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April Issue

Pharmacovigilance Programme of India (PvPI) Newsletter

Inside This Issue:

Secretary-cum-Scientific Director's Message

The National Coordination Centre for PvPI is committed to publishing and circulating 'PvPI Newsletter' to its stakeholders on a quarterly basis. The objectives are to disseminate information on Pharmacovigilance activities nationally and globally, to create awareness among the healthcare professionals on drug safety issues, to promote rational use of medicines and to promote spontaneous reporting. This issue focuses on Adverse Events attributable to immunization.

Vaccines protect against disease by inducing immunity. In India, the Ministry of Health & Family Welfare, (MoHFW) Government of India is offering a comprehensive immunization Programme to reduce morbidity and mortality. Since the majority of the vaccines are administered to a vulnerable population (children), it is essential to monitor their safety. Vaccine Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, prevention, and communication of adverse events following immunization, or of any other vaccine-or immunization-related issues. The recently conducted WHO National Regulatory Authority (NRA) assessment of India and affiliated institutions by a WHO-led team of international experts from eight countries from 10-14 December 2012, led to the gap analysis of a need for a greater coordination and interaction amongst all stakeholders of vaccine Pharmacovigilance at national and sub-national levels, including Indian Pharmacopoeia Commission, CDSCO and Immunization Division. This newsletter aims to bridge that gap amongst all key stakeholders and ADR monitoring centers functioning under Pharmacovigilance Programme of India (PVPI). In India, the safety of vaccines is monitored by the Division of Adverse Events Following Immunization (AEFI), MoHFW, Government of India and through PvPI. PvPI is collaborating with AEFI to monitor the safety of vaccines.

This issue focuses exclusively on AEFI, current status of AEFI in PvPI and other regulatory issues of vaccines. Stakeholders are requested to provide their feedback for better coordination between AEFI& PvPI with respect to vaccines safety.

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AEFI SURVEILLANCE PROGRAMME IN INDIA

The AEFI Surveillance System in the country has come a long way since its inception in 1986. Intensive efforts are being made by Ministry of Health & Family welfare, Government of India to strengthen Surveillance and Monitoring of AEFI in the country and include publishing of National AEFI Operational Guidelines in 2010 to streamline the system. These revised Operational Guidelines for surveillance and response to AEFI enable the health system to detect report and monitor the adverse events in a timely manner as well as help to prevent AEFIs due to program errors. As per the operational guidelines District and State level AEFI Committees have been formed and their members trained by National and state level workshops conducted by MoHFW to intensify AEFI surveillance. In 2012, the year of intensification of routine immunization, the National AEFI Secretariat has been established at the Immunization Technical Support Unit (ITSU) which has been set up by MoHFW with Public Health Foundation of India.

The Universal Immunization Programme aims at vaccinating the largest cohort of eligible beneficiaries in the world -2.7 crores children and 3.0 crores pregnant women. Immunization services are provided through a network of fixed centers and outreach sessions covering urban and rural areas which reach out to every village in the country. Therefore monitoring of AEFI and executing such a large scale program correctly in a diverse and large geographical area like India is a unique challenge and an opportunity to sustain public confidence in the immunization program.

An adverse event following immunization (AEFI) is defined as a medical event that takes place after immunization, causes concern and is believed to be caused by immunization. Some AEFIs are inevitable but their impact can be minimized by providing quality immunization services, appropriate case management and communication strategies. To ensure their safety and efficacy, vaccines are subjected to lot release at CDL, Kasauli before release for public use. However, due to their intrinsic property, vaccines and constituents like stabilizers, adjuvant, antibiotics, diluents etc. added to the vaccine or hypersensitivity of some individuals to vaccine component(s) AEFIs may occur. Such incidents are rare but may become apparent in terms of number when vaccinating a large cohort. AEFI may also result from programmatic errors as a result of inappropriate storage; improper handling, preparation and administration etc. of vaccines AEFI surveillance and timely management will build public confidence and prevent additional clustering of cases if they occur due to a programmatic error.

