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Issue 10

Pharmacovigilance Programme of India (PvPI)

Newsletter

To ensure safety of medicines

Over the years, PvPI has setup the benchmark to promote patients' safety

ADRs Monitoring Centres
Set up to monitor Adverse Drug Reactions (ADRs)

Patient Empowerment
Dedicated Helpline (toll free)& ADRs reporting forms in Hindi & other regional languages

Collaboration with National Health Programmes (NHP)
Ensuring safety of medicines & vaccines

Training & Education
More than 10,000 Health Care Professionals trained

Regulatory Intervention
Evidence based recommendations to National Regulatory Bodies

Let us join the hands with PvPI to ensure patients' safety

We invite you to join Pharmacovigilance Programme of India

Helpline: 1800-180-3024
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website: www.ipc.gov.in

Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201002

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Secretary-cum-Scientific Director's Message

Dear Colleagues,

I am honoured that the 10th edition of the PvPI newsletter is being published and I am sure this issue will also serve to satisfy and enthrall all the readers as it has been in its previous editions.

I am pleased to share with you the four years of success journey of our PvPI, how far we have come ever since the PvPI came into its existence at IPC in 2011. Starting from scanty ADR Monitoring Centres (AMCs), today the PvPI expanded its patient safety programme to 150 AMCs across the country and we expect these numbers to grow in the future.

The sanctified and foremost objective of PvPI is to ensure patient safety for which PvPI has taken several steps, recently PvPI collaborated with RNTCP & NACO and provided 32 ART centres with VigiFlow's user ID and password to facilitate ADR reporting by their centres. To create public awareness the posters featuring importance of ADR reporting has been displayed in different AMCs & government hospitals. PvPI also released medicines side effect reporting form for consumers in different regional languages and apart from this PvPI is to launch android phone application for ADR reporting that has also been set up and is expected to be functional soon.

I am sure by our mutual interactions and cooperation we shall jointly take positive steps to take our patient safety programme to further future heights.

I congratulate all technical staff of NCC & AMC(s) for working tirelessly in bringing the programme to where it is today.

Lastly, I wish that the achievements of our PvPI should be "HEARD" through the progress in the field of patient safety and public health.

Best Wishes & Regards

Dr. G.N. Singh

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Memorable Events in PvPI

100,000 ICSRs - Keep Reporting

Dr. Marie Lindquist, (Director, Uppsala Monitoring Centre) & Mr. Backman Christer (MPA, Sweden) visited IPC on 25th November 2014 and appreciated the ongoing progress of pharmacovigilance activities in India. They also congratulated PvPI for making India as a first Asian country having more than 1.0 lakhs ICSRs in VigiBase. On this auspicious occasion, PvPI poster was released with an objective to create awareness among Health Care Professionals (HCPs), patients and consumers regarding ADR reporting.

Dr. Marie Lindquist (2nd from right), Mr. Backman Christer (3rd from right) along with other PvPI members releasing PvPI poster on 25th November 2014 IPC, Ghaziabad

Health Secretary Shri Lov Verma Inaugurated the National Workshop on Pharmacovigilance in National Health Programmes (NHPs)

The National workshop for coordinators of drug resistant tuberculosis and antiretroviral treatment in India, organized by WHO & NCC- PvPI on 10th & 11th Dec. 2014 at hotel "The Lalit", New Delhi was inaugurated by Health Secretary Shri. Lov Verma. In inaugural address Shri. Lov Verma said that ***"The workshop is historic in terms of introducing pharmacovigilance in two of the most significant public health programmes: TB and HIV in the country".***

The purpose of the workshop was to learn the basics and essentials of pharmacovigilance & setting up of a system and process for ADR monitoring, reporting & their causality assessment. The two days workshop included three technical sessions. First technical session was based on Basic *Concepts and Essentials of Pharmacovigilance* and was chaired by Dr. S. K. Gupta, Advisor PvPI & Professor Emeritus, Clinical Research, DIPSAR. Second technical session was on Causality Assessment of ADRs which was presided over by Dr. Nilima A. Kshirsagar, National Chair Clinical Pharmacology, ICMR, New Delhi and third technical session was on Causality Assessment & Hands on Training on VigiFlow Software.

