Medicines & Healthcare products Regulatory Agency

MHRA

Mr N. Parsley
Senior Coroner
West Suffolk

16 December 2020

Medicines and Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

gov.uk/mhra

Dear Mr Parsley,

Regulation 28 Report concerning SUSAN WARBY

Thank you for your letter of 25th September 2020 in which you asked the Medicines and Healthcare products Regulatory Agency (MHRA) to provide a response to the Regulation 28 Report to Prevent Future Deaths following the inquest into the death of Susan Warby.

Your report listed a number of matters of concern. In relation to the responsibilities of the MHRA one of your concerns was in the context of the labelling of the intravenous fluids which were implicated in Susan Warby's death and the potential for these to be confused at the point of selection and administration. You have asked that MHRA review the labelling and product design of the fluids in question.

Although the medicines regulations do not address issues of pack design and the presentation of the statutory information on the labelling, the MHRA has, nonetheless, published guidance for the pharmaceutical industry on how to optimise the presentation of the information on the labelling so that medicines may be selected and supplied safely and reduce the likelihood of error. This has been well received and many companies have embraced the principles contained therein.

Intravenous fluids as described in your report are supplied in bags known as 'Viaflo' which are composed of polyolefin/polyamide co-extruded plastic. The way that these containers are manufactured means that *'judicious use of colour'* (as recommended in our best practice guidance) cannot be used within the labelling, to aid differentiation and reduce the likelihood of error at the point of selection. As a result, other risk minimisation measures must be employed locally within clinical areas to assist in the correct identification of intravenous fluids one from another.

Nonetheless, we will consider further with the marketing authorisation holder whether improvements could be made to assist clinical staff to more easily assimilate the statutory information to reduce the likelihood of errors of this nature in future.

Yours sincerely

Chief Executive, MHRA

T
E