Courts and Tribunals Judiciary

RESPONSE TO A REPORT TO PREVENT FUTURE DEATHS

REGULATION 28 OF THE CORONERS (INVESTIGATIONS) REGULATIONS 2013

When a coroner sends a prevention of future deaths (PFD) report to a person or organisation, they must respond within 56 days. Recipients of a PFD report can apply to the coroner for an extension. A response to a PFD report must detail the action taken or to be taken, whether in response to the report or otherwise, or it must explain why no action is proposed.

The purpose of the response template below is to promote clarity, ensure that responses address the coroner's concerns directly and transparently, and support consistency and good practice across organisations and sectors. It does not restrict how a person or organisation formulates their response; recipients remain responsible for determining what action is appropriate and for ensuring that their response accurately reflects the steps taken or planned.

In accordance with the Chief Coroner's PFD Publication Policy (2026) representations regarding publication of a response should be sent to the coroner. These representations should be made at the same time as the response is provided. The coroner will pass any representations received to the Chief Coroner for a decision

	RESPONSE TO A REPORT TO PREVENT FUTURE DEATHS **REGULATION 28 OF THE CORONERS (INVESTIGATIONS) REGULATIONS 2013** (Please do not include any living persons' names in this document, in accordance with the Chief Coroner's PFD Publication Policy (2026)) THIS RESPONSE IS BEING SENT TO: HM **SENIOR/AREA/ASSISTANT** Coroner **Ian Wade KC** for Berkshire in response to a '**REPORT TO PREVENT FUTURE DEATH REGULATION 28'** following an inquest into the death of **Alexander Warrick Mulroney** that concluded on **06 August 2026.**
1	**RESPONDENT** In line with our duty under Regulation 29 of the Coroners (Investigations) Regulations 2013, **The National Institute for Health and Care Excellence** provides this response within 56 days (plus any extension granted) of the date of the Report to Prevent Future Deaths
2	**DATE OF RESPONSE** 23 September 2026

3	**CONFIRMATION OF CORONER'S MATTERS OF CONCERN** The **MATTERS OF CONCERN** were identified in the report as follows: “Ofloxacin is an antibiotic medicine within the class described as fluoroquinolones. It is known to be associated with or give rise to a variety of harms or risk of harms to the patient, which are recognised by MHRA, which are catalogued as such in professional publications such as the British National Formulary and software applications in widespread use by healthcare professionals providing on-screen alerts when prescribing the drug, and which are stated within Patient Information Leaflets provided by manufacturers within the product packaging. The warnings refer to a wide range of possible harms, mainly of possible physical harm to tissue, or organs, or joints, or of convulsions, or other injurious consequences, by and large in patients known to be suffering from, or who have previously suffered from, defined pre-disposing conditions. They are broadly referred to as side effects. The warnings include reference to the risk of psychiatric harm, including suicidal thoughts, self-harming behaviour and suicide. The warning includes the statement: “Fluoroquinolones can cause psychiatric side-effects, including depression and psychosis, even after the first dose. In rare cases, these can lead to thoughts or attempts of suicide, and have been associated with the completed suicide of a patient without a history of psychiatric disorders.” I heard evidence that these warnings within software applications are expressed as either High Severity Warning (of which there is one) or Medium Severity Warnings (of which there are 12). The high severity warning refers in non-specific terms to “very rare reports of disabling and potentially long-lasting or irreversible side effects” without mentioning suicide. The terms used would not ordinarily prompt consideration of death. The medium severity warnings begin with a reference to MHRA advising the use of Ofloxacin with caution in psychiatric disorders – can exacerbate existing symptoms which may lead to thoughts of suicide or suicide attempts. After the recital of many other warnings comprising some 41 lines of dense and small print text, all relating to non-fatal outcomes, the 12th warning states, “Alert - MHRA advises quinolones can cause psychiatric side effects including depression and psychosis which can lead to thoughts or attempts of suicide.” I heard evidence that in a typical time constrained doctor/patient consultation, the placing of an under stated reference to the possibility of suicidal thoughts at the end of a relatively long and complex list of so-called medium severity alerts is missed, or is misleading, or is ineffective. The death by suicide of Alexander Mulroney, a patient with no previous history of emotional or mental ill-health, nor a person considered to be at risk of self-harm, soon after commencing a course of a fluoroquinolone is not the first such fatal outcome linked to such medication. Ofloxacin is a dangerous product, notwithstanding its benefits and widespread use. The current approach to publishing warnings of possible harm provides insufficient safeguards and fails properly and adequately to inform both prescribers and patients of danger.”

4	**DETAILS OF ACTION TAKEN**, how has the concern been addressed. (If no action is proposed please explain why here) Please note that any links to webpages included in the response will not be checked for sensitive information prior to publication, as the information is already online. We have noted that the prevention of future deaths (PFD) report centres on the warnings on the harms or risk of harms to the patient when taking Ofloxacin, and their prominence in documents such as the summary of product characteristics (SPC), Patient Information Leaflets (PILs), the British National Formulary (BNF) and in software applications used by healthcare professionals. The content of such prescribing information and how different risks are highlighted in the named external publications are not matters for NICE to respond to. At NICE we host the BNF on our website, but we are not responsible for the content of the BNF. I note that you have also addressed your report to the BNF for their direct response. In addition, I note that you have also addressed your report to the Medicines and Healthcare products Regulatory Agency (MHRA). As the UK's regulator for medicines and medical devices, the MHRA, along with the product manufacturers and the BNF, are the appropriate bodies to address the matters of concern that you have raised in your report. The content of software applications used by clinicians is the responsibility of the software providers but should reflect the SPC and any advice from the MHRA. NICE avoids duplicating safety advice in our guidance which is found elsewhere, namely the BNF and/or SPC. We updated relevant guidance in response to drug safety updates from the MHRA in 2023 and 2024, and would do so again should there be a further update from the MHRA.

5	**DETAILS OF FURTHER ACTION PROPOSED** Please *note that any links to webpages included in the response will not be checked for sensitive information prior to publication, as the information is already online.* No further action proposed by NICE.
6	**SIGNATURE**  [redacted] Chief Executive