Approved New Drugs in India

The following new drugs were approved by the CDSCO during October-December 2017

Apremilast bulk & film coated tablets 10 mg/ 20 mg/ 30 mg
[illegible]

Tenofovir Alafenamide Fumarate bulk & 25 mg tablets
For the treatment of chronic Hepatitis B [illegible] adults with compensated liver disease

Arbekacin bulk & Injection 200 mg/ 4 ml
Treatment of following infections caused by Methicillin resistant *Staphylococcus aureus* (MRSA): sepsis, pneumonia

Arterolane Maleate and Piperaquine phosphate Dispersible tablets (37.5 mg + 187.5 mg)
Indicated in children aged 6 months to 12 years for the treatment of
- Acute uncomplicated *Plasmodium falciparum* [illegible]
- Acute uncomplicated *Plasmodium vivax* malaria infection

Midostaurin 25 mg Capsules
- In combination with standard induction and consolidation chemotherapy, followed by single agent maintenance therapy for adult patients with newly diagnosed with acute myeloid leukaemia (AML) who are FLT3 Mutation positive
- For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM)

Macitentan Bulk and Tablets 10 mg
Macitentan is an endothelin receptor antagonist (ERA) indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group 1) to delay disease progression

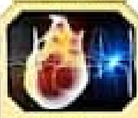
Drug Safety Alerts for Oct-Dec 2017

A preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from PvPI database reveals that the following drugs are risk prone:

AMIKACIN	ALLOPURINOL	QUETIAPINE	CEFTRIAXONE	FLUOXETINE
Indication: Short term treatment of serious infections 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	**Indication:** Prophylaxis of gout, prophylaxis of hyperuricaemia associated with cancer chemotherapy	**Indication:** For treatment of Schizophrenia and bipolar disorder	**Indication:** Serious infections due to sensitive bacteria, including septicaemia, pneumonia and meningitis, surgical prophylaxis, prophylaxis of meningococcal meningitis, gonorrhoea, bone and joint infection	**Indication:** [illegible] is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation
ADVERSE REACTION: STEVENS-JOHNSON SYNDROME	ADVERSE REACTION: UVEITIS	ADVERSE REACTION: GYNAECOMASTIA	ADVERSE REACTION: PALPITATIONS	ADVERSE REACTION: URINARY INCONTINENCE

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above-mentioned adverse events while prescribing/consuming above-quoted suspected drugs and report to the NCC-PvPI either by filling up Suspected Adverse Drug Reactions Reporting Form/Medicines Side-Effect Reporting Form for Consumer (http://www.ipc.gov.in) or via PvPI **Helpline # 1800-180-3024**

Comparative Status of Global Drug Alerts with PvPI Database

Name of Drug	Risk	International Status	India Status
Azithromycin	 Acute generalized exanthematous pustulosis (AGEP)	The Ministry of Health, Labour and Welfare (MHLW), Japan and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for Azithromycin [illegible] has been updated to include the risk of AGEP as a clinically significant adverse reaction	Five cases of AGEP reported
Hyoscine butylbromide [illegible]	 Caution of use in patients with pre-existing cardiac conditions	The Therapeutic Goods Administration (TGA) has updated product information for hyoscine butylbromide (Buscopan®) to include a caution regarding the use of Hyoscine ampoules in patients with pre-existing cardiac conditions (for example cardiac failure, coronary heart disease). The Australian product information for Hyoscine butylbromide already lists tachycardia, decreased blood pressure and anaphylaxis as potential adverse effects, but the product information has been updated to include a stronger warning in the precautions section because these adverse events can be more serious in patients with cardiac conditions	Five cases of palpitations and three cases of tachycardia reported
Doxycycline	 Risk of fixed drug eruptions	The Saudi Food and Drug Authority (SFDA) has updated the summary of product characteristics and patient information leaflet for Doxycycline to include the risk of fixed drug eruptions (FDE). Doxycycline is a tetracycline broad-spectrum antibiotic, used in treatment or prophylaxis against a wide range of susceptible strains of gram-negative and gram-positive bacteria and other microorganisms	62 cases of drug eruptions reported

Healthcare professionals are sensitized to carefully monitor the above-mentioned alerts. Any event related to these drugs has to be reported to NCC-PvPI.