AEFI surveillance monitors immunization safety, detects and responds to adverse events following immunization; corrects unsafe immunization practices reduces the negative impact of the event on health and contributes to the quality of immunization activities. Operational Guidelines of AEFI mainly relate to vaccines included in the National Immunization Program and issues of vaccine manufacturing, safety & quality control of AEFI cases are handled by Central Drugs Control Standards Organization (CDSCO) headed by Drug Controller General of India (DCGI).

Objectives of AEFI Surveillance

- Detect, Report and Respond to AEFIs timely and promptly
- Identify unusual high rates of AEFI with any specific vaccine lots/brands
- Promptly address Programmatic Error through implementation of corrective measures
- Maintain confidence of the community and health workers in the immunization programme by properly and promptly responding to their concerns
- Estimate serious AEFI rates in the population as compared with the local and Global data
- Identify signals for unexpected Adverse Event and generate new hypotheses about these events that must be confirmed by planned studies and laboratory investigation

Key Elements of the AEFI Surveillance System

- Rapid notification and evaluation of AEFI information followed by effective response
- Adequate education and training of the key personnel
- Well defined standard operating procedures to ensure clarity, uniformity and avoid duplication of efforts
- An AEFI Database for comprehensive analysis at appropriate levels
- **AEFI Reporting System**
  Within the rural areas of the country, the primary responsibility of AEFI reporting is with the Auxiliary Nurse Midwife (ANM) and Medical officer of the Primary Health Centre and in urban areas AEFI reporting is primarily the responsibility of the health workers and the Medical Officers of the Corporations, municipalities or towns who provide immunization services through Urban Health facilities, Maternal and Child Health centers and District Hospitals.
- **Channels of Reporting**
  1. Monthly Routine Reporting
  Monthly reports of serious and non-serious AEFIs are to be sent by health workers up to the national level using existing monthly progress report forms such as

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NRHM/HMIS etc. and include death, injection site abscesses, others such as (persistent inconsolable screaming, seizure, hypotonic hypo responsive episode (HHE))

2. Immediate Serious AEFI Reporting

All serious AEFI are to be immediately notified by the first person who identifies the event as they need systematic causality assessment. Serious AEFI are defined as any untoward medical occurrence that results in hospitalization, prolonged hospitalization, persistent or significant disability /incapacity or is life threatening and death. In addition AEFIs that maybe caused by a Programme error, serious unexplained AEFI occurring within 30 days after vaccination and not listed in the product label or events that cause significant parental or community concern are also serious AEFI requiring investigation.

In the advent of a serious AEFI case, the following reports are used to guide the AEFI investigation and causality assessment process:

i) **First Information Report (FIR):** Upon notification of a serious AEFI by a health worker/supervisor, the Medical Officer should begin an investigation immediately and collect the relevant information about the patient, vaccine and the immunization session and send the FIR to the District Immunization Officer (DIO) within 24 hours of the AEFI being reported. If considered serious the DIO should complete the FIR within 24 hours of receiving it and submit a copy to the state/national AEFI committees (Figure 1), the state immunization officer and the assistant commissioner of the immunization.

ii) **Preliminary Investigation Report (PIR):** The DIO spearheads the PIR. The PIR needs to be submitted to the State Immunization Officer, assistant commissioner of the immunization division no more than 7 days after the submission of the FIR. The PIR should contain patient details, relevant medical files, details of the immunization session, vaccine lot and batch number and other details missed out in the FIR.

iii) **Detailed Investigation Report (DIR):** Within 3 months of onset of the AEFI the DIO should compile all relevant documents including complete FIR and PIR, district reports, results of any lab tests conducted etc. Following this a meeting of the district AEFI committee should be organized in order to review the tests and come up with a hypothesis.

