REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. Chair of the General Pharmaceutical Council, 25 Canada Square, London E14 5LQ
1	**CORONER** I am Ms L J Hashmi, HM Area Coroner for the Coroner area of Manchester North.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroner's and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On the 10th October 2017, I commenced an inquest into the death of **Ms Christina Ann Fletcher.**
4	**CIRCUMSTANCES OF DEATH:** **At the time of her death, the deceased was under treatment for a number of complex health issues. Her diagnoses included Macular Dystrophy resulting in marked visual impairment and Somatisation Disorder. Prescribed medication was delivered to her home address in Dosette boxes on a weekly basis by the community pharmacist.** **On the 4th August 2016 medication (Zomorph - an opiate and controlled drug) was delivered to the deceased as a result of human error. The intended recipient lived in close proximity to the deceased's home address (within doors, on the same side of the street) and had a very similar name to that of the deceased. The erroneous medication was delivered alongside medication that was intended for the deceased.** **The Standard Operating Procedure ('SOP') in force at the material time relating to the delivery of controlled drugs ('CDs') was not followed. A signature was not obtained at the point of delivery, the name and address of the intended recipient was not verified and the duplicating delivery book was not checked for a delivery signature upon its return to the pharmacy (rather, verbal confirmation of delivery was accepted). This resulted in the drug error going undetected until the 12th August.** **Adequate training of the delivery driver was not evidenced however, more likely than not, he had seen something akin to an SOP.** **Steps were subsequently taken by the Pharmacy to try and trace the deceased (and retrieve the Zomorph). On the thrust of the evidence, the deceased had last been seen/spoken to on the 10th August. On the afternoon of the 12th August the Pharmacist contacted the deceased's father who reassured him regarding the deceased's apparent lack of response. However there was sufficient ongoing cause for concern, given the nature of the erroneous medication delivered 8 days earlier.** **Initial enquiries proved fruitless and there was no response at the deceased's home address. Police were contacted at 19:53 on the 12th August regarding concern for the deceased's welfare. In reliance upon the information provided by the Pharmacist, the deceased's family and prevailing circumstances, a decision was taken not to force entry to the deceased's house. That was a reasonable decision based on the information available to police at the time.** **Delays were placed on the police FWIN. An Officer attended the deceased's home in the early hours of the 13th August. There was no response and therefore a further 5 hour delay was entered. Later the same morning an Officer was allocated and the decision made to force entry whereupon the deceased was found dead in the living room. The Zomorph was found within the property. Nine 30mg tablet were missing.** **Forensic post mortem examination and toxicological analysis revealed the presence of pneumonia and a markedly elevated level of free morphine, alongside a slightly elevated level of Pregabalin (relevant as to cumulative effect).** **Despite any potential post-mortem redistribution, on the balance of probabilities it was still possible to directly attribute the level of free Morphine found to the direct cause of death.**

5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows:- 1. There is no specific guidance, policy or protocol from the GPhC on the requirement for a 'red flag' system within pharmacies in relation to patients with identical names, similar addresses, living in close proximity etc. as demonstrated by the very tragic circumstances of this case. Whilst the Pharmacy in question did have internal processes in place at the time, concern remains that other Pharmacies throughout England and Wales might not, in the absence of specific guidance from their Regulator. 2. Again, there is no specific guidance, policy or protocol from the Regulator (or indeed legal definition) as to when, where and how the chain of custody (for Controlled Drugs) is completed. It currently appears to be a matter of local practice with some Pharmacies make an entry into the CD Register at the point the CD is handed to the delivery driver, with others making an entry once delivery has been confirmed. Both matters potentially give rise to a risk of future deaths in the absence of guidance and/or policy from the Regulator.
6	**ACTION SHOULD BE TAKEN** **In my opinion action should be taken to prevent future deaths and I believe each of you respectively have the power to take such action.**
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 16:30 on the 11th December 2016. I, the Coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons namely:- - The deceased's son - The deceased's sister - The delivery driver - The Pharmacy - Greater Manchester Police - The Locum Pharmacist I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary from. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me the coroner at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	Date: 13·10·2017 Signed: