REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **Chief Executive of the Medicines and Healthcare Products Regulatory Agency**
1	**CORONER** I am Joanne Kearsley Area Coroner for Manchester South
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On the 11th January 2016 I concluded the Inquest into the death of Christine Marie Stevenson date of birth 27.01.1969 who died on the 21.07.2015. The cause of death was 1a) Combined Drug Toxicity (from prescribed and illicit drug use) I recorded an open conclusion.
4	**CIRCUMSTANCES OF THE DEATH** The Court heard evidence that the deceased had a history of illicit drug use. In addition she had a number of medical issues and undergone a right leg amputation in February 2015. At the time of her death she was residing with her Mother and was effectively housebound. The deceased had been admitted to hospital in February 2015 and was released from hospital on a reducing dose of slow release oral morphine, initially 90mg x2 day and tramadol. At the time of her discharge she was registered with Heaton Moor Medical Practice. She attended her GP practice on the 24th February when her Tramadol medication was changed to Oramorph. She is seen again by Heaton Moor on the 3rd March when she was also prescribed Tramadol, Mirtazapine and Pregabalin. On the 4th March 2015 the deceased changed medical practice to the Brinnington Surgery where she was a temporary patient until the 29th June 2015. Throughout this time Brinnington Surgery only had a summary of her medical records they

did not receive all her medical records.

She attended at this practice on the 6th March requesting Oramorph. It was noted that she had been discharged from hospital on Zomorph but that the advice from the hospital was that the dose should be gradually reduced and if their advice was followed then use of Zomorph should have been stopped by the time she registered with the Brinnington Practice. On this initial visit the deceased requested Oramorph. However, on this date she was issued with a prescription for Tramadol but not Oramorph.

She was on also on pregabalin. On the 20th March she advised that her pain was not being controlled and she was prescribed Oramorph (10mg/ 5mls, on an as required basis every 4 hours), it was discussed that this should be for short term use.

The initial prescription on the 20th March was for 10mgs per 5 ml solution and 300 mls were issued.

This was increased in June to 10 mgs per 5 ml solution and 500 mls were prescribed on 5th then a further 500 mls on 19th (suggesting averaging 7 doses daily, when advise was every 4 hours thus maximum of 6 doses daily). At the time this was increased she was overdue a medication review.

On the 29th June 2015 she returned to the Heaton Moor practice. Again the medical records from Brinnington were now not immediately available to the Heaton Moor practice.

She had further prescription of Oramorph issued on the 29.06.15 (100mls), 03.07.15 (280mls). On the 20th July she telephoned the practice requesting more morphine and a prescription of 500 mls was issued.

This prescription was collected from the pharmacy on the same day the 20th July. It was usual practice for her Mother to collect her prescriptions but the evidence to the Court was that her Mother did not collect this prescription. It could not be established who collected this prescription. The pharmacy were able to confirm that 500mls of 10mg/5ml morphine sulphate were dispensed in two 100mls bottles and one 300 mls bottle.

Whilst there is an illegible signature on the back of the prescription there was no name or address printed.

You will be aware that Morphine 10mg/5ml is a Schedule 5 Controlled drug and therefore not subject to any requirements to check the identification of the person collecting it.

The deceased was at home on the 20th July, she was seen by her Mother when she returned home from work at 2pm. She went to her room around 6pm and was later discovered deceased in bed.

The police attended but at the time of the police attendance they were not advised

	of any medication which may be missing from the property. They seized some medication which was also issued on the 20th July but were not aware that Morphine Sulphate was also issued. Later two empty 100mls bottles of morphine sulphate were found by her Mother in the handbag of the deceased. The bottle containing 300mls which was issued on the day of the deceased's death has never been located.
5	**CORONER'S CONCERNS** The concerns noted by the Court during the course of the Inquest are as follows: Concerns were raised at the Inquest as to the lack of control for Oramorph medication. A 10mgs per 5ml solution does not fall under the controlled drug requirements in the BNF. It is noted that whilst the Misuse of Drugs Act 1971 lists morphine as a Schedule 2, Part 1, Class A Controlled drug, Section 5 gives and exemption for preparation that contain not more than 0.2% morphine Oramorph (10 mg per 5 millilitres) has a morphine content that is under the 0.2% (as the 10 mg is present as morphine sulphate). However even though the solution at this strength is not to be subject of control, should there be restrictions on the amount of the solution which can be prescribed? This lady was prescribed 500mls (a total available dose of 1000 mg) of this solution which poses as a dose a serious risk to health. The Court heard evidence that in a naïve user 50mls of the solution at this strength can be a risk to life. Given that Oramorph has an increasing street value and is a commonly abused drug whilst the strength of the solution may not require control the issuing of 500mls without control seems a matter which requires consideration.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you 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 24th May 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 family of Mrs Stevenson.** 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 form. 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	10.03.2016 **Joanne Kearsley Area Coroner**