A dedicated email address has been established since 2009 for receiving AEFI reports has been created and can be accessed aefiindia@gmail.com

Types of AEFIs

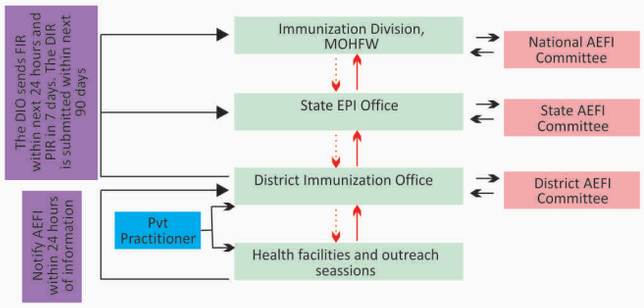

Figure 1: AEFI Reporting, routing, Timeline and Actions

(Ref: www.vaccine-safety-training.org/classification of aefis.html)

AEFIs can be classified as the following types;

1. Vaccine Reaction
2. Programme error-Vaccine transportation or storage error, Reconstitution error, Un-sterile practice, incorrect administration technique.
3. Coincidental reactions
4. Injection reactions
5. Unknown

1. Vaccine Reactions

- Non serious vaccine reactions
- Serious vaccine reactions

Non serious vaccine reactions

These include common mild side effects, such as local reactions (pain, swelling and/or redness), fever and systemic symptoms (e.g. vomiting, malaise, diarrhea), which can result as part of the normal immune response to the vaccine. Some of the non-antigenic vaccine components (e.g. adjuvant, stabilizers or preservatives) can also cause some of these reactions. The frequency and nature of common non serious vaccine reactions are outlined in Table 1. *(Ref: www.cdsco.nic.in/pharmacovigilance.htm)*

Table 1: Frequency and nature of non-serious vaccine reaction

Vaccine	Local reaction (pain, swelling, redness)	Fever (greater than 38°C)	Irritability, malaise and non-specific symptoms
BCG	Common	- -	
Hepatitis B	Adults up to 30% Children up to 5%	1 – 6%	
Hib	Up to 25%	- -	
Measles/MMR	Up to 10%	5-15%	Up to 5%(rash)
OPV	Less than 1%	Less than 1%[a]	
Tetanus/DT/Td	Up to 10%[b]	Up to 10%	Up to 25%
Pertussis (DPT-Whole cell)[c]	Up to 50%	Up to 50%	Up to 60%
Management	a. Cold cloth at injection site b. Paracetamol	• Give extra fluids • Wear light clothing • Tepid Sponge or bath • Paracetamol	Symptomatic

a Diarrhea, headache and/ or muscle pains
b Rate of local reaction likely to increase with booster doses up to 50-85%
c Acellular pertussis vaccine causes lower rates of injection.

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Occurrence of non-serious AEFI with any change in nature, severity or frequency should be reported. While a mild fever is a common reaction, high (39-40.4 0 C/102-104.8 0 F) to extreme fever (>40.5 0 C/1050 C) may indicate the possibility of sepsis or Toxic Shock Syndrome (TSS) resulting from a Programme error or a coexisting illness.

Serious vaccine reactions

Serious vaccine reactions are rare and may or may not have long term sequelae. For example serious reactions such as anaphylaxis though potentially fatal are treatable without leaving any long-term effects. An increase in the expected frequency of rare, serious reactions may indicate a problem with a specific batch of vaccine or a Programme error. It is important to reiterate that not all AEFIs are actually caused by vaccines. Table 2 summarizes the serious vaccine reactions, their time of onset and frequency.
(Ref: www.cdsco.nic.in/pharmacovigilance.htm)

