GMCA GREATER MANCHESTER COMBINED AUTHORITY

NHS in Greater Manchester

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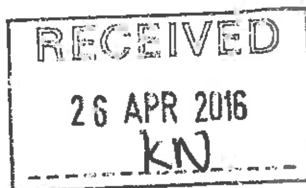

22 April 2016

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Miss J Kearsley
Area Coroner
Coroner's Court
1 Mount Tabor Street
Stockport
SK1 3AG

joanne.kearsley@stockport.gov.uk

By post and email

Dear Miss Kearsley

Re: Christine Marie Stevenson (deceased)
Your ref: JK/ER/01806-2015

Thank you for copying me into the Regulation 28 Report you sent to the Chief Executive of the Medicines and Healthcare Products Regulatory Agency.

Karen O'Brien, the Controlled Drug Accountable Officer for Greater Manchester has prepared a response on my behalf.

You have raised a number of issues that I would like to respond to. The first concerns the Home Office regulation of controlled drugs. Morphine (Oramorph) regulation is currently dependent on the potency (strength) of morphine present within each type of preparation, e.g. tablets, solution, injection, etc. and not the drug itself, i.e. morphine.

Under the 2001 Misuse of Drugs Regulations, controlled drugs were classified into five Schedules.

Schedule 1
Drugs belonging to this schedule are thought to have no therapeutic value and therefore cannot be lawfully possessed or prescribed. These include LSD, MDMA (ecstasy) and cannabis. Schedule 1 drugs may be used for the purposes of research but a Home Office license is required.

Schedule 2 & 3
The drugs in these schedules can be prescribed and therefore legally possessed and supplied by pharmacists and doctors. They can also be possessed lawfully by anyone who has a prescription. It is an offence contrary to the 1971 Act to possess any drug belonging to Schedule 2 or 3 without prescription or lawful authority. Examples of schedule 2 drugs are methadone and diamorphine (heroin). Schedule 3 drugs include subutex and most of the barbiturate family.

The difference between Schedule 2 and Schedule 3 drugs is limited to the application of the 2001 Regulations concerning record keeping and storage requirements in respect of schedule 2 drugs.

Schedule 4 (i) & (ii)
Schedule 4 was divided into two parts by the 2001 Regulations [as amended by the Misuse of Drugs (Amendment No. 2) Regulations 2012].

Schedule 4(i) controls most of the benzodiazepines. Schedule 4(i) drugs can only be lawfully possessed under prescription. Otherwise, possession is an offence under the 1971 Act.

Schedule 4(ii) drugs can be possessed as long as they are clearly for personal use. Drugs in this schedule can also be imported or exported for personal use where a person himself carries out that importation or exportation. The most common example of a schedule 4(ii) drug is steroids.

Schedule 5
Schedule 5 drugs are sold over the counter and can be legally possessed without a prescription.

This control by schedule was based on evidence of the potential of a drug to cause harm, to be abused or to be available illegally; therefore the potency of a drug is important as this is a contributory factor.

In your report you raise concerns about the lack of control for Oramorph 10mg/5ml solution as it is not treated as a controlled drug, but good practice would expect the drug to be stored and usage recorded appropriately. There are unfortunately a number of drugs that would fall into the same category as Oramorph 10mg/5ml oral liquid such as codeine containing products that can actually be purchased over-the-counter from a pharmacy.

The second issue you raise is concerning the volume of Oramorph prescribed which in this instance was 500ml and whether this could restricted. Prescribers are aware they are responsible for all prescriptions they sign (EL(91)127). This Executive Letter states clinical responsibilities lies with the clinician who signs the prescription. This means they should prescribe appropriately for each patient and this has been reinforced to all new prescribers and existing prescribers since 1991.

This patient was unlikely to be opioid naive as she was released from hospital on a reducing dose of slow release oral morphine 20mg (Schedule 2) twice daily and tramadol (Schedule 3) drugs. Tramadol is sometimes substituted by Oramorph solution as currently there is a significant problem with abuse and addiction to tramadol. The prescriber may have decided that the Oramorph was more appropriate option.

All prescribers are advised to keep the prescribed volume of drugs to a minimum especially with controlled drugs. Patients taking drugs such as morphine do find that over time they need increasing doses to control their symptoms and this varies greatly between patients. Limiting the volume of Oramorph prescribed may disadvantage some patients who are legitimately on a high dose at the end of their life.

We will take the following actions:

- Greater Manchester along with all areas of NHS England has established Local Intelligence Networks where information is shared across a network of healthcare providers such as hospitals, hospices, private hospitals, clinics, the police, the Care Quality Commission, and regulators such as the General Pharmaceutical Council. The Network meets twice a year to share learning concerning controlled drugs and more recently "legal highs". We are going to raise the issue concerning the volumes and strengths of controlled drugs prescribed and provide guidance to prescribers.

- Greater Manchester has a web based reporting system where all providers report incidents involving controlled drugs. This means we have real time data of incidents across the Network so early warnings can be distributed. We will examine the system to identify high volume prescribers and question reasons for prescribing high volumes.

- We have shared your letter with the Local Intelligence Network (LIN); one of the recommendations from the group was to highlight the issue of prescribing high volumes of controlled drugs in the next national newsletter from the Care Quality Commission "Controlled Drugs Vigilance Newsletter", which is a published every two months; Karen O'Brien will take this recommendation forward as a member of this group.

The LIN also suggested that we use local newsletters to highlight the issues especially around volume of prescribing. Some of the Clinical Commissioning Groups are working with their GP practices already to reduce high doses and volumes being prescribed.

The Network felt there is a significant problem in that patients could travel around practices, out-of-hours services and A&E departments in order to obtain controlled drugs. Since the controlled drug reporting tool was introduced we have seen a great

deal of this behaviour and we now have an alert system to inform providers of possible abuse. The system is not full proof but it does provide a safety net.

I trust this replies to your query in respect of local learning, if I can be of further assistance please do not hesitate to contact me.

Yours sincerely

Medical Director
Greater Manchester Health & Social Care Partnership