

**File No. P. 11011/01/2021-PvPI****Date: 2<sup>nd</sup> February, 2023****Subject: Outcome of Pharmacovigilance Programme of India (PvPI) communicated to Central Drugs Standard Control Organisation (CDSCO) for taking appropriate regulatory actions.**

The action taken by CDSCO/PvPI on the following India specific drugs safety Signals/Prescribing Information Leaflet (PIL) changes/Drug Safety Alerts are as:

S. No	Suspected drugs	Adverse drug reactions	PvPI outcome	Action taken by CDSCO/PvPI
<b>4<sup>th</sup> Signal Review Panel (SRP) Recommendation (SRP held on December 8-9, 2014)</b>				
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	The Order has been issued by CDSCO to all State Drugs Controllers for the same on dated 12.05.2015.
<b>5<sup>th</sup> SRP Recommendations (SRP held on May 9, 2015)</b>				
2	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 23.12.2015.
3	Mannitol	Hypokalaemia	To include in PIL	The SRP recommendations received from PvPI deliberated by the SEC (Cardiovascular & Renal) committee in its 103 <sup>rd</sup> meeting on 19.05.2022.  After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include mannitol induced Hypokalaemia in the corresponding package insert of the drug.

4	Rota-Virus Vaccine	Intussusception	To include in PIL	Updated by the MAHs
<b>6<sup>th</sup> SRP Recommendations (SRP held on October 6, 2015)</b>				
5	Rabies Vaccine	Erythema Multiforme	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 04.10.2016.
6	Ranitidine	Cardiac Arrest	To include in PIL	<p>The 43<sup>rd</sup> Subject Expert Committee – Gastroenterology Hepatology on 17.12.2021 at CDSCO, HQ, committee noted that, SRP after critical evaluation of the ADR concluded that the causal relationship between intravenous ranitidine and cardiac arrest can be established but no association can be established with effervescent tablet with available data. Product labelling information also refer that as with other</p> <p>H2 receptor antagonists bradycardia, AV block with injection only was mentioned in the package insert of Ranitidine IV marketed in UK.</p> <p>After detailed deliberation, the committee recommended that CDSCO should request State Drugs Controllers to direct the manufacturers of the drug that same label should be incorporated in the package insert of Ranitidine IV product marketed in India.</p> <p>However, the committee also requested CDSCO to share the details received from PvPI, IPC to the experts.</p>
7	Pulmonary Surfactant	Pulmonary Haemorrhage	To include in PIL	The 58 <sup>th</sup> Subject Expert Committee – Pulmonary on 29.03.2022 at CDSCO, HQ recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of the drug to include pulmonary haemorrhage as adverse drug reaction to the corresponding PIL of the drug.
<b>7<sup>th</sup> SRP Recommendations (SRP held on March 01, 2016)</b>				

8	Ceftriaxone	Stevens Johnson syndrome	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens Johnson syndrome (SJS) in the package insert of the drug.
9	Lamotrigine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in PIL	The 73 <sup>rd</sup> Subject Expert Committee – Neurology & Psychiatry held on 14.10.2021 at CDSCO, HQ, after detailed deliberation recommended that CDSCO may request the State Drug Controllers to direct manufacturers of the drug to incorporate lamotrigine induced SJS/TEN in PIL of the drug.
10	Betamethasone	Photosensitivity Reaction	To include in PIL	The 62 <sup>nd</sup> Subject Expert Committee – Dermatology & Allergy held on 13.10.2021 at CDSCO, HQ, after detailed deliberation, Committee noted that the misuse of steroids such as Betamethasone ointment formulations over the face is associated with the sensitive skin–Topical Steroid Dependent Faces (Which may induce photosensitivity) and rarely contact allergy with photosensitivity.  After detailed deliberation, the committee opined that more data may be obtained from PvPI, IPC in support of the ADR-betamethasone induced photosensitivity.
11	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Acute Generalised Exanthematosus