Table 2: Frequency and nature of serious vaccine reactions

Vaccine	Reaction	Interval between vaccination and onset	Number of events per million doses
BCG	Suppurativeadenitis BCG Osteitis Disseminated BCG infection	2-6 months Up to several years 1-12 months	100-1000 - -
Hib	None known	-	-
Hep B	Anaphylaxis	0 -1 hour	1-2
Measles/MMR[a]	Febrile Seizures Thrombocytopenia Anaphylaxis	5-12 days 60 days 0-1 hour	330 30 1
OPV	Vaccine-Associated Paralytic Poliomyelitis[b]	4-30 days	Up to 0.4[b]
Tetanus	Brachial Neuritis Anaphylaxis Sterile abscess	2-28 days 0-1 hour 1-6 weeks	5-10 1-6 6-10
DPT	Persistent (>3 hours) inconsolable screaming Seizures Hypotonic Hypo Responsive Episode (HHE) Anaphylaxis/Shock	0-48 hours 0-3 days 0-24 hours 0-1 hour	1,000-60,000 600[c] 30-990 1-6
Japanese	Serious allergic reaction	0-2 weeks	10-1000
Encephalitis	Neurological events	0-2 weeks	1-2.3

a Reactions (except anaphylaxis) do not occur if already immune (~90% of those receiving a second dose): Children over six years are unlikely to have febrile seizures
b VAPP risk is higher for first dose (12 per 1.4 to 3.4 million doses) compared to 1 per 5.9 million for subsequent doses and 1 per 6.7 million doses for subsequent contacts
c Seizures are mostly febrile in origin, and the rate depends on past history, family history and age, with a much lower risk in infants under the age of 4 months

2. Programme Errors

Programme error occurs as a result of inappropriate transport, storage, handling, preparation and administration of vaccines. They must be immediately reported and investigated to ensure rapid response and corrective measures instituted quickly to prevent additional cases. A Programme error often occurs when a vaccinator does not follow the standard immunization policies and practices.

3. Coincidental Events

In general, coincidental events are clearly unrelated to the vaccination but still require investigation to confirm and classify the event (e.g. pneumonia after OPV). In general if the same or similar event also affected other in the same age group around the same time, but they didn't receive the suspect vaccine(s), then a coincidental event is more likely. There may also be clinical or laboratory evidence showing that the event is not related to the immunization. However, certain serious events may be blamed on the vaccines by the parents or community because of the close temporal association with immunization, especially if the vaccinated individual was previously healthy. Such cases need to be investigated, to allay public fear and maintain credibility and confidence in the immunization Programme.

4. Injection Reaction

Some vaccinated children or adults may develop reaction such as fainting, light headedness, dizziness, tingling around mouth and in hands and breath-holding (sometimes even leading to unconscious especially in young children) in anticipation to or as a result of an injection of any kind. This reaction is unrelated to the content of the vaccine.

5. Unknown

The cause of the event cannot be determined. All efforts must be made to rule out all the above mentioned causes before reaching this conclusion.

Causality assessment

Causality assessment for vaccines differs from that for drugs (Figure 2 & 3). For vaccines, causality assessment includes a systematic review of data about an AEFI case to determine the likelihood of a causal association between the event and the vaccine (s) received. Causality assessment is to be done at State or National level. The Quality of the Causality assessment depends upon

- The Quality of the AEFI case investigation and report and the effectiveness of the reporting system, and
- The Quality of the Causality review process

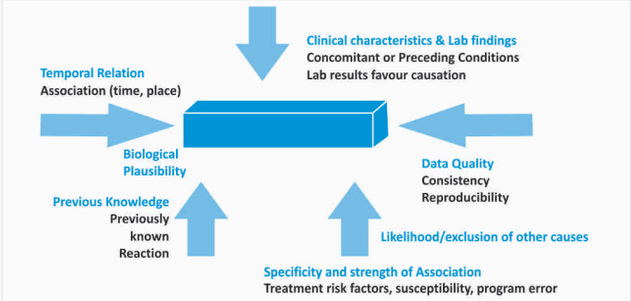

Figure 2: Causality Assessment of AEFI

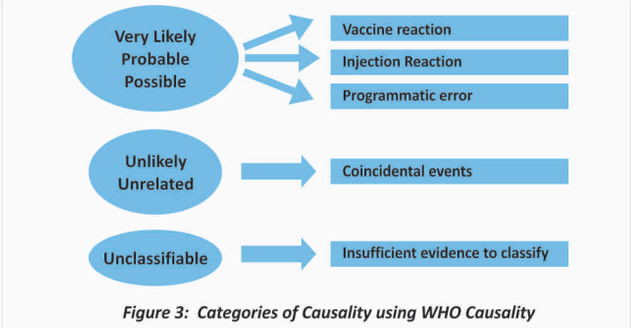

Figure 3: Categories of Causality using WHO Causality assessment criteria

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First Experience on AEFI Reported to NCC-PvPI

