

**File No. P.17019/03/2025-DSA**

**Date: 26<sup>th</sup> September, 2025**

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following suspected drugs are associated with the ADRs as given below;

S. No	Issue Date	Suspected drugs	Indication(s)	Adverse Reactions
01	March 2016	Phenytoin	Generalised tonic clonic seizure, partial seizure, status epilepticus	Angioedema
02		Phenytoin	Generalised tonic clonic seizure, partial seizure, status epilepticus	Osteoporosis
03		Nicorandil	Angina pectoris, Vasodilator	Risk of ulcer complication
04		Olanzapine	Schizophrenia, acute mania episodes in bipolar disorder	Hyponatraemia
05		Crizotinib	Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK)	Risk of cardiac failure
06	April 2016	Roflumilast	Reduce the risk of chronic obstructive pulmonary disease exacerbation	Gynecomastia
07		Clozapine	Management of schizophrenic patients	Neutropenia
08		Disulfiram	Alcohol – abuse deterrent	Erythroderma
09	May 2016	Peginterferon alpha – 2a	Chronic active Hepatitis B & C	Vasculitis
10		Piperacillin + Tazobactam	In the treatment of lower RTI / UTI / intra-abdominal infection, skin and skin structure infection, bacterial septicaemia polymicrobial infection	Vision abnormal
11		Mometasone furoate, topical	Steroid responsive dermatitis, eczema, or atopic dermatitis	Hypertrichosis / Hirsutism, Skin depigmentation
12	June 2016	Ranibizumab	Neovascular age related macular degeneration (AMD), Visual impairment due to Diabetic macular edema (DME), Visual impairment due to Choroidal Neovascularization	Myocardial Infarction



			(CNV) secondary to pathologic myopia (PM)	
13		Amphotericin B	Life threatening fungal infection including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis, blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis, and candidiasis, visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds, severe meningitis. Perioral candidiasis	Bone marrow depression
14		Doxorubicin	Soft tissue and bone sarcomas, Acute leukaemia, Malignant lymphoma, Hodgkin' disease, Breast carcinoma, small cell carcinoma of lungs, AIDS-related Kaposi's sarcoma, Multiple myeloma, Gastrointestinal tract carcinoma, Bladder cancer, Ovarian carcinoma, Acute myeloblastic leukaemia, Thyroid carcinoma, Neuroblastoma	Photosensitivity reaction
15		Crizotinib	Locally advanced or metastatic Non – Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) positive.	Pneumonitis, Hepatic encephalopathy
16		Febuxostat	For treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (Including a history, or presence of tophus and / or gouty arthritis)	Allergic vasculitis
17	July 2016	Oxcarbamazepine	Monotherapy or adjunctive therapy in the treatment of partial seizure, secondary generalized seizure, substitution for carbamazepine can be made abruptly with an oxcarbamazepine – to-carbamazepine ratio of 300: 200	Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH)



18		Artemether & Lumefantrine	For treatment of uncomplicated falciparum malaria, mixed infection of falciparum and chloroquine resistant vivax malaria.	Stevens- Johnson Syndrome / Toxic Epidermal Necrolysis
19		Cefixime	Otitis media, respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Acute Generalized Exanthematous Pustulosis (AGEP)
20	August 2016	Hepatitis B Immune globulin (human)	Active immunization against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV – positive material	Encephalopathy
21		Cefotaxime	Infection due to sensitive Gram – positive and Gram-negative bacteria such as bacteraemia, cellulitis, Intra-abdominal infection, Gonorrhoea, bone or joint infection, skin and skin structure infection, Urinary tract infection, Septicaemias, surgical prophylaxis, Endometritis, life threatening resistant/ hospital acquired infections, infection in immune –compromised patient, Haemophilus epiglottitis and meningitis	Anaphylactic shock
22		Lacosamide	As an adjunctive treatment of partial onset seizure in patient >17 years of age	Red Man Syndrome
23		Dimethyl fumarate	For relapsing remitting multiple sclerosis	Osteonecrosis
24		Sodium citrate +Diphenhydramine hydrochloride +Ammonium chloride	For symptomatic treatment of cough	Myocardial infraction
25	November 2016	Cabergoline	For the treatment of hyperprolactinemia and inhibition of lactation	Steven- Johnson Syndrome
26		Amlodipine	Angina, Hypertension, Coronary Artery Disease	Alopecia