				Pustulosis (AGEP) in the package insert of the drug.
12	Cloxacillin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Acute Generalised Exanthematosus Pustulosis (AGEP) in the package insert of the drug.
<b>8<sup>th</sup> SRP Recommendations (SRP held on July 8, 2016)</b>				
13	Cefixime	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal (To include in PIL)	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
14	Sodium Valproate	Gum Hyperplasia	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
15	Itraconazole	Photosensitivity reaction	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Photosensitivity in the package insert of the drug.
16	Ibuprofen	SJS/TEN	To include in PIL	Under consideration of CDSCO
17	Amoxicillin/Clavulanate Potassium	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens Johnson syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) in the package insert of the drug.
18	Ciprofloxacin	Stevens Johnson syndrome (SJS) and Toxic	To include in PIL	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that



		Epidermal Necrolysis (TEN)		CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens Johnson syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) in the package insert of the drug.
<b>9<sup>th</sup> SRP Recommendations (SRP held on November 29, 2016)</b>				
19	BCG vaccine	Lymphadenopathy	To include in PIL	Under consideration of CDSCO
20	Docetaxel	Candidiasis	To include in PIL	The SRP recommendations received from PvPI deliberated by the SEC (Oncology & Rheumatology) committee in its 126 <sup>th</sup> meeting on 26.05.2022.  After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include Docetaxel associated Candidiasis as an adverse drug reaction in the corresponding prescribing information leaflet.
21	Itraconazole	AGEP	Signal (To include in PIL)	The 110 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.03.2022 & 24.03.2022 at CDSCO, HQ recommended that CDSCO should communicate the State Drugs Controllers to direct the manufacturers of the drug Itraconazole to include AGEP as a potential Signal in the drug PIL.
22	Furosemide	Dermatitis Lichenoid	Signal (To include in PIL)	The 24 <sup>th</sup> Subject Expert Committee - 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 (To include in PIL)	The 26 <sup>th</sup> Subject Expert Committee - 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 PIL	The 26 <sup>th</sup> Subject Expert Committee - 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.
<b>10<sup>th</sup> SRP Recommendations (SRP held on May 16, 2017)</b>				
25	Sulfasalazine	Stevens Johnson Syndrome (SJS)	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
26	Sulfasalazine	Toxic Epidermal Necrolysis (TEN)	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
<b>11<sup>th</sup> SRP Recommendations (SRP held on October 5, 2017)</b>				
27	Fluconazole	Hyperpigmentation	Signal (To include in PIL)	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
28	Terbinafine	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
29	Dipeptidyl peptidase-4 (DPP4) Inhibitors	Arthralgia	To include in PIL	The 82 <sup>nd</sup> Subject Expert Committee – Endocrinology & Metabolism held on 21.12.2021 & 22.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to include DPP4 inhibitors induced Arthralgia in the package insert of the drug.
<b>12<sup>th</sup> SRP Recommendations (SRP held on March 27, 2018)</b>				
30	Carbamazepine	DRESS Syndrome	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 19.06.2019

31	Meropenem	Hypokalaemia	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 19.06.2019.
32	Artemether + Lumefantrine	Stevens Johnson syndrome (SJS)	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 19.06.2019.
33	Diclofenac	Nicolau Syndrome	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 24.07.2019.
34	Lamivudine	Hearing Loss	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 13.01.2020.
35	Amlodipine	Alopecia	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 13.06.2019.
36	Cefixime	Mouth Ulceration	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 19.06.2019.
37	Carvedilol	Hyperkalaemia	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 13.06.2019.
38	Amlodipine	Gingival Hypertrophy	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 13.06.2019.
<b>13<sup>th</sup> SRP Recommendations (SRP held on August 21, 2018)</b>				
39	Cefotaxime	Angioedema	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
40	Ofloxacin	SJS/TEN	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
41	Tranexamic Acid	Seizure/Convulsion	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.

