy. Ideally pharmacy SOPs, processes or clinical policies will be consistent with and support sound clinical decisions. However, in pharmacies where the system is unsafe, they will not, but this is where the professional judgement and accountability of a PIP or any pharmacy professional should intervene to safeguard patients.
27. Where inspections have identified poor PIP decisions, or where members of the public or other healthcare professionals have referred concerns implicating a PIP prescription, the issue is not simply the particular prescription the GPhC has been told about. The key issue is whether or not their prescribing practice as a whole is safe and effective. The GPhC approach to identifying the pattern and nature of failings may include looking at a representative sample of their prescriptions. This will include, but not limited to, the clinical prescribing rationale and record keeping justifying the prescribing decisions. The GPhC will also assess their prescribing scope of practice, competence and training to prescribe the medicines they have prescribed and the

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<sup>4</sup> In practice: Guidance for pharmacist prescribers (Feb 2020)

illnesses or conditions the medicines treat. An assessment will also be carried out of the PIP's prescribing decisions against relevant national guidelines.

28. We will not ordinarily take explanations of an isolated prescribing error in these particular models at face value. In the context of a poor system and high-volume dispensing of habit-forming medicines or those subject to abuse or overuse, looking at the pattern and scope of the PIP's prescribing will be an essential element of our assessment of the PIP's role. This is to see whether there is a wider and more serious fundamental failing in their prescribing practice. Secondly, it is to see whether there is a more serious unprofessional aspect to their prescribing practice in that they have used their qualification to 'rubber stamp' prescriptions with little or no clinical input.