Speaking on the occasion Dr. G.N. Singh, DCG(I) called for an active and dynamic participation from all the HCPs in building synergies for monitoring adverse drug reactions in public health programmes of the country. He also mentioned that organizing this workshop is a commendable step in the domain of pharmacovigilance which will set the stage for creating a nation-wide system for patient safety reporting in India. He appreciated the proactive role of NCC in integrating pharmacovigilance in NHP(s).

Shri Lov Verma (Fourth from right), Health Secretary, MoHFW, Dr. G. N. Singh (Sixth from left), DCG(I) along with other eminent personalities at National collaborative workshop on 10th-11th December 2014

Unveiling of Intensive Monitoring - Lareb

Dr. Eugene along with Dr. Ruth Savage

Dr. Eugene (Pharmacovigilance Centre, Lareb, Netherlands) along with Dr. Ruth Savage (Medical Assessor, New Zealand) visited IPC on 4th December 2014. Dr. Eugene delineates about the Pharmacovigilance activities at Netherlands with special emphasis on Lareb Intensive Monitoring (LIM) programme that follows the prescription-event monitoring methodology. This system is totally web-based that used to actively collect information about ADRs using patients as a source of information in which questionnaires can be send via email to participating patients at different points, allowing the collection of data. These data are collected and analysed for new signals. PvPI looks forward the possibility to develop and adapt this web-based intensive monitoring as a new method of active surveillance.

Now Patient Can Report ADR(s) In Their Own Language

Dr. Shanthi Pal (Fourth from right), along with other eminent personalities releasing consumer reporting forms in different regional languages on 16th December 2014 at IPC, Ghaziabad

NCC-PvPI released first version of "Medicines Side Effect Reporting Form (For Consumer)" in different regional languages (Hindi, Bengali, Tamil, Gujarati, Kannada, Oriya and Malayalam). The objective is to encourage the important role of consumers/ patients as a key partner to enhance the ADRs reporting without the issue of any language barrier. Reporting forms were released in the august presence of Dr. Shanthi Pal, (Medicine Safety Programme Manager, WHO, Geneva), she briefed about the importance of consumer reporting and also focused on coding of new ADR terminologies in MedDRA and WHO-Adverse Relation Terminology (WHO-ART). She also emphasized that we can start active surveillance and which is also possible even in spontaneous reporting. NCC is in process of developing patient reporting form in Assamese and Marathi.

Training and Education Programmes

NCC-PvPI Organized Induction cum Training Programme for Newly Recruited Technical Associates

NCC-PvPI, Ghaziabad organised an induction cum training programme for newly recruited technical associates from 8th to 12th September, 2014. The purpose of the training programme was to make new technical associates acquainted with the basic and essentials of pharmacovigilance terminologies, standards and processes for ADR reporting and causality assessment.

Five days of induction cum training programme include the presentation by eminent speakers, hands on training for filling of "Suspected ADR reporting form" and data entry in "VigiFlow Software" for case processing and one-day field visit to AMC at UCMS & GTB hospital, New Delhi.

Training session was ended by the distribution of certificates to all the participants.

Continuous Medical Education (CME) in Kerala

NCC-PvPI, IPC, Ghaziabad & Drugs Control Department, Govt. of Kerala in association with Department of Pharmacology, Pushpagiri Institute of Medical Sciences, conducted a CME on "Pharmacovigilance & Pharmacovigilance Programme of India" on 22nd November 2014, Tiruvalla, Kerala to sensitize the HCPs regarding the importance of ADR monitoring, reporting & its assessment. CME started with the opening remarks by Dr. V. Kalaiselvan, Principal Scientific Officer, IPC, Ghaziabad, which was preceded by the formal launch of ADR reporting form in Malayalam by Shri S. S. Venkitakrishnan, former Drugs Controller, Kerala and release of poster on ADR reporting awareness by Dr. A. Marthanda Pillai.

Dr. Y. K. Gupta, National Scientific Coordinator, Professor & Head Department of Pharmacology,

AIIMS, New Delhi; Dr. Bikash Medhi, Additional Professor, Department of Pharmacology, PGIMER, Chandigarh; Dr. Reneega Gangadhar, Professor Head Department of Pharmacology, MCH Trivandrum & Dr. V. Kalaiselvan were the eminent speakers shared their work and illuminated the delegates with their insight and views on various topics of pharmacovigilance and ADR reporting.

