Medicines & Healthcare products Regulatory Agency

MHRA

Mr Andrew J Cox,
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Dear Mr Cox,

Your ref: AJC/LJB, MHRA Ref: 2019/006/028/601/004
Regulation 28 Report concerning Jeanette Ann Robinson

Thank you for your letter of 3 June 2019 in which you asked the MHRA to provide a response to the Regulation 28 Report to Prevent Future Deaths following the inquest into the death of Jeanette Ann Robinson.

You wanted to know whether this incident may properly be regarded as a "one-off' or, alternatively, if this is a product where there is an ongoing concern that similar deaths may arise in the future unless action is taken. You stated it would seem to be a relatively simple matter to install an alarm or other warning to a user that a particular mattress is becoming deflated.

Mattresses are medical devices which must be CE marked before they are placed on the market in the UK and throughout the EU. MHRA's expectation is that, when CE marking and placing a medical device on the market, manufacturers will have evaluated the potential risks that could occur.

The CE mark demonstrates that the medical device is fit for its stated intended purpose and meets legislation relating to safety. This requires the manufacturer to demonstrate their medical device meets the requirements in the Medical Devices Directive (MDD) by carrying out a conformity assessment. Additionally, higher risk medical devices (including these types of mattresses) require certification from a third party conformity assessment body ("Notified Body") located in the EU prior to being placed on the market. MHRA is responsible for the oversight of UK Notified Bodies and has a post-market role in investigating reported safety issues via a voluntary reporting system for users (Yellow Card) and a mandatory reporting system for manufacturers.

MHRA were unaware of this adverse incident as it was not reported to us by the Royal Cornwall hospital or other third party. Arjo Huntleigh, the manufacturer of the Nimbus 3 alternating pressure mattress, was also unaware of the incident as it was not recorded within their post market surveillance system.

Arjo Huntleigh has since logged this event on their system and will present MHRA with their conclusion, although without a serial number to identify the mattress, their report may be inconclusive.

Arjo Huntleigh's initial findings were that Nimbus 3 mattress was on loan from the Adult Social Care service of Cornwall Council, who had no record of problems associated with it, prior to its removal from service and subsequent destruction.

The Nimbus 3 alternating pressure mattress pump includes audible and visual alarms for mains power failure, low or high pressure and pump fault conditions.

The mains power failure alarm is powered by a rechargeable battery and the instructions for use advise that this function is tested before the system is put into use, as the battery may be flat if the mattress hasn't been in regular use. The instructions also convey the battery test sequence to be followed.

There are no similar adverse incidents involving the Nimbus 3 alternating pressure mattress on MHRA's adverse incident database, so it is reasonable to assume that there is not a systemic failure with this mattress and there is no further action that MHRA can take. As it has not been possible to investigate the specific mattress involved, we cannot be certain how the failure was caused.

I hope the above information is useful.

Yours sincerely,

Dr Ian Hudson
Chief Executive
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Telephone: 020 3080 6100
[redacted]