27		Nitrofurantoin	Urinary tract infection, Cystitis	Drug reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome)
28		Cefoperazone + Sulbactam	For treatment of RTI, UTI, (lower & upper), Septicaemia, Meningitis, Skin & Soft tissue infection, Endometritis, Other infection of genital tract, Intra-abdominal infection bone & joint infection	Acute Generalized Exanthematous pustulosis (AGEP)
29	December 2016	Cefixime	Otitis media, Respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Anal ulcer
30		Atenolol	Angina and myocardial infarction, Arrhythmias, Hypertension, Migraine prophylaxis	Dermatitis Lichenoid
31		Olanzapine	Schizophrenia and other psychotic disorders, mania/ mixed episode, psychomotor agitation and violent behaviour	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS Syndrome)
32		Meropenem	Nosocomial infection like Septicaemia, Febrile neutropenia, intra-abdominal and pelvic infection, etc, caused by cephalosporin's resistant bacteria, meningitis cystic fibrosis	Hypokalaemia
33		Montelukast	Prophylaxis of mild to moderate asthma	Tinnitus
34	January 2017	Cefepime	For serious CRTI, uncomplicated and complicated UTI, Uncomplicated skin & skin structure, infection acute exacerbation of chronic bronchitis & intra-abdominal infection	Dermatitis Lichenoid
35		Losartan	Congestive Heart Failure, Hypertension (myocardial infarction along with stroke including reduction of stroke risk in hypertension) with	Burning Micturation





			left ventricular hypertrophy, Diabetic Nephropathy in type II diabetes	
36		Amisulpride	For acute and chronic schizophrenic disorder, in which positive symptoms, and or negative symptoms are prominent, including patients characterized by predominant negative symptoms	Tinnitus
37		Ranitidine	Partial seizure with or without secondary generalization, Trigeminal neuralgia, bipolar disorder	Bruxism
38	February 2017	Clomipramine	Obsessive –compulsive disorder, panic disorder	Melasma
39		Glimepiride	Type 2 diabetes mellitus	Lichenoid Drug Eruption
40		Metoprolol	Supra-ventricular arrhythmia, Angina pectoris, Hypertension, Myocardial infarction, Migraine prophylaxis, Hyperthyroidism, Heart failure	Lichenoid Drug Eruption
41		Levamisole	For the treatment of roundworm and hookworm infestations	Skin Exfoliation
42	March 2017	Deferasirox	Treatment of chronic iron overload in patients with Non – Transfusion Dependent Thalassemia (NTDT) Syndrome	Osteoporosis
43		Ambroxol	All forms of tracheobronchitis, Emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, Bronchiectasis, Bronchitis with bronchospasm asthma	Lacrimation
44		Lurasidone	Treatment of patient with schizophrenia	Thrombocytopenia
45		Etoricoxib	Short term use in acute painful condition	Skin hyperpigmentation
46	April 2017	Dexamethasone	Adjunct in the emergency treatment of anaphylaxis, short term suppression of inflammation in allergic disorders, adrenocortical insufficiency. Ocular inflammation, autoimmune disorder. Rhematic	Hiccups



			disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics	
47		Cabergoline	For the treatment of parkinson's disease, hyperprolactinemia and inhibition of lactation	Skin hyperpigmentation
48		Sodium valproate	Generalised tonic-clonic seizure, partial seizure, atonic seizure, absence seizure, myoclonic seizure, acute migraine	Psoriasis
49		Amoxycillin	Urinary tract infection, upper respiratory tract infection, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, lyme disease in children, endocarditis prophylaxis, post – splenectomy prophylaxis, gynaecological infection, gonorrhea, helicobacter pylori eradication	Eye irritation
50	May 2017	Tinidazole	Amoebiasis, trichomoniasis and giardiasis, anaerobic infection, necrotising ulcerative gingivitis, bacterial vaginosis, H. pylori associated peptic ulcer, abdominal surgery prophylaxis	Hyperpigmentation
51		Amlodipine	Angina, Hypertension, Coronary artery disease	Psoriasis
52		Hydroxyzine	For management of pruritus due to allergic condition such as chronic urticaria and atopic contact dermatoses, and in histamine – mediated pruritus	Bullous pemphigoid
53		Amitriptyline	Moderate to severe depression, migraine prophylaxis, tension type headache, neuropathic / chronic pain, fibromyalgia	Gingival discolouration
54	June 2017	Paracetamol	Mild to moderate pain including dysmenorrhoeal pain, headache, pain relief in osteoarthritis and soft tissue lesions, pyrexia, acute migraine attack	Baboon syndrome
55		Lamivudine	HIV Infection in combination with at least two other antiretroviral drugs	Hearing loss



