General
Pharmaceutical
Council

Private & Confidential

[redacted]
Coroner's Officer
H M Coroner's Court

via email only – Margaret.Turner@Rochdale.gov.uk

7 December 2017

Please quote: G-CM1705-051

Dear Margaret,

Re: Concern regarding delivery of incorrect medication by Hopwood Pharmacy, 50 Manchester Road, HEYWOOD OL10 2AH

The General Pharmaceutical Council ("GPhC") has now completed its inquiries into information you provided concerning an Inquest into the death of a Christina Ann Fletcher.

Investigation into the concern

As part of the GPhC's investigation, we contacted the local GPhC Inspector at the time of the incident and the CDLO at Greater Manchester Police to obtain information about their visit to the pharmacy shortly after the incident in August 2016. Neither had concerns about the pharmacy and were satisfied that the error was human error and noted that the Superintendent ("SI") had taken action, such as amending the SOP relating to the Delivery of Controlled Drugs ("CD").

We also obtained information from the SI in relation to the investigation he had undertaken into the error and the changes he had made within the pharmacy to prevent a delivery error like this occurring again in the future.

We have reviewed all of the available evidence and information and have concluded that the concern should not progress to the Investigating Committee. There was not enough evidence to prove that either the SI or the Responsible Pharmacist ("RP") could be held accountable for the delivery error made by the driver who failed to follow the Standard Operating Procedure ("SOP") in place at the time. On that basis, there was not enough evidence to establish that any specific pharmacy professional's fitness to practise was impaired. We were satisfied that the changes that the SI had made, such as updating the SOP and enrolling their drivers on the Buttercup training course would assist in the prevention of a similar error occurring in the future.

To reach this decision, we have also considered the GPhC's Threshold Criteria. The GPhC uses its

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Threshold Criteria to decide whether the case should be closed or referred to the Investigating Committee. The Threshold Criteria have been developed against the principles in the Standards for conduct, ethics and performance which all pharmacy professionals must comply with. The Threshold Criteria are published on our website at: **http://www.pharmacyregulation.org/raising-concerns/registrants/what-happens-if-complaint-made-against-me/investigation-procedure**.

The GPhC is committed to upholding professional standards and. although this matter will not progress to a hearing, we have written to the SI to provide them with advice to remind him to ensure that all staff, including delivery drivers, are regularly reviewing and refreshing their knowledge of the SOPs, and that locum staff are aware of the pharmacy's SOPs.

The GPhC takes all concerns against pharmacy professionals very seriously and I would like to assure you that all reasonable lines of enquiry were pursued prior to our decision to close our investigation.

We should be grateful if you would share your experience of the Fitness to Practise process by completing the feedback survey at the following link: **http://surveys.pharmacyregulation.org/s/review**

Thank you for your cooperation with my inquiries into this matter. My colleagues in the Standards and Policy team will be responding the Regulation 28 notice in due course.

Yours sincerely

[redacted]
Case Officer
Professionals Regulation Team
GPhC
[redacted]
[redacted]

General Pharmaceutical Council

Ms L J Hashmi
HM Area Coroner for the Coroner area of Manchester North
H M Coroner's Court
Phoenix Centre
L/Cpl Stephen Shaw MC Way
Heywood
OL10 1LR

By email: coroners.office@rochdale.gov.uk

11 December 2017

Dear Ms Hashmi

Re: Regulation 28 Notice response - Christina Ann Fletcher, deceased.

Thank you for your letter regarding the tragic circumstances surrounding the death of Ms Christina Ann Fletcher. As you are aware, we carried out an investigation and wrote to you with the outcome on 7 December 2017. This letter deals specifically with the Regulation 28 Notice.

We have a statutory purpose to protect patients by setting and upholding standards for individual pharmacists and pharmacy technicians and for registered pharmacies, and also maintaining a register of pharmacists, pharmacy technicians and pharmacies. The purpose of our standards for registered pharmacies is to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy. The standards can be found at **https://www.pharmacyregulation.org/standards/standards-registered-pharmacies** .

The responsibility for meeting the standards for registered pharmacies lies with the pharmacy owner and superintendent pharmacist. The pharmacy owner and superintendent pharmacist must decide how to meet these standards, taking into consideration the services they will be providing, the associated risks and the needs of the patient. As well as meeting our standards the pharmacy owner must make sure they comply with all legal requirements. Our standards require the pharmacy owner/superintendent pharmacist to consider their governance arrangements including assessing and managing any risks involved with the way they have chosen to set up the services they offer and to provide services that are managed and delivered safely and effectively. When a GPhC inspector visits the pharmacy they will expect to see evidence to help them decide whether a pharmacy is meeting these standards.

We publish a range of guidance, which is focussed on helping pharmacy professionals, pharmacy owners and superintendent pharmacists meet our regulatory standards. We have produced guidance for pharmacy owners and superintendent pharmacists who provide services at a distance:

https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_providing_pharmacy_services_at_a_distance_including_on_the_internet_april_2015.pdf

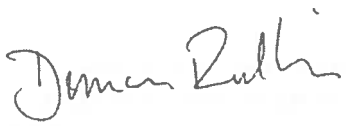
This guidance applies to the delivery of medicines. Whether a pharmacy service is provided face to face in the pharmacy or delivered to a patient's home, it is important that the pharmacist is satisfied the medicine is delivered safely. The guidance sets out some of the areas that should be considered before setting up this type of service and specifically highlights the risk around medicines being lost or delivered to the wrong person and the importance of staff training.

Whilst we produce guidance and advice of our standards, we do not produce detailed advice on the law. However, the Royal Pharmaceutical Society (RPS) (www.rpharms.com) is the professional body for pharmacists in Great Britain and has produced guidance on the delivery and posting (including abroad) of medicines to patients and maintains practice guidance on the management of controlled drugs. For further information about the chain of custody for Controlled Drugs the Home Office, as the body responsible for controlled drug legislation, is best placed to provide you with this information.

It is important that pharmacy learns from the tragic circumstances of the death of Ms Fletcher, and whilst we will of course not make reference to the specific circumstances of her death, we will raise awareness of this issue through an article our online registrant bulletin, Regulate. We produce the bulletin every two months and notify all our registrants and pre-registration pharmacy trainees (around 75,000 recipients in total) of a new edition via email.

Thank you again for writing to me and raising this important matter.

Yours sincerely,



Duncan Rudkin
Chief Executive and Registrar

Email: [redacted]