ISSN: 2320-7760

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August Issue

Pharmacovigilance Programme of India (PvPI) Newsletter

INSIDE THIS ISSUE

EDITORIAL TEAM

SECRETARY-CUM-SCIENTIFIC DIRECTOR'S MESSAGE

Dear Colleagues!

Medicines provide enormous health benefits, however associated with risk. National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) has received about 54,000 Individual Case Safety Reports (ICSRs) till date. We review these reports regularly to assess the benefits and risk of medicines. Spontaneous adverse event reports are one of the basis for updating product labelling and communicating new information about risks associated with the use of medicines to healthcare professionals and patients. The broad aim of this issue is to bring together recent information on drug safety and regulatory measures from India and across the world. It is important to note that any suspected Adverse Drug Reactions (ADRs) following the use of medicine can be reported to the nearest ADR Monitoring Centres (AMCs) using suspected adverse reaction reporting form or via pvpi@ipcindia.net/pvpi.ipcindia@gmail.com. To make this communication more effective and nationwide, I take this opportunity to encourage clinicians, team of AMCs, other healthcare professionals and other stakeholders to continue to report all ADRs.

I wish to thank all stakeholders especially those who have been working tirelessly with the AMCs. I also encourage other stakeholders for their active participation and cooperation.

EXPERT REVIEWERS

Mr. Lahouari reviewing the functioning of NCC-PvPI on 15th July 2013 at IPC, Ghaziabad

Mr. Lahouri Belgharbi, Technical Officer WHO-HQ: Appreciating NCC PvPI

Mr. Lahouari Belgharbi (WHO HQ-Geneva) Technical Officer visited IPC on 15th July 2013 to address the Induction course for Drug Inspectors of CDSCO at IPC Ghaziabad. He also reviewed the activities of PvPI and appreciated the progress.

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WHO-UMC QUALITATIVE COMPLETENESS SCORING FOR INDIAN ICSRs

WHO-UMC assesses and circulates the completeness score of the ICSRs to their respective National Centres periodically. IPC is functioning as NCC for PvPI since 2011 and the quality of ICSRs submitted from India is increasing. WHO-UMC completeness score varies from 0-1 depending upon the quality of report. On an average the Indian status issued by UMC for three consecutive years are as follows.

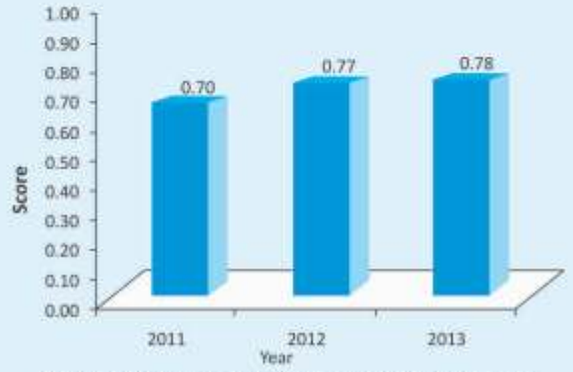

Fig.1 WHO-UMC Completeness Score for Indian ICSRs for Consecutive Years.

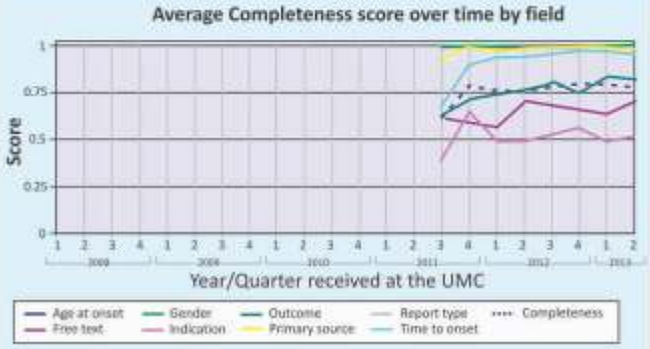

Fig.2 WHO-UMC-Average Completeness Score for Indian ICSRs.

