




	<p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <p>1. Medicines & Healthcare products Regulatory Agency.</p>
1	<p>CORONER</p> <p>I am Emma Brown Area Coroner for Birmingham and Solihull</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 31/05/2016 I commenced an investigation into the death of Raymond Charles Woodward. The investigation concluded at the end of the inquest on the 18th August 2016. The conclusion of the inquest was:</p> <p><i>"Death during a routine medical investigation as a result of a reaction to medication given in conjunction with previously undiagnosed coronary artery disease."</i></p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>The Deceased passed away in the accident and emergency department of the Queen Elizabeth Hospital, Birmingham on the 19th February 2016 having suffered a cardiac arrest whilst undergoing a colonoscopy for the investigation of abdominal pain, dyspepsia and constipation at the Edgbaston BMI Hospital. The colonoscopy had been proceeding normally when the Deceased suddenly deteriorated after the administration of Buscopan to reduce spasm. Despite comprehensive cardio-pulmonary resuscitation he did not regain circulation. He was transferred to the Queen Elizabeth Hospital to maximise treatment if resuscitation were achieved but was declared deceased at 18.10.</p> <p>Following a post mortem examination and toxicological analysis the Cause of Death was determined as:</p> <p>1(a) CARDIORESPIRATORY ARREST 1(b) CORONARY ARTERY DISEASE AND A REACTION TO ADMINISTERED BUSCOPAN</p> <p>Evidence was provided to me there have been 5 reported instances of adverse reactions to Buscopan in the presence of coronary artery disease resulting in death. It is reasonable to suppose that there could be more unreported instances.</p>
5	<p><u>CORONER'S CONCERNS</u></p> <p>During the course of my investigation and 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>(1) The risk of an adverse reaction to Buscopan in the presence of coronary artery disease is not widely known despite the wide use of Buscopan.</p> <p>(2) The SPC relating to the use of intravenous Buscopan references the following in relation to the cardiovascular system – 'Buscopan Ampoules should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac</p>

	<p>surgery where it may further accelerate the heart rate’.</p> <p>(3) The term ‘cardiac insufficiency’ is unwieldy and does not immediately relate to a specific diagnosis, lacks specificity and does not necessarily encompass those patients with ischaemic heart disease.</p> <p>(4) [REDACTED] the Deceased’s Consultant Physician and Gastroenterologist, gave firm evidence, having extensively researched the issue, that the wider medical community needs to be alerted to potential cardiovascular problems in using IV Buscopan and this could be achieved by incorporating into the SPC ‘additional caution should be exercised in administering IV Buscopan to patients with ischaemic heart disease’.</p>
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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> <p>This opinion was fully supported by [REDACTED] and also [REDACTED] Consultant Cardiac Anaesthetist who lead Mr. Woodward’s resuscitation.</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 14th October 2016. 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: Mr. Woodward’s family, the BMI Edgbaston Priory and [REDACTED]</p> <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>26/08/2016</p> <p>Signature  _____</p> <p>Emma Brown Area Coroner Birmingham and Solihull</p>