56		Mebeverine	For irritable bowel syndrome (IBD)	Retrosternal pain
57	July 2017	Clindamycin	Respiratory tract infection, penicillin resistant staphylococcal infection and many anaerobes such as bacteroides, skin, soft tissue and dental infection	Acute Generalised Exanthematous Pustulosis (AGEP)
58		Triamcinolone	Corticosteroid	Skin peeling
59		Polymyxin B	Other antibiotic	Mottled skin
60		Diclofenac	Acute musculo- skeletal pain, arthritis, gout, spondylitis, migraine, post – operative pain	Nicolau Syndrome
61	August 2017	Terbinafine	Treatment of fungal infection	Acute Generalised Exanthematous pustulosis (AGEP)
62		Nitrofurantoin	Urinary tract infection, Cystitis	Vasculitis
63	September 2017	Acetazolamide	Adjunct in treatment of chronic open-angle glaucoma, secondary glaucoma, as a part of pre- operative treatment of acute angle –closure glaucoma	Drug hypersensitivity syndrome
64		Linagliptin	Type 2 diabetes mellitus	Acute Generalised Exanthematous Pustulosis (AGEP)
65		Diloxanide	Amoebiasis	Glossitis
66	17 <sup>th</sup> October 2017	Amikacin	Short term treatment of serious infection due to susceptible strains of gram- negative bacteria, including pseudomonas species, Escherichia coli species of indole – positive and indole negative proteus, providencia species, Klebsiella, Enterobacter, Serratia species and acinetobacter species	Stevens Johnson Syndrome
67		Allopurinol	Prophylaxis of gout prophylaxis of hyperuricaemia associated with cancer chemotherapy	Uveitis
68	28 <sup>th</sup> November 2017	Quetiapine	For treatment of schizophrenia and bipolar disorder	Gynaecomastia
69		Ceftriaxone	Serious infection due to sensitive bacteria, including septicaemia, pneumonia and meningitis, surgical prophylaxis of meningococcal meningitis, gonorrhoea, bone and joint infection	Palpitation



70	27 <sup>th</sup> December 2017	Fluoxetine	Fluoxetine is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation	Urinary incontinence
71	30 <sup>th</sup> January 2018	Levetiracetam	For treatment of myoclonus – generalised epilepsy with photosensitivity, idiopathic epilepsy – control of generalised tonic – clonic seizure, post anoxic and post – encephalitic myoclonic epilepsy, epileptic encephalopathies, severe myoclonic epilepsy, absence seizure, rolandic epilepsy	Hypokalaemia
72	28 <sup>th</sup> February 2018	Dapsone	For the treatment of leprosy, acne vulgaris, dermatitis, Pneumocystic pneumonia	Erythema Nodosum
73	27 <sup>th</sup> March 2018	Cefixime	For treatment of otitis media, respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Skin Hyperpigmentation
74	27 <sup>th</sup> April 2018	Dexamethasone	Adjunct in the emergency treatment of anaphylaxis, short term suppression of inflammation in allergic disorder, adrenocortical insufficiency, ocular inflammation autoimmune disorder, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics	Peripheral neuropathy
75	10 <sup>th</sup> July 2018	Fluoxetine	Bipolar disorder, Depressive episode	Hypoacusis (Hearing impairment)
76	3 <sup>rd</sup> December 2018	Telmisartan	Hypertension	Lichenoid keratosis
77	1 <sup>st</sup> January 2019	Miltefosine	Directly Observed Therapy (DOT) of visceral Leishmaniasis caused by Leishmania donovani	Acute Pancreatitis
78	14 <sup>th</sup> February 2019	Levetiracetam	Anti-epileptic, 1) As monotherapy in partial onset seizures with or without	Anencephaly





