

447/2014

Mr J Pollard Senior Coroner Coroner's Court 1 Mount Tabor Street Stockport SK1 3AG Richmond House 79 Whitehall London SW1A 2NS

Tel: 020 7210 4850

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Dear Mr. Pollard,

Thank you for your letter of 13 October following the inquest into the death of Mary Fenton. In your report you state that Mary Fenton died from Coronary Artery Atheroma and Acute Cerebral Infarction.

I was sorry to read of Ms Fenton's death and wish to extend my sincere sympathies to her family.

On the 26th April 2014 Ms Fenton was admitted into Tameside Hospital in need of an urgent heart pacemaker.

You state that various delays occurred and that opportunities were missed to treat Ms Fenton. You express concerns about the lack of specialist staff and facilities at Tameside Hospital and point out failures in Ms Fenton's care and assessment.

I note that many of your concerns are directed to the Tameside Hospital NHS Foundation Trust and I would expect the Trust to respond appropriately.

You raise the following concerns for our attention:-

- This patient was being kept alive by the use of Isoprenaline. It transpires that there were severe shortages of this drug in the hospital but also nationally. I was told that this drug is produced as an unlicensed drug by NHS Pharmaceutical Productions. If so why do they not ensure sufficient supply?
- The National pharmaceutical supply chain was described in evidence by a Chief Pharmacist as being "very fragile".

I would like to respond initially by making a general point about the scale of pharmaceutical supply and dispensing in England, and set out the following facts of interest.

Currently there are over 15,000 licensed medicines products comprising different dosage forms (such as capsules, tablets, injections and other formulations). Over 2 million prescription items are dispensed in England every day of which the vast majority are not subject to supply problems. At the end of March 2013, there were nearly 11,500 community pharmacies in England and in that same year, over 1 billion NHS prescription items were dispensed.

Medicines shortages are not new, nor are they confined to the UK. There are a number of reasons why such shortages do arise but the two main reasons are commonly referred to as 'upstream' and 'downstream':-

- upstream issues arise due to manufacturing difficulties, regulatory problems and problems with the supply of raw materials. The nature of these issues means that some supply problems with medicines are inevitable and unavoidable; and,
- downstream issues arise due to changes in the distribution of medicines.

Supply issues are complex and most have to be dealt with on a case by case basis but in recognising the main problems it is possible to take action to mitigate them. Our Government is currently working with other countries in Europe and with North America to resolve some of these supply issues.

With regard to your concerns about the supply of Isoprenaline, I can confirm that Isoprenaline injection is not licensed for use in the UK. It is available from NHS Pharmaceutical Manufacturing Units (PMUs) as an unlicensed "special", and as an unlicensed import from abroad.

The Department of Health is aware that there have been problems with the availability of isoprenaline and that earlier this year the NHS PMUs experienced problems obtaining the active pharmaceutical ingredient. The Department of Health therefore asked the NHS UK Medicines Information service (UKMI) to produce a "Shortage Memo" which summarises the situation and advises on alternative sources of supply. This was sent out to hospitals and uploaded to the UKMI website, at the following address, on 24 April 2014:-



http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Medicines-Information/Discontinuation-Supply-Shortage-Memos/Shortage-of-isoprenaline-injection/

For ease of reference I have also attached it as Annex A for your information.

I hope that this response is helpful and I am grateful to you for bringing the circumstances of Ms Fenton's death to my attention.

Your sneary