# भारतीय भेषजसंहिता आयोग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार  
सैक्टर - 23, राज नगर  
गाजियाबाद - 201 002 (उ.प्र.), भारत



# INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Government of India  
Sector-23, Raj Nagar  
Ghaziabad - 201 002 (U.P.) INDIA

42	Quetiapine	Urinary Incontinence	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
43	Sulfasalazine	DRESS Syndrome	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 09.04.2019.
<b>14<sup>th</sup> SRP Recommendations (SRP held on February 28, 2019)</b>				
44	Tramadol	Hiccups	To include in PIL	The 49 <sup>th</sup> Subject Expert Committee (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.
f45	Phenobarbital	DRESS Syndrome	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
46	Cefepime	Urticaria	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 12.06.2019.
47	Glibenclamide	Palpitation	To include in PIL	The 54 <sup>th</sup> Subject Expert Committee – Endocrinology & metabolism held on 23.04.2019 at CDSCO, HQ. The committee opined that palpitation is a known and reported symptom of Hypoglycaemia associated with Glibenclamide which is already mentioned in package insert of Glibenclamide. It is not clear whether the palpitations as reported in 12 ICSRs are due to hypoglycaemia or otherwise. Therefore, further details in this regard should be obtained from NCC-PvPI for further consideration.
<b>15<sup>th</sup> SRP Recommendations (SRP held on August 21, 2019)</b>				

INDIAN PHARMACOPOEIA  
(IP)

Official Book of Drug Standards  
in India

IP REFERENCE SUBSTANCES  
(IPRS)

Official Physical Standards for  
Assessing the Quality of Drugs

NATIONAL FORMULARY OF INDIA  
(NFI)

Reference Book to Promote Rational  
Use of Generic Medicines

PHARMACOVIGILANCE PROGRAMME OF INDIA  
(PVPI)

WHO Collaborating Centre for Pharmacovigilance  
in Public Health Programmes and Regulatory  
Services



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48	Chloroquine	TEN/SJS	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 13.01.2020.
49	Proton Pump Inhibitors	Acute Kidney Injury	To include in PIL	The Order has been issued by CDSCO to all State/UT Drugs Controllers for the same on dated 14.11.2019.
<b>16<sup>th</sup> SRP Recommendations (SRP held on December 27, 2019)</b>				
50	Oseltamivir	Sinus Bradycardia/Bradycardia	Signal (To include in PIL)	The recommendation of the SRP was appraised before the committee. After detailed deliberation, 117 <sup>th</sup> committee on 26/08/2022 recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Oseltamivir associated sinus bradycardia/bradycardia as ADR in the corresponding PIL of the drugs.
51	Alfuzosin	Palpitation	To include in PIL	The 84 <sup>th</sup> Subject Expert Committee – Cardiovascular & Renal held on 04.02.2021 & 05.02.2021 at CDSCO, HQ. The committee deliberated the recommendation of the NCC-PvPI & recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the Alfuzosin formulation to include Palpitation as an ADR of the drug Alfuzosin in the package insert.
52	Benidipine	Photosensitivity reaction	To include in PIL	The 84 <sup>th</sup> Subject Expert Committee – Cardiovascular & Renal held on 04.02.2021 & 05.02.2021 at CDSCO, HQ. The committee deliberated the recommendation of the NCC-PvPI & recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the Benidipine formulation to include Photosensitivity

				as an ADR of the drug Benidipine in the package insert.
53	Pentoxifylline	Palpitation	To include in PIL	<p>The 84th Subject Expert Committee – Cardiovascular &amp; Renal held on 04.02.2021 &amp; 05.02.2021 at CDSCO, HQ.</p> <p>The committee deliberated the recommendation of the NCC-PvPI &amp; recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the Pentoxifylline formulation to include Palpitation as an ADR of the drug Pentoxifylline in the package insert.</p>
54	Piperacillin+Tazobactam	Acute Generalised Exanthematous Pustulosis (AGEP)	To include in PIL	<p>The recommendation of the SRP was appraised before the committee.</p> <p>After detailed deliberation, 117<sup>th</sup> committee on 26/08/2022 recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include</p>
55	Tinidazole	Skin Hyperpigmentation	To include in PIL	<p>The 98<sup>th</sup> Subject Expert Committee – Antimicrobial &amp; Antiviral held on 20.01.2021 at CDSCO, HQ.</p> <p>The committee deliberated the recommendation of the NCC-PvPI &amp; recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the Tinidazole formulation to include Hyperpigmentation as an ADR of the drug Tinidazole.</p>
<b>17<sup>th</sup> SRP Recommendations (SRP held on November 03, 2020)</b>				
56	Cefpodoxime	DRESS Syndrome	Drug Safety Alert	PvPI had issued Drug Safety Alert on 01 <sup>st</sup> February, 2021
57	Zinc (Acetate/Oxide/Sulphate/Gluconate)	Diarrhoea	Drug Safety Alert	PvPI had issued Drug Safety Alert on 05 <sup>th</sup> April, 2021

