

13 SEP 2017



12 September 2017

Your ref: HK/1067-2015

Pauline Taylor

Ms M Burke
Assistant Coroner
Her Majesty's Coroner
West Yorkshire (Western) Coroner Area
City Courts
The Tyrls
Bradford BD1 1LA

Dear Ms Burke

Re: Regulation 28: Report to Prevent Future Deaths

Thank you for your letter of 21 July 2017.

Safety is of paramount importance to the consumer healthcare industry and we are extremely concerned about incidents where emollient creams and ointments have been found to have contributed to the intensity of accidental fires with grave and fatal consequences.

PAGB, together with member companies that manufacture emollient medicines and medical devices, acknowledges the seriousness of this situation and we are committed to doing what we can to address the concerns you raise in your letter and ensure people are aware of the potential risks.

Paraffin-containing emollient products are the first line of treatment for helping people manage dry or scaly skin conditions, such as eczema and psoriasis. When severe, these conditions can be highly debilitating and it is important for people to have access to effective emollients to manage these conditions. Paraffin based oils such as liquid paraffin and white soft paraffin have been carefully chosen for use in emollients because extensive clinical experience has shown these particular ingredients to be effective for softening and moisturising medically dry skin conditions and are well tolerated by sensitive skin.

It is important to note that paraffin-containing emollients are not flammable in and of themselves. However, repeated applications of larger quantities of these products can lead to a build-up of residue on clothing and bedding, which results in the fabric becoming more flammable. If an individual is then subsequently exposed to a naked flame, for example a lighted match or cigarette, there is an increased risk of fire.

Having considered the issues raised in your letter, PAGB and its member companies have identified three areas where we feel we have a role to play in reducing the likelihood of future incidents.

1. By ensuring there is an accurate and meaningful warning statement on product packaging
2. By helping to effectively communicate the potential risk to consumers, healthcare professionals and care workers

3. By providing information and evidence to the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

I will address these points in turn.

1. Accurate and meaningful warning statement

PAGB and its member companies recognise that clear information needs to be made available to warn of the risk of increased flammability of clothing and bedding which has been in contact with paraffin-containing emollients.

In addition to ensuring warning statements are included on the packaging of all appropriate products, it is imperative that these warnings are consistent as well as clear and meaningful to members of the public who will read them. PAGB has been working with its member companies to develop wording which we will submit for user-testing to ensure its clarity.

User-testing is a vital part of this process. It is important that users are involved in the drafting of any warning statements, such that we can be confident they will be clearly understood when placed on packaging.

Following the results of user-testing, PAGB will work with MHRA to ensure there is consistency in implementation of a standard warning for packaging and patient information leaflets.

PAGB requested a meeting with MHRA to discuss this process in May 2017, we have been given the opportunity to make a written submission to the agency, which we will do by 30th September 2017 and we hope to have the opportunity to meet with MHRA officials thereafter.

2. Communicate the potential risk effectively

The Coroner's report of Mrs Taylor's accidental death highlights that repeated advice of the fire hazards from healthcare professionals and family members was ignored.

It is therefore important that, in addition to the inclusion of an appropriately worded warning on packaging and on patient information leaflets, the risk is adequately communicated to healthcare professionals, care workers and other key professional groups. PAGB will continue to work collaboratively with MHRA, Fire Brigades and other stakeholders to ensure there is clear and consistent communication, and those health and care professionals have appropriate information on how to minimise and manage the risk with their patients.

3. Provide information and evidence to MHRA

PAGB member companies have already submitted data on adverse events associated with paraffin-containing products to the MHRA review, which is currently underway.

PAGB has been advised that following this MHRA review, expert advice will be sought from the Commission on Human Medicines (CHM), the timescale for this is autumn 2017. As mentioned previously, PAGB will be providing a written submission to the CHM (via MHRA) by 30 September 2017 and we hope to have the opportunity to meet with MHRA officials after that date.

To conclude, I would like to reassure you that together with our member companies, we are taking this issue seriously and working hard to ensure we take all the appropriate actions we can as an industry to prevent future incidents from occurring.

Please do not hesitate to contact me if you have any further questions or require any additional information.

Yours sincerely



PP John Smith
Chief Executive Officer