# The Inimical Repercussions of Unauthorised Prescribing: Binary Reports Featuring Cutaneous Adverse Drug Reaction

**Suvajit Das[1], Kaushik Mukhopadhyay[2], Sudipta Kumar Dey[3], Sonali Mukherjee[4], Chandan Chatterjee[5,*]**

[1,3]Assistant Professor, [2]Clinical Tutor, [4]Professor, [5]Associate Professor, Department of Pharmacology, ESI-PGIMSER, ESIC Medical College, Kolkata

**ABSTRACT**

*We present a couple of cases of cutaneous adverse drug reactions (CADRs) which occurred of late in our premises and were attributed to inappropriate use of OTC medications due to the fallacious prescribing by shop owners. The first case is an urban middle class middle-aged house-wife presented with significant cosmetic problems including hypopigmentation and telangiectasia over her face, along with patchy hypopigmentation over elbow. In the second case, an urban middle-aged man was prescribed an inappropriate regimen of nimesulide tablets and presented with maculopaupular rash in the extremities and erythema multiforme all over his body. Lack of legal supervision over 'quack' prescribing may lead to therapeutic misadventures which oftentimes remain undetected by pharmacovigilance programmes.*

**Key Words**: *Cutaneous Drug Reaction, OTC, Drugs, Shop Owners*

## INTRODUCTION

Over-the-counter (OTC) prescribing by shop-owners or appointed 'quack' practitioners in medicine shops is rampant in our country. This often leads to otherwise avoidable therapeutic misadventures including medication errors and adverse drug reactions (ADRs), which usually remain unnoticed and unreported.[1,2] We present a couple of cases of cutaneous ADRs which occurred of late in our premises and were attributed to inappropriate use of OTC medications due substantially to the fallacious prescribing by shop owners.

## CASE DESCRIPTION

**Case Report 1**: An urban middle class middle-aged house-wife presented with significant cosmetic problems in her face including hypopigmentation and telengiectasia over the periorbital and malar regions, along with patchy hypopigmentation over both elbows (Fig. 1).[3] She reported of being prescribed topical betamethasone valerate(0.05%) ointment topical high potency steroid for treatment of mild rashes over her face and elbows. The prescriber-cum-medicine shop owner advised her to apply the ointment lavishly over affected areas for an indefinite period till 'skin texture' normalises. The patient had been applying the ointment twice daily over the last two-and-a-half months. She was not on any other concomitant medication and had no history of similar episode in the past. The drug was immediately withdrawn and she was treated with antihistaminic medication and was advised to apply face non-irritant moisturiser after washing with normal saline. The cutaneous hypopigmentation reactions gradually subsided over three weeks, though multiple residual telengiectatic spots were still persisting during her last visit.

**Case Report 2:** The second case was one of an urban middle-aged man, labourer by occupation, who was prescribed an inappropriate regimen of nimesulide tablets, in a relatively high dose, over the counter by a locally appointed 'quack' practitioner, for managing pain around his knee joint. On interrogation, he ascertained of having 'sulfa' allergy which the treating person had not queried for. He eventually developed maculopapular rash with severe itching and exfoliation of the affected skin areas, involving almost four-fifths of his body (Fig. 2). These lesions progressed to erythema multiforme, without any obvious mucosal involvement or systemic manifestations.[4,5] Not an offender in his eyes, the practitioner did not bother to withdraw the drug.

Having sought medical attention in our hospital not for the cutaneous reactions but for uncontrolled diabetes (HbA1c 14%), the CADR was diagnosed and the case was referred to us. He had been on metformin 500mg for more than 6 months, though utterly non-compliant and had not taken any other medication barring nimesulide during the past two weeks. He ascertained us of having 'sulfa' allergy though he could not recollect any similar nimesulide-related past episodes. The patient was admitted, drug was withdrawn and treatment was initiated with fexofendine (180 mg

daily), topical steroid (mometasone cream) and emollient moisturiser. Baseline investigations including liver and renal function tests, routine haemogram were normal. His symptoms have subsided to some extent over the past two weeks.