ADRs REPORTING STATUS OF INDIVIDUAL AMCs FOR THE PERIOD OF MAY TO JULY 2013

This summary report includes the status of ICSRs submitted by AMCs to NCC through Vigiflow (WHO global drug safety database) from the period of May 2013 to July 2013. A total of 7124 ICSRs were received in this period from the AMCs of different zones, the details are depicted in Figure 3 to 7.

Fig.3. ICSRs Reported Zone Wise (May to July 2013)

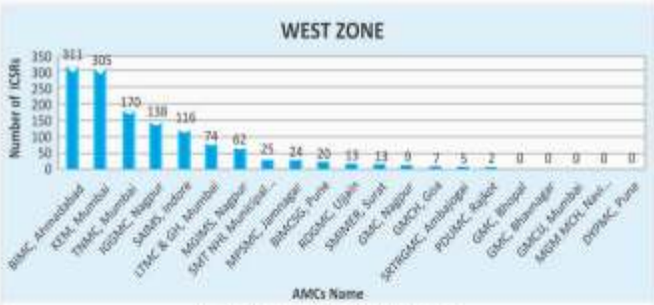

Fig.5. ICSRs Reported from AMCs of West Zone

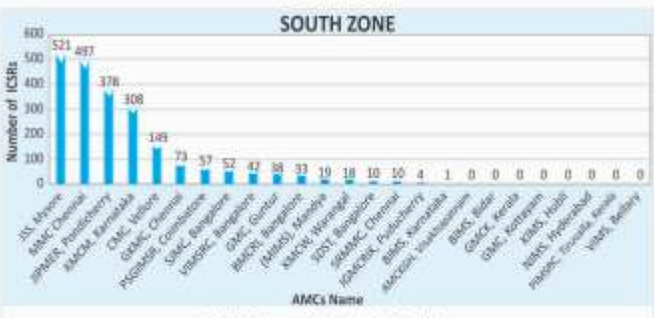

Fig.6. ICSRs Reported from AMCs of South Zone

Fig.4. ICSRs Reported from AMCs of East Zone

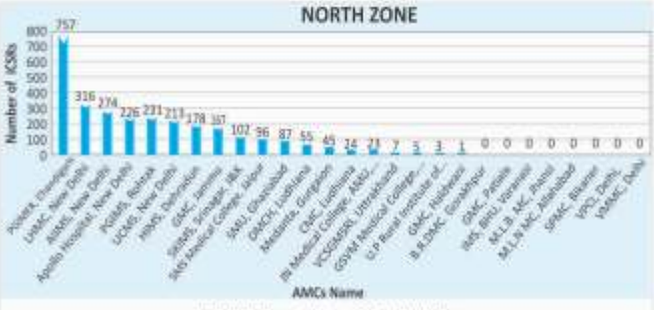

Fig.7. ICSRs Reported from AMCs of North Zone

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PIOGLITAZONE

Key message:
Patient should be regularly monitored while prescribing pioglitazone. Surveillance is required to assess the benefit and risk to the patient for the use of pioglitazone.

Status at NCC-PvPI

Till June, 2013 a total number of 50 ICSRs were reported to NCC-PvPI in which Pioglitazone is suspected drug for occurrence of ADRs. From the total ICSRs of Pioglitazone received at NCC, we found that females are more prone to develop ADRs as compared to males as shown in the fig 8. The patients in age group of 45-60 year (56%) are at higher risk of having ADRs related with the use of Pioglitazone as shown in fig 9.