The CME was wrapped up with the certificates distribution by Shri S. S. Venkitakrishnan and vote of thanks was given by Shri. K. J. John, Assistant Drugs Controller, South Zone, Kollam.

Welcome to Corporate Hospitals in PvPI

With a surge in PvPI, the importance and relevance of corporate hospitals in ADR reporting cannot be undermined. The collaboration with corporate hospitals shall leverages the strength of PvPI and promote patient safety. Aditya Birla Memorial Hospital, Pune, Artemis Hospital, Gurgaon and Kovai Medical Centre and Hospital Ltd., Coimbatore were the latest three new Corporate AMCs under PvPI in addition to Medanta Medicity, Gurgaon and Indraprastha Apollo Hospitals, New Delhi. PvPI aims to support the corporate hospitals with training programs, which help HCPs to offer quality, safe and focused care to patients.

Drug of Current Interest

Isotretinoin-A Safety Concern

Isotretinoin is used to treat severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring), resistant to adequate courses of standard therapy with systemic antibacterial and topical therapy. Isotretinoin is a form of vitamin A (13-cis Retinoic acid) and comes under pregnancy category X.

The issue of female reproductive disorder and psychiatric adverse reactions associated with isotretinoin has been kept under close review by PvPI. It can cause severe, life-threatening teratogenic effects which includes serious craniofacial, cardiovascular, thymic and central nervous system malformations. Apart from this, there is an increased risk of psychiatric disorder associated with the use of isotretinoin, which prompt us to have a close monitoring to consider the evidence for an association between isotretinoin and psychiatric adverse reactions.

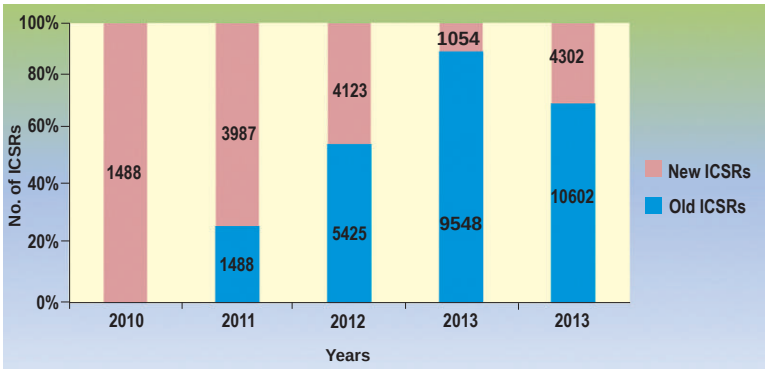

Figure 1- Worldwide distribution of new ADR cases of Isotretinoin per year

Worldwide Scenario of *Isotretinoin*

WHO global ICSRs database i.e. "Vigibase" during 2010 to 2014 contained 14,904 ICSRs of isotretinoin. Figure 1 represents the number/percentage of new ADR cases (i.e. incidence rate) added per year due to isotretinoin from 2010 to 2014.

These reported ADRs included a large spectrum of clinical manifestations which were summarized based on WHO-ART System Organ Class (SOC). This reveals that the largest share of reported ADRs was from the SOC gastrointestinal disorder (49%) followed by psychiatric disorder (35%), secondary term event (22%), skin

& appendages disorder (15%), musculoskeletal disorder (12%) and reproductive system disorder (9%).

On the basis of gender, worldwide distribution of ICSRs shows that males (51%), females (45%) and remaining unknown (4%) were affected by the ADRs due to isotretinoin and the percentage of males and females affected by reproductive system disorder alone were 8% and 86%. In female reproductive system disorder 80% ADRs were associated with "Complication of Pregnancy" which comes under high level term (HLT) in WHO-ART.

In psychiatric disorder most commonly observed ADRs were depression (62%), anxiety (27%), personality disorder (25%) and suicide (23%).

