

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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	<p>THIS REPORT IS BEING SENT TO:</p> <p><u>Bayer Plc:</u> Bayer House, Strawberry Hill, Newbury, RG14 1JA.</p>
1.	<p>CORONER</p> <p>I am Peter James Bedford, Senior Coroner, for the coroner area of Berkshire.</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>I conducted an Inquest into the death of Mr Charles Hugh Rendell that was heard at Reading Town Hall on 5th January 2017. The conclusion of the Inquest was that Mr Rendell took his own life.</p>
4.	<p>CIRCUMSTANCES OF THE DEATH</p> <p>Mr Rendell was a 76 year old gentleman who underwent a needle biopsy of the prostate on 19th September 2016 at Wexham Park Hospital for diagnostic purposes. Post procedure, he was prescribed Ciprofloxacin 500mg twice daily for five days. He had no history of depression or mental health problems.</p> <p>On the morning of his death on 24th September 2016, he was found by a neighbour wandering in a state of confusion some 8 miles from his home and was returned safely. Later that day, the same neighbour saw Mr Rendell wheel his bicycle with a stool attached, round to his nearby garage block. When the neighbour checked Mr Rendell a little later, Mr Rendell was found hanging in the garage. No note was left.</p>

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5. CORONER'S CONCERNS

During the course of the Inquest, I referred to a letter I had received from [REDACTED], Acting Head of Pharmacovigilance at your company dated 28 November 2016. I was also referred to a variety of published literature relating to Ciprofloxacin and Quinolone Antibiotics and a potential link to suicide behaviour in patients.

The evidence revealed matters that I consider give 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.

The **MATTERS OF CONCERN** are as follows. –

- (1) Apart from the fact that Mr Rendell had undergone a diagnostic biopsy to test for the possibility of Prostate Cancer, the only change in his daily routine was the prescription of Ciprofloxacin medication.
- (2) Ciprofloxacin carries warnings/precautions that, in rare cases, depression or psychosis can progress to suicidal ideations/thoughts culminating in attempted suicide or completed suicide. However, it is unclear how clearly this is made known to Ciprofloxacin users.
- (3) The literature suggests that this type of side effect can occur even soon after commencing Ciprofloxacin at a comparatively low dose. As it is an antibiotic, there is no compelling reason why patients should expect to have this effect unless this fact, and potential symptoms, are brought clearly to their attention by prescribing clinicians.
- (4) One of Mr Rendell's family members is a general practitioner in New Zealand. At the Inquest, she advised that she had no knowledge of the potential effect of Ciprofloxacin and, in conversation with her colleagues, nor did they. I am therefore concerned that this potential risk has not been given sufficient emphasis and that consideration should be given to prescribing clinicians highlighting the symptoms and suggesting to patients that they are alert of the possibility and react appropriately.

6. **ACTION SHOULD BE TAKEN**

In my opinion urgent action should be taken to prevent future deaths and I believe your organisation has the power to take such action.

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7. YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report, namely by 8th March 2017. 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 family of Mr Rendell.

You are 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. 11th January 2017

Peter J. Bedford
Senior Coroner for Berkshire