

26th September 2018

Your ref: MDF-HK/2544-2017

Mr M. D. Fleming
Senior Coroner
Her Majesty's Coroner
West Yorkshire (Western) Coroner Area
City Courts
The Tyrls
Bradford BD1 1LA

Dear Mr Fleming

**Re: Brian Leonard Bicat, deceased
Report to Prevent Future Deaths
Paragraph 7, Schedule 5 of the Coroners and Justice Act 2009 and
Regulations 28 and 29 of the Coroners (investigations) Regulations 2013**

Thank you for your letter of 2 August 2018.

The safety of our products is something we take extremely seriously, and we are committed to ensuring safety information is prominent, clear and readable.

We have identified the following areas where action can and will be taken:

1. Warnings of such risk displayed on all product packaging
2. Consider more prominent labels and alerts re fire hazard on product containers
3. Consider fire warning labelling on all emollients including those below 50% content, making clear the mechanisms of the risk

1. Warnings of such risk displayed on all product packaging

We have completed a product labelling review to improve prominence, clarity and content as well as ensuring consistency across the Hydromol range, regardless of paraffin content. The revised product labelling, website and promotional materials is expected to be available throughout the remainder of 2018 and 2019.

The labelling now states:

"If this product comes into contact with dressings, clothing and bedding the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product."

We continue to work with the MHRA and PAGB to input into the labelling review. If changes are recommended by the MHRA, we commit to further updates, in addition to the changes we have already implemented.

2. Consider more prominent labels and alerts re fire hazard on product containers

We will undertake an assessment of the labelling throughout the remainder of this year, this activity will review all information from this event to determine any further opportunities for improvement of the current labelling. The assessment will be performed by a cross functional group of experts who have knowledge and experience of Hydromol and its use. We will implement any required changes to the product, product labelling or promotional materials which the risk assessment identifies. We will also apply required labelling amendments to marketed paraffin containing products, regardless of paraffin content.

Furthermore, any proposed changes to the labelling will be reviewed by user groups who will support us in ensuring the intended message is understandable. We are also engaging with West Yorkshire Fire Service to ensure the mechanisms of risk are clearly stated on our labelling.

Any and all personnel in contact with healthcare professionals and the general public will be updated appropriately to ensure communications are in line with, and convey, the correct message which communicates the outcome of the assessment and any subsequent labelling changes.

3. Consider fire warning labelling on all emollients including those below 50% content, making clear the mechanisms of the risk

We are proactively working with the MHRA and PAGB to ensure a consolidated warning is displayed on all product packaging, across industry. And we further commit to revisiting warnings on the product packaging, or any supporting processes, if additional information from the MHRA, trade bodies or any other expert groups becomes available.

Alliance takes this issue extremely seriously and is working proactively to address the issues raised by the coroner. Clearly this is a tragic incident and we hope that these actions will help to prevent future incidents from occurring.

Yours sincerely



Peter Butterfield
Chief Executive Officer

MF



Mr M.D. Fleming
HM Senior Coroner for West Yorkshire (Western)
City Courts
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Dear Mr Flemming

Brian Leonard Bicat (deceased): report to prevent further deaths issued under Regulation 28 Coroners (Investigations) Rules 2013

We refer to the report to prevent further deaths dated 18 July 2018 ("the Report"), issued following the inquest into the death of Mr Bicat and sent to Bayer under cover of a letter dated 2 August 2018.

The Report indicates that, at the time of his death, Mr Bicat suffered from leg ulcers for which he was under the care of a district nurse and receiving daily applications of Diprobase Cream and Hydromol Ointment. On 22 September 2017, Mr Bicat experienced severe burns as a result of a fire inadvertently started when a flame from his cigarette lighter came into contact with his dressing gown. Evidence given at the inquest by West Yorkshire Fire and Rescue Service stated that the speed and intensity of the fire had been increased by the presence of the cream and ointment on Mr Bicat's dressing gown and pyjamas.

We are seriously concerned to learn of the death of Mr Bicat and the fact that his use of Diprobase Cream, together with Hydromol Ointment, may have contributed to the intensity of the fire which caused his injuries.

The Report to Prevent Further Deaths

The Report raises various concerns in relation to the risk of fire associated with use of paraffin based ointments and emollient creams, including those with a paraffin content below 50%. It has been sent to a number of Government, NHS and industry persons and bodies, including Bayer as the manufacturer of Diprobase Cream. Bayer was not asked to provide evidence for the purposes of the inquest and has no knowledge of the circumstances of Mr Bicat's death save for the information set out in the Report.