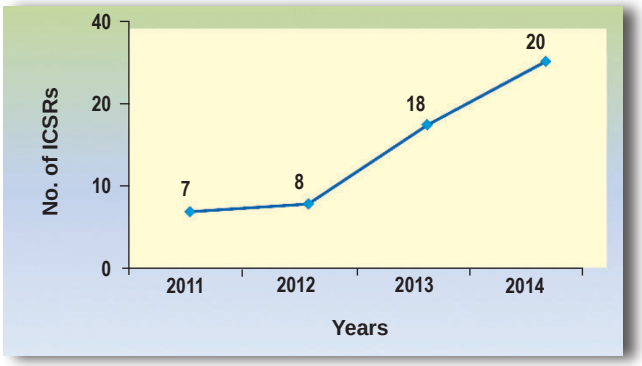

Figure 2- Time trend analysis of ICSRs associated with Isotretinoin related ADR (s) received at NCC-PvPI

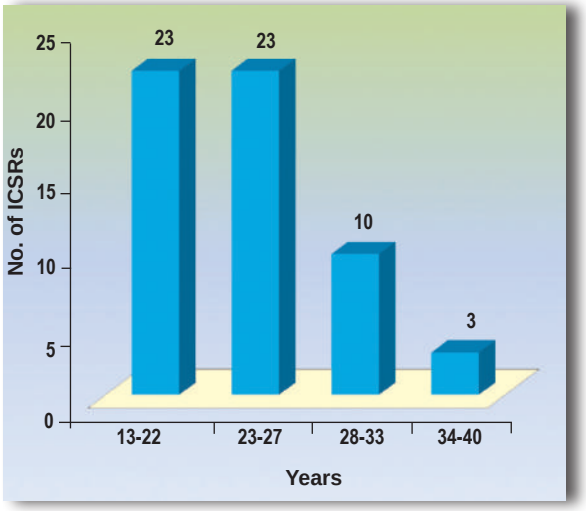

Figure 3- Distribution of ICSRs of Isotretinoin based on age group

Scenario of *Isotretinoin* in India

During the last four years, NCC-PvPI has received 59 ICSRs of isotretinoin. The time trend analysis of ICSRs (figure 2) represent that, there has been a continuous increase in the number of ADR cases due to isotretinoin. The most affected age group of patients found to be 13 to 40 years, in which age group between 13 to 27 years seems to be more prone to ADRs with isotretinoin (figure 3). Gender wise analysis of data shows that there is an equal probability of occurrence of ADRs in both the genders (out of 59 ICSRs, 29 related to males and 30 related to females).

SOC wise distribution of ADRs in figure 4 depicts that out of 59 ICSRs; 3 ICSRs were of psychiatric disorder and 2 were of female reproductive disorder which shows the probability of occurrence of ADRs in both psychiatric & female reproductive disorder.

Based on the current available evidences, all HCPs are advised to keep in check about this possible risk while prescribing isotretinoin.

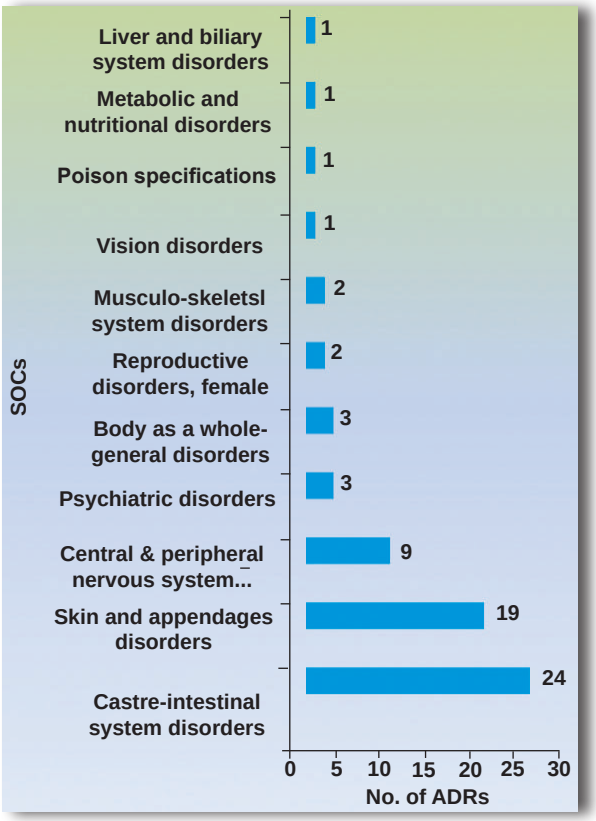

Figure 4- Distribution of ICSRs on the basis of SOCs

Important Safety Information for Physicians while Prescribing Isotretinoin

Isotretinoin is a potent teratogen and comes under pregnancy category X drugs. To avoid teratogenicity and psychosis disorder attention should be given to women of childbearing age, pregnant women and also patients with history of psychosis. Isotretinoin should be prescribed for severe nodular acne, if other anti-acne treatments are ineffective.

