Medicines & Healthcare products
Regulatory Agency

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Mr Graeme Irvine
Senior Coroner
[redacted]

30 August 2024

Dear Mr Irvine,

CEC 191775: Regulation 28 Report – David John Morris

I would like to thank you for your email dated 4 July 2024 regarding the Regulation 28 Report for the death of David John Morris; we appreciate you bringing this report to our attention.

Firstly, I would like to express our condolences to the Morris family and our thoughts are with them at this difficult time.

As you are likely aware, 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 through the collection of information and assessment of any potential risks, followed, when necessary, with communications and regulatory action to minimise those risks. The MHRA does not have a role in providing medical advice or guidance relating to medical practice or care quality and therefore cannot comment on those aspects of this case.

From the timeline of events, from the Regulation 28 report, the MHRA understands that Mr Morris underwent a surgical gastrostomy, due to an oesophageal stricture, and a feed leak was observed on multiple occasions, but no actions were taken by the clinical staff.

Without information regarding the specific brand and manufacturer of the gastrostomy device within the Regulation 28 report the MHRA have not been able to review the specific Instructions for Use (IFU) for the product, however, in general gastrostomy devices do include warnings regarding checking for leaks and stopping treatments and potentially replacing the

device if leaks do occur. Additionally, it is stated that the device was removed and tested and appeared functional, therefore there does not appear to be a particular fault with the device that would be within the remit of the MHRA to address.

It is important to note that the MHRA did receive a safety report in December 2022 from NHS England from the National Reporting and Learning System (NRLS) regarding a fatality with a gastrostomy balloon device. Whilst the NRLS report did not include all the same details as this Regulation 28 report, the MHRA are confident that this is regarding the same patient due to the timeline of events. The NRLS report focussed on the possibility of human error and confusion between the enteral feeding port and the balloon port. The MHRA contacted all manufacturers for balloon gastrostomy devices who confirmed that they had received no similar reports and that they were implementing ENFit standards for their devices with the last of the non-ENFit products being available in June 2023. ENFit is the standard to ensure enteral tubing connectors are designed to be mechanically incompatible with connectors from other areas of therapy, to minimize misconnection risks. ENFit implementation began in 2015 throughout the UK and was a phased approach to allow manufacturers time to produce ENFit compliant products. For this reason, the investigation into this issue was considered closed in August 2023.

If the brand name and manufacturer of the gastrostomy device used on Mr Morris is available, please provide this and we will be able to check the wording in their specific product information to ensure the appropriate advice on checking for leaks is present.

I would like to thank you once again for contacting us regarding this sad case and I hope the information provided is useful. Please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

[redacted]

[redacted]
Chief Safety Officer
Medicines and Healthcare products Regulatory Agency