Medicines & Healthcare products
Regulatory Agency

13 SEP 2017

MHRA
Regulating Medicines and Medical Devices

H.M Coroner
For the West Yorkshire (Western) Coroner Area
City Courts
The Tyrls
BRADFORD
BD1 1LA

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

12 September 2017

Dear Ms Burke

Regulation 28 Report concerning Pauline Taylor – Ref: HK/1067-2015

Thank you for your letter of 21July 2017, with the attached Regulation 28: Report to Prevent Future Deaths, to the MHRA regarding the death of Pauline Taylor. This response deals with medical device aspects, relating to both the issues raised regarding emollients and mattresses. A response dealing with the medicines aspects of emollients will be supplied to you separately, in line with your request.

As you may be aware, The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. The aim of the MHRA Devices Division is to take all reasonable steps to protect the public's health and safeguard the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant Directives of the European Union.

One major area of MHRA Devices' responsibilities is the investigation of adverse incidents. An adverse incident is an event involving a medical device, which produces, or has the potential to produce, unwanted effects involving the safety of patients, users and other persons. These effects may arise from shortcomings in the device, its operating instructions, user practice or conditions of use.

We have addressed the points relevant to medical device aspects in our response below.

MHRA received the first adverse incident reports of fires involving emollients in March 2017. However, we were aware of the work undertaken by the National Patient Safety Agency (NPSA) in 2007 and highlighted this work to healthcare workers when it was published. In the form of a "One Liner" publication in March 2008, issue 56. Since that time, as no adverse incident reports were received. it was not considered necessary to issue any further communication.

It is recognised that there are differences in the labelling of these products and in light of this during 2017, both Medicines and Devices parts of MHRA are undertaking an in-depth review of instructions for use and reported adverse incidents.

We aim to have completed our review by the end of 2017 and will consider the need for publication of any additional safety advice at this time in conjunction with our medicine colleagues.

Additionally, we have worked with manufacturers to raise awareness of this potential risk. This work highlighted the need for risk of fire to be included in their product risk analysis and ensuring warnings of the potential risk were placed either on packaging or included in the device's instructions for use. We have previously issued warnings regarding the dangers around smoking and bed fires (MDA/2013/073).

Medical devices 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, including that of fire.

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 require certification from a third party conformity assessment body ("Notified Body") 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.

Emollients may fall into any of the risk classes according to their constituents and mode of action. The paraffin content of these products varies over a wide range, also, from as little as 5%, in some cases and has no bearing on whether the product is classed as a device or as a medicine. This difference is due to their mode of action.

In Spring 2017 MHRA wrote to UK manufacturers of Class I medical devices (the lowest risk category) directly and asked them to undertake a review of their products. In addition, we asked the UK Notified Bodies to ensure that a review and risk assessment was undertaken by manufacturers of higher risk classification medical devices.

We also brought the issue to the notice of European regulatory colleagues to highlight the dangers internationally. All European Competent Authorities were asked to share the letter mentioned above with Notified Bodies they oversee to ensure coverage of all manufacturers with products in the European market.

The issue has been raised with NHS Improvement and Medical Device Safety Officers (MDSOs). The latter are individuals in each NHS Trust in England who ensure safety information is made available to relevant staff. MHRA is also liaising with the Care Quality Commission to highlight the potential dangers to users within the care community.

The therapeutic benefits of the mattress system will generally have been found to outweigh the likelihood and consequences of a fire, in part mitigated by the labelling and instructions for use, advising against smoking or using naked flames whilst in bed.

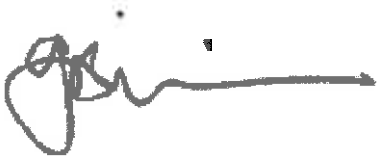
Polyurethane (PU) is the industry standard cover material on most types of healthcare mattress, including pressure reduction mattress systems, such as the ArjoHuntleigh Nimbus 3. The cover

material of healthcare mattresses has to withstand heavy use, must be impervious to liquid ingress and withstand frequent exposure to decontamination agents.

MHRA has contacted the manufacturer, ArjoHuntleigh, to confirm that their current risk mitigation factors are appropriate. This includes meeting the standard BS7175:1989, (Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources) and the product labelling and instructions for use, which contain the warning about fire risk.

MHRA is continually reviewing methods of communicating important healthcare information to healthcare professionals and members of the public. However, communication to the general public is a challenging area for all aspects of healthcare. The MHRA does publish Medical Device Alerts and Drug Alerts issued via the Central Alerting System (CAS). Within CAS there are thousands of subscribers from organisations in the independent/private sectors, with frequent requests received at the helpdesk to add new subscribers and alter existing records. This is a well-established and effective mechanism for communicating important safety information to healthcare professionals throughout the NHS and private health sectors.

Yours sincerely



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Director of Devices

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