			secondary generalisation in patient with 16 year of age with newly diagnosed epilepsy. 2) As adjunctive therapy in myoclonic seizures in adult and adolescent from 12 years of age with juvenile.	
79		Cetirizine	For the treatment of seasonal/perennial allergic rhinitis & chronic idiopathic urticaria in infants & children.	Tachycardia
80	25 <sup>th</sup> March 2019	Dabigatran	For prevention of stroke, systemic embolism and reduction of vascular mortality in adult patient with atrial fibrillation	Alopecia
81		Sertaline	Major depressive disorders, obsessive compulsive disorders (OCD), panic disorders	Maculopathy
82	15 <sup>th</sup> May 2019	Amiodarone	In the treatment of control of ventricular and supraventricular arrhythmia where other drug cannot be used, arrhythmia associated with Wolf-White Syndrome.  For cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.	Acute Pancreatitis
83		Teicoplanin	Glycopeptide antibiotic-use in serious gram +Ve infection, staphylococcal infection in patients sensitive or unresponsive to penicillin and cephalosporin CAPD related peritonitis, prophylaxis in ortho paedic surgery at risk of gram +Ve infection	Red Man Syndrome
84	06 <sup>th</sup> June 2019	Teicoplanin	Glycopeptide antibiotic-use in serious gram +Ve infection, staphylococcal infection in patients sensitive or unresponsive to penicillin and cephalosporin CAPD related peritonitis, prophylaxis in ortho	Toxic Epidermal Necrolysis (TEN)



			paedic surgery at risk of gram +Ve infection	
85	03 <sup>rd</sup> July 2019	Febuxostat	For treatment of chronic hyperuricemia in conditions where urate crystals deposition has already occurred (including a history, or presence of tophus and /or gouty arthritis).	Toxic Epidermal Necrolysis/Stevens Johnson Syndrome
86		Netilmicin	Aminoglycoside antibiotic - Indicated in the treatment of septicaemia including neonatal sepsis and other severe systemic infections.	Tetany
87	6 <sup>th</sup> August 2019	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Vasculitis
88		Risperidone	Indicated as monotherapy or as adjunctive therapy in lithium or valproate for the maintenance treatment of Bipolar-1 disorder.	Rabbit Syndrome
89	5 <sup>th</sup> September 2019	Teneligliptin	For the treatment of type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise	Arthralgia
90		Atorvastatin	As an adjunct to diet to reduce elevated total cholesterol & triglyceride level in patients with primary hypercholesterolemia & mixed dysbetalipoproteinemia (Type IIa & IIb)	Vit-D deficiency
91	30 <sup>th</sup> October 2019	Cetirizine	For the treatment of allergic rhinitis and chronic urticaria.	Acute Generalized Exanthematous Pustulosis
92		Clozapine	Indicated in the management of Schizophrenic patients.	Neural Tube Defects



93	22 <sup>nd</sup> November 2019	Cetirizine	For the treatment of allergic rhinitis and chronic urticaria.	Hiccups
94		Cilostazole	For the treatment of stable intermittent claudication, acting or cramping in legs that occur with walking.	Tinnitus
95	30 <sup>th</sup> December 2019	Levamisole	Indicated in the treatment and control of mature and developing immature infections of haemonchus, ostertagia, trichostrongylus, cooperia, nematodinus, bunostomum, oesophagostomum and dictyocaulus and all forms of liver fluke infection	Stevens Johnson Syndrome
96		Cephalosporin	Indicated in the treatment of serious infections due to susceptible organisms-respiratory tract infections, urinary tract infections, skin billiary tract infections, septicaemia, meningitis other infections due to susceptible organisms and in the treatment of infections due to penicillin resistant strains of straphylococci.	Acute Generalized Exanthematous Pustulosis
97	15 <sup>th</sup> January 2020	Disulfiram	Antidotes, Detoxifying Agents & Drugs Used in Substance Dependence.	Skin Hyperpigmentation
98		Fluconazole	For the treatment of systemic candidiasis, mucosal candidiasis, pityriasis versicolor, prevention of fungal infections in patients with malignancy.	Mouth Ulceration
99	12 <sup>th</sup> February 2020	Olanzapine	For the treatment of Schizophrenia.	Hyponatremia



