NICE National Institute for Health and Care Excellence

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30 August 2024

Mr Chris Morris
Area Coroner for Manchester South

Sent via email: [redacted]

Our reference: [redacted]

Dear Mr Morris,

Re: Regulation 28 Prevention of Future Deaths Report – Sasha Esther Moira Drysdale (ref: 30303936)

I write in response to your regulation 28 report dated 18 July 2024 regarding the sad death of Miss Drysdale. I would like to express my sincere condolences to Miss Drysdale's family.

We have reflected on the circumstances surrounding Miss Drysdale's death and the concerns raised in your report. We note your concerns that further research is needed to refute or confirm whether or not taking clozapine materially increases the risk of a patient developing certain blood cancers.

For context, you may find the following information that NICE holds on clozapine useful.

There are strict monitoring requirements for Clozapine as listed in the BNF; Clozapine | Drugs | BNF | NICE

These are also reflected in the CKS summary Scenario: The routine schizophrenia or psychosis review | Management | Psychosis and schizophrenia | CKS | NICE.

The BNF is a joint publication of the British Medical Association and the Royal Pharmaceutical Society. Although we make the BNF accessible from the NICE website, we are not responsible for its content.

The CKS are developed externally to NICE. We commission an external organisation (Agilio software) to compile the CKS. They are designed to provide a summary of the published evidence on the treatment of a range of health conditions that present in primary care. They use a variety of sources and may include NICE guidance, if there is any that is relevant, but they use many other sources too. We publish them on our website as a source of advice and information for health professionals working in primary care, but they do not constitute formal NICE guidance.

In relation to the main issue that you have asked us to respond to, you may be aware that NICE is not the regulator for medicines and medical devices in the UK; this is the role of the Medicines & Healthcare products Regulatory Agency (MHRA). The MHRA is responsible for issuing the marketing authorisation for medicines (also known as the licence) and has ongoing responsibility for monitoring their safety.

Following receipt of your report, senior clinical advisors within the patient safety team at NICE have reviewed the concerns raised. They have advised that these concerns would be best investigated by the MHRA as the responsible body for the regulatory approval of medicines. The safety of Clozapine and risk of developing haematological malignancy requires surveillance which should be led by the MHRA, however NICE would welcome any findings that may impact our current recommendations and advice on this treatment.

We are aware that the MHRA currently have an ongoing safety review into Clozapine, so this may well be a good opportunity for them to capture the issues raised in this case as part of their review.

Our clinical adviser added that the haematological risks of Clozapine need to be considered in the context of risks from mental illness that is responding poorly to treatment. It is used for patients who have not responded to 2 other antipsychotics.

He added that NICE would normally suggest that when balancing risks, patient consent is important, but this would be almost impossible in the context of refractory psychosis.

Finally, NICE does not have a direct role in clinical research the UK; this is the role of the National Institute for Health and Care Research (NIHR) . You may wish to contact them directly regarding any upcoming research on this subject area.

I hope this response has helped outline our role in relation to this specific area and I would like to reiterate my sincere condolences to Miss Drysdale's family.

Yours sincerely,

[redacted]

Chief Executive