REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. MHRA** **2. Secretary of State for Health** **3. NHS England** **4. General Pharmaceutical Council** **5. Royal Pharmaceutical Society** **6. Crescent Pharma Ltd**
1	**CORONER** I am Louise Hunt, Senior Coroner, for the coroner area of Birmingham and Solihull.
2	**CORONER'S LEGAL POWERS** 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** On 7th October 2014 I commenced an investigation into the death of Annette Charlton aged 75. The investigation concluded at the end of the inquest on 6th January 2015. The conclusion of the inquest was natural causes.
4	**CIRCUMSTANCES OF THE DEATH** The deceased suffered from emphysema and lung Fibrosis requiring continuous oxygen therapy. On 24/09/14 her GP prescribed a course of antibiotics – Phenoxymethylpenicillin 250mg. Her husband attended their local pharmacy. She was inadvertently dispensed Naproxen 250mg. On 27/09/14 she was admitted to Queen Elizabeth Hospital Birmingham very short of breath. They realised the error in the medication and prescribed antibiotics. She died on 28/09/14. The cause of death following post mortem examination was confirmed as end stage pulmonary fibrosis and bronchiectasis. Neither the pathologist, nor a Professor from Queen Elizabeth Hospital Birmingham were able to say that the delay in antibiotics had caused or contributed to the death. Both were able to confirm that the naproxen had not caused the death. The dispensing error occurred as the 2 tablets were in almost identical looking boxes and made by the same manufacturer. The Naproxen had been put on the Phenoxymethylpenicillin shelf by mistake. A further mistake had occurred when the pharmacists failed to spot the wrong medication had been chosen. I attach a colour copy of the medication boxes to show the similarity. I heard evidence at the inquest that this was a national problem namely drug companies packaging medication in almost identical boxes which meant dispensing errors had become "very common issues" Please note the pharmacist in question has already taken remedial action and introduced new process and procedures within his pharmacy to avoid similar events.

5	**CORONER'S CONCERNS** 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. The **MATTERS OF CONCERN** are as follows. – (1) Manufacturers are able to produce medication in almost identical boxes which is very likely to contribute to dispensing errors and potentially patient deaths.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you AND/OR your organisation has the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 6th March 2015. I, the coroner, may extend the period. 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** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:- [redacted] I am also under a duty to send the Chief Coroner a copy of your response. 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.
9	**9th January 2015** Bethell