100		Piperacillin+Tazobactam	In the treatment of LRTI/UTI/Intra-abdominal infections, skin and skin structure infections, bacterial septicemic polymicrobial infections.	Blurred Vision
101	12 <sup>th</sup> March 2020	Terlipressin	In the treatment of bleeding oesophageal varices.	Atrial Fibrillation
102	1 <sup>st</sup> June 2020	Hydroxychloroquine Sulphate	Off Label drug use as Prophylactic & Treatment of COVID-19 disease	Mouth Ulceration
103		SGLT-2 Inhibitors	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus.	Genital Pruritus
104	7 <sup>th</sup> July 2020	Fluconazole	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy.	Symmetrical Drug-Related Intertriginous And Flexural Exanthema (SDRIFE)
105	31 <sup>st</sup> August, 2020	Pramipexole	Pramipexole is indicated for the treatment of sign and symptoms of idiopathic Parkinsons disease.	Photosensitivity Reaction
106	04 <sup>th</sup> September, 2020	Fluvoxamine	Fluvoxamine is a Selective Serotonin Reuptake Inhibitor (SSRI) indicated for the treatment of obsessive-compulsive disorder and Depression.	Intracranial/Pulmonary Hypertension
107	05 <sup>th</sup> October 2020	Clindamycin	Antibiotic-Indicated in the treatment of gram +ve organism pathogens, staphylococcus & streptococci, pneumococci.	Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE)
108	04 <sup>th</sup> November 2020	Clarithromycin	For the treatment of mild to moderately severe infections like acute exacerbation of chronic	Acute Generalised Exanthematous Pustulosis (AGEP)





			bronchitis community acquired pneumonia including infections due to Chlamydia, Mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	
109		Tamsulosin + Deflazacort	For the treatment of sign & symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteriod therapy is warranted.	Ear pain
110	30 <sup>th</sup> December 2020	Beta-Blockers (Atenolol, Bisoprolol, Metoprolol)	Anti-arrhythmic agent- Indicated in the treatment of hypertension, angina pectoris, cardiac arrhythmias, Congestive Heart Failure (CHF).	Lichen Planus
111		Omeprazole	Anti-ulcer, short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of Zollinger Ellison Syndrome.	Dysuria
112	04 <sup>th</sup> January 2021	Fexofenadine	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.	Blurred Vision
113		Ambroxol	Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.	Fixed Drug Eruption
114	01 <sup>st</sup> February 2021	Cefpodoxime	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome
115		Clarithromycin	Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired	Burning Sensation



			pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	
116	01 <sup>st</sup> March 2021	Hydroxyzine	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus.	Photosensitivity Reaction
117		Salicylic Acid	For the treatment of acne vulgaris.	Photosensitivity Reaction
118	05 <sup>th</sup> April 2021	Zinc (Acetate/Oxide/Sulphate/Gluconate)	In treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea
119	28 <sup>th</sup> June, 2021	Clobazam	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome
120		Baclofen	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.	Encephalopathy
121		Rosuvastatin & Ticagrelor Interaction	<b>Rosuvastatin:</b> Risk reduction of MI stroke and arterial revascularisation procedure in patients without clinically evident CHD but with multiple risk factors. <b>Ticagrelor:</b> For the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non-ST Elevation Myocardial	Rhabdomyolysis



			Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG).	
122	28 <sup>th</sup> July 2021	Etoricoxib	For the treatment of pain, swelling & inflammatory conditions due to arthritis.	Acute Generalized Exanthematous Pustulosis (AGEP)
123		Torsemide	For the treatment of oedema associated with congestive heart failure & hypertension.	DRESS Syndrome
124		Quetiapine & Valproic Acid Interaction	<p><b>Quetiapine:</b></p> <ul style="list-style-type: none"> <li>For the management of the manifestation of psychotic disorders (schizophrenia).</li> <li>For the additional indication "acute manic episode associated with bipolar disorder".</li> </ul> <p><b>Valproic Acid:</b></p> <ul style="list-style-type: none"> <li>As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure.</li> <li>As monotherapy or adjunctive therapy in the treatment of patients with complex partial seizure and manic episodes associated with bipolar disorder.</li> </ul>	Neuropsychiatric Adverse Events (Depressed level of consciousness/Coma & Disorientation)
125	31 <sup>st</sup> August 2021	Sofosbuvir	In combination with other medicinal products for the treatment of chronic hepatitis C in adults.	Stevens-Johnson Syndrome



126		Dimethyl Fumarate	For Relapsing remitting multiple sclerosis	Alopecia
127	30 <sup>th</sup> September, 2021	Cefazolin	Cephalosporin antibiotic-indicated in the treatment of serious infections due to susceptible organisms – respiratory tract infections, urinary tract infections, skin & skin structure infection, biliary tract infections, septicaemia	Acute Generalised Exanthematous Pustulosis
128	30 <sup>th</sup> November, 2021	Diclofenac	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery, migraine attack and post-operative inflammation in patients who have undergone cataract operation.	Skin hyperpigmentation
129	28 <sup>th</sup> December, 2021	Remdesivir	Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19	Sinus Bradycardia
130	18 <sup>th</sup> January, 2022	Ibuprofen	For the treatment of chronic arthritic disorders and painful musculoskeletal conditions.	Fixed Drug Eruption
131	28 <sup>th</sup> February, 2022	Losartan	For the treatment of hypertension	Muscle Spasm
132	17 <sup>th</sup> March, 2022	Cephalosporin Class	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria	Fixed Drug Eruption
133	28 <sup>th</sup> April, 2022	Cefuroxime	<ul style="list-style-type: none"> <li>Antibiotic- Indicated for lower &amp; upper respiratory tract infection, UTI, gynaecological infection, skin or soft tissue infection etc.</li> <li>Antibiotic- Indicated in the treatment of respiratory tract infections, UTI, ENT soft tissue infections etc.</li> </ul>	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)





