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Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
(Ministry of Health & Family Welfare, Govt. of India)

Sector-23, Rajnagar,
Ghaziabad-201002, U.P
Dated: 14th June 2019

PvPI Recommendations to CDSCO for Regulatory Actions

The India specific drug safety signals/PI changes as identified from the reported ADRs by the Signal Review Panel (SRP) of Pharmacovigilance Programme of India (PvPI) and recommended to Central Drugs Standard Control Organisation (CDSCO) till date for the appropriate regulatory actions are as follows:

S.No	Suspected drugs	Adverse drug reactions	Recommendations	Action taken by CDSCO
4th SRP Recommendations (SRP held on December 8-9, 2014)				
1	Carbamazepine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	For Drug Safety Label Change – Patient may be screened for HLA-B*1502 prior to initiating the Carbamazepine treatment	CDSCO requested all State/UT Drugs Controllers to instruct all the manufacturers licensed for the said product should be asked for inclusion of the same in prescribing information and same should be available on the official website of all the manufacturers manufacturing Carbamazepine in the country.
5th SRP Recommendations (SRP held on May9, 2015)				
2	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	To include in Prescribing Information	CDSCO requested all State/UT Drugs Controllers to instruct all the manufacturers of the said FDC product to include Hypokalaemia and Bronchospasm in their package inserts as well as any other promotional literature.
3	Mannitol	Hypokalaemia	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
4	Rota-Virus Vaccine	Intussusception	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
6th SRP Recommendations (SRP held on October 6, 2015)				
5	Rabies Vaccine	Erythema Multiforme	To include in Prescribing Information	All the manufacturers and importers of Rabies Vaccine are directed to ensure that Erythema Multiforme is inserted in the drug safety label of the Rabies Vaccine.
6	Ranitidine	Cardiac Arrest	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
7	Pulmonary Surfactant	Pulmonary Haemorrhage	To include in Prescribing Information	The information has been sent to CDSCO and is in process.

7th SRP Recommendations (SRP held on March 01, 2016)				
8	Ceftriaxone	Stevens Johnson syndrome	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
9	Lamotrigine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
10	Betamethasone	Photosensitivity Reaction	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
11	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
12	Cloxacillin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
8th SRP Recommendations (SRP held on July 8, 2016)				
13	Cefixime	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal	The 53rd Subject Expert Committe- Antimicobial & Antiviral on 16.01.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the concerned manufacturers to incorporate AGEP as one of the adverse effects of Cefixime in the package inserts of its formulations.
14	Sodium Valproate	Gum Hyperplasia	To include in Prescribing Information	The 43rd Subject Expert Committe - Neurology & Psychiatry on 09.01.2019 at CDSCO, HQ recommended that the manufacturers of Sodium Valproate formulations should include following statement in the package inserts of the drug: "Long term use of the drug may be associated with gum hyperplasia".
15	Itraconazole	Photosensitivity reaction	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
16	Ibuprofen	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
17	Amoxicillin/ Clavulanate Potassium	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
18	Ciprofloxacin	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.

9th SRP Recommendations (SRP held on November 29, 2016)				
19	BCG vaccine	Lymphadenopathy	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
20	Docetaxel	Candidiasis	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
21	Itraconazole	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal	The information has been sent to CDSCO and is in process.
22	Furosemide	Dermatitis Lichenoid	Signal	The 24th Subject Expert Committe - Reproductive & Urology on 20.04.2017 at CDSCO, HQ agreed with the recommendation of Signal Review Panel, PvPI and update the package inserts accordingly.
23	Lithium Carbonate	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)	Signal	The 26th Subject Expert Committe - Neurology and Psychiatry on 17.03.2017 at CDSCO, HQ agreed with the recommendation of Signal Review Panel, PvPI to incorporate Lithium Carbonate associated DRESS in to the package inserts of suspected drug marketed in India.
24	Phenytoin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	The 26th Subject Expert Committe - Neurology and Psychiatry on 17.03.2017 at CDSCO, HQ agreed with the recommendation of Signal Review Panel, PvPI to incorporate Phenytoin associated AGEP in to the package inserts of suspected drug marketed in India.
10th SRP Recommendations, SRP held on May 16, 2017)				
25	Sulfasalazine	Stevens Johnson Syndrome (SJS)	To include in Prescribing Information	The 19th Subject Expert Committe – Gastroenterology & Hepatology on 23.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Sulfasalazine to include Stevens Johnson Syndrome (SJS) as an ADR in the package insert of the product.
26	Sulfasalazine	Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	The 19th Subject Expert Committe – Gastroenterology & Hepatology on 23.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Sulfasalazine to include Toxic Epidermal Necrolysis (TEN) as an ADR in the package insert of the product.
11th SRP Recommendations, (SRP held on October 5, 2017)				
27	Fluconazole	Hyperpigmentation	Signal	The 57th Subject Expert Committe – Antimicrobial & Antiviral on 22.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Fluconazole to include Hyperpigmentation as

