



## Improvement

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Dear Dr Swann,

### **Regulation 28 Report concerning Christopher Michael HOLYOAKE**

Your reference: [REDACTED]

Thank you for your letter dated 24<sup>th</sup> May 2016 informing us of the tragic death of Christopher Michael Holyoake and the inquest findings. You have requested that NHS Improvement provide a response to your matters of concern outlined in the original Regulation 28 report that you had addressed to NHS England, and we understand you have also written to the Medicines and Healthcare products Regulatory Agency (MHRA).

NHS Improvement is responsible for overseeing foundation trusts, NHS trusts and independent providers. We offer the support these providers need to give patients consistently safe, high quality, compassionate care within local health systems that are financially sustainable. By holding providers to account and, where necessary, intervening, we help the NHS to meet its short-term challenges and secure its future.

NHS Improvement is the operational name for the organisation that brings together Monitor, NHS Trust Development Authority, Patient Safety, the National Reporting and Learning System, the Advancing Change team and the Intensive Support Teams.

Your letter described how Mr Holyoake had been prescribed E45 cream® to be applied daily, and that because E45 cream® is a paraffin containing product that had become soaked into his clothing and bedding, it was implicated in a fire resulting in his death.

Firstly it may be helpful to understand previous advice issued in relation to the risk. An alert was issued by the National Patient Safety Agency in November 2007, following a similar fatality which occurred in a hospital.

This alert highlighted the fire hazard risks associated with paraffin based products, particularly when they become soaked into dressings and clothing. The alert can be viewed at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59876>

Since hearing of Mr Holyoake's tragic death we have worked closely with the MHRA in seeking to take steps to reduce the risk of future deaths.

You may already be aware that the MHRA issued a Drug Safety Update bulletin in April 2016, which reminds all healthcare professionals of the fire hazard risks associated with paraffin based products. Please see link to this MHRA update <https://www.gov.uk/drug-safety-update/paraffin-based-skin-emollients-on-dressings-or-clothing-fire-risk> and also please see enclosed paper version.

As you are aware, E45 cream® does not at present have warnings on its packaging concerning potential fire hazards, however since receiving your letter we have been informed by the MHRA and the manufacturers of E45®, Reckitt Benckiser Group, that the company plan to introduce a warning onto the packaging of all E45® products as soon as possible. We understand that the MHRA also plan to require manufacturers of similar aqueous based paraffin containing products to introduce this warning onto their packaging.

The British National Formulary (BNF) is a widely used resource that contains essential information on the safe and effective use of medicines that are prescribed, monitored, supplied and administered to patients by healthcare professionals. The BNF already provides important safety information on fire hazard for paraffin based emollients such as emulsifying ointment, white soft paraffin 50% and liquid paraffin 50% ointment in their online and paper based publications. NHS Improvement have informed the editors of the BNF that the risk also applies to less concentrated aqueous based paraffin containing products, and the BNF will in future include a revised warning that will inform healthcare professionals of the risk applying to all paraffin containing products.

NHS England and the MHRA have a network of Medication Safety Officers (MSOs) working within NHS trusts and other providers of NHS-funded healthcare. The role of MSOs is to ensure that systems are in place to improve medication safety. This risk will be communicated by NHS Improvement to this MSO network so the risk can be appropriately communicated and addressed within their organisations.

Whilst the MHRA Bulletin, the MOSO network and the changes to BNF are helpful for healthcare professionals, including GPs, as you are aware, E45 cream® is widely available to the general public without prescription. The changes of labelling will be important to ensure awareness of the risk reaches people who buy E45 cream® without prescription. We appreciate that similar risks may apply even to substances sold as moisturisers when these are used by less mobile adults and children. AS this vulnerable group may not always have routine contact with NHS staff we have asked the Care Quality Commission, the Royal College of Nursing, and networks within the care home sector to communicate the risk via suitable newsletter and bulletin articles.

I appreciate you making me aware of this risk and giving me and my team the opportunity to take action to prevent future deaths. Please do pass my sincere condolences on to Mr Holyoake's friends and family.

Please accept my best wishes,



NHS National Director of Patient Safety  
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