134	30 <sup>th</sup> May, 2022	Itraconazole	<ul style="list-style-type: none"> <li>Systemic aspergillosis and candidiasis, cryptococcosis, sporotrichosis, Paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses.</li> <li>Empiric therapy of febrile neutropenic patients with suspected fungal infections.</li> </ul>	Symmetrical Drug Related- Intertriginous and Flexural Exanthema (SDRIFE)
135	17 <sup>th</sup> June, 2022	Trimetazidine	<ul style="list-style-type: none"> <li>Ischaemic heart disease, angina pectoris, sequelae of infarction.</li> <li>Cardiac drug indicated in the treatment of angina pectoris and intermittent claudication.</li> </ul>	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
136	15 <sup>th</sup> July, 2022	Tacrolimus	<ul style="list-style-type: none"> <li>For prophylaxis of transplant rejection in adult kidney or liver allograft rejection.</li> <li>Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient.</li> <li>For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products.</li> <li>By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant.</li> <li>For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.</li> </ul>	Gingival Hypertrophy



137	23 <sup>rd</sup> August, 2022	Cefoperazone	Urinary infections, biliary infections, respiratory infections, infections of skin tissues, meningitis, septicaemia, Pseudomonas, Salmonella typhi & B. fragilis infections.	Coagulopathy
138	26 <sup>th</sup> September, 2022	Piroxicam	<ul style="list-style-type: none"> <li>In the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other musculoskeletal disorder.</li> <li>Anti-inflammatory agent- Indicated in the treatment of rheumatoid arthritis, ankylosing spondylitis and other musculoskeletal disorders.</li> <li>3. Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma and in primary dysmenorrhoea (12 years age or older)</li> </ul>	Fixed Drug Eruption
139	17 <sup>th</sup> October, 2022	Amoxicillin	For treatment of urinary tract infections, upper respiratory-tract infections, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme diseases in children, endocarditis prophylaxis, post-splenectomy prophylaxis, gynaecological infections, gonorrhoea, helicobacter pylori eradication enteric fever.	Fixed Drug Eruption
140	28 <sup>th</sup> November, 2022	Norfloxacin	<ol style="list-style-type: none"> <li>Antibacterial- Indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, cystitis, urethritis &amp; gonococcal infections.</li> <li>Wide variety of infections caused by susceptible Gram +ve and Gram -ve organism including mixed infection in poultry.</li> </ol>	Skin Hyperpigmentation



141	26 <sup>th</sup> December 2022	Minoxidil	For the treatment of alopecia (male pattern baldness in men).	Folliculitis
142	31 <sup>st</sup> January 2023	Amphotericin B (Liposomal)	1. Febrile Neutropenia in cancer patients.	Hearing disorders
143			2. For invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin B therapy.	Tachycardia
			3. By RMP- for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy.	
			4. Indicated for the treatment of visceral leishmaniasis.	
144	20 <sup>th</sup> February 2023	Cephalosporins	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria.	Purpura
145		Amikacin	Indicated in the treatment of serious infections due to amikacin sensitive organisms.	Vision blurred
146	29 <sup>th</sup> March 2023	Metoprolol	For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.	Hyponatraemia
147		Nebivolol	For the treatment of essential hypertension	Hyperkalaemia
148		Olmesartan	Use as an Anti-hypertensive	Muscle Spasm
149				Taste Disorder



