**ANNEX A**

## REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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| | **REGULATION 28 REPORT TO PREVENT FUTURE DEATHS**<br><br>**THIS REPORT IS BEING SENT TO:**<br><br>**1. MHRA** |
| 1 | **CORONER**<br><br>I am Philip Barlow, assistant coroner, for the coroner area of Northamptonshire |
| 2 | **CORONER'S LEGAL POWERS**<br><br>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. |
| 3 | **INVESTIGATION and INQUEST**<br><br>On 17.5.19 I commenced an investigation into the death of Andrew Cook, age 53. The investigation concluded at the end of the inquest on 16.6.21. The Medical Cause of Death was: 1a) Anaphylaxis reaction during percutaneous coronary intervention for ischaemic heart disease.<br><br>The narrative conclusion was: Died of anaphylaxis during a medical procedure. |
| 4 | **CIRCUMSTANCES OF THE DEATH**<br><br>On 31 March 2019 Andrew Cook underwent percutaneous coronary intervention at Kettering General Hospital following a myocardial infarction. During the procedure he suffered anaphylaxis leading to cardiac arrest and attempts at resuscitation were unsuccessful.<br><br>Mr Cook had a previous diagnosis of allergy to PEG (polyethylene glycol) and some of the equipment used during the procedure was coated with PEG to act as a lubricant. Although it was not possible to draw a conclusion on the balance of probabilities, the evidence at the inquest suggests that it might have been exposure to this PEG which caused the anaphylaxis. |
| 5 | **CORONER'S CONCERNS**<br><br>During the course of the inquest the evidence 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.<br><br>The **MATTERS OF CONCERN** are as follows. –<br><br>(1) PEG allergy is rare but may be under-reported. PEGs are ubiquitous and more research into their effect as allergens is required.<br><br>(2) Whether the existence, dose and molecular weight of PEG should be made clear on medical product information (such as the Instructions For Use, data sheets, packaging and marketing information). |

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| | The existence of PEG in the equipment (in this case, the Sion and Sion Blue guidewires manufactured by Asahi Intecc) was not apparent from the packaging or product information available to the clinicians.<br><br>PEGs are available in various molecular weights. There was expert evidence that reaction to PEG may depend on the dose and exact molecular weight to which an individual is exposed.<br><br>It was acknowledged that labelling can have negative effects and therefore needs to be considered with care. Labelling also requires coordination with other national regulators.<br><br>(3) There is inconsistency and potential confusion in nomenclature. For example, PEG can be referred to as "Macrogol", "polyethylene oxide" (PEO) or "polyoxyethylene" (POE). Nomenclature may also vary between countries. There was evidence that clinicians reviewing product information in urgent situations are not aware of the various synonyms. |
| 6 | **ACTION SHOULD BE TAKEN**<br><br>In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action. |
| 7 | **YOUR RESPONSE**<br><br>You are under a duty to respond to this report within 56 days of the date of this report, namely by 10 August 2021. I, the coroner, may extend the period.<br><br>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. |
| 8 | **COPIES and PUBLICATION**<br><br>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:<br>• The deceased's family<br>• Kettering General Hospital<br>• Abbott<br>• Asahi Intecc<br><br>I have also sent it to the experts that provided evidence, who may find it useful or of interest.<br><br>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.<br><br>I may also send a copy of your response to any other person who I believe may find it useful or of interest.<br><br>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.<br><br>You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response. |
| 9 | **18 June 2021** **Philip Barlow** |