For the Period of 2010-12: An Analysis of Individual Case Safety Reports in Indian Database

Introduction

Active and timely immunization for pregnant women and children is paramount. In order to reach out to these beneficiaries around 8-9 lakh immunization sessions were conducted every month across the country both in rural as well as in urban areas with crores of doses of vaccines administered. To enhance the safety data collection, which would facilitate detection of a potential safety signal, a reinforced monitoring plan was introduced in India, according to the recommendations of the CDSCO. For these purposes, ADR Monitoring Centers (AMCs) under PvPI are also involved in the data collection process. For the first time in India, AMCs reported an Adverse Drug Reactions Following Immunization (ADRFI) through National Immunization Program for the year 2011 to 2012 directly to AMCs. Reporting formats (Suspected ADRs form) were disseminated to the Coordinators of AMC's.

Methods

In total 581 Individual Case Safety Reports (ICSRs) on vaccines received by the NCC-PvPI between April 2011 and December 2012, were taken into account for analysis. The health care professionals reported ADRs on vaccines to their respective AMCs by using suspected ADRs form which in turn was submitted to NCC through Vigiflow. The ADRs were entered manually into VigiFlow along with the mandatory field of 'Information on Primary Source' where the ADRs reporter has to specify his/her name, contact details and qualification. The number of received ICSRs was analyzed for seriousness and non-seriousness. The summary of the ICSRs are depicted in table 3.

Classification of Reporters

Under the PvPI, the persons submitted suspected ADRs forms (reporters) are classified into physicians, pharmacists, nurses, other health care professionals, other non-health care professionals and lawyers.

National Immunization Schedule Vaccines

ADRs involving any one of the administered vaccines under this national immunization schedule like BCG, OPV, DPT, Hepatitis B, Measles, Tetanus, MMR, Typhoid, Hepatitis B, Influenza, Pneumococcal, and Rabies were included.

Definitions and classification of Serious Adverse drug reactions Following Immunization

A 'serious' ADR is "any untoward medical occurrence that at any dose results in hospital admission or prolongation of existing hospital stay, result in persistent or significant disability/incapacity, or is life threatening and death" and other unknown seriousness. The summary of the serious ADRs are depicted in table 4.

Table: 3 Summary of reported vaccine ICSRs from April 2011 to December 2012 to NCC-PvPI

Name of the Vaccine	Death	Life threatening	Hospitalized	Congenital anomaly	Others	Total serious ICSRs	Total Non serious ICSRs	Total ICSRs	Total ADRs
BCG vaccine	0	0	1 (along with Hep B, DPT)	0	1	2	13	15	15
DPT vaccine	0	3	15(1 with HepB,BCGand 2 withHep B)	0	6(2 with Polio)	24	250	282	297
Hepatitis B vaccine	0	1	4(2 with DPT and with BCG,DPT)	0	0	5	43	48	48
Haemophilus Influenza type B vaccine	0	0	1 (along with DPT)	0	0	1	11	12	12
Influenza vaccine	0	0	0	0	0	0	1	1	4
Measles	0	0	0	0	0	0	7	7	10
MMR vaccine	0	0	0	0	0	0	15	15	15
Pneumococcal vaccine	0	1	0	0	0	1	1	2	3
Polio vaccine	0	0	0	0	2 (with DPT)	2	186	188	198
Rabies vaccine	0	0	1	0	0	1	4	5	5
Tetanus vaccine	0	0	0	0	0	0	2	2	2
Typhoid	0	0	0	0	0	0	4	4	4
Total	0	5	22	0	9	36	537	581	613