150		Sulfasalazine	Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases.	Visual Impairment
151	24 <sup>th</sup> April 2023	Ziprasidone	1. Use for the treatment of schizophrenia. 2. Use for rapid control of agitation in psychotic patients.	DRESS Syndrome
152	31 <sup>st</sup> May 2023	Ceftriaxone	For the treatment of urinary tract infections, lower respiratory tract infections, bacteraemia, septicaemia, meningitis, abdominal infections and infections caused by pseudomonas species.	Electrocardiogram QT prolonged
153		Levosulpiride	<ul style="list-style-type: none"> <li>Use for the treatment of depression and schizophrenia in adults.</li> <li>For the treatment of different G.I. problems like functional dyspepsia, nausea, vomiting and diabetic gastroparesis.</li> </ul>	Restless Legs Syndrome (RLS)
154	22 <sup>nd</sup> June 2023	Teneligliptin	For the treatment of Type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.	Bullous Pemphigoid
155	28 <sup>th</sup> July 2023	Colistimethate Sodium	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance.	Bartter's like syndrome
156	22 <sup>nd</sup> August 2023	Levonorgestrel	<ul style="list-style-type: none"> <li>Used as emergency Contraceptive.</li> <li>For Control of Fertility.</li> <li>For the treatment of Contraception, Menorrhagia &amp; Endometrial Hyperplasia during</li> </ul>	Deep Vein Thrombosis





			Estrogen replacement therapy in women.	
157	27 <sup>th</sup> September 2023	Esomeprazole	<ul style="list-style-type: none"> <li>GERD, erosive reflux esophagitis, prevention of relapse of esophagitis &amp; helps in eradication of H. Pylori associated peptic ulcer.</li> <li>For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome.</li> </ul>	Hyperprolactinaemia
158	25 <sup>th</sup> October 2023	Co-trimoxazole	Indicated in the treatment of respiratory tract infection, urogenital infections, G.I. tract infections etc.	FDE
159	30 <sup>th</sup> November 2023	Mefenamic Acid	Treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever, dental pain.	DRESS Syndrome
160	27 <sup>th</sup> March 2024	Cefuroxime	Antibiotic- Indicated for lower & upper respiratory tract infection, Urinary Tract Infection (UTI), gynaecological infection, skin or soft tissue infection etc.	AGEP
161		Dutasteride + Tamsulosin	In the treatment of Benign Prostatic Hyperplasia	Palpitation
162		Nimesulide	<ul style="list-style-type: none"> <li>Use in Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever.</li> <li>Acute pain in Orthopaedic, ENT, Dental and Post Operative condition.</li> <li>Additional indication; for short treatment of adult patients with inflammation &amp; pain associated with arthritis, soft tissue, ENT condition, trauma, dental pain, Musculo skeletal &amp; gynaecology &amp; obstetric painful condition.</li> </ul>	FDE



			<ul style="list-style-type: none"> <li>For the treatment of pyrexia and inflammatory conditions in livestock</li> </ul>	
163		Beta blockers (Metoprolol, Propranolol, Atenolol)	<p><b>Metoprolol:</b> For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.</p> <p><b>Propranolol:</b> Cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine.</p> <p><b>Atenolol:</b> For the treatment of hypertension, angina pectoris, cardiac arrhythmias</p>	Erectile dysfunction (Reversible)
164	21 <sup>st</sup> May 2024	Meropenem	For treatment of pneumonia, nosocomial pneumonia, UTI, intra-abdominal infection, gynaecological infection, skin & soft tissue infection, meningitis, septicaemia & empiric treatment of presumed infection in adult patients with febrile neutropenia.	Acute Generalized Exanthematous Pustulosis (AGEP)
165	28 <sup>th</sup> June 2024	Acetazolamide	As an adjunct in the treatment of chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute-angle closure glaucoma.	Choroidal effusion or Choroidal detachment
166		Amlodipine	<ul style="list-style-type: none"> <li>To reduce fatal coronary heart disease, non-fatal myocardial infarction, risk of stroke and treatment of hypertension.</li> </ul>	Lichenoid Keratosis



			<ul style="list-style-type: none"> <li>To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases</li> </ul>	
167	18 <sup>th</sup> July 2024	Vancomycin	Treatment of serious infection due to Gram-positive cocci including methicillin-resistant staphylococcal infections, brain abscess, staphylococcal meningitis and septicaemia.	DRESS Syndrome
168	8 <sup>th</sup> August 2024	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	FDE
169	25 <sup>th</sup> September 2024	Tetracycline	Treatment of Rocky Mountain spotted fever, typhus, Q fever, rickettsial pox, tick fever caused by Rickettsiae, respiratory tract infections caused by Mycoplasma pneumonia, Chlamydia infection, nongonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and klebsella infections, psittacosis.	FDE
170	28 <sup>th</sup> November 2024	Amphotericin B	<ol style="list-style-type: none"> <li>Treatment of Febrile Neutropenia in cancer patients.</li> <li>Treatment for invasive fungal infection in patients, who are refractory to or intolerant of conventional Amphotericin B therapy.</li> <li>Indicated for the treatment of Visceral Leishmaniasis.</li> </ol>	Hyperkalaemia