Both cases scored six and showed a 'probable' causation on assessment using Naranjo ADR Probability Scale (Table 1) and the results were similar (probable causation) using WHO causality assessment scale.[6,7] Rechallenge Test was not performed due to ethical reason in both cases.

**Table 1: Causality Assessment of Case 1 and Case 2 using Naranjo ADR Probability Scale**

| NARANJO CAUSALITY ASSESSMENT SCALE | | Case Report 1 | Case Report 2 |
|---|---|---|---|
| 1 | **Are there previous conclusive reports on this reaction?** *Yes (+1) No (0) Do not know or not done (0)* | 1 | 1 |
| 2 | **Did the AE appear after the suspected drug was given?** *Yes (+2) No (-1) Do not know / Not done (0)* | 2 | 2 |
| 3 | **Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?** *Yes (+1) No (0) Do not know or not done (0)* | 1 | 1 |
| 4 | **Did the adverse reaction appear when drug was read ministered?** *Yes (+2) No (-1) Do not know / Not done (0)* | 0 | 0 |
| 5 | **Are there alternative causes that could have caused the reaction?** *Yes (-1) No (+2) Do not know or not done (0)* | 2 | 2 |
| 6 | **Did the reaction reappear when a placebo was given?** *Yes (-1) No (+1) Do not know or not done (0)* | 0 | 0 |
| 7 | **Was the drug detected in any body fluid in toxic concentrations?** *Yes (+1) No (0) Do not know or not done (0)* | 0 | 0 |
| 8 | **Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?** *Yes (+1) No (0) Do not know or not done (0)* | 0 | 0 |
| 9 | **Did the patient have a similar reaction to the same or similar drugs in any previous exposure?** *Yes (+1) No (0) Do not know or not done (0)* | 0 | 0 |
| 10 | **Was the adverse event confirmed by any objective evidence?** *Yes (+1) No (0) Do not know or not done (0)* | 0 | 0 |
| **Total Score** ***(Definite: 9 or higher / Probable: 5 to 8 / Possible: 1 to 4 / Doubtful - 0 or less)*** | | 6 | 6 |
| **Interpretation** | | **Probable** | **Probable** |

