Targeted Spontaneous Reporting on Drug Safety Alerts Issued by Pharmacovigilance Programme of India: A New Origin of Pharmacovigilance in India

Sir,

To find out the prevalence among safety alerts issued by National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI). The Department of Pharmacology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, took an opportunity to closely monitor PvPI alerts by implementing targeted spontaneous reporting system on already issued alerts, mentioned in Table 1.

Although PGIMER is functioning as one of the Adverse Drug Reaction (ADR) Monitoring Centre (AMC) under NCC-PvPI, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Ghaziabad, since 2010. Furthermore, it is also functioning as a regional training center for pharmacovigilance in the north zone to create awareness among the health-care professionals (HCPs) in reporting ADRs through continuous medical education programs.[1]

Table 1: List of drug safety alerts issued by the National Coordination Centre for Pharmacovigilance Programme of India

Serial number	Suspected drugs	Adverse reactions	Serial number	Suspected drugs	Adverse reactions
1	Phenytoin	Angioedema	31	Olanzapine	DRESS syndrome
2	Phenytoin	Osteoporosis	32	Meropenem	Hypokalemia
3	Nicorandil	Risk of ulcer complication	33	Levamisole	Skin Exfoliation
4	Olanzapine	Hyponatremia	34	Montelukast	Tinnitus
5	Crizotinib	Risk of cardiac failure	35	Cefepime	Dermatitis lichenoid
6	Roflumilast	Gynecomastia	36	Losartan	Burning micturition
7	Clozapine	Neutropenia	37	Deferasirox	Osteoporosis
8	Disulfiram	Erythroderma	38	Ambroxol	Lacrimation
9	Peginterferon alfa-2a	Vasculitis	39	Lurasidone	Thrombocytopenia
10	Piperacillin and Tazobacam	Vision abnormal	40	Etoricoxib	Skin hyperpigmentation
11	Mometasone furoate, topical	Hypertrichosis/hirsutism, skin depigmentation	41	Dexamethasone	Hiccups
12	Ranibizumab	Myocardial infarction	42	Cabergoline	Skin hyperpigmentation
13	Amphotericin B	Bone marrow depression	43	Sodium valproate	Psoriasis
14	Doxorubicin	Photosensitivity reaction	44	Amoxicillin	Eye irritation
15	Crizotinib	Pneumonitis, hepatic encephalopathy	45	Tinidazole	Hyperpigmentation
16	Febuxostat	Allergic vasculitis	46	Amlodipine	Psoriasis
17	Oxcarbamazepine	Hyponatremia	47	Hydroxyzine	Bullous pemphigoid
18	Artemether and lumefantrine	Stevens-Johnson syndrome/toxic epidermal necrolysis	48	Amitriptyline	Gingival discoloration
19	Cefixime	AGEP	49	Paracetamol	Baboon syndrome
20	Hepatitis B immune globulin (human)	Encephalopathy	50	Lamivudine	Hearing loss
21	Cefotaxime	Anaphylactic shock	51	Mebeverine	Retrosternal pain
22	Lacosamide	Red man syndrome	52	Clindamycin	Acute generalized exanthematous pustulosis
23	Dimethyl fumarate	Osteonecrosis	53	Triamcinolone	Skin peeling
24	Sodium citrate/diphenhydramine hydrochloride/ammonium chloride	Myocardial infraction	54	Polymyxin B	Mottled skin
25	Cabergoline	Stevens–Johnson syndrome	55	Diclofenac	Nicolau syndrome
26	Amlodipine	Alopecia	56	Amisulpride	Tinnitus
27	Nitrofurantoin	DRESS syndrome	57	Carbamazepine	Bruxism
28	Cefoperazone sulbactam	AGEP	58	Clomipramine	Melasma
29	Cefixime	Anal ulcer	59	Glimepiride	Lichenoid drug eruption
30	Atenolol	Dermatitis lichenoid	60	Metoprolol	Lichenoid drug eruption

AGEP=Acute Generalized Exanthematous Pustulosis, DRESS=Drug reaction with eosinophilia and systemic symptoms

However, our primary goal is to increase the safety alerts by utilizing already established AMC setup. There are some methods which are employed in the collection of ADRs, a few of which include enclosure of suspected ADR reporting form with inpatients case sheets, using social networking sites, websites, and handouts being placed. Apart from the active surveillance, passive surveillance also plays a pivotal role in present topic of interest. The objective of this study was to analyse the reporting rate of safety alerts by adopting targeted spontaneous reporting methodology, which is a complementary method to routine safety monitoring system. To implement a targeted spontaneous reporting method, initial data are required to support the study; however, in the present scenario, we considered PvPI alerts[2,3] as basic data. We conducted this study to increase the reporting rate on safety alerts to establish the safety signals,[4] and to further communicate to the national database for regulatory inventions.[5] Hence, the information is communicated to all HCPs working at the PGIMER to pay attention during the medical care and treatment while prescribing respective medications.

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Conflicts of interest

There are no conflicts of interest.

Prasad Thota[1,2], Shabir Sidhu[1], Bikash Medhi[3], Phulen Sarma[3], Ajay Prakash[3], Kalaiselvan Vivekanandan[2], Anusha Thota[2]

[1]Department of Life Sciences, IKG-Punjab Technical University, Jalandhar, Punjab, [2]National Coordination Centre-Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh, [3]Department of Pharmacology, Post Graduate Institute of Medical Education and Research, Chandigarh, India

Address for correspondence: Dr. Prasad Thota, Department of Life Sciences, IKG-Punjab Technical University, Kapurthala, Jalandhar - 144 603, Punjab, India; National Coordination Centre-Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad - 201 002, Uttar Pradesh, India.
E-mail: prasad.thota187@gmail.com

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