REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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

REGULATION 28 REPORT TO PREVENT FUTURE DEATHS THIS REPORT IS BEING SENT TO: 1. UCB Pharma 2. British National Formulary CORONER I am Mr. T. G. Moore, Assistant Coroner, for the area of Avon. **CORONER'S LEGAL POWERS** 2 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. **INVESTIGATION and INQUEST** On I commenced an investigation into the death of Dafydd Rhys WATTS, Aged 34. The investigation concluded at the end of the inquest on 14th March 2014. The conclusion of the inquest was: la Pericarditis Ib Drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) Ic Epilepsy treated with levetiracetam Conclusion: Dafyyd Watts died suddenly of pericarditis following an unrecognised and exceptionally rare drug reaction to his necessary anti-epileptic treatment CIRCUMSTANCES OF THE DEATH The deceased died of eosinophilic pericarditis and DRESS syndrome due to Levetiracetam. He had previously been prescribed Carbamazepine but suffered pulmonary eosinophilia. He ceased this treatment and started Levetiracetam. **CORONER'S CONCERNS** 5 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. -Although the evidence suggests that this is only the fourth such death documented it appears that the possibility (albeit remote) of such an occurrence is not drawn to physicians attention in the drug literature or in the BNF entry. **ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation have the power to take such action. YOUR RESPONSE 7 You are under a duty to respond to this report within 56 days of the date of this report, namely by 26th June 2014. 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 – family, North Bristol NHS Trust, University Hospitals NHS Trust and the GP.

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 29th April 2014

Mr. T. G. Moore