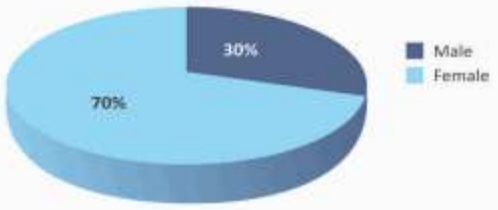

Fig.8: Distribution of ICSRs Based on Gender

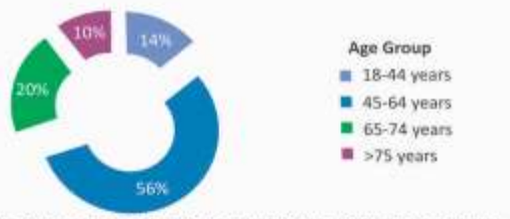

Fig. 9: Percentage of ICSRs Received Among Different Age Groups

Out of 54 ADRs reported for Pioglitazone, the most commonly affected System organ Class (SOC) are metabolic and nutritional disorders (37.04%) followed by body as whole-general disorder (31.48%) of the total ADRs observed, the summary of these ADRs based on SOC is depicted in fig 10. Out of 50 ICSRs received, 13 cases (26%) were reported to be serious and rest of the 37 cases (74%) were non-serious (as shown in the fig 11) and the summary of serious case reports is given in table 1.

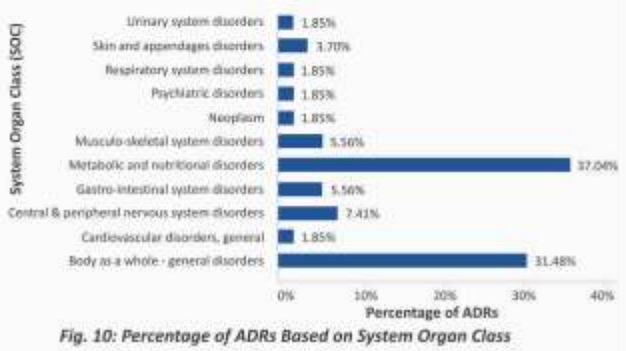

Fig. 10: Percentage of ADRs Based on System Organ Class

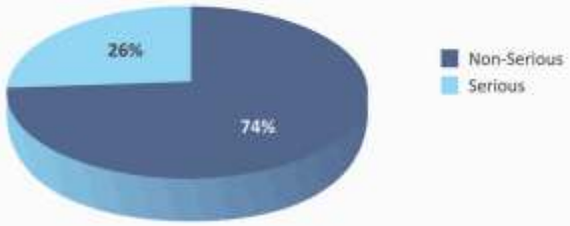

Fig. 11: Distribution of Serious and Non-Serious ICSRs

Table.1: Summary of Serious ICSRs of Pioglitazone

S. No	Suspected Adverse Reaction	Gender	Age (years)	Reason for Seriousness	SOC Affected	Outcome of Reaction
1.	Facial oedema	female	48	Hospitalization	Urinary system disorder	recovering/ resolving
2.	Hypoglycaemia	female	58	Other medically important condition	Metabolic and nutritional disorders	recovered/resolved
3.	Hypoglycaemia	male	55	Life threatening	Metabolic and nutritional disorders	recovered/resolved
4.	Hypoglycaemia	female	36	Other medically important condition	Metabolic and nutritional disorders	recovered/resolved
5.	Hypoglycaemia	female	50	Life threatening	Metabolic and nutritional disorders	recovered/resolved with sequelae
6.	Hypoglycaemia	female	70	Hospitalization	Metabolic and nutritional disorders	recovered/resolved
7.	Hypoglycaemia	male	70	Hospitalization	Metabolic and nutritional disorders	recovered/resolved
8.	Oedema	female	48	Other medically important condition	Body as a whole - general disorders	recovered/resolved
9.	Hypoglycaemia aggravated	female	80	Hospitalization	Metabolic and nutritional disorders	recovered/resolved
10.	Giddiness	female	80	Hospitalization	Central & peripheral nervous system disorders	recovered/resolved
11.	Hypotension	female	80	Hospitalization	Cardiovascular disorders, general	recovered/resolved
12.	Drowsiness	female	80	Hospitalization	Psychiatric disorders	recovered/resolved
13.	Oedema legs	female	38	Other medically important condition	Body as a whole - general disorders	not recovered/not resolved

In Indian database it was found that one case of bladder carcinoma was reported due to Pioglitazone. Whereas 1241 ICSRs have been reported globally showing bladder carcinoma till June 2013 (table 2). However still more evidence are required from India to assess their impact on the balance of benefits and risks with the use of Pioglitazone.