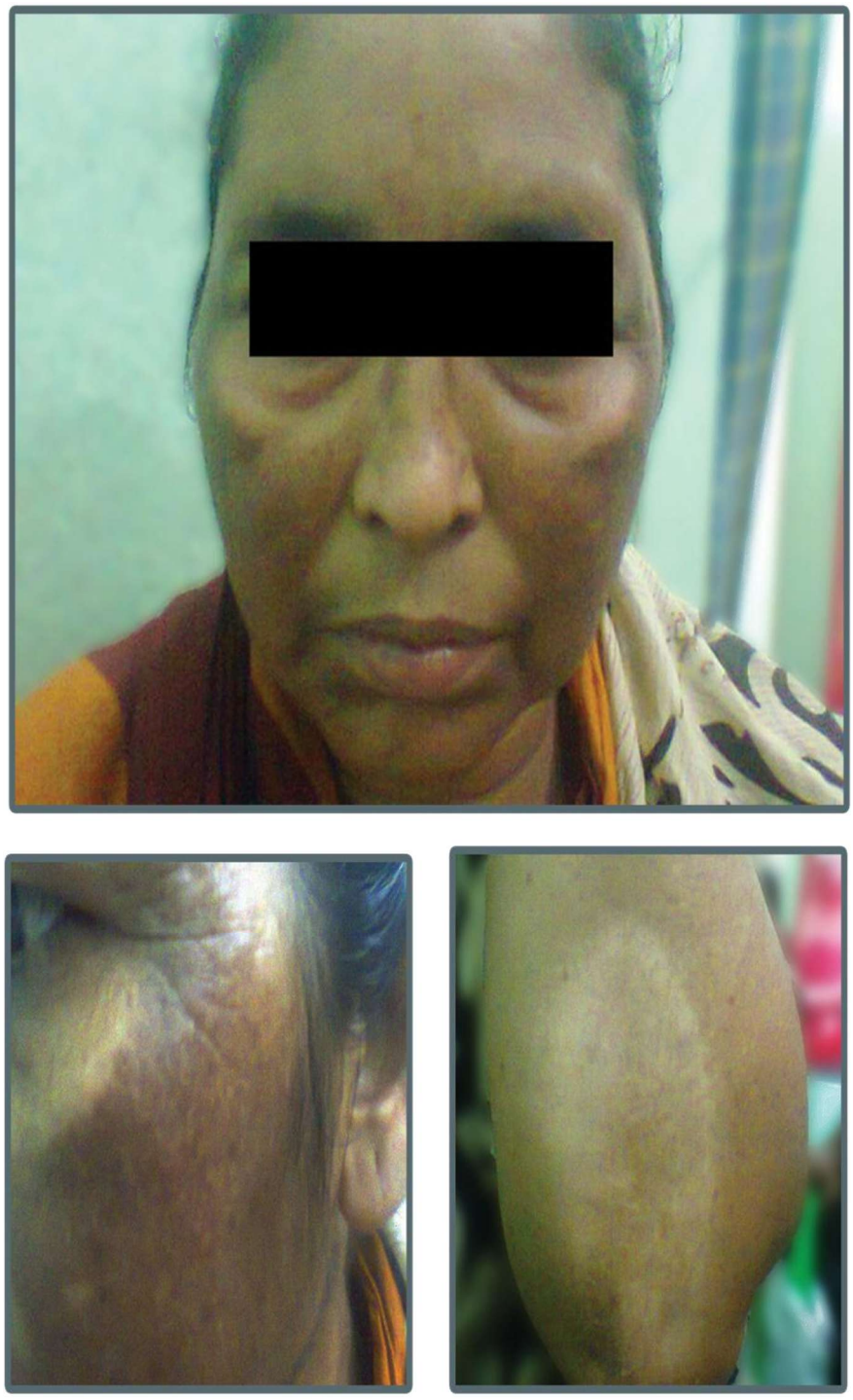

**Fig. 1: Front and side view of facial telengiectasia and hypopigmentation with hypopigmentation over left elbow (Case Report 1)**

