Medicines & Healthcare products
Regulatory Agency

MHRA

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30th November 2018

Dear Mr Fleming

Regulation 28 Report concerning Brian Leonard Bicat – Your Ref: [redacted]

Thank you for your letter of August 2018 in which you asked the MHRA to provide a response to the Regulation 28 Report to Prevent Future Deaths following the inquest into the tragic death of Brian Leonard Bicat.

In the UK an emollient may be regulated as a medicine, a medical device or a cosmetic. One of the emollient products referred to in your Regulation 28 Report is regulated as a medical device – Hydromol Ointment; the other, Diprobase Cream is a medicine. This response deals with the aspects of your report which relate to medical devices and device regulation. A response dealing with the medicine aspects will be provided separately, in line with your request for two separate responses.

Your report listed seven matters of concern which fall within the remit of MHRA & medical device regulation.

1. Paraffin based ointments and emollient creams which contain a low level of paraffin pose a potential fire hazard risk
2. Warnings of such risks are not displayed on all product packaging
3. Consider more prominent labels and alerts re fire hazard on product containers
4. Healthcare professionals in both hospital and community setting may not be aware of the potential for fire hazard posed by emollient creams which contain a low level of paraffin.
5. To consider fire warning labelling on all emollients including those below 50% content, making clear the mechanism of the risk
6. Healthcare professionals including pharmacists to verbalise product warnings at the point of prescription, dispensing or point of sale.
7. Members of the public are able to purchase such products in retail outlets and online where verbal warnings from healthcare professionals are not given.

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") 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.

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. The classification difference is due to their mode of action.

In March 2008 MHRA Devices issued a reminder to healthcare professionals of the potential risks associated with paraffin based emollients, as highlighted by the work of the National Patient Safety Agency (NPSA) in 2007. This reminder was in the form of a "One Liner" which was published in issue 56. Since, at that time, as no adverse incident reports had been received, it was not considered necessary to issue any further communication.

However, in addition, we have written to manufacturers to raise awareness of this potential risk. This highlighted the need for the 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).

No reports of adverse events, injuries or fatalities were reported to MHRA regarding devices until 2017. At this point it was noted that there are differences in the labelling between products regulated as devices and medicines.

Working in collaboration with colleagues in the medicines regulatory part of the Agency in Spring 2017 MHRA Devices 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 to 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.

In response to more recent evidence regarding the risk with emollient products paraffin, including a number of fatalities reported since 2017 (many of which were historical), MHRA is reviewing the available evidence regarding the risk for a wider range of paraffin-containing medicines and devices and has convened an ad hoc Expert Group to advise on the appropriate regulatory action for both medicines and medical devices.

The Expert Group met for the first time on 7th September 2018 and will meet again on Friday 30th November 2018 when it is expected to deliver its final recommendations for regulatory action to protect public health.

Each of the seven matters of concern raised in your report within MHRA's remit is being put to the group for consideration and advice. In making its recommendations, the ad hoc Group will consider evidence from five Coroners Regulation 28 reports including those for Pauline Taylor (Regulation 28 Report by Assistant Coroner Mary Burke, West Yorkshire Western District; Ref: HK/1067-2015) and Brian Bicat; data on additional possible cases reported by ten Fire and Rescue Services across the UK; the results of

flammability tests conducted by West Yorkshire Fire and Rescue Service and Anglia Ruskin University; data from the International Burn Injury Database, as well as data provided by the companies which market emollients in the UK.

I will write to you following the ad hoc Expert Group's meeting on 30th November 2018, to inform you of its recommendations and the regulatory action we will take to protect public health.

Yours Sincerely,

Dr Ian Hudson
Chief Executive
Medicines and Healthcare products Regulatory Agency