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Regulatory Status: India and Global

Table 2 : Regulatory status of Pioglitazone with respect to bladder cancer

S. No.	COUNTRY	NO. OF ICSRs OF BLADDER CANCER	REGULATORY STATUS
1	India	1	1. The drug should not be used as first line therapy for diabetes. 2. The manufacturer should clearly mention following box warning in bold red letters. **Box warning:** • Patient with active bladder cancer or with a history of bladder cancer and those with un-investigated haematuria, should not prescribed pioglitazone. • Prescribers should review the safety and efficacy of pioglitazone in individuals after 3-6 months of treatment to ensure that only patient who are deriving benefits continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (e.g. reduction in glycosylated haemoglobin, HbA1c). • Before prescribing pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age, current or past history of smoking, exposure to some occupational or chemotherapy agents such as cyclophosphamide or previous irradiation of the pelvic region. • Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patient should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone.
2.	France	-	Banned in July 2011
3.	Italy	3	Under review
4.	United States	1108	**Label warning:** • Not to use in patients with active bladder cancer. • Use with caution in patients with a prior history of bladder cancer.
5.	Japan	41	**Label warning:** • Pioglitazone is not to be used in patients with active bladder cancer. • Patients or their families are to be given a full explanation of the risk of bladder cancer before initiating the therapy. • Patients should be instructed to see their doctor immediately if they have any signs or symptoms of blood in the urine, pollakiuria or pain on urination during the treatment with this drug.
6.	United Kingdom	30	**Label warning** • Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone. • Should be stopped in patients who do not respond adequately to treatment (e.g. reduction in glycosylated haemoglobin, HbA1c). • Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region. • Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with Pioglitazone.
7.	Germany	10	**Label warning:** • Due to a slightly increased risk of bladder cancer doctors should not prescribe (visible blood in the urine) in patients with bladder cancer, a bladder cancer or a history). • Risk factors for bladder cancer such as age, smoking status or contact with other chemicals (e.g. Aromatic amines) should be taken into account when deciding on treatment with Pioglitazone. • As a risk minimising measure it recommends that physicians should only administer Pioglitazone to patients if it is proven that they will benefit from its therapy.
8.	Canada	8	**Label warning:** • Pioglitazone is now contraindicated in patients with active bladder cancer, history of bladder cancer or uninvestigated macroscopic haematuria. • Any macroscopic haematuria should be investigated before starting pioglitazone therapy. • Risk factor of bladder cancer should be assessed before treatment with Pioglitazone (risk include age, smoking, family history of bladder, exposure to chemical in the workplace, certain cancer treatments and radiation therapy.
9.	Australia	4	**Label warning:** Do not use Pioglitazone in patients with bladder cancer or a history of bladder cancer. Consider the risk of bladder cancer in the care of all patients treated with Pioglitazone. Counsel patients about the possible risk of bladder cancer and ask them to report any signs or symptoms of blood in the urine, urinary urgency, pain on urination, or back or abdominal pain, as these may be due to bladder cancer.
10.	Netherlands	5	**Label warning:** • Use of pioglitazone is now contraindicated in patients with current active bladder cancer or a history of bladder cancer or uninvestigated macroscopic haematuria. • Risk factors for bladder cancer should be assessed before initiating pioglitazone treatment. Any unexplained macroscopic haematuria should be investigated before starting pioglitazone therapy. • Patients should be advised to promptly seek the attention of their physician if macroscopic haematuria or other symptoms such as dysuria or urinary urgency develop during treatment.
11.	Switzerland	2	**Label warning:** • Pioglitazone-containing products should only be prescribed if metformin is contraindicated or not tolerated. • Bladder cancer, even in prehistory, as well as an unexplained hematuria was newly added as a contraindication. • Avoid pioglitazone in patients with bladder cancer or a history of bladder cancer.