171		Carbimazole	Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis.	Agranulocytosis
172	26 <sup>th</sup> December 2024	Beta-blockers (Metoprolol, Propranolol, Atenolol)	<b>Metoprolol:</b> For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF and angina pectoris. <b>Propranolol:</b> For the treatment of cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine. <b>Atenolol:</b> For the treatment of hypertension, angina pectoris, cardiac arrhythmias.	Hypokalaemia
173	12 <sup>th</sup> March 2025	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	AGEP
174		Luliconazole	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris.	Chloasma/Melasma
175		Dalteparin	For the extended treatment of symptomatic Venous Thromboembolism (VTE) proximal Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer.	Muscle spasms





176		Gliclazide	Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults.	Erythema multiforme
177		Tramadol	For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain.	Fixed Drug Eruption
178	13 <sup>th</sup> May, 2025	Sulfamethoxazole + Trimethoprim	For the treatment of Urinary Tract infection; Respiratory-tract infection including Bronchitis, Pneumonia, infections in Cystic Fibrosis, Melioidosis, Listeriosis, Brucellosis, Granuloma Inguinale, Otitis Media, Skin infection, Pneumocystis Carinii Pneumonia.	Leukopenia
179	27 <sup>th</sup> June 2025	Beta-blockers (Propranolol, Metoprolol)	<b>Propranolol</b> For the treatment of cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of angina, essential and renal hypertension, prophylaxis of migraine. <b>Metoprolol</b> For the treatment of supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure.	Psoriasis
180		Beta blockers (Metoprolol, Propranolol, Atenolol, Carvedilol)	<b>Metoprolol</b> For the treatment of Supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure. <b>Propranolol</b> For the treatment of Cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of	Erectile Dysfunction (Reversible)



			<p>angina, essential and renal hypertension, prophylaxis of migraine.</p> <p><b>Atenolol</b></p> <p>For the treatment of hypertension, angina pectoris, cardiac arrhythmias</p> <p><b>Carvedilol</b></p> <ul style="list-style-type: none"> <li>To reduce cardiovascular mortality in clinically stable patients, who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of 40% (with or without symptomatic heart failure).</li> <li>For the treatment of mild to severe chronic heart failure.</li> <li>For the treatment of left ventricular dysfunction following myocardial infarction in clinically stable patients</li> <li>For the treatment of hypertension.</li> <li>For the treatment of Congestive Heart Failure (CHF)</li> </ul>	
181	29 <sup>th</sup> August 2025	Tranexamic Acid	<ul style="list-style-type: none"> <li>For the treatment of abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, haemorrhage, epistaxis, renal bleeding abnormal bleeding during or after prostate surgery).</li> <li>Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditary angioneurotic oedema.</li> <li>For the treatment of excessive bleeding in</li> </ul>	Nasal Congestion

			<p>patients with hemophilia during &amp; following tooth extraction.</p> <ul style="list-style-type: none"> <li>• For the treatment of menorrhagia.</li> <li>• For the prevention of oral hemorrhage in anticoagulant treated patients undergoing oral surgery.</li> </ul>	
182		Metoclopramide	<ul style="list-style-type: none"> <li>• To restore normal coordination and tone the upper digestive tract and relieve symptoms of gastro-duodenal dysfunction including heart burn, dyspepsia, nausea and vomiting associated with such conditions as reflux oesophagitis, gastritis, duodenitis and hiatus hernia.</li> <li>• For the treatment of nausea and vomiting.</li> </ul>	Tachycardia
183	26 <sup>th</sup> September 2025	Erythromycin	<p>Alternative to penicillin in hypersensitive patients; pneumonia; legionnaires' diseases; syphilis; chancroid; chlamydia; non-gonococcal urethritis; prostatitis; lymphogranuloma venereum; campylobacter enteritis; relapsing fever; diphtheria and whooping cough prophylaxis upper respiratory tract infection, acne vulgaris, sycosis, vulgaris.</p>	FDE

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (<https://www.ipc.gov.in>), through **PvPI Helpline No. 1800-180-3024**.