Department of Health & Social Care

[redacted]
Parliamentary Under-Secretary of State for
Patient Safety, Women's Health and Mental Health

39 Victoria Street
London
SW1H 0EU

Our ref: [redacted]

Dr Julian Morris
HM Deputy Coroner, Inner London South
Southwark Coroner's Court
1 Tennis Street
Southwark
SE1 1YD

8th January 2025

Dear Dr Morris

Thank you for the Regulation 28 report of 15th November 2024 sent to the Secretary of State about the deaths of Yousef Al-Kharboush, Oscar Barker and Aviva Otte. I am replying as the Minister with responsibility for Patient Safety, Women's Health and Mental Health.

Firstly, I would like to say how saddened I was to read of the circumstances of these tragic deaths and I offer my sincere condolences to their families and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention.

The key matters of concerns were:

- that there is no requirement for a section 10 unit to report any of its findings to the Medicines & Healthcare products Regulatory Agency (MHRA), other Trusts or the industry in general if an adverse event occurs.

- Under section 10, the current reporting structures involve reporting to NHS England and the Care Quality Commission (CQC), but the threshold or necessity for such reporting appears unclear and is often up to the Trust.

- There is no forum (formal or otherwise) for section 10 units to share information that help other Trusts and commercial organisations in assessing their own risks.

- The same may also be true of commercial organisations (or specials license holders) but because of MHRA's role regulating these organisations, where MHRA identify risks, they can issue recalls and disseminate information more widely

In preparing this response, my officials have made enquiries with NHS England, CQC and MHRA to ensure that we adequately address your concerns.

Since these tragic deaths occurred, there has been considerable strengthening of NHS England guidance on aseptic preparation of medicines and auditing (NHS England » Assurance of aseptic preparation of medicines) replacing previous guidance. Furthermore, NHS England has introduced strengthened oversight and external quality audit commissioned through the NHS Specialist Pharmacy Services (SPS), including iQAAPS which is a web-based quality reporting system to support oversight and external audit of unlicensed NHS pharmacy aseptic preparation.

However, the gap you identified has not been fully addressed by this and there is more work to do in this area. NHS England, MHRA and CQC will be sending their individual responses to the PFD report to set out how they will address the concerns raised. This includes:

- A 2-way information sharing agreement between CQC and NHS England, which was not in place in 2014.
- NHS England to review, update and strengthen their 2023 guidance (linked above) to provide further direction on thresholds for reporting and escalation of concerns from section 10 aseptic units into NHS England regionally and nationally.
- MHRA and NHS England intend to agree and implement a 2-way information sharing agreement at organisational level to share learning of serious incidents related to aseptic medicines (by end of June 2025).

Furthermore, DHSC will meet with CQC, NHS England and MHRA to ensure that the actions of each organisation to address your concerns are complementary, coordinated and completed. I have asked my officials to write to you once these actions are fully completed.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

Yours sincerely,

[redacted]

[redacted]

PARLIAMENTARY UNDER-SECRETARY OF STATE FOR
PATIENT SAFETY, WOMEN'S HEALTH AND MENTAL HEALTH