USE OF MEDICINE IN PREGNANCY - SAFETY INFORMATION

Key message:
Prescribers and healthcare professionals needs to pay attention while prescribing medicine like phenytoin (congenital anamoly), carbamazipine (multiple joint contractures of new born), sodium valproate (congenital anamoly) and ciprofloxacin (foetal death) to pregnant women to avoid damage to the foetus.

There are increasing concerns about the safety of medicines during pregnancy. Many pregnant women take prescription medicines for health problems like diabetes, asthma, seizures, heartburn, and morning sickness. Not all medicines are safe when used during or before pregnancy. Only a small proportion of drugs are known to be harmful to the foetus, but for the vast majority of drugs, little evidence of foetal safety exists. Prescribing medicines to pregnant women requires the balancing of benefits and risks.

Medicines exposure during the third to eleventh week of pregnancy is associated with the highest risk of malformation. During the second and third trimester, medicines may affect the growth and functional development of the foetus or may have toxic effects on foetal tissues. Drugs given shortly before term or during labour may have adverse effects either on foetus or on the neonate after delivery. Risk assessment must always be made on an individual basis and pregnant women with illnesses requiring treatment must always be treated adequately.

The National Formulary of India 2011 categorizes the medicines risks to the foetus from: "category A" (safest) to "category X" (Known danger—do not use). Table 3 describes the categorisation.It should be noted that this categorization only applies at the recommended therapeutic doses in women.

It cannot be applied to situations such as overdose, occupational exposure or other situations where the recommended therapeutic dose has been exceeded. Herbal medicines, mineral and nutritional supplements are exempted from this classifications but this does not indicate that these are safe during pregnancy. Although data is very limited and

ISSN: 2320-7760

insufficient to determine the safety yet category C, D and X are based not just on risk, but risk weighed against benefit. This means drug in category C or D may pose risks similar to a drug in category X.

Table.3: Pregnancy Category of drugs

Category A Controlled studies in women fails to demonstrate a risk to the foetus in the first trimester (and there is no evidence of a risk in later trimesters), and the possibility of foetal harm appears remote.
Category B Either animal-reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimester).
Category C Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus.
Category D There is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).
Category X Studies in animals or human beings have demonstrated foetal abnormalities, or there is evidence of foetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

NCC-PvPI has received a total of 4 reports where pregnant female were administered medicines resulting in reactions involving the foetus or where a reaction has been noted in the new-born (Table 4).

According to the National Formulary of India phenytoin, carbamazepine and sodium valproate falls under the category D, whereas ciprofloxacin falls under category C of pregnancy drugs (table 3). NCC-PvPI received one report for each of phenytoin, carbamazepine and sodium valproate with

Table.4: ADRs in Pregnancy: India and Global Status

Medicine	Pregnancy Category	Description of ADRs	Number of ICSRs in India and Global					
			India	America	Africa	Europe	Oceania	Asia other than India
Phenytoin	D	Congenital anomaly	1	308	0	163	45	7
Carbamazepine	D	New born developed arthrogryposis (multiple joint contractures)	1	464	6	593	67	7
Sodium valproate/ valproic acid	D	New born developed congenital anomaly	1	912	4	992	103	18
Ciprofloxacin	C	Death of 8 month foetal due to anaphylaxis reaction in mother	1	39	1	78	0	1

congenital anomaly during pregnancy and one report of foetal death with the use of ciprofloxacin. It was found in Vigilyze (search and analyse VigiBase –WHO global database of ICSRs) that there were reports of foetal disorders in pregnant women in other countries who prescribed antiepileptic drugs and ciprofloxacin alone or in combination with other drugs. Table 4 gives an outline of number of similar ICSRs reported globally. The pregnancy category of a drug may change depending upon the number of clinical evidence on the safety data. However more number of such reports is required to draw any conclusion to upgrade/downgrade pregnancy category of the above mentioned drugs

