



CFOA
Chief Fire Officers
Association

The professional voice of the
UK Fire & Rescue Service

Chief Fire Officers Association
9-11 Pebble Close
Amington
Tamworth
Staffordshire
B77 4RD

Dr C J L Swann
Assistant Coroner
Leicester City and South Leicestershire
The Town Hall
Town Hall Square
Leicester
LE1 9BG

22 June 2016

Dear Dr Swann

RE: Christopher Michael HOLYOAKE

Thank you for your letter dated 27 April 2016 in respect of the above. I am responding as the current President of the Chief Fire Officers Association (CFOA). [REDACTED] recently retired from the service.

Accordingly, I can advise you that your letter and attached Regulation 28: Report to Prevent Future Deaths has been circulated to Chief Fire Officers/Chief Executives and other practitioners in the fire and rescue services via a number of the CFOA Communities. Particular attention has been drawn to Section 5 of your report i.e the Matter of Concern.

Chief Fire Officers/Chief Executives will ensure that the information and details contained within your report are shared with the appropriate staff.

Please do not hesitate to contact me if I can be of any further assistance.

Yours sincerely

[REDACTED]

President



Medicines & Healthcare products
Regulatory Agency

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom
www.gov.uk/mhra

H.M Coroner
Leicester City and South Leicestershire
The Town Hall
Town Hall Square
Leicester
LE1 9BG

30 June 2016



Regulation 28 Report concerning Christopher Michael HOLYOAKE CEM/GA/02481-2015

Thank you for your letter of 24th May 2016 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 Mr Christopher Michael Holyoake.

The MHRA as a regulatory agency has a responsibility to ensure that medicines are efficacious and acceptably safe and that guidance on the use of a medicine is appropriately described in the authorised product information (summary of product characteristics, labelling and patient information leaflet).

Your report identified two matters of concern which falls within the remit of the MHRA.

- 1. E45 is highly flammable as it is a paraffin based product, the residue of which acts as an accelerant. In this case there was a distinct lack of awareness of this fact by the carers and the deceased. This was in part due to lack of communication by the GP but also due to the fact that there were no fire hazard warnings on the product itself.***

The MHRA issued advice to healthcare professionals in 2008 to inform them that whilst paraffin based emollients in themselves are not flammable they can act as accelerants when use in large quantities and patients' clothes or bedding become saturated with these products. A reminder article, reiterating that healthcare professionals should advise patients not to smoke or use naked flames whilst emollients are in contact with their dressings, clothing or bedding was issued in our publication Drug Safety Update in April 2016. This article was linked to support materials published by NHS Improvement along with details of how to report incidents of harm. The article is attached at annex A.

Separately the British National Formulary has been [updated](#) to make reference to this risk of fire with predominantly paraffin based topical medicines so that healthcare professionals could be alerted.



2. ***This product is widely available over-the-counter to the general public and commonly used for vulnerable individuals such as children and the elderly. Worryingly there would appear to be no warnings on the packaging that this is indeed highly flammable with the potential risk of ignition.***

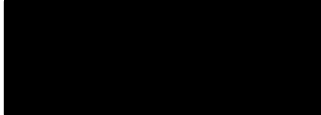
In 2009 on the basis of the evidence available at the time, the MHRA added label warnings to those emollient products which included predominantly paraffin based ingredients to warn patients and carers of the risks if used in large quantities of acting as an accelerant. The warning statement which appears on the outer packaging is

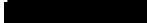
WARNING: If this product comes into contact with dressing and clothing, the fabric can be easily ignited with a naked flame. You should keep away from the fire and do not smoke when using this product.

Aqueous-based products such as E45 Cream were not included in this review. In light of this case we will now take action to ensure all emollient medicines, including those aqueous based products such as E45 Cream carry a similar warning statement. We aim to have completed regulatory action by the end of the year and will accompany this with appropriate communications to relevant healthcare professionals including nurses to reinforce the warning and advice.

I will write to you again when our action is completed.

Yours sincerely




Chief Executive Officer
Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road, London, SW1W 9SZ
www.mhra.gov.uk

ANNEX A

Paraffin-based skin emollients on dressings or clothing: fire risk

Summary

Smoking or a naked flame could cause patients' dressings or clothing to catch fire when being treated with paraffin-based emollient that is in contact with the dressing or clothing.

Reminder for healthcare professionals:

- Advise patients not to: smoke; use naked flames (or be near people who are smoking or using naked flames); or go near anything that may cause a fire while emollients are in contact with their medical dressings or clothing
- Change patient clothing and bedding regularly—preferably daily—because emollients soak into fabric and can become a fire hazard
- Incidents should be reported to NHS England's [Serious Incident Framework](#) (includes Wales), [Healthcare Improvement Scotland](#), or to the [Health and Social Care Boards](#) in Northern Ireland

Main article

When patients are being treated with a paraffin-based emollient product that is covered by a dressing or clothing, there is a danger that smoking or using a naked flame could cause dressings or clothing to catch fire. We informed healthcare professionals of this risk in [January 2008](#).

Examples of paraffin-based emollients include:

- white soft paraffin
- white soft paraffin plus 50% liquid paraffin
- emulsifying ointment

The risk is greater when these preparations are applied to large areas of the body, or when dressings or clothing become soaked with emollient.

We are aware of a recent fatal incident reported to the NHS England National Reporting and Learning System, in which a naked flame ignited emollient in contact with a patient's dressings and clothing. [Posters](#) have previously been available from the National Patient Safety Agency, and may be a useful source of information for local use.

Article citation: [Drug Safety Update volume 9 issue 9, April 2016: 9.](#)