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25th September 2018

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The specific concerns raised in the Report are as follows:

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. Health care professionals in both hospital and community setting may not be aware of the potential 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 mechanisms of the risk;
6. Health care professionals including pharmacists to verbalize 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;
8. Review patients with repeat prescriptions for emollients and cross reference those that smoke. Give safety advice retrospectively and review prescriptions;
9. Raise awareness with health care professionals and include paraffin based skin products in annual continuing fire safety training;
10. Review information sharing of burns data between hospitals, YAS and fire service so that incidents that didn't receive a fire service attendance can be investigated fully;
11. The NHS prescribing systems (system One and Optimise) appear to be updated by individual CCG's resulting inconsistent alerts and warnings;
12. Consider a review of the current effectiveness of obtaining fire incident reports involving paraffin based skin products since there is currently a lack of accurate national data involving paraffin based skin products.

Bayer's response to items 1-5 is provided below. We understand that other recipients of the Report will address items 6-12.



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1. Paraffin based ointments and emollient creams which contain a low level of paraffin pose a potential fire hazard risk

Paraffin based skin products represent first line treatments for patients with dry or scaly skin conditions, including psoriasis and eczema. They are highly effective, well tolerated and easily and conveniently applied by both patients and carers. They therefore provide important therapies for conditions which can, when severe, be both disabling and distressing.

Paraffin based ointments and emollient creams are not themselves flammable. However use of products containing paraffin which results in an accumulation of paraffin from the ointment or cream on clothing or bedding, increases the flammability of such fabrics in the context of environmental hazards, such as cigarettes and cigarette lighters.

Diprobase Cream, manufactured by Bayer, contains 15% white soft paraffin and 6% liquid paraffin. It is currently regulated as a medicinal product.

Bayer is committed to ensuring the highest standards of safety of all of its products and, where appropriate, providing relevant warnings about the use of such products. The Medicines and Healthcare products Regulatory Agency (MHRA) and other bodies have issued general warning statements informing patients, carers and healthcare professionals of the risks posed by naked flames to persons using emollients and we are currently, as described below, working with the MHRA and with the Proprietary Association of Great Britain (PAGB), the industry association representing the consumer healthcare industry, in order to reinforce this information. We support the development of common warnings and information to be applied to relevant paraffin containing ointments and emollient creams across the industry.



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2. Warnings of such risks are not displayed on all product packaging

While warnings regarding the possibility that paraffin containing products may accumulate on clothing and bedding increasing their flammability, have been issued by the MHRA, NHS bodies and fire services, Bayer supports the inclusion of warnings on product packaging in order to strengthen the existing warnings and to provide an immediate reminder of the risks to users of emollients.

In 2017, the MHRA commenced a review of the labelling of paraffin-containing emollients and the instructions for use provided in relation to such products, with a view to determining consistent warnings to apply to all such products, where appropriate. Bayer has co-operated fully with this review, but understands that it has not yet been completed.

The labelling and patient information provided in relation to all medicinal products forms part of the product's marketing authorization and must be approved by the competent regulatory authority (the MHRA in the UK) before it is put into circulation. MHRA has advised Bayer that it will not approve labelling changes to emollients regulated as medicinal products until it has completed the review referred to above.

However, Bayer is in the process of re-classifying Diprobase Cream as a Class 1 medical device under the Medical Devices Regulations 2002 and has conducted a conformity assessment in accordance with such Regulations. In compliance with the Regulations, Bayer may apply warnings to the labelling of medical devices without external regulatory approval. When the re-classified product is launched in the UK (anticipated around February 2019) Diprobase Cream will include the warning "*Keep fabric which has been in contact with this product away from sources of fire including lit cigarettes*". The warning will be visible on the external labelling/packaging of the product as well



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as being included in the patient information leaflet supplied with it.

3. Consider more prominent labels and alerts re fire hazard on product containers

As indicated above, Bayer supports the effective provision of warnings to patients, carers and healthcare professionals regarding the risk of flammability following accumulation of paraffin containing emollients on bedding and clothing. However, it is important that such warnings should convey a consistent message when applied to relevant products. We are therefore co-operating fully with the MHRA review, as described above, in order to ensure that effective and appropriate information can be provided with Bayer products and other emollients, as soon as this has received regulatory approval.

4. Health care professionals in both hospital and community setting may not be aware of the potential fire hazard posed by emollient creams which contain a low level of paraffin

We refer to our responses above.

In addition to the measures described, Bayer operates a consumer-facing website for Diprobase products, which includes a warning in respect of the risk of flammability associated with the use of Diprobase Cream. Following receipt of your letter in relation to Mr Bicat, Bayer is in the process of updating the content of the website to include the same warning as that which will be included on the labelling for Diprobase Cream as a medical device, namely "*Keep fabric which has been in contact with this product away from sources of fire including lit cigarettes*". The updating of the website will be completed no later than the end of October 2018.



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5. **To consider fire warning labelling on all emollients including those below 50% content, making clear the mechanisms of the risk**

We refer to our responses above.

We hope that the information provided in this letter addresses your concerns and reiterate our commitment to ensuring that appropriate warnings and information are provided with all Bayer products to ensure safe usage by patients, carers and healthcare professionals.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Lars Bruening".

Lars Bruening
CEO, UK/Ireland / Managing Director Bayer Plc