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Essex Coroner's Service
Essex County Council
County Hall
Chelmsford
CM1 1QH

National Medical Director
NHS England
Wellington House
133-155 Waterloo Road
London
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2nd February 2024

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Frederick William Le Grice who died on 23 September 2022.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 13 December 2023 concerning the death of Frederick William Le Grice on 23 September 2022. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Frederick's family and loved ones. NHS England are keen to assure the family and the coroner that the concerns raised about Frederick's care have been listened to and reflected upon.

In your Report you raised the concerns that there was a lack of awareness among health professionals and patients as to the possible respiratory side effects of Nitrofurantoin and of the need to be alert to signs of coughing and breathlessness in patients taking the drug.

NHS England has recently undertaken considerable work to raise awareness of the possible respiratory symptoms of Nitrofurantoin and the need for vigilance of any emerging symptoms, following another case where a patient developed lung disease following long term treatment of nitrofurantoin.

The National Patient Safety and Antimicrobial Resistance Teams at NHS England worked closely on this issue with the Medicines and Healthcare products Regulatory Agency (MHRA). This has culminated in the wording in both the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) for Nitrofurantoin being updated and strengthened to emphasise the need for vigilance of emerging respiratory symptoms during treatment and to ensure that these warnings are prominent. The SmPC is used by healthcare professionals such as GPs and pharmacists for guidance on how to use and prescribe a medicine and a PIL must be given to all patients with information on their medications when they receive them.

Subsequently, the updates were also communicated to healthcare professionals via a [MHRA Drug Safety Update](#) on 26 April 2023. This work is also highlighted in an NHS England Patient Safety [Case Study](#) in August 2023.

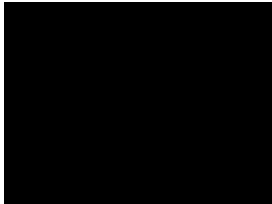
In consideration of the concerns raised in your Report, my regional colleagues in the East of England have been engaging with the relevant Trust to learn what actions have

been taken in response to the concerns raised. The Trust have advised that their Urology and Respiratory Leadership Teams have agreed to send a Patient Safety Alert to the Urology Teams to advise of the possible respiratory side effects of Nitrofurantoin. They will also be raising further awareness of the case at the next Urology Divisional Audit Session.

I would also like to provide further assurances on national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around preventable deaths are shared across the NHS at both a national and regional level and helps us pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,



National Medical Director