International Scientific Supplies Ltd

Unit 6
Valley Road
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United Kingdom

Thank you for your Regulation 28 report concerning the late Mr Anthony Jonathan Lodge and the use of red-topped urine sample bottles containing boric acid supplied by International Scientific Supplies Ltd (ISS).

International Scientific Supplies Ltd (ISS) wishes first to acknowledge the seriousness of the concerns raised in the Regulation 28 report following the death of Mr Anthony Jonathan Lodge and thanks the Court for the opportunity to respond.

ISS manufactures and labels its urine specimen containers in accordance with all applicable UK regulatory and quality requirements for this type of medical container, including those relating to stability, expiry dating, batch control and packaging information. For the product range used by the County Durham and Darlington NHS Foundation Trust district nursing team, the expiry date and batch number are printed on the outer packaging (box) in line with recognised practice for small containers, and the containers are released only within their approved shelf life under our quality-management system. The 10 ml primary tubes are of limited size and are therefore not designed to carry the full set of outer-pack details; however, they are traceable to the labelled outer carton under our established manufacturing and distribution processes. On that basis, ISS is confident that the product, as supplied, complied fully with our regulatory and compliance obligations at the time of manufacture and supply.

Following notification of this case, ISS requested confirmation of the specific product code and the lot (batch) number of the container in question, in order to verify the manufacturing and expiry details of the exact batch allegedly used. We understand that the Trust has been unable to provide either a product code or a lot number, so it has not been possible to perform a batch-specific review of the individual container referred to in the report. Notwithstanding this, ISS's internal records and controls give us confidence that, when supplied to the Trust, the relevant batches were released within their assigned shelf life, with expiry dating clearly indicated on the associated outer packaging.

ISS notes the Coroner's conclusion that it is unlikely that the out-of-date container contributed to Mr Lodge's death. We also note the concern that, in other cases, delay arising from the use of an out-of-date container could contribute to a death and that action should be considered to reduce such risk.

Within the scope of a manufacturer's responsibilities, ISS addresses this risk primarily by:

- Ensuring that stability studies, assigned shelf lives and expiry dates are scientifically justified and appropriately controlled.

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- Ensuring that expiry dates and batch numbers are applied and legible on packaging, and that product is not released beyond its approved shelf life.

ISS is satisfied that, for the product range concerned, these controls were in place and that the labelling and release of the product were compliant with the applicable regulatory and quality requirements at the time of manufacture and supply.

In summary:

- The urine specimen containers concerned were manufactured, tested, labelled and released in full compliance with applicable regulatory and quality requirements for this type of product.
- Expiry date and batch information were applied to the outer packaging in accordance with established practice for small containers, and product was not released beyond its approved shelf life.
- Although the Trust has been unable to provide the product code or lot number for the specific container, ISS's records and controls support the conclusion that the container, as supplied, would not have been expired.

ISS remains committed to maintaining robust quality-management and regulatory-compliance systems and to cooperating with healthcare providers and the Court to support patient safety.

Signed on behalf of the Supplier:

[redacted]

[redacted]

Managing Director