Note: Pregnancy category X drugs (contraindicated in pregnancy)

Regulatory Pharmacovigilance

Recommendation of PvPI to Regulatory Authority (CDSCO)

The NCC-PvPI & signal review panel meeting was held on 9th December 2014 at IPC, Ghaziabad and recommended the following advisories.

Advisory note for usage of Sunitinib Malate

Hepatotoxicity, haemorrhage and cardiovascular events have been observed following the usage of Sunitinib in Indian patients suffering from metastatic renal cell carcinoma.

Hepatobiliary disorders (4.2%)

Severe hepatobiliary disorders including hepatitis elevated liver enzymes and hyperbilirubinemia has been reported in Indian Patients. HCPs are advised to monitor liver function tests (ALT, AST and bilirubin) before initiation and during each cycle of treatment as clinically indicated. Patients are advised to obtain medical help if they develop persistent nausea/ vomiting, severe stomach/ abdominal pain, dark urine, pale stool, yellowish eye/skin.

Cardiovascular dysfunction (11%)

Congestive heart failure (CHF) and ischemic heart disease during Sunitinib therapy have been reported, some of which were fatal leading to cardiac arrest. Close monitoring for clinical signs and symptoms of CHF should be performed, especially in patients with cardiac risk factors and/ or history of coronary artery disease. Estimation of electrolytes is recommended for patients before treatment initiation or as per clinical requirements.

Haemorrhage/Bleeding disorder (5.6%)

Cases of GI haemorrhage, haematuria, cerebral haemorrhage, bruising, urinary tract and brain haemorrhage have been reported, some of which were fatal. Sunitinib should be used with caution in patients with high risk of haemorrhage. Periodic monitoring of complete blood counts platelets and coagulation factors (PT/INR) are recommended in such patients.

Note: *Based on cases received by IPC from pharmaceutical industries from 29/09/2014 to 16/12/2014.*

Advisory Note for Usage of Pazopanib Hydrochloride

Cardiac Dysfunction/Heart Attack

ICSRs of Indian metastatic renal cell carcinoma patient on Pazopanib hydrochloride therapy revealed events of cardiac dysfunction of fatal

nature. This includes congestive heart failure and ischemic heart diseases leading to death in 23.40% patients. Patient commonly had symptoms of shortness of breath and leg swelling.

Patients are recommended to take immediate medical help if they have fast/irregular heartbeat, dizziness, fainting, chest pain radiating to jaw/left arm, shortness of breath and unusual sweating. Patient should be carefully monitored for Congestive Heart Failure (CHF) and Ischemic Heart Diseases. Base line and periodic evaluation of left ventricular ejection fraction (LVEF) is recommended in patient with risk of cardiac dysfunction.

Note: *Based on cases received by IPC from Pharmaceutical industries from 04/07/2014 to 29/12/2014.*

Label change for Carbamazepine

Stevens Johnson Syndrome, Toxic Epidermal Necrolysis

PvPI has received 119 reports of life threatening or fatal skin reactions (Stevens Johnson Syndrome, Toxic Epidermal Necrolysis) that may have been caused by carbamazepine. These 119 reports are out of 1887 reports of carbamazepine induced ADRs from India in VigiBase till 31st December 2014.

Literature shows that there is an increased association of HLA-B* 1502 with carbamazepine induced Stevens Johnson Syndrome in Indian population.

Recommendations

It is recommended that the following statement is added to the package insert of carbamazepine containing products:

"It is recommended that patients may be screened for HLA-B*1502 prior to initiating treatment with carbamazepine because it is a known risk factor for carbamazepine induced Stevens Johnson Syndrome. Patients testing positive for the allele should not be treated with carbamazepine unless the benefit clearly outweighs the risk."

