

## Your questions to the PBAC

### Fungal toenails and terbinafine

Sir, - Fungal infections of the toenails can be painful, smelly and even inhibit a right royal sex life. Terbinafine has revolutionised treatment with guaranteed success. To obtain an authority prescription a doctor needs laboratory evidence of dermatophyte infection.

But of the last six patients for whom I wished to prescribe terbinafine the repeated laboratory results of well collected specimens were only positive for three patients. A check with the laboratory that I use showed that only 25.5% of all nails sent for confirmation of dermatophytes had a positive result. So three patients received their course of treatment for \$40 and the other three for \$312. Since all were cured, I can only conclude that my clinical diagnosis was the gold standard and the sensitivity of the repeated laboratory tests only 50%. This means that I can cure the laboratory-negative well-off but not those who cannot afford the \$312. In the interests of equity and patient well-being, would it not be logical to trust doctors' judgement over the prescribing of terbinafine?

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#### *PBAC response:*

Terbinafine is registered for the treatment of a range of dermatophyte infections but has been listed as a benefit only for the treatment of patients with severe onychomycosis, in whom other treatments have failed. The requirement for laboratory testing has been included because the Committee believes that reliance on clinical diagnosis alone would result in over-prescribing of terbinafine, and usage under these circumstances would not be cost-effective. Furthermore, many patients who do not have dermatophyte infection would inevitably be prescribed the drug. Such prescribing would be outside the terms of registration of terbinafine.

The Committee's concerns on this matter are based not on hypothetical considerations but on actual experience with the listing of terbinafine during 1993-97. Excessive use of terbinafine as a pharmaceutical benefit during this period, which occurred partly as a result of promotion by the sponsor of terbinafine, resulted in the drug eventually being deleted from the Pharmaceutical Benefits Scheme.

*David Ellis, Head, Mycology Unit, Adelaide Women's and Children's Hospital, and Associate Professor, Department of Microbiology and Immunology, University of Adelaide, comments:*

It is important to stress that only 50% of dystrophic nails have a fungal aetiology. This is why laboratory proof of a dermatophyte infection has become an essential requirement for the diagnosis of onychomycosis. However, the performance of laboratories varies considerably and Professor Kamien's finding of only a 25.5% success rate is not surprising. The better performing laboratories have a positive strike rate of around 45% for nail samples examined by both direct microscopy and culture. The high percentage of negative laboratory results may be due to:

- an incorrect clinical diagnosis (remember only 50% of dystrophic nails are fungal)
- sampling errors associated with an inadequate specimen and/or in splitting the sample to perform both microscopy and culture
- the presence of non-viable hyphal elements in the distal region of the nail
- an uneven colonisation of the nail by the fungus
- overgrowth by contaminant saprophytic fungi (nails are a non-sterile site), and/or
- poor processing of the specimen by the laboratory.

Current laboratory methods are labour intensive and require special interpretative skills, especially when examining direct microscopic slides of nail material.

I do not believe that terbinafine was prescribed inappropriately during 1993-97, rather that there was an underestimation of the incidence of onychomycosis; which is about 7% in the general population, reaching up to 20% in patients over 60 years of age. This was further compounded by the listing of amorolfine on the Pharmaceutical Benefits Scheme, without the need for laboratory proof. Topical therapy is not appropriate for the treatment of onychomycosis. The inclusion of a statement in the current authority that patients must have failed other therapy is pointless. Similarly, to treat only patients with severe infection is poor medicine. Onychomycosis does not resolve spontaneously, the earlier the treatment the better it is for the patient. Terbinafine has always had an authority requiring laboratory proof, something I agree with, however the ultimate responsibility for treating a patient must rest with the clinician, as does the *interpretation of laboratory reports*. The PBAC needs to recognise the poor performance of many laboratories in diagnosing onychomycosis and implement some form of safety net to allow general practitioners to exercise their clinical judgement in conjunction with laboratory studies for the good of their patients.