				an ADR in the package insert of the product.
28	Terbinafine	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	The 57th Subject Expert Committe – Antimicrobial & Antiviral on 22.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Terbinafine to include Acute Generalised Exanthematosus Pustulosis (AGEP) as an ADR in the package insert of the product.
29	Dipeptidyl peptidase-4 (DPP4) Inhibitors	Arthralgia	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
12th SRP Recommendations, (SRP held on March 27, 2018)				
30	Carbamazepine	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
31	Meropenem	Hypokalaemia	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
32	Artemether + Lumefantrine	Stevens Johnson syndrome (SJS)	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
33	Diclofenac	Nicolau Syndrome	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
34	Lamivudine	Hearing Loss	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
35	Amlodipine	Alopecia	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
36	Cefixime	Mouth Ulceration	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
37	Carvedilol	Hyperkalaemia	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
38	Amlodipine	Gingival Hypertrophy	To include in Prescribing Information	The information has been sent to CDSCO and is in process.
13th SRP Recommendations, (SRP held on August 21, 2018)				
39	Cefotaxime	Angioedema	To include in Prescribing Information	The 53rd Subject Expert Committe- Antimicobial & Antiviral on 16.01.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the concerned manufacturers to incorporate Angioedema as one of the adverse effects of Cefotaxime in the package inserts of its formulations.
40	Ofloxacin	Stevens-Johnson Syndrome	To include in Prescribing Information	The 53rd Subject Expert Committe- Antimicobial & Antiviral on 16.01.2019 at CDSCO, HQ recommended that CDSCO

				should request the State Drugs Controllers to direct the concerned manufacturers to incorporate SJS/TEN as one of the adverse effects of Ofloxacin in the package inserts of its formulations.
41	Tranexamic Acid	Seizure/Convulsion	To include in Prescribing Information	The 79th Subject Expert Committe-Oncology & Haematology on 18.01.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the concerned manufacturers to incorporate seizure/convulsion as one of the adverse effects of Tranexamic Acid in the package inserts of its formulations.
42	Quetiapine	Urinary Incontinence	To include in Prescribing Information	The 43rd Subject Expert Committe – Neurology & Psychiatry on 09.01.2019 at CDSCO, HQ recommended that the manufacturers of Quetiapine formulations should include following statement in the package inserts of the drug: "the use of the drug may be associated with Urinary Incontinence".
43	Sulfasalazine	DRESS Syndrome	To include in Prescribing Information	The 46th Subject Expert Committe – Analgesic & Rheumatology on 17.01.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the concerned manufacturers to incorporate DRESS Syndrome as one of the adverse effects of Sulfasalazine in the package inserts of its formulations.
14th SRP Recommendations, (SRP held on February 28, 2019)				
44	Tramadol	Hiccups	To include in Prescribing Information	The 49th Subject Expert Committe (Analgesic & Rheumatology) meeting held on 11.04.2019 at CDSCO, HQS, New Delhi. After detailed deliberation, the SEC recommended that the details of Individual Case Safety Reports should be obtained from PvPI for further review by the Committee.
45	Phenobarbital	DRESS Syndrome	To include in Prescribing Information	The 47th Subject Expert Committe – Antimicrobial & Antiviral on 15.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Phenobarbital to include Drug Rash with Eosinophilia & Systemic Symptoms (DRESS) as an ADR in the package insert of the product.
46	Cefepime	Urticaria	To include in Prescribing Information	The 57th Subject Expert Committe – Antimicrobial & Antiviral on 22.05.2019 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of formulations of Cefepime to include Urticaria as an ADR in the package insert of the product.
47	Glibenclamide	Palpitation	To include in Prescribing Information	The information has been sent to CDSCO and is in process.