Note: *Based on cases received by IPC from Pharmaceutical industries from 01/04/2011 to 31/12/2014.*

New Drugs Approved in India

The following drugs were approved during the period of July to December 2014 by Central Drugs Standards Control Organization (CDSCO).

1) Lactobacillus brevis CD2 Lozenges 100 mg (Additional Indication)

Lactobacillus brevis CD2 (Cluster of differentiation 2) Lozenges 100 mg (corresponding to not less than 1 billion) of live, lyophilised, lactic acid bacteria, approved for prevention of radiotherapy and chemotherapy induced oral mucositis in cancer patients.

2) Rivaroxaban Tablet 15/20 mg (Additional Strength/Indication)

Rivaroxaban is a Factor Xa inhibitor that inhibits platelet activation by selectively blocking the active site of factor Xa without requiring a cofactor (eg, antithrombin III) for activity. Rivaroxaban is approved for treatment of Deep Vein Thrombosis (DVT) and for prevention of recurrent DVT and pulmonary embolism, also for the prevention of stroke and systemic embolism in patient with non-valvular arterial fibrillation.

3) Hydroxychloroquine Sulphate Tablet 400 mg (Additional Indication)

Hydroxychloroquine Sulphate approved as an adjunct to diet and exercise to improve glycemic control of patients on metformin, sulfonylurea combination in patients with type II Diabetes.

4) Hydroxychloroquine Sulphate Tablet 300mg (Additional strength/ indication)

Hydroxychloroquine Sulphate Tablet 300 mg approved for the treatment of patients with lower body weight i.e 45 to 60 kg in rheumatoid arthritis, systemic lupus erythematosus and polymorphic light eruption.

5) Sorafenib Tosylate Tablet 200 mg (Additional Indication)

Sorafenib Tosylate is a kinase inhibitor drug approved for the treatment of patients with locally advanced or metastatic differentiated thyroid carcinoma refractory to radioactive iodine.

6) Deferasirox Dispersible Tablet 100/400 mg (Additional Indication)

Deferasirox is a chelator that is selective for iron (Fe^{3+}). It is a tridentate ligand that binds iron with high affinity in a 2:1 ratio. It is approved for treatment of chronic iron overload in patients with non-transfusion dependent thalassemia syndromes aged 10 years and older.

7) Imatinib Mesylate 100/400mg tablets &100 mg Capsules (Additional Indication)

Imatinib mesylate is classified as a signal transduction inhibitor - protein-tyrosine kinase inhibitor. This drug approved for treatment of paediatric patients with newly diagnosed "Philadelphia chromosome positive acute lymphoblastic leukemia" integrated with chemotherapy.

8) Rivastigmine Transdermal Patch (Additional Indication)

Rivastigmine transdermal patch (Each transdermal patch of 15 cm^2 contains rivastigmine 27 mg, is a acetyl-cholinesterase inhibitors approved for the treatment of patients with severe dementia of the Alzheimer's type.

9) Dabigatrane texilate mesylate hard gelatin capsule 75/110/150 mg (Additional Indication)

Dabigatrane texilate mesylate is a synthetic, non-peptide, competitive, oral direct thrombin inhibitor that specifically and reversibly inhibits thrombin, the final enzyme in the coagulation cascade. It is approved for the treatment of acute as well as prevention of recurrent DVT and /or pulmonary embolism and related death.

10) Roflumilast Tablet 500 µg

Roflumilast and its active metabolites are selective inhibitors of phosphodiestrase 4 (PDE4). It is approved for the treatment of severe Chronic Obstructive Pulmonary Diseases (COPD), (FEV 1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.

11) Alogliptin Tablet 6.25/12.5/25 mg

Alogliptin is a selective inhibitor of enzymatic activity of Dipeptidyl peptidase-4 (DPP-4). It is approved for glycemic control in combination with other glucose lowering medicinal products including insulin when these together with diet and exercise, do not provide adequate glycemic control or as monotherapy as adjunct to diet and exercise to improve glycemic control in adults aged 18 years or older with type II Diabetes mellitus.

