



Response to [ARM 16](#) (Request to reclassify Lamisil AT 1% Spray and Lamisil AT Cream from P to GSL) from the NPA.

Response of the National Pharmaceutical Association to ARM 16

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 16 on proposals to reclassify Lamisil AT 1% Spray and Lamisil AT cream as a GSL product.

The NPA does not support this proposal, as the organisation is not convinced that it can be used safely and effectively without the supervision of a healthcare professional.

Indications

The symptoms of tinea cruris and tinea pedis are similar to those of several other skin conditions including eczema, psoriasis and scabies. It is important that the diagnosis of athlete's foot is confirmed by a pharmacist or the patient may not receive the appropriate treatment. The pharmacist can also identify patients who require referral to their doctor such as those with symptoms such as yellow crusts or pus which may indicate a secondary bacterial infection, involvement of the nail bed which would require systemic treatment and patients with diabetes. In patients with diabetes the symptoms may be due to a more serious cause such as peripheral neuropathy. This important safety check by the pharmacist would be lost if the application were approved.

Risk of misuse

Topical terbinafine is not recommended for use in children. If the product is available GSL consumers may inappropriately purchase the product for children, including infants with nappy rash. In a pharmacy the staff will check whom the product is intended for before sale. There is also the risk of confusion as the proposed GSL product has the same name as the POM systemic product.

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. In our view, the risk of embarrassment to consumers, as described in the application, is also not a relevant consideration as pharmacists and their staff are accustomed to advising patients suffering from a range of conditions that are considered "embarrassing". Most pharmacies have a consultation area or quiet area where the patient may ask for advice in private.

Role of the pharmacist

The pharmacist and their staff will provide information to the patient that is vital for the successful treatment of athlete's foot. The patient will be advised on appropriate footwear and foot hygiene. The necessary precautions to prevent transmission of athlete's foot to others and reinfection of the patient will be discussed. Unless the product is applied at the correct frequency and length of time, the condition is likely to recur. The patient will be advised that the product should be applied beyond the affected area of the skin. Without the involvement of the pharmacist and their staff this advice is not available to the patient and treatment may be unsuccessful and the condition is likely to recur.

Specific GSL requirements

If, despite our concerns, the application is approved we recommend further information should be included on the pack and patient information leaflet. All the advice that is available from the pharmacist, as listed above, should be included. Patients with diabetes should be excluded from treatment and advised to visit their practitioner. Product information and advertisements must state that further advice is available from the pharmacist. Also, because of the issues outlined above, advertisements should contain a clear recommendation to read the product literature before use.

We hope you take our comments on board.