Healthcare professionals are advised to closely monitor the cases of pregnant women/ child bearing mothers who has been administered a medicine resulting in a reaction involving the foetus or where a reaction has been noted in the neonates to AMCs to ensure the safety of these medicines in vulnerable population.

DRUG SAFETY INFORMATION

Key Message

- **Leflunomide:** Severe skin reactions (Stevens Johnson's Syndrome) and Hepatic Disorders are reported as a potential adverse reaction
- **Methotrexate**: Potential risk of Hepato-toxicity
- **Ceftriaxone**: Risk of Hepatitis

Leflunomide

Severe Skin Reactions (Stevens Johnson's Syndrome) and Hepatic Disorders are reported as a potential adverse reaction from the use of Leflunomide

Leflunomide is a disease-modifying antirheumatic drug, used in active moderate to severe rheumatoid arthritis and psoriatic arthritis. It is a pyrimidine synthesis inhibitor.

India

PvPI data shows that the risk of severe skin and appendage disorder and hepatic disorder with the use of Leflunomide. Eleven cases of severe skin and appendages disorders reported through Vigiflow including four serious cases of Stevens Johnson's Syndrome (also one fatal case). Four cases of rash, one case of erythema multiforme, one case of dermatitis exfoliative, & one fatal case was also reported due to skin exfoliation.

Serious cases of Hepatic disorder were also reported with Leflunomide including liver enzymes elevation and one fatal case with jaundice.

United Kingdom

Medicines and Healthcare products Regulatory Agencies (MHRA) of United Kingdom also issued safety alert for prescribing Leflunomide. It is contraindicated in the patients with hypersensitivity to the active substance (especially previous Stevens-Johnson Syndrome, toxic epidermal necrolysis, erythema multiforme) or to any of the excipients and patients with impairment of liver function. Also in patients with severe immunodeficiency states (AIDS), impaired bone marrow function and rheumatoid or psoriatic arthritis and patients with serious infections.

Ref:http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/index.htm

Methotrexate

Potential risk of Hepatotoxicity from the use of Methotrexate

Methotrexate is an antimetabolite and antifolate drug. It acts by inhibiting the dihydrofolate reductase blocking the conversion of dihydrofolic acid to tetrahydrofolic acid. It is used for the treatment of active rheumatoid arthritis in adults which cannot be controlled with the use of anti-inflammatory substances (NSAIDs), disseminated chronic psoriasis when other treatments have failed and also cytostatically.

India

PvPI data reveals that the patients experiencing potential risk of hepatotoxicity when treated with methotrexate. Four cases of hepatotoxicity were reported including two cases of serious hepatic cirrhosis.

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Note: In one case of hepatotoxicity suspected drug was given in combination with 6-Mercaptopurine

Denmark

Liver fibrosis was also reported as a potential adverse reaction from the use of methotrexate in Denmark. In March, 2013 the Danish Health and Medicines Authority (DHMA) have received a total of nine adverse reaction reports of possible development of liver fibrosis/liver cirrhosis in association with the use of methotrexate.

Ref:http://laegemiddelstyrelsen.dk/en/service-menu/news/danish-pharmacovigilance-update/danish-pharmacovigilance-update,-23-may-2013

Ceftriaxone

Risk of Hepatitis associated with Ceftriaxone

Ceftriaxone is indicated for the treatment of severe bacterial infections. Ceftriaxone is a member of the cephalosporin group and is active in both Gram-positive and Gram-negative bacteria.

