

INDIAN ASSOCIATION OF DERMATOLOGISTS, VENEREOLOGISTS & LEPROLOGISTS (IADVL)

2016



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1st April, 2016

To

Dr. G. N. Singh,

The Drugs Controller General of India,

New Delhi

Dear Dr. Singh,

We are grateful to you for including the topic of curbing topical steroid abuse in the agenda of the forthcoming DTAB meeting. We look forward to presenting our perspective and explaining the gravity of the issue to the learned members of DTAB during the meeting.

Our meetings in your office held on April 27 and November 19, 2015 have given us hope and encouragement, as has the recently announced ban on 15 Fixed Drug Combinations (FDCs) containing potent topical steroids.

You are well aware of the enormous damage inflicted by topical steroid misuse to the skin of Indian citizens and the havoc being wrecked by the irrational combinations promoting antibiotic and antifungal resistance.

We are sure that you will utilize your position as our country's guardian of health to look into this matter urgently. We also hope that the current government under the dynamic leadership of Prime Minister Shri Narendra Modi and Union Minister for Health and Family Welfare Shri JP Nadda will also take required action in this matter to curb this public health menace.

Our specific requests are as under:

1. Please remove the clause in Schedule H of the Drugs and Cosmetics Rules (1945) that apparently exempts topical agents from its provisions. We hope that the presence of one of our fraternity members in the forthcoming DTAB meeting would help.
2. Please include all topical steroids in schedule H; clobetasol propionate, betamethasone, mometasone furoate, fluticasone propionate, clobetasone 17-butyrate and hydrocortisone which are already mentioned in the schedule are but a part of the list.

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3. Please enforce a ban on all irrational combinations of steroids with antibiotics, antifungals and on mometasone combinations with skin lightening agents.

All supporting scientific evidence in the form of research papers, market data, indicative lists of brands and manufacturers and some copies of advertisements of such products in newspapers are attached herewith for your perusal.

Hoping for swift and strict action from your esteemed office in this matter.

Sincerely,

Dr. Devesh Mishra

President, IADVL

Dr. Shyamanta Barua

Hon. Secretary General, IADVL

Dr. Kiran Nabar

Chairperson, ITATSA

Dr. Rajetha Damisetty

Convener, ITATSA

Annexures:

1. Copy of Schedule H of the Drugs and Cosmetic Rules (1945)
2. Copy of Gazette notification no. GSR 289(E) prohibiting advertisement of Schedule H and H1 drugs
3. Verma SB. Topical corticosteroid misuse in India is harmful and out of control. BMJ 2015; 351: h6079.
4. Verma SB. Sales, status, prescriptions and regulatory problems with topical steroids in India. Indian J Dermatol Venereol Leprol 2014; 80: 201-3.
5. Saraswat A, Lahiri K, Chatterjee M, Barua S, Coondoo A, Mittal A, Panda S, Rajagopalan M, Sharma R, Abraham A, Verma SB, Srinivas C R. Topical corticosteroid abuse on the face: A prospective, multicenter study of dermatology outpatients. Indian J Dermatol Venereol Leprol 2011; 77: 160-6.
6. Indicative lists of some brands of irrational combinations containing steroids and other Schedule H and H1 drugs with their manufacturers.
7. IMS data revealing that most of the steroid combinations sold in India are OTC.

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