## <u>Press release: Emollient cream build-</u> <u>up in fabric can lead to fire deaths</u>

The Medicines and Healthcare products Regulatory Agency (MHRA) is recommending that labelling and product information for these emollient products should include a warning about the fire hazard, with clear advice not to smoke or go near naked flames and information about the risk of severe burn injury or death when clothing, bedding and dressings with emollients dried on them are accidentally ignited.

Emollients are moisturising treatments applied directly to the skin to soothe and hydrate it. They cover the skin with a protective film to trap in moisture. Emollients are important treatments, widely used to help manage dry, itchy or scaly skin conditions such as eczema, psoriasis and ichthyosis.

The likelihood of fabric that has been in contact with emollient products catching fire through an individual smoking or being near a naked flame is low, but if this does occur it could cause severe burns which may result in death. We want users to be aware that fabrics which have come into contact with an emollient can be highly flammable, even after washing. The risk is greater when emollients are applied in large quantities or to large areas of the body.

Following an extensive review of the available evidence, the Commission on Human Medicines (CHM) recommends that:

- outer packaging and product containers should include a warning about the fire hazard and advice not to smoke, accompanied by short explanatory text and a picture warning in the most prominent field of view
- where available, the Patient Information Leaflet or Instructions for Use and the Summary of Product Characteristics (SmPC) should be updated to include warnings about the risk and how best to minimise it

The text will clearly warn users not to smoke or go near naked flames due to the risk of severe burns, that as fabric (such as clothing, bedding and dressings) which has been in repeated contact with these products burn more easily and can be a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

TThe MHRA and industry are working together to apply the CHM recommendations and develop suitable ways to make sure the warning is appropriately prominent. Additionally, we are setting up a specific stakeholder group to manage education and awareness of this issue.

It was previously thought the risk occurred with emollients which contain more than 50% paraffins. However, evidence now points to a risk with emollients which contain lower levels of paraffin and with paraffin-free emollients. This advice therefore applies to all emollients whether they contain paraffin or not.

It is important people prescribing, dispensing or using any emollient, or caring for someone who uses an emollient, are aware of the potential fire risks and take appropriate action to reduce it.

June Raine, Director of MHRA's vigilance and risk management of medicines division said:

We don't want to unduly worry people into not using these products which offer relief for what can be chronic skin conditions, but it is equally important people are aware of the risks and take steps to mitigate them.

Our new evidence-based recommendations are intended to empower proper use of these tried and trusted treatments and we are working with industry to support delivery of prompt packaging and labelling warnings and advice.

If you use emollients and have any questions or concerns, we'd recommend speaking to a healthcare professional, such as your pharmacist or GP.

Patient safety is our highest priority. We strongly encourage anyone to report any issues with this product, or more generally with any medical device, to our <u>Yellow Card Scheme</u>.

Watch Manager Chris Bell from West Yorkshire Fire and Rescue Service and National Fire Chiefs Council's lead for emollient creams, said:

We welcome this recommendation. There have now been in excess of 50 deaths in the UK where the build-up of emollients on bedding, dressings or clothing may have contributed to the speed and intensity of the fire. Many of these fires were caused by people who smoked and were unaware of the fire risks associated with emollient build-up on fabrics.

We have been trying to raise awareness about this issue with the public and health and care professionals. Ensuring that these products carry warnings will certainly help us as we continue to work with pharmacists, the NHS and care sector to prevent any future deaths.

John Smith, Chief Executive of PAGB, the consumer healthcare association, said:

Emollient products are an important and effective treatment for chronic and often severe dry skin conditions, such as eczema and

psoriasis. People should continue to use these products, but it is vital they understand the fire risk associated with a build-up of residue on fabric and take steps to mitigate that risk.

Safety is of paramount importance to the consumer healthcare industry and PAGB member companies are committed to adding a clear warning statement to the packaging of emollient products. We have been working with MHRA during its review of the evidence to ensure the warning is implemented consistently across industry and to support efforts to raise awareness of this issue.