REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

THIS REPORT IS BEING SENT TO: 1) [redacted], Chief Executive, National Institute for Health and Care Excellence; 2) [redacted], Chief Executive Officer, Vitaris UK Healthcare Ltd; 3) [redacted], Managing Director, Britannia Pharmaceutical Ltd; and 4) [redacted], Director, Leyden Delta Ltd.

CORONER

I am Chris Morris, Area Coroner for Manchester South.

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.
http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7
http://www.legislation.gov.uk/uksi/2013/1629/part/7/made

INVESTIGATION and INQUEST

On 28th April 2023, Alison Mutch OBE, Senior Coroner for Manchester South, opened an inquest into the death of Sasha Drysdale who died on 28th March 2023 at Beckett Place, Buckton Building, Tameside General Hospital, aged 52 years. The investigation concluded with an inquest which was heard before a jury between 8th – 12th July 2024.

The inquest determined Miss Drysdale died as a consequence of:

1) a) Acute Myeloid Leukaemia (Transformed from Myelodysplastic Syndrome)

At the end of the inquest, the jury returned a conclusion of Natural Causes.

CIRCUMASTANCES OF THE DEATH

Sasha Drysdale died on 28th March 2023 at Beckett Place, Tameside General Hospital, Ashton-under-Lyne as a consequence of Acute Myeloid Leukaemia (Transformed from Myelodysplastic Syndrome). Miss Drysdale was a patient on the ward who, at the time of her death, was detained under section 3 Mental Health Act 1983 (as amended).

Miss Drysdale had previously been prescribed the anti-psychotic medication Clozapine as a consequence of treatment-resistant schizoaffective disorder.

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. –

The court heard evidence as to a small number of studies conducted internationally which, whilst having small sample sizes, could be read as suggesting an increased incidence of certain forms of blood cancer amongst those taking Clozapine.

I am concerned that further research is needed to either refute or confirm whether or not taking Clozapine materially increases the risk of a patient developing certain blood cancers.

ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action.

YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report, namely by **12th September 2024**. 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.

COPIES and PUBLICATION

I have sent a copy of my report to the Chief Coroner, and [REDACTED] [REDACTED].

I have also sent a copy to the Medicines and Healthcare products Regulatory Agency and the legal representatives of Pennine Care NHS Foundation Trust, The Christie NHS Foundation Trust, and Tameside and Glossop Integrated Care NHS Foundation Trust, who may find it useful or of interest.

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.

Dated: **18th July 2024**

Signature: Chris Morris, Area Coroner, Manchester South.