

October 14, 2025

FAO Susan Ridge
HM Assistant Coroner for Surrey

Dear Ms Ridge,

We write in response to the Regulation 28 Report dated 19th August 2025 (the "Report").

We were sorry to read about the passing of Mrs Pierce, and we would like to take this opportunity to offer our condolences to her family following their loss.

We have undertaken an internal review of EMIS Web (the "System"), focusing on the issue raised as a concern in the Report that was relevant to Optum as a healthcare IT supplier. We understand your view is that more needs to be done in terms of MHRA Drug Alerts, specifically in this case, regarding the risks of pulmonary and hepatic adverse drug reactions in relation to Nitrofurantoin.

This review was undertaken by our internal team, including two Medical Directors, a Clinical Safety Officer, the Head of Clinical Safety and a Clinical Informatician.

Investigation Findings

EMIS Web provides a number of alerts and warnings, when relevant, specifically to a patient's current medication, diagnoses or applicable laboratory results. Alerts are embedded at natural decision points in the user flow and are tiered in terms of severity. This is designed to reduce alert fatigue and ensure critical alerts are prominent and presented early to the user. It should be noted however that alerts and warnings do not replace a clinician's clinical reasoning but are there to assist in the decision-making process.

Following consent being granted by Springfield Surgery, we investigated her medical record, and it was established that Mrs Pierce received Nitrofurantoin on 5 occasions, across 2 prescribed courses.

When first prescribed on the 19th February 2024; and upon the commencement of the second course on the 17th May 2024, the system displayed several warnings (please see Fig 1). The warnings are displayed in order of severity (as per the description above) and are driven by coded information within the clinical record, alerting the user to a high-risk situation for Mrs Pierce. In order to progress with the prescription of Nitrofurantoin, the user had to override the warnings.

- An allergy warning based upon a coded adverse drug reaction to Nitrofurantoin placed upon the record on the 4th March 2013. This was evident from the Audit function within the System.
- High Severity warnings regarding cautionary use in patients with reduced kidney function (eGFR).
- A Medium Severity warning relating to age; with advice to monitor lung and liver function on long-term therapy.

Warnings

Selected Drug - Nitrofurantoin 50mg tablets

Contains - Nitrofurantoin 50 mg

Allergies (1)

- **Adverse Drug Reaction** History of Adverse Drug Reaction to Nitrofurantoin
Adverse reaction to nitrofurantoin

High Severity Warnings (2)

- ⚠ **Contra-Indication** Avoid Nitrofurantoin if eGFR less than 45 mL/minute/1.73 m sq; may be used with caution if eGFR 30-44 mL/minute/1.73 m sq as a short-course only (3 to 7 days), to treat uncomplicated lower urinary-tract infection caused by suspected or proven multidrug resistant bacteria and only if potential benefit outweighs risk; risk of peripheral neuropathy; antibacterial efficacy depends on renal secretion of the drug into the urinary tract.
eGFR_{creat} (CKD-EPI)/1.73 m²
- ⚠ **Contra-Indication** Avoid Nitrofurantoin if eGFR less than 45 mL/minute/1.73 m sq; may be used with caution if eGFR 30-44 mL/minute/1.73 m sq as a short-course only (3 to 7 days), to treat uncomplicated lower urinary-tract infection caused by suspected or proven multidrug resistant bacteria and only if potential benefit outweighs risk; risk of peripheral neuropathy; antibacterial efficacy depends on renal secretion of the drug into the urinary tract.
Estimated creatinine clearance (Cockcroft-Gault formula)

Medium Severity Warnings (3)

- ⚠ **Caution** Use Nitrofurantoin with caution in The Elderly. Monitor lung and liver function on long-term therapy, discontinue if deterioration in lung function.
Age
- ⚠ **Caution** Use Nitrofurantoin with caution in susceptibility to peripheral neuropathy.
Neuralgia unspecified
- ⚠ **Caution** Use Nitrofurantoin with caution in vitamin B deficiency.
Cobalamin deficiency

⌂

Override Do Not Use Drug

(Fig 1)

These warnings remained accessible to any user of the System at all other times, either via the Safety Check function or by accessing the British National Formulary (BNF) via the System – which includes all MHRA Safety Alerts.

Conclusion

As a provider of Clinical Decision Support tools, Optum always looks for opportunity to enhance its products to enable clinicians to be best supported when taking ultimate responsibility for any clinical decisions and / or care that is provided.

In this instance, based on the information provided in the Report, and our subsequent review, we do not believe there are any software developments beyond the existing functionality in the System that are required to mitigate the specific risk raised in the Report.

We trust that the details outlined above are helpful. If you have any further queries then please contact our Senior Clinical Director, [REDACTED] in the first instance.

Kind regards,

[REDACTED]

Chief Medical and Strategy Officer