Medicines & Healthcare products
Regulatory Agency

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Ian Wade KC,

Assistant Coroner for the Coroner Area of Berkshire

[redacted]

21 September 2026

Dear Mr Wade,

Re: Regulation 28 Report concerning the Inquest into the Death of Alexander Warrick Mulroney

We are very sorry to hear of the death of Mr Alexander Warrick Mulroney and would like to extend our sincere sympathies to his family for their loss.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been asked to provide a contribution to the response to the Regulation 28 Report to Prevent Future Deaths following the inquest into Mr Mulroney's death. Your report raised concerns about the adequacy of current risk communications for fluoroquinolones, particularly in relation to psychiatric adverse reactions and the risk of suicidal thoughts and behaviour. The report suggests that warnings presented within product information and software applications used by healthcare professionals, which provide on-screen alerts, may not be sufficiently prominent and could be missed during routine clinical practice, potentially limiting their effectiveness in informing prescribing decisions and patient awareness of risk.

Thank you for bringing these concerns to our attention. We recognise the seriousness of the issues raised in your report and appreciate that this matter is particularly sensitive given the tragic circumstances surrounding Mr Mulroney's death.

The MHRA has a responsibility to ensure that medicines are efficacious and acceptably safe, and that information supporting their safe use, including information on possible side effects, is appropriately described in the authorised product information. This comprises the Summary of Product Characteristics (SmPC, intended for healthcare professionals), labelling, and the Patient Information Leaflet (PIL, provided to patients in each medicine

pack). The product information is intended to support discussions between healthcare professionals and patients about the benefits and risks of treatments.

The current ofloxacin PIL currently contains the following wording:

'you may experience psychiatric reactions when taking Ofloxacin, including when taking it for the first time. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ofloxacin. In rare cases, depression or psychosis can progress to thoughts of suicide or suicide attempts. If this happens, stop taking Ofloxacin and contact your doctor immediately. You may not notice some changes in your mood and behaviour so it is very important to tell your friends and family that you are taking Ofloxacin, and that there may be rare psychiatric side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about'

The current ofloxacin SmPC states in Section 4.4, "*Psychotic reactions have been reported in patients receiving fluoroquinolones, including ofloxacin. In some cases these have progressed to suicidal ideation or self-endangering behavior including suicide attempt, sometimes after a single dose of ofloxacin (see section 4.8).*"

We note the concerns raised regarding both the risk of serious psychiatric adverse reactions associated with fluoroquinolones, including ofloxacin, and the effectiveness of current risk communications. We will therefore consider this matter further through the MHRA's medicines safety review processes. As part of this review, we will consider whether the current regulatory and risk-minimisation measures remain appropriate and whether any further action is required to support the safe use of these medicines.

We appreciate you raising these concerns with us and will give careful consideration to the matters identified in your report, and update you accordingly of the findings following the safety review.

Yours sincerely,



Chief Safety Officer