



Response of the National Pharmaceutical Association to [ARM 24](#)

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 24, on proposals to reclassify Benadryl Allergy Relief capsules as a GSL product.

Indications

The indication of chronic idiopathic urticaria is not appropriate for a GSL product. In our view, this is not a condition that could be diagnosed by the patient as the symptoms are similar to several other skin conditions including viral infections. In a pharmacy the pharmacist is available to advise on rashes and refer when necessary.

Convenience

Due to the wide distribution of pharmacies throughout the country, many of which have extended opening hours, we believe that convenience is not a relevant consideration for reclassification.

Specific GSL requirements

In our opinion there exists the potential for confusion between the products in the Benadryl range. Benadryl cream, lotion, solution and tablets are currently available containing a range of different active ingredients. In particular there needs to be clear differentiation between the proposed GSL product Benadryl Allergy Relief (containing acrivastine) and the existing GSL product Benadryl One a Day Relief (containing cetirizine). In a pharmacy, the pharmacist and their staff are available to advise patients and to minimise any risk of confusion between the products.

Advertising and product information

We have particular concerns about the risks of sedation with acrivastine. Although acrivastine is classified as a non-sedating antihistamine a risk of sedation still exists. This risk is increased if patients are taking other medication or have consumed alcohol. A report for the Department of Transport called for stricter guidelines for manufacturers on labelling over the counter medicines¹. The report highlighted concerns about “non-sedating antihistamines”, including acrivastine, and recommended that the risks of drowsiness should be stated on the exterior packaging. The report also suggested that patients may consume more than the recommended daily dose thus increasing the risks of sedation and driving performance impairment. Within the pharmacy the pharmacist and their staff are able to advise patients to use the product safely and appropriately.

If despite our concerns the product is reclassified as a GSL product we recommend that the product advertisements for Benadryl Allergy Relief clearly warn about the risks of sedation particularly if the patient is using the product for the first time or taking other medication or alcohol. Advertisements should contain a clear recommendation to read the product literature before use with a recommendation to ask the pharmacist for further advice.

We hope you take our comments on board.

¹ Over the counter medicines and the potential for unwanted sleepiness. December 2001