



Regulation 28: REPORT TO PREVENT FUTURE DEATHS

NOTE: This form is to be used **after** an inquest.

	<p>REGULATION 28 REPORT TO PREVENT DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>1 The Rt Hon Victoria Atkins MP – Secretary of State for Health and Social Care Department for health and Social Care 39 Victoria Street London SW1H 0EU</p> <p>██</p> <p>2 ██████████ Content Director BNF Publications</p> <p>██</p> <p>3 Chief Executive Medicines and Healthcare Products Regulatory Agency</p> <p>██</p>
1	<p>CORONER</p> <p>I am Crispin OLIVER, Assistant Coroner for the coroner area of County Durham and Darlington</p>
2	<p>CORONER'S LEGAL POWERS</p> <p>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.</p>
3	<p>INVESTIGATION and INQUEST</p> <p>On 30/12/2020 12:36 an investigation was commenced into the death of Sean Benjamin CRAWFORD [born 29/12/1978]. The investigation concluded at the end of the inquest on 13/02/2024 09:20. The conclusion of the inquest was that Sean died on 18 December 2020 at ██████████ Darlington. His death resulted from the "Unpredicted combined toxic effect of alcohol and clozapine".</p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>Sean died on 18 December 2020 at ██████████ Darlington. His death resulted from the combined toxic effect of alcohol and clozapine (individually not at toxic levels) acting to suppress his central nervous system.</p>
5	<p>CORONER'S CONCERNS</p> <p>During the course of the investigation my inquiries revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you.</p>



	<p>The MATTERS OF CONCERN are as follows: (brief summary of matters of concern)</p> <p>The circumstances in which Sean came by his death, the combined effects of clozapine with alcohol, seems to be, statistically, very rare. None of the professionals who gave evidence in this case could cite a death with the same cause of death as that suffered by Sean. This said, clozapine is a well-established medication whose side effects are well known. It was originally developed in the 1950's. It is well-known that it requires careful management and monitoring. The side effects are recognised ones and widely known. None of the professional witnesses expressed any lack of familiarity with it or its side effects. One of these side effects is sedation. Likewise, obviously, alcohol is a recognised central nervous system depressant. This is a death from Central Nervous System Depression, consequent to a comparatively high level of clozapine and a comparatively high level of ethanol in the blood – neither individually fatal. It is evident that there is no guidance in any academic literature, British National Formulary, or NICE or MHRA advices on the dangers of death in this scenario. It is noticeable that the leaflet that comes with the Clozaril (clozapine) packages clearly states that it must not be taken with alcohol, and the evidence to me was that the medication comes with a further label, in a similar vein, on the packaging. Neither, however, advises of death being a possibility. All the literature advises that sedation is a potentially dangerous side effect of clozapine. Death from Central Nervous System Depression, over-sedation, is not uncommon. It is often associated with alcohol, and other substance, use.</p>
6	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe you (and/or your organisation) have the power to take such action.</p>
7	<p>YOUR RESPONSE</p> <p>You are under a duty to respond to this report within 56 days of the date of this report, namely by April 11, 2024. I, the coroner, may extend the period.</p> <p>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.</p>
8	<p>COPIES and PUBLICATION</p> <p>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:</p> <p>Sean Crawford's family</p> <p>Tees Esk Wear Valley NHS Foundation Trust</p> <p>who may find it useful or of interest.</p> <p>I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it.</p> <p>I may also send a copy of your response to any person who I believe may find it useful or of interest.</p> <p>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.</p> <p>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.</p>
9	<p>Dated: 15/02/2024</p>



Crispin Oliver

Crispin OLIVER
Assistant Coroner for
County Durham and Darlington