12) Axitinib Tablet 1/5 mg

Axitinib is a receptor protein-kinase inhibitor. It inhibits the actions of vascular endothelial

growth factor (VEGF) and is an angiogenesis inhibitor. It is approved for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.

13) Ulinastatin Injection

Ulinastatin, a serine protease inhibitor, inhibits several pro-inflammatory proteases and decreases inflammatory cytokine levels and mortality in sepsis. It is approved for the treatment of mild to severe acute pancreatitis.

14) Canagliflozin Tablet 100/300 mg

Canagliflozin is an inhibitor of sodium-glucose cotransporter 2 (SGLT2), the transporter responsible for reabsorbing the majority of glucose filtered by the kidney. Canagliflozin, approved as an adjunct to diet and exercise to improve glycemic control in adults with type-II Diabetes mellitus.

15) Cerebrolysin solution for injection. Each ml contains: porcine brain derived peptide preparation (Cerebrolysin concentrate) 215.2 mg

Cerebrolysin protects the brain nerve cells (neurons) from getting damaged by lactic acidosis, increases their survival, prevents free radical formation, prevents the death of neurons during ischemia and hypoxia, and lowers some amino acids (glutamate) damaging neurotoxic effects. Cerebrolysin is approved for amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia.

References: www.cdsco.nic.in

Drug Safety Information

Azithromycin: Drug Reaction/Rash with Eosinophilia and Systemic Symptoms (DRESS)

Azithromycin belongs to a group of antibiotics called macrolides used to treat mild to moderate infections in adults or children depending on the type of infection (e.g. pneumonia, influenza and sinus infections). DRESS describes a group of rare but serious and potentially life threatening adverse reaction which usually occur from two weeks to two months after starting of medication.

Source: www.hc-sc.gc.ca, safety review, October 21, 2014.

Sulfamethoxazole-Trimethoprim: Risk of Drug -Induced Immune Thrombocytopenia

Sulfamethoxazole and Trimethoprim are different antibiotics that can be used alone or in combination. When used separately, these antibiotics only stop the growth of bacteria. However, when combined together, these antibiotics kill the bacteria.

A safety review was conducted to evaluate the available information regarding the potential risk of drug induced immune thrombocytopenia, also known as a low number of platelets in the blood, with products containing sulfamethoxazole and/or trimethoprim.

Source: www.hc-sc.gc.ca, safety review, November 18, 2014.

Zoledronic Acid: Possible Risk of Tendon Injury/Tendinitis

Zoledronic acid belongs to a class of drug called bisphosphonates, which reduces the rate of bone turnover and is indicated for treatment of osteoporosis in both postmenopausal women and men and also treatment of Paget's disease, tumour induced hypercalcaemia, prevention of glucocorticoid-induced osteoporosis, prevention of clinical fractures in after bone fracture and in malignancies involving bone. Zoledronic acid associated with tendon rupture, tendinitis and tenosynovitis.

Source: www.medsafe.govt.nz.

Clopidogrel: Association with Acquired Haemophilia

Clopidogrel is an oral, thienopyridine class antiplatelet agent; it is indicated for the prevention of atherothrombotic events in myocardial infarction, ischaemic stroke, and established peripheral arterial disease, acute coronary syndrome including non-ST segment elevation myocardial infarction and unstable angina, and ST segment elevation acute myocardial infarction with aspirin in medically treated patients eligible for thrombolytic therapy. Clopidogrel is also indicated in combination with aspirin for the prevention of atherothrombic and thromboembolic events in atrial fibrillation in patients unsuitable for vitamin K antagonist treatment.

The Egyptian Pharmaceutical Vigilance Center has recommended:

- Acquired haemophilia must be promptly recognised to minimise the time of the patient is at risk of bleeding and avoid major bleeding.
- In case of confirmed isolated activated Partial Thromboplastin Time (aPTT) prolongation with or without bleeding, acquired haemophilia should be considered.
- Patients with a confirmed diagnosis of acquired haemophilia should be managed and treated by specialists, clopidogrel should be discontinued and invasive procedures should be avoided.

Source: WHO Pharmaceuticals Newsletter No.6, 2014

Use of Sodium Valproate in Pregnancy

Valproate is contraindicated in pregnancy due to the risk of congenital malformations and developmental effects. It should not be used in women of childbearing potential unless other treatments are ineffective or not tolerated.

