

Mrs D Hocking  
Assistant Coroner for Leicester City and South Leicestershire



16 December 2021

Dear Mrs Hocking

**Regulation 28: Report to prevent future deaths**

Thank you for sending us your report regarding the circumstances surrounding the death of Jamie O'Connor. We would like to pass on our sincere condolences to Jamie's family.

**Our standards and guidance**

To provide some background context, the GPhC has a statutory purpose to protect patients by setting and upholding the **standards for registered pharmacies** and the **standards for pharmacy professionals** to ensure that registered pharmacies are safe to provide services, and that pharmacy professionals are fit to practise.

We seek assurance that pharmacy professionals and pharmacies continue to meet our standards. One of the methods we use to monitor compliance and establish if safe and effective care is being provided is by inspecting pharmacies. Since April 2019 we have published inspection reports on our inspection website **here**.

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. One of our key roles is to investigate concerns about pharmacists and pharmacy technicians that could suggest they pose a risk to patient safety or could affect the public's confidence in pharmacy. We also investigate concerns about registered pharmacies.

Pharmacy professionals must also take action to safeguard people, particularly those that are vulnerable. All pharmacy professionals are personally accountable for meeting the standards. We expect pharmacy professionals to meet our standards, comply with their legal duties, as well as considering any relevant guidance when making decisions. In addition, pharmacy owners are responsible for meeting our standards for registered pharmacies and everyone in the pharmacy team should be familiar with these standards and play a key role in delivering person-centred care.

## **The issues in the report**

I wanted to provide some further information about what we expect from registered pharmacies, specifically in the context of providing online services, as this is relevant to the issues you have raised.

We acknowledge your concern that there is no central tracking system or central database to record what each person has been prescribed and dispensed and by whom. Although this specific aspect is outside of our remit, we do produce guidance, which is designed to support pharmacy owners and pharmacy professionals to meet our standards.

### **Our guidance for registered pharmacies providing services at a distance, including on the internet**

highlights the different risks that pharmacy owners should consider as part of their initial risk assessment for the pharmacy when deciding whether or not they can safely, and effectively, sell and supply medicines at a distance, rather than in the traditional face-to face way. We published this updated guidance in April 2019, which includes more stringent safeguards where medicines are supplied to patients at a distance.

To ensure the safe management and supply of medicines, the guidance sets out the key responsibilities of the pharmacy owner in relation to the issues you have outlined in your report.

In particular, we expect pharmacy owners to:

- Make sure that their website and the websites of companies they work with are arranged so that a person cannot choose a prescription only medicine and its quantity before there has been an appropriate consultation with a prescriber. It should be made clear that the decisions about treatment are for both the prescriber and the person to jointly consider during the consultation. However, the final decision will always be the prescriber's.
- Make sure that their pharmacy staff can identify requests for medicines that are inappropriate, by being able to identify multiple orders to the same address or orders using the same payment details – this includes inappropriate combinations of medicines and requests that are too large or too frequent.
- Make sure they consider the design and layout of their website and make sure that it works effectively and looks professional.

We also expect pharmacy owners make sure that an online prescribing service, or a prescriber, that they choose to work with is aware that some categories of medicines are not suitable to be supplied online unless further safeguards have been put in place to make sure that they are clinically appropriate. This includes medicines liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important. In this scenario, the following additional safeguards need to be put in place:

- The person has been asked for the contact details of their regular prescriber, such as their GP, and for their consent to contact them about the prescription.

- The pharmacy owner has assured themselves that the prescriber will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP).
- The pharmacy owner has assured themselves that the prescriber has contacted the GP in advance of issuing a prescription, and that the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place.
- If there are circumstances where the person does not have a regular prescriber such as a GP, or if there is no consent to share information, and the prescriber has decided to still issue a prescription, the pharmacy owner should assure themselves that the prescriber has made a clear record setting out their justification for prescribing.

You can read more about our approach to regulating online pharmacies here:

<https://www.pharmacyregulation.org/standards/standards-registered-pharmacies/meeting-online-pharmacies-guidance-faqs>

We have also worked with other healthcare organisations including regulators, royal colleges and faculties and have jointly-agreed **High level principles for good practice in remote consultations and prescribing** that set out the good practice of healthcare professionals when prescribing medication online. **The ten principles**, underpinned by existing expected standards and guidance, include that healthcare professionals are expected to:

- Understand how to identify vulnerable patients and take appropriate steps to protect them
- Carry out clinical assessments and medical record checks to ensure medication is safe and appropriate

We have also published '**In practice: Guidance for pharmacist prescribers**', which set outs the key areas we expect pharmacist prescribers to consider when applying the standards to their prescribing practice. The guidance states that prescribing information should be shared with the person's prescriber, or others involved in their care, so the person receives safe and effective care.

### **Taking action if our standards are not met**

Our standards set out compulsory requirements which all pharmacies must follow, and our guidance describes how we expect them to do this, in different contexts. The guidance is clear that the pharmacy owner is responsible for making sure the guidance is followed. Not following our guidance, or not taking the appropriate steps to achieve a desired outcome under our standards, could mean that the pharmacy fails to meet one or more of our standards and enforcement action may be taken.

We have taken enforcement action against the owners of online pharmacies who are supplying high risk, habit-forming medicines without appropriate steps being taken to check that the medicine being prescribed and dispensed is clinically appropriate for the patient.

Where our inspectors have found insufficient safeguards in place to manage risks to patients, we have served Improvement Notices and/or put conditions on a pharmacy's registration. Typically, where the pharmacies are supplying high-risk medicines, the conditions imposed restrict the sale or supply of controlled drugs in line with our **enforcement policy**. As a result of our enforcement action, there have been a number of examples where pharmacies have either decided to stop supplying high-risk medicines, or, where this was the main focus of their service, have decided to cease trading altogether.

We have also referred individual pharmacy professionals involved in both the prescribing and supply of medicines to our Fitness to Practise process where their conduct has fallen short of professional standards. If a pharmacy professional's fitness to practise is found to be impaired, our Fitness to Practise Committee can impose a range of sanctions, including suspension or removal from the register.

We hope this is helpful in providing some further background information about what we expect from pharmacies in this context.

Yours sincerely,

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**Chief of Staff / Associate Director of Corporate Affairs**