India

Based on the data available from PvPI, ceftriaxone is suspected at the risk of causing hepatitis. NCC has received two cases of ceftriaxone induced hepatitis including one case of serious hepatitis.

Note: The suspected drug was given in combination with isoniazid, rifampicin & pyrazinamide (case 1) and Piperacillin & amikacin (case 2)

Netherlands

The database of the Netherlands Pharmacovigilance Centre Lareb has reported three cases of hepatitis associated with the use of Ceftriaxone.

Ref:http://www.lareb.nl/getmedia/96068332-412d-49cf-aaca-61fb4fb41523/2013-1-LQR.pdf

Table.5: Drug Alerts

Drug Name	Drug alert
Pioglitazone	Bladder Cancer
Leflunomide	Stevens Johnson's Syndrome Hepatic Disorders
Methotrexate	Hepatotoxicity
Ceftriaxone	Hepatitis
Montelukast	Neuropsychiatric disorders in children and adolescents

Important safety information for Physician while prescribing Montelukast:

Health professionals are requested to monitor the possibility of neuropsychiatric adverse events in patients treated with montelukast especially *children* and *adolescents*.

Therapeutic Goods Administration (TGA) of **Australia** issued an alert on Neuropsychiatric risk while prescribing montelukast. Reports of neuropsychiatric adverse events were observed in 58 **children and adolescents** including suicidal ideation (5 reports), depression (5), agitation (8) and others (nightmares, altered mood, and insomnia).

http://www.tga.gov.au/hp/msu-2013-02.htm

In India eight ICSRs are also reported including tremor, headache, dizziness, and somnolence but only in adults. Therefore monitoring should be required while prescribing montelukast in **children.**

LIST OF AMCs UNDER PvPI

State	S. No.	Centre Name	Coordinator name	Email
Andhra Pradesh	1.	Andhra Medical College King George Hospital, Visakhapatnam	Dr. J. Sudha	prabhakar2202@gmail.com
	2.	Guntur Medical College, Guntur	Dr. Zaheda Bano	drzahedabano@gmail.com
	3.	Kakatiya Medical College, Warangal	Dr. Raju Devde	rajudevde_dr@yahoo.co.in
	4.	Nizam Institute of Medical Sciences, Hyderabad	Dr. Shobha Udutha	shobnaudutha@gmail.com
Assam	5.	Govt. Medical College, Guwahati	Dr. Mangala Lahkar	dr_mlahkar@rediffmail.com
	6.	Silchar Medical College & Hospital, Silchar	Dr.Pinaki Chakravarty	dr_pinaki@yahoo.com
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Prof. Y.K Gupta along with the subject review committee members for the 4th edition of NFI

Dr S.K Gupta & Dr. G. N. Singh, presenting 'NFI 2011' to Mr. Lahouari Belgharbi at IPC, Ghaziabad

3rd training cum meeting of Coordinators & Technical Associates of Northern Zone AMCs under PvPI organized by Department of Pharmacology, PGIMER, Chandigarh.

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ISSN: 2320-7760

Pharmacovigilance Programme of India (PvPI) Newsletter

IMPORTANT ACTIVITIES UNDER PvPI

INTEGRATION OF NATIONAL HEALTH PROGRAMS UNDER PvPI

NCC-PvPI invited all National Health Programs (Cancer control, Tuberculosis, HIV-AIDS, Leprosy Eradication, Universal Immunization, Mental Health etc) under Ministry of Health and Family Welfare (MoHFW), Government of India to collaborate with NCC-PvPI for reporting of ADRs with the respective drugs used in their program. Preliminary meeting between IPC and Central Tuberculosis Division, MoHFW was held on 2nd July, 2013 at CDSCO to collaborate together in ensuring the safety of antitubercular drugs.

