Medicines & Healthcare products
Regulatory Agency

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Ms Caroline Topping
HM Assistant Coroner
[redacted]

27 November 2023

Dear Ms Topping,

[redacted]: Regulation 28 Report - Reginald Edwin Bourn

I would like to thank you for your email dated 1 November 2023 regarding the Regulation 28 Report for the death of Reginald Edwin Bourn and the subsequent response from [redacted] Chief Executive, NICE, regarding instructions for nasogastric decompression tubes. I would like to express our condolences to the Bourn family and hope that the information provided below may help at this difficult time.

Firstly, it may be helpful if to provide background information relating to the MHRA and the work we carry out. The MHRA is the executive Agency of the Department of Health and Social Care that acts on behalf of the Ministers to protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment, including medical devices, are used safely and meet appropriate standards of safety, quality, performance, and effectiveness. The MHRA assesses the balance of risks and benefits of medical devices throughout their use in clinical practice in a process known as vigilance. This involves the collection of information and assessment of any potential risks, followed, when necessary, with communications and regulatory action to minimise those risks. Where serious incidents involving medical devices have been reported to other authorities including the Police, Coroners and the Health and Safety Executive (HSE), the MHRA provides technical expertise and facilitates independent testing if required. The MHRA ensures any concerns raised from these investigations are disseminated to the health service to prevent further incidents or taken up with the manufacturer.

Following receipt of the Regulation 28 Report we have considered point two in the matters of concern: "*Feeding tubes have instructions both as to how to insert them and as to how to ensure that they are correctly placed. The decompression tubes have neither".* We have reached out to the manufacturers of nasogastric tubing to confirm their primary intended use and to review their instructions for use (IFU) for both feeding and decompression tube placement.

We expect to complete the initial review of the IFUs by 4 January 2024. Following this review, we will work with manufacturers to update their IFU where applicable. If updates are made, the MHRA is of the opinion that they should issue a Field Safety Notice (FSN) to highlight the changes to clinicians, and ensure that their staff are fully trained in the changes so that they can provide advice to clinicians where necessary.

I would like to thank you once again for raising this important safety issue to our attention and I hope the information provided is useful and I will provide a summary of any planned actions by 4 January 2024. In the meantime, please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

Chief Safety Officer
Medicines and Healthcare products Regulatory Agency