RESPONSE DOCUMENT FOR MHRA CONSULTATION ON SOLEVE SUNBURN RELIEF CUTANEOUS EMULSION PHARMACY TO GENERAL SALE LIST RECLASSIFICATION (ARM 89)

Your details
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1. Do you consider that Soleve Sunburn Relief should be available as a General Sale List medicine?

Yes ☒ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

Oral NSAIDs are available on supermarket shelves and therefore it seems reasonable that this product could be reclassified to GSL. However, we do have some concerns below which will need to be addressed.

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Soleve Sunburn Relief?

We are concerned about the potential use of this product for severe or very severe sunburns over widespread areas of the body. Topical ibuprofen products are usually used on very small areas where the skin is not erythematous. However, this product may be used on large areas of skin which might be erythematous and eroded, all of which would raise the risk of significant systemic absorption. It is important to note that children have higher ratios of body surface area to volume, and therefore raising the risk of significant systemic absorption even further. The British National Formulary advises against the use of topical NSAIDs in children but does not specify an age cut off. There is also a real risk of the product being used incorrectly by the public in relation to interpretation of sunburn severity. Also, this product can act as a photosensitizer and may be used in the sun inappropriately.

We highly recommend that guidance is provided on the product leaflet and label on:

1. the size of the area to which the product could be applied in adults and in children
2. the maximum duration of use, e.g. 3 days, with the maximum amount of product used per day
3. seeking advice from a pharmacist or doctor if in doubt about the product

We highly recommend that a warning is clearly featured on the product leaflet and label on:

1. avoiding use of the product on broken or blistered skin
2. avoiding use of the product with sun exposure

The leaflet and label for the product must contain the preventative message to avoid getting sunburnt in the first instance due to long-term consequences, including increased risk of developing skin cancers, rather than resorting to an antidote.

3. Do you have any other comments on the reclassification?

Please see the first paragraph in our response to question 2.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ☒

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.