18 <sup>th</sup> SRP Recommendations (SRP held on March 12, 2021)				
58	Tinidazole	Fixed Eruption	Signal (To include in PIL)	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated Fixed Drug Eruption in the package insert of the drug.
59	Tramadol	Urinary Retention	To include in PIL	The SRP recommendations received from PvPI deliberated by the SEC (Analgesic & Rheumatology) committee in its 84 <sup>th</sup> meeting on 19.05.2022.  After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include urinary retention as adverse drug reaction in the corresponding package insert of the drug.
19 <sup>th</sup> SRP Recommendations (SRP held on October 25, 2021)				
60	Mefenamic Acid	Fixed Drug Eruption	Signal (To include in PIL)	The SRP recommendations received from PvPI deliberated by the SEC (Analgesic & Rheumatology) committee in its 84 <sup>th</sup> meeting on 19.05.2022.  After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include fixed drug eruption as adverse drug reaction in the corresponding package insert of the drug.
61	Doxycycline	Fixed Drug Eruption	Signal (To include in PIL)	The 107 <sup>th</sup> Subject Expert Committee – Antimicrobial & Antiviral on 23.12.2021 at CDSCO, HQ recommended that CDSCO may request State Drug Controllers to direct the manufacturers of the drug to incorporate drug associated

				Fixed Drug Eruption in the package insert of the drug.
<b>20<sup>th</sup> SRP Recommendations (SRP held on March 11, 2022)</b>				
62	Minoxidil	Folliculitis	Signal (To include in PIL)	Under consideration of CDSCO
63	Cephalosporins	Fixed Drug Eruption	Signal (To include in PIL)	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the 117 <sup>th</sup> committee on 26/08/2022 recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Cephalosporin Class associated with Fixed Drug Eruption (FDE) as ADR in the corresponding PIL of the drugs.
64	Tigecycline	Coagulopathy	To include in PIL	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the 117 <sup>th</sup> committee on 26/08/2022 recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Tigecycline associated coagulopathy as ADR in the corresponding PIL of the drugs.
65	Olanzapine	Hyponatraemia	To include in PIL	The SRP recommendation was appraised before the committee. After detailed deliberation the 81 <sup>st</sup> SEC (Neuro & Psychiatry) committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include ADR of Olanzapine associated Hyponatraemia in the package insert of the drug marketed in the country
66	Haloperidol	Cogwheel rigidity	To include in PIL	The SRP recommendation was appraised before the committee. After detailed deliberation the 81 <sup>st</sup> SEC (Neuro & Psychiatry) committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include ADR



				of Haloperidol associated Cogwheel Rigidity in the package insert of the drug marketed in the country.
67	Remdesivir	Sinus bradycardia	To include in PIL	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the 117 <sup>th</sup> committee on 26/08/2022 recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Remdesivir associated sinus bradycardia as ADR in the corresponding PIL of the drugs.
<b>22<sup>nd</sup> SRP Recommendations (SRP held on November 22, 2022)</b>				
68	Paracetamol	Fixed Drug Eruption	Signal (To include in PIL)	The recommendation of signal review panel, PvPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to instruct the manufacturers of the drug to incorporate Paracetamol associated Fixed Drug Eruption (FDE) in the PIL of the drug marketed in the country.
69	Losartan	Muscle Spasm	To include in PIL	The committee was appraised the SRP recommendation. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controller to instruct the manufacturers of the drug to include muscle spasm as an adverse drug reaction in the PIL of Losartan marketed in India.
70	Piroxicam	Fixed Drug Eruption	To include in PIL	The recommendation of signal review panel, PvPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to instruct the manufacturers of the drug to incorporate Piroxicam associated Fixed Drug Eruption (FDE) in

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## INDIAN PHARMACOPOEIA (IP)

Official Book of Drug Standards  
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## IP REFERENCE SUBSTANCES (IPRS)

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## NATIONAL FORMULARY OF INDIA (NFI)

Reference Book to Promote Rational  
Use of Generic Medicines

## PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI)



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