Female who could become pregnant should be given medical advice on the benefits and risks of treatment before valproate is prescribed.

Source: www.medsafe.govt.nz

National and International Status of Suspected Unexpected Serious Adverse Drug Reactions (SUSARs)

Suspected Unexpected Serious Adverse Drug Reactions related to any medicinal product are subjected to expedited reporting.

Table 1: National and International Status of Reported SUSARs

S.No	Name of the Drug	Reported ADR	Indian Status (ICSRs Received)	Global Status (ICSRs Received)
1	Rifaximin	Extrapyramidal disorder	1	3
2	Norethisterone	Cerebral infarction	1	9
3	Piperacillin/Tazobactam	Bronchospasm	2	18
4	Prulifloxacin	Haemoptysis	1	1
5	Miltefosine	Pancreatitis acute	1	1

News Digest

Completeness score reaches 0.94

The completeness score provided by WHO-UMC to NCC- PvPI for the ICSRs from PvPI database for the last quarter i.e. September to December 2014 is 0.94 out of 1. It is very heartening to see that during 2014, PvPI database contributed 40,000 ICSRs to global database & there has been a continuous improvement in completeness score from the last year.

Expansion of PvPI across the country

The national workshop was organised by WHO & NCC- PvPI on 10th & 11th December 2014 for the coordinators of drug resistant tuberculosis and antiretroviral treatment in India to encourage & harmonise the ADR reporting. Training on different topics of pharmacovigilance, ADR monitoring, reporting, causality assessment & hands on training on "VigiFlow software" was provided.

In the first phase of collaboration, 32 RNTCP/ART centres are being identified and provided with user ID & password for VigiFlow software to facilitate ADR reporting from their centres. List of RNTCP/ART centres where AMCs centres are attached is given below:-

S. No.	Name of the AMC (s)	Centre (s)
1.	Gandhi Medical College,Secunderabad	ART
2.	Andhra Medical College, King George Hospital (KGH), Visakhapatnam	ART
3.	PDU Medical College, Civil Hospital Campus, Rajkot	ART
4.	BJ Medical College, New Civil Hospital, Ahmedabad	ART
5.	BJ Medical College & Sassoon General Hospital, Pune	ART
6.	Grant Medical College & JJ Medical College, Mumbai	ART
7.	SMS Medical College, Jaipur	ART
8.	Institute of Medical Sciences, Banaras Hindu University, Varanasi	COEARTIMS
9.	School of Tropical Medicine, Kolkata	COEARTSTM
10.	PGIMER, Chandigarh	COEARTPGI
11.	Maulana Azad Medical College and associated LNJP Hospitals, New Delhi	COEARTMAMC
12.	All India Institute of Medical Sciences (AIIMS),New Delhi	ART
13.	VMMC & Safdarjung Hospital, New Delhi	ART
14.	University College of Medical Sciences, & GTB Hospital, New Delhi	ART
15.	Karnataka Institute of Medical Sciences, Hubli	ART
16.	Bowring & Lady Curzon Hospital, Bengaluru	COEARTBH
17.	JSS Medical College Hospital, Mysore	ART
18.	Government Hospital of Thoracic Medicines, Chennai	ART
19.	Madras Medical College, Chennai	ART
20.	Christian Medical College (CMC), Vellore	ART
21.	Guntur Medical College, Guntur	RNTCP
22.	Silchar Medical College & Hospital, Silchar	RNTCP
23.	Pt. JNM Medical College, Raipur	RNTCP
24.	BJ Medical College, Ahmedabad	RNTCP
25.	Pt. Bhagwat Dayal Sharma, Rohtak	RNTCP
26.	Dr. Rajendra Prasad Medical College, Tanda	RNTCP
27.	Karnataka Institute of Medical Sciences, Hubli	RNTCP
28.	Govt. Medical College, Thiruvanthapuram	RNTCP
29.	RD Gardi Medical College, Ujjain	RNTCP
30.	Govt. Medical College, Aundh, Pune	RNTCP
31.	VSS Medical College, Sambalpur, Odisha	RNTCP
32.	Govt. Medical College, Patiala	RNTCP

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