

INDIAN ASSOCIATION OF DERMATOLOGISTS, VENEREOLOGISTS & LEPROLOGISTS (IADVL)

2016



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To

24 March, 2016

Member, Drugs Technical Advisory Board

Sir,

On behalf of the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) and the IADVL Taskforce Against Topical Steroid Abuse (ITATSA), this is an appeal to you. We Indian dermatologists need your help. As an esteemed member of the Drugs Technical Advisory Board (DTAB), you are in a unique position to recommend changes in the Drugs and Cosmetics Act. We submit that one such change is urgently needed in the field of topical therapy of skin ailments.

Indian doctors are witnessing an epidemic of adverse effects induced by rampant misuse of creams containing topical corticosteroids (TS)¹. Increasing number of cases of Topical Steroid Damaged Face (TSDf)² and steroid modified recalcitrant and/or extensive tinea (fungal infection of the skin, also known as ringworm)^{3,4,5} are being confronted by dermatologists all across our country. Studies have revealed that 59.3% urban patients² and 96% rural patients⁶ have bought TS creams without a doctor's prescription.

This situation has serious implications⁷. Numerous side effects in the skin, the psyche and other systems of the body including immune, endocrine and metabolic disturbances may occur due to TS abuse. Misuse of combinations of TS with antifungals has led to the emergence of recalcitrant fungal infections⁸.

The first step to control this public health problem is to empower the regulatory authorities by strong legislation and by removing ambiguity from the current laws.

In view of the above facts, our humble submission to you is:

- Please amend the Schedule H of the Drugs and Cosmetics Act and ensure that no topical steroid can be sold over the counter legally. This can only happen when the footnote excluding all topical medications from schedule H is deleted and the list expanded to include relevant drugs other than clobetasol propionate, clobetasone 17-butyrate, fluticasone propionate and mometasone furoate which are currently included in the list of Schedule H drugs.
- Please include super-potent topical steroids in schedule H1 to ensure that dispensing is done with scruples and the red box warning may serve as a deterrent to unsupervised use.
- Please ban all irrational combinations of steroids with antibiotics, antifungals and mometasone combinations with skin lightening agents.

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As a part of the crusade against topical steroid abuse, IADVL representatives had met the Director General of Health Services, Dr. Jagdish Prasad and the Drug Controller General of India, Dr. G N Singh last year. Dr. Singh grasped the gravity of the issue and kindly consented to include this issue in the agenda for the next DTAB meeting.

Our IADVL and ITATSA representatives would be glad to meet you to further elaborate on this burning issue. We hope that your support will help make the change needed to end misuse of corticosteroid containing creams in India.

Yours sincerely

Dr. Devesh Mishra

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Dr. Kiran Nabar

Chairperson, ITATSA

Dr. Shyamanta Barua

Hon. Secretary General, IADVL

Dr. Rajetha Damisetty

Convener, ITATSA

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