Medicines & Healthcare products
Regulatory Agency

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Mr Hassan Shah
Assistant Coroner for Northamptonshire
West Northamptonshire Council
The Guildhall, St Giles' Square
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24 April 2025

Dear Mr Shah,

Regulation 28: Report to Prevent Future Deaths – Dominic Martin Philip

Thank you for the Regulation 28 report for Mr Dominic Martin Philip dated 14 March 2025.

I am very sorry to hear that Mr Philip died on 3rd February 2023 at Kettering General Hospital as a result of an anaphylactic reaction to a contrast medium injected for the purposes of an abdominal CT scan to investigate a bowel obstruction. We extend our sincere condolences to his family.

I note that you have raised three matters of concern during the course of your investigation, and I have addressed them in turn as below:

1. **Might there be some possibility of testing for an allergic reaction to the contrast medium in advance of an imaging procedure? If a patient has never before had contrast medium (as was the case with Mr Philip) they cannot possibly know if they have an allergy to it. Making arrangements for ALS after the event seems reactionary and I wondered if any other options might be available which would flag a potential allergy before the contrast is injected.**

   The use of diagnostic imaging has been increasing year-on-year with annual figures for the NHS reporting a total of 7.7 million CT scans performed in England in the year to March 2024. As such, the feasibility of pre-procedure screening for contrast medium allergy will need careful evaluation and further discussion with local healthcare providers

and professional bodies with expertise in radiology, in particular the consideration of the potential burden being placed on the healthcare system.

At present, there is no standardised sensitivity test for allergy testing of contrast medium. The approved product information (also known as Summary of Product Characteristics) for contrast medium does not refer to a requirement for allergy testing to be performed in advance of an imaging procedure, as severe reactions to contrast media may not consistently be predictable from sensitivity tests, and there are risks of other adverse reactions associated with contrast medium.

From a regulatory perspective, there are existing and substantial warnings of the potential for allergic reactions/anaphylactoid reactions in the approved product information (SmPC) for contrast medium. Specifically, healthcare professionals are advised to exercise special caution in patients with a positive history of allergy, asthma or untoward reactions to iodinated contrast media. Clinicians are advised to consider the use of contrast media when the benefits outweigh the risks, and the SmPC states that a course of action should be planned in advance to ensure that there are appropriate resources such as necessary medicines, equipment, medical experience and skilled personnel available for the management of anaphylactic reactions should they occur. The SmPC advises that pre-medication (such as antihistamines and steroids) may also be considered in patients at risk of intolerance. However, these are to be decided on a case-by-case basis, as anaphylaxis may occur despite pre-medications. The decision to administer a contrast medium alongside a particular imaging modality, such as CT, should take into account the patient's presentation and clinical indication based on factors in the individual case. The total potential diagnostic benefits of an imaging examination are determined by a trained practitioner legislated in the UK under The Ionising Radiation (Medical Exposure) Regulations 2017.

The MHRA will continue to monitor and review adverse event reporting for contrast media as part of our pharmacovigilance activities and consider appropriate actions where applicable.

2. I am concerned that Mr Philip has come into contact with Lidocaine without any explanation – could there be a contaminated supply of medication? Have there been any similar unexplained occurrences anywhere else in the country? This is of course of particular concern to those who, like Mr Philip, are allergic to Lidocaine.

Your concerns around the unexplained presence of lidocaine in Mr Philip's system is noted. It seems unclear whether there may have been potential use of over-the-counter products or medical devices prior to Mr Philip's imaging procedure at Kettering General Hospital that may account for the detection of plasma lidocaine levels post-mortem.

To date, the Defective Medicines Report Centre (DMRC) of the MHRA have not received any reports identified by Marketing Authorisation Holders of licensed medicines that relate to product contamination issues with lidocaine. There was a company-led medicines recall for an over-the-counter product (EXS Delay Spray Plus) in 2024[1], whereby lidocaine was

[1] Company-led medicines recall

found to be present in two affected batches supplied to the UK. However, this incident is unlikely to be related to this case as the affected batches only entered the UK supply chain as of November 2023, which was after the death of Mr Philip.

Based on the MHRA's pharmacovigilance and post-marketing surveillance activities, we are also not aware of any product contamination issues with prescription only medicines or medical devices in relation to contamination with lidocaine, nor any similar unexplained occurrences elsewhere in the country.

3. **Lidocaine is not a Controlled Drug, which means that clinicians do not need a double signature to remove the medication from the stock, and it is not subject to a count of the stock each time an ampoule is used.**

   The MHRA can confirm that lidocaine is a prescription only medication (POM), however it is not listed in Schedule 2 of the Misuse of Drugs Act 1971 as a Controlled Drug. Regulation 214 of The Human Medicines Regulation 2012 mandates that a person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.

   For medicines that are not Controlled Drugs, the requirement for double signatures for stock count and supply processes is generally determined by medicine management procedures within individual hospitals and healthcare providers, who may sometimes consider more stringent controls are warranted due to a medicine's potential for misuse, cost or other supply-related considerations. Unless there is a safety concern, any additional procedures for the handling of medicines would be outside the remit of the MHRA.

   It should be noted that lidocaine is contained in multiple drug formulations which can be administered by different routes, including during medical procedures in the emergency department. Therefore, the consideration of additional governance processes for the management of lidocaine (such as double signatures) should be carefully considered to avoid undue delay to patient access and minimise additional burden on healthcare professionals. As this is not a decision for the MHRA we would advise that additional guidance is sought from the relevant medicines management committee at the local NHS Trust.

I hope that you find this information helpful.

Yours sincerely,

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