INTERNATIONAL PHARMACOVIGILANCE TRAINING PROGRAMME AT UPPSALA, SWEDEN

The UMC organized its 15th International Pharmacovigilance training course at Uppsala, Sweden, from 20th May to 4th June 2013. Theoretical and practical aspects of adverse drug reactions and Pharmacovigilance were covered. Health care professionals from various countries participated in this training course. The Indian delegation consisted of Dr. M. K Agarwal, Commissioner, UIP, MoHFW, Dr. Ayyanar, State Immunization Officer, Government of Tamil Nadu, Mr. Naresh Sharma, Assistant Drugs Controller, CDSCO and Dr. V. Kalaiselvan, Senior Scientific Officer, IPC. Dr. V. Kalaiselvan was invited by the organizers to present the status of PvPI during the training.

Indian delegation attending International Pharmacovigilance Training Programme held at Uppsala Monitoring Centre, Sweden

NATIONAL LEVEL TRAINING WORKSHOPS ON AEFI MONITORING AND CAUSALITY ASSESSMENT

Immunization Technical Support Unit (ITSU), MoHFW, Govt. of India in collaboration with WHO-Country Office for India organized a national level training workshop on Adverse Event Following Immunization (AEFI) monitoring and causality assessment at New Delhi (3-6 June 2013 & 22-23rd July 2013), Goa (9-12 July 2013) and Bengaluru (16-19th July 2013). Coordinators of respective state AMCs participated and interacted with AEFI committee for bridging the gap in vaccine safety. In all the workshops, officials from NCC-PvPI participated and presented the activities of PvPI with special emphasis on vaccine safety.

TRAINING PROGRAMME AND WORKSHOP AT NCC-PvPI

IPC organised one day training programme on Pharmacovigilance & Causality Assessment on 10th May 2013 at IPC, Ghaziabad in order to update the knowledge of causality assessment of drugs and vaccines. The training programme focused on general introduction on Pharmacovigilance, exercise of practical causality assessment of drugs with ICSRs in Vigiflow, practical causality assessment of Adverse Events Following Immunization to stakeholders of AMCs in Delhi NCR.

EMPHASIS ON PvPI DURING THE DRUG INSPECTORS TRAINING PROGRAMME

CDSCO in collaboration with IPC conducted three weeks Induction cum Training Programme for the newly inducted Drug Inspectors in CDSCO at IPC Ghaziabad from 15th July to 2nd Aug 2013. During this induction course the current status of PvPI was presented and PvPI checklist for inspection of AMCs was discussed.

What to report? You do not need to be certain, just suspicious!!

The IPC encourages the reporting of all suspected adverse reactions of drugs, including over-the-counter drugs, medical devices, and herbal, traditional or alternative remedies. We particularly request to report:

- All suspected reactions to new drugs as well as existing drugs
- All suspected drug interactions
- Suspected reactions causing death, admission to hospital or prolongation of hospitalisation, life-threatening, temporary or permanent disabling or any birth defects.

REPORTS MAY BE SUBMITTED:

- Using the '**SUSPECTED ADVERSE DRUG REACTION REPORTING FORM**' which is available on the IPC as well as CDSCO official website. http://ipc.gov.in/ http://www.cdsco.nic.in
- filled ADR form is submitted either to the nearest ADR Monitoring Centre (AMC)/ pvpi@ipcindia.net/ pvpi.ipcindia@gmail.com

PMS Arts & Communications

AKNOWLEDGEMENT

NCC-PvPI acknowledge the support of Technical Associates at NCC namely Ms Ritika Mehra, Mrs Surbhi Sharma, Mr Ranvir Kumar, Mr Sumit Bhalla, Ms Ismeet Kaur, Ms Archana Saurabh, Mr Ashish Verma, Mr Prabhakar Mishra, Mr Vivek Dabas, Mr Iftekhar Hussain, Ms Sakshi Gakhar, Mrs Madhvi Rathore, Mr. Varun Chopra, Ms Vaishali Bharadwaj for their cooperation in bringing out this issue of newsletter.

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