


REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	<p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>1. Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ</p>
1	<p>CORONER</p> <p>I Alexander Forrest, Assistant Coroner, for the coroner area of South Yorkshire (West).</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 29th August 2017 I commenced an investigation into the death of Michael John Spencer. The investigation concluded at the end of the inquest on 31st January 2018. The conclusion of the inquest was 1a) Intracerebral haemorrhage; 1b) Rivaroxaban anticoagulant treatment; 2) Ischaemic stroke (treated), Hypertension (treated).</p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>Michael Spencer had a fatal midbrain haemorrhage when being treated with Rivaroxaban as part of a clinical trial.</p>
5	<p><u>CORONER'S CONCERNS</u></p> <p>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.</p> <p>The MATTERS OF CONCERN are as follows. –</p> <p>Rivaroxaban is one of 4 Factor Xa inhibitor anticoagulants currently available. Potentially fatal bleeding can take place following overdose of these drugs or following even relatively injury when patients are taking them. A drug specifically designed to reverse the anti-coagulant effect of the Factor Xa antagonist, Andexanet alfa, is available in some countries which can be used in such circumstances to reverse the anticoagulant effect of these drugs. Evidence was given at the inquest to the effect It is not yet available in the UK, even for compassionate use, and that its availability could be lifesaving when severe bleeding occurs during treatment with Factor Xa inhibitor anti-coagulant drugs. For the avoidance of doubt, this evidence was given in the course of a general explanation of the action of Rivaroxaban and the management of pathological bleeding during its use. It was made clear that the ready availability of Andexanet alfa would not have changed the outcome in Mr Spencer's case. The concern expressed was in relation to the current non-availability of this specific reversal agent in the face of the increasing clinical use of Factor Xa inhibitor anticoagulants.</p>
6	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe you 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 24^h April 2018. 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> <ul style="list-style-type: none"> • The family of the late Mr Spencer • Chief Executive, Sheffield Teaching Hospitals Trust NHS Foundation Trust • [REDACTED] Sheffield Teaching Hospitals Trust NHS Foundation Trust • [REDACTED], Consultant Neurologist, Royal Hallamshire Hospital, Sheffield <p>I am also under a duty to send the Chief Coroner a copy of your response.</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. 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> 5th February 2018</p> <p style="text-align: right;">Alexander Forrest</p>