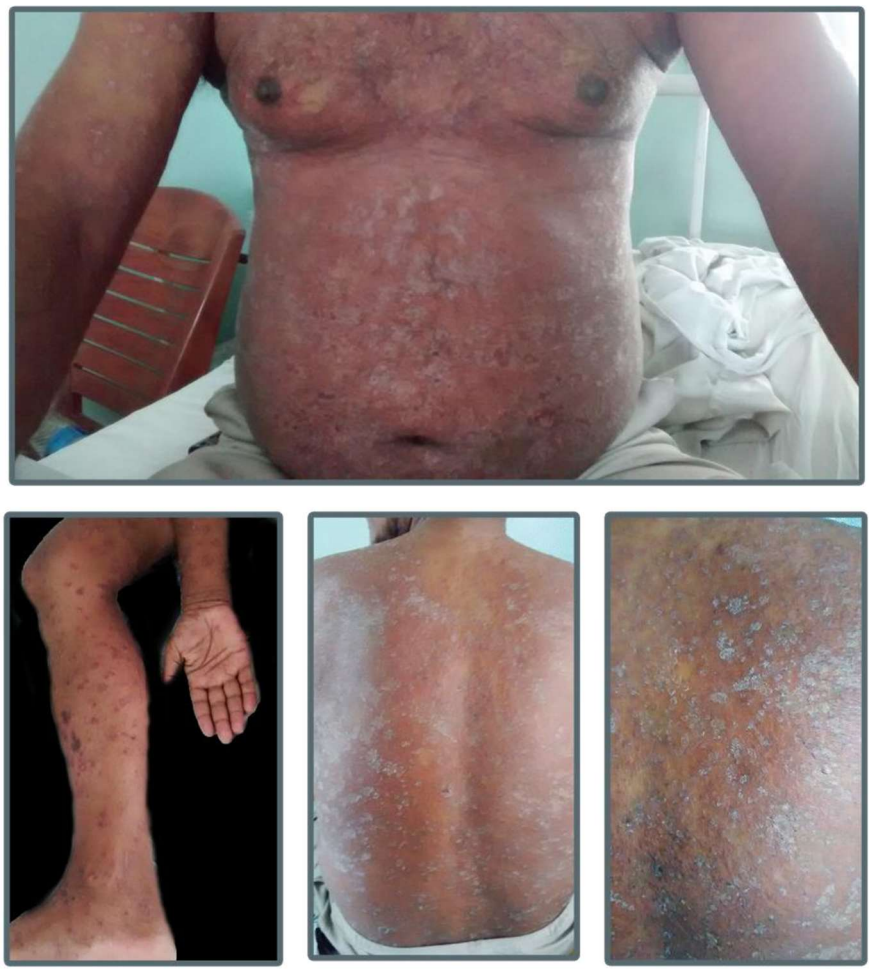

**Fig. 2: Erythema multiforme over chest, back and extremities (Case Report 2)**

## DISCUSSION

We came across two similar cases, both related to unauthorised prescribers prescribing irrational regimens, both ending up into CADRs which could have been otherwise avoided. Evenmore, both coming to our notice accidentally (they had not sought medical attention from our hospital for the CADRs per se). Presently, both are under due medical supervision, drug reactions gradually resolving, though we are yet uncertain about their favourable denouements.[4,5]

These episodes may suggest a glitch in the modus operandi of case detection in pharmacovigilance programmes in our country, whereby similar instances of unauthorised prescribing associated therapeutic misadventures go unnoticed.

Till recently, the right to report ADRs was only restricted to physicians, nurses and pharmacists. Presently, even when public reporting of ADRs is being encouraged, expecting that 'quack' practitioners might be adequately trained to report such instances of adverse drug events is too farfetched an expectation, the reasons being obvious.

However, legally condemning OTC prescribing is also not an option as of now, taking into account the current healthcare scenario in India where there underlies a severe shortage of public sector primary care physicians.

Taking into account these varied issues, the national pharmacovigilance program should pay considerable attention towards detecting cases of irrational and unauthorized prescribing which tend to be significant sources of avoidable drug related problems. The lack of general awareness among the mass regarding the pernicious consequences of 'quack prescribing' needs to be duly addressed as well. Physicians and healthcare providers should remain vigilant and proactively counteract unauthorized prescribing and related adversities.

## REFERENCE

1. Mhatre SK, Sansgiry SS. Assessing a conceptual model of over-the-counter medication misuse, adverse drug events and health-related quality of life in an elderly population. Geriatr Gerontol Int. 2015 Jan 22. doi: 10.1111/ggi.12443.
2. Yu YM, Shin WG, Lee JY, Choi SA, Jo YH, Youn SJ, Lee MS, Choi KH. Patterns of Adverse Drug Reactions in Different Age Groups: Analysis of Spontaneous Reports by Community Pharmacists PLoS One. 2015 Jul 14;10(7):e0132916.

3. Side-effects of topical steroids: A long overdue revisit. Arijit Coondoo, Meghana Phiske, Shyam Verma, Koushik Lahiri. Indian Dermatol Online J. 2014.5: 416–425.
4. Peter O. Fritsch, Ramon Ruiz-Maldonado; Erythema Multiforme, Stevens-Johnson syndrome, and Toxic Epidermal Necrolysis; Fitzpatrick's DERMATOLOGY in General Medicine; Vol 1. Sixth Edition, The McGraw Hill,2003,543- 556.
5. S.M. Breathnach, Erythema Multiforme, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis. Rook's Textbook of Dermatology.Vol.4, Seventh Edition. Blackwell Publishing,2004:74.1-74.19.
6. Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239245.
7. The use of the WHO-UMC system for standardised case causality assessment, available from http://who-umc.org/Graphics/24734.pdf, accessed on 20th Nov., 2015.