Mr Daniel Howe
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[redacted]

National Medical Director
NHS England
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[redacted]

22 January 2025

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Gemma Louise Helen Ralph who died on 26 January 2024

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 8 November 2024 concerning the death of Gemma Louise Helen Ralph on 26 January 2024. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Gemma's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about Gemma's care have been listened to and reflected upon.

I am grateful for the further time granted to respond to your Report, and I apologise for any anguish this delay may have caused Gemma's family or friends. I realise that responses to Coroner Reports can form part of the important process of family and friends coming to terms with what has happened to their loved ones, and I appreciate this will have been an incredibly difficult time for them.

Your Report raised concerns over a lack of robust monitoring of the supply, storage and use of Sevoflurane at Cannock Chase Hospital, and that The Royal Wolverhampton NHS Trust was unable to confirm or refute that a bottle of Sevoflurane found at Gemma's home had originated from the hospital.

Professional guidance on the safe and secure handling of medicines, published by the Royal Pharmaceutical Society (RPS), sets out the principles that should inform the approach of all NHS hospitals to ensuring that there are processes in place for the safe storage, supply and use of all medicines. These should include an assurance mechanism. Such processes are developed under the professional leadership of the Trust Chief Pharmacist and will be informed by a local risk assessment, which will include the potential harm caused by the inadvertent or deliberate diversion and/or misuse of the medicine, against the need for timely and appropriate access for administration to patients where clinically indicated.

The specific challenges that arise in operating departments are acknowledged in the RPS guidance, as access to some of the medicines used during surgery, including Sevoflurane, may be required rapidly. The Royal College of Anaesthetists (RCoA)

endorsed the RPS guidance and also subsequently published "Safe Drug Management in Anaesthetic Practice" to supplement this. The RCoA supplementary guidance reinforces the need to have processes in place that support patient safety, the health and safety of colleagues and public protection.

The risk of anaesthetics being diverted by colleagues was highlighted in the Care Quality Commission's (CQC) "The safer management of controlled drugs: Annual update 2021". They stated that they had received some reports that an anaesthetic (not Sevoflurane) was both being diverted and misused. This information was shared by the CQC and NHS England with all NHS trusts. The importance of considering the risks and possibilities associated with the potential misuse and/or diversion of anaesthetics, including where it is stored and who has access to it, was emphasised.

The CQC, as the independent regulator of health and social care in England, includes the "…proper and safe management of medicines…" (required under the The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 - SI 2014/2936 r.12(2)(g)) as part of the medicines optimisation domain of their single assessment framework. Where the CQC inspects services that include operating departments and/or theatres, the safe and secure use of anaesthetics would form part of that assurance, with any concerns raised with the trust and NHS England as necessary.

NHS England will continue to explore and support improvements in the controlled, authorised and auditable access to medicines.

With regard to your specific concerns about how Sevoflurane is stored and monitored at Cannock Chase Hospital, I note that you have also addressed your Report to the hospital and refer you to their response on these issues. NHS England will also consider the hospital's response and any actions arising from this in due course.

I would also like to provide further assurances on the 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 events, such as the sad death of Gemma, are shared across the NHS at both a national and regional level and helps us to 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,

[redacted]
National Medical Director