



Department of Health & Social Care

*From the Rt Hon Andrew Stephenson CBE MP
Minister of State for Health and Secondary Care*

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[REDACTED]

HM Coroner Crispin Oliver
HM Coroner's Office
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[REDACTED]

09 May 2024

Dear Mr Oliver,

Thank you for the Regulation 28 report to prevent future deaths of 15 February 2024 about the death of Sean Crawford. I am replying as Minister with responsibility for Medicines.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Crawford's death, and I offer my sincere condolences to their family and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention. Thank you for the additional time provided to the department to provide a response to the concern raised in the report.

The report raises concerns over the combined effects of clozapine with alcohol and the lack of guidance that provides advice on the dangers of death in this scenario.

In preparing this response, Departmental officials have made enquiries with National Institute for Health and Care Excellence (NICE). The National Institute for Health and Care Excellence (NICE) is the independent body responsible for developing authoritative, evidence-based guidance on best practice for the health and care system. NICE guidelines are developed by experts based on a thorough assessment of the available evidence and through extensive engagement with stakeholders. Healthcare professionals are expected to take them into full account in their decision making, although it is important to note that NICE guidelines are not mandatory and do not override a clinician's responsibility to make decisions appropriate to individual patients.

NICE's guideline on the prevention and management of psychosis and schizophrenia in adults was published in 2014. Recommendation 1.3.6.7 states that, when a patient starts antipsychotic medication (such as clozapine), the use of alcohol, tobacco, prescription and non-prescription medication, and illicit drugs, should be discussed. This includes the possible interference of these substances with the therapeutic effects of prescribed medication and psychological treatments. Furthermore, information provided by the British National Formulary on clozapine (which can be accessed on NICE's website) states that alcoholic and toxic psychoses are contraindications, or conditions with which clozapine

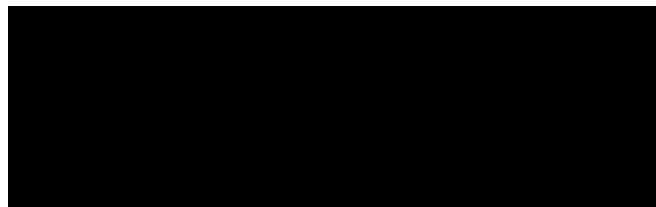
should not be taken due to the potential harm to the patient. Departmental officials, however, have shared your report with NICE, so it can consider the impact of your findings on its published guidance.

I am aware that the Medicines & Healthcare products Regulatory Agency (MHRA) has provided a response in respect of the key concern you raise in the report. As you will be aware, MHRA is an executive agency of the Department of Health and Social Care (DHSC) with responsibility for the regulation of medicinal products in the UK. The MHRA ensures that medicines are efficacious and acceptably safe, and that any possible side effects which have been recognised to occur with use of a medicine are appropriately described in the authorised product information. However, MHRA has recognised in the response that none of the authorised product information specifically mention any risk of death because of the interaction with alcohol.

As I understand, MHRA has considered the concerns raised in your reports and intends to conduct a further assessment of the information provided within the clozapine product information regarding drug-drug interactions. As part of this assessment, MHRA will be giving careful consideration to the information which is provided to healthcare professionals, patients and their families and carers, and whether this can be improved. This will be part of a wider review of clozapine which will be completed this year. MHRA will engage with relevant stakeholders such as BNF during this process to ensure that their concerns are addressed. In the meantime, MHRA will continue to closely monitor the safety of clozapine, including cases of drug-drug interactions. Should any updates to the product information be required MHRA will issue an article in a bulletin to healthcare professionals, "Drug Safety Update" accordingly.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

Yours sincerely,



**THE RT HON ANDREW STEPHENSON CBE MP
MINISTER OF STATE FOR HEALTH AND SECONDARY CARE**