Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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Dear Dr Bedford,

Reference: regulation 28: report to prevent future deaths – Charles Hugh Rendell

The MHRA has been provided with a copy of the above Regulation 28 report sent to Bayer Plc, which concerns the death of Mr. Charles Hugh Rendell. The report was brought to our attention by [redacted] who is a General Practitioner in New Zealand and is Mr Rendell's niece. The MHRA has also seen a copy of the letter from Bayer Plc in response to your report. [redacted] has also submitted to MHRA a Yellow Card report of Mr. Rendell's suicide whilst taking ciprofloxacin.

We have considered the information provided from these documents on the circumstances leading to Mr Rendell's death. We have focussed on the course of ciprofloxacin that was given to him to take following his prostate biopsy procedure, and have considered whether the statutory information currently provided by the MHRA to prescribers on the safe use of these medicines contains all necessary information.

Looking at the events relevant to these considerations, it is reported that Mr Rendell was being investigated with a needle biopsy of the prostate on 19 Sept 2016 for the possibility of prostate cancer. After the procedure, he was given ciprofloxacin 500 mg tablets to take twice a day for a period of 5 days. It is reported that Mr Rendell had no history of depression or other mental health problems. However, on the fourth day of ciprofloxacin tablets, he became confused, agitated and was found wandering 10 miles from home. Later the same day, he committed suicide by hanging in his garage.

Information on the safe use of medicines is provided to healthcare professionals through the Summary of Product Characteristics (SmPC) available from the electronic medicines compendium (https://www.medicines.org.uk/emc/) and to patients through the Patient Leaflet in every pack of product. Full details of the SmPCs may also be found on the MHRA's website (http://www.mhra.gov.uk/spc-pil/).

With respect to Mr Rendell's case, the following advice is provided in the Ciproxin SmPC:

- Psychiatric adverse reactions may occur even after first administration of Ciproxin.
- Depression or psychosis can progress in rare cases to suicidal ideations/thoughts culminating in attempted suicide or completed suicide, and that Ciproxin should be discontinued if such psychiatric reactions occur.

- The rare undesirable effects of agitation, confusion, disorientation, depression and very rare psychotic reaction (potentially culminating in suicidal ideations/thoughts or suicide attempts and completed suicide) are also mentioned.

The Package Leaflets for Ciproxin (Bayer) provides the following advice:

- Patients taking Ciproxin may experience psychiatric reactions, even at the first dose.
- Patients suffering depression or psychosis may experience worsening of the symptoms of these conditions under therapy with Ciproxin.
- In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide.
- Patients should contact their doctor immediately if any of the aforementioned undesirable effects occur while taking Ciproxin.
- Agitation, confusion, disorientation, anxiety, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide) while taking Ciproxin are also mentioned as possible side effects

In light of the above, we consider that the product information for Ciproxin provides comprehensive, up-to-date information on the risk of mental disturbances including agitation, confusion, psychosis, depression, suicidal ideation and the possibility of completed suicide. In addition, there is clear advice on the need for immediate contact with the prescribing doctor, should these undesirable effects occur whilst taking Ciproxin.

We will review all the UK Package Leaflets for generic ciprofloxacin products to ensure that the information mentioned above is consistently presented across these products.

Yours sincerely

[redacted]

[redacted]
Director
VRMM Division (Vigilance and Risk Management of Medicines)

[redacted]