Table: 4 Summary of Serious Vaccines ICSRs reported to NCC-PvPI for the period of April 2011 to December 2012

Name of the Vaccine	No of Serious ICSRs	WHO-Preferred Terms	Reporter	Labeled/ Unlabeled	Outcome of ADR	Gender of Serious ICSRs
BCG vaccine	2	1-Dyspnoea, 1-Injectionsite infection	2-Other healthcare professionals	2-Labelled	1-recovering, 1-not recovered	1-male, 1-female
DPT vaccine	24	15-Convulsions, 2-Fever, 1-Cellulitis, 1-Rash, 1-Injectionsite swelling, 1-Eczema, 1-Staring, 2-Dyspnoea	5-Physicians, 1-Pharmacist, 18-Other healthcare professionals	19-Labelled 5-Unknown	3-not recovered, 13-recovered, 6-recovering, 1-Unknown, 1-Blank	9-female, 15-male
Hepatitis-B vaccine	5	1-Fever, 1-convulsion, 1-Dyspnoea, 1-Eczema, 1-Bronchospasm	4-Other healthcare professionals 1-Pharmacist	4-Labelled, 1-Unknown	2-resolved, 3-resolving	3-male, 2-female
Haemophilus Influena type-B vaccine	1	1-Induration	1-Pharmacist	1-Unknown	1-recovering	1-female
Pneumococcal vaccine	1	1-Anaphylactic reaction	1-Pharmacist	1-Unknown	1-recovered	1-male
Polio vaccine	2	2-Convulsions	2-Other healthcare professionals	1-Labelled, 1-Unknown	2-recovering	2-male
Rabies Vaccine	1	1-Vasculitic rash	1-Pharmacist	1-Unknown	1-recovered	1-female

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Regulatory Matters

International

Novartis obtains EU approval for meningitis B vaccine "Bexsero"

The European Commission granted marketing authorization to Novartis in the European Union for Bexsero on 14 January 2013. It is the first vaccine to prevent the leading cause of life threatening meningitis across Europe and is available as a suspension for injection in a pre-filled syringe. It contains parts of the bacteria Neisseria meningitidis (N. meningitidis) group B. Bexsero is used to protect individuals from the age of two months and older against invasive meningococcal disease.

The most common side effects with Bexsero in children up to 10 years of age (seen in more than 1 patient in 10) are loss of appetite, sleepiness, unusual crying, diarrhea, vomiting, rash, fever and irritability as well as tenderness, swelling, hardness and redness of the skin at the injection site. The most common side effects with Bexsero in adolescents (seen in more than 1 patient in 10) are headache, nausea and malaise (feeling unwell), myalgia (muscle pain) and arthralgia (joint pain) as well as pain, swelling, hardness and redness of the skin at the injection site. The medicine can only be obtained with a prescription.

(Ref:http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/human_med_001614.jsp&mid=WC0b01ac058001d124)

Package inserts amendment in Cervarix®, GSK (Human Papilloma virus vaccine)

The Human Papillomavirus (HPV) vaccine is the first vaccine against cancer which prevents infection with certain species of human Papillomavirus associated with the development of cervical cancer, genital warts, and some less common cancers. Two HPV vaccines are currently on the market: Gardasil and Cervarix. Health Science Authority (HSA) Singapore has approved the Anaphylactic & anaphylactoid reactions, angioedema, syncope or vasovagal response to injection, sometimes accompanied by tonic-clonic movements in Cervarix® as a package insert changes due to these new ADRs reported in post marketing surveillance.

(Ref: http://www.hsa.gov.sg/label_amend (Jan-April 2010)

Omontys (Anaemia drug) was recalled by FDA

Omontys is an erythropoiesis-stimulating agent (ESA) that aids in the formation of red blood cells, was approved by the FDA in March 2012 for the treatment of anaemia in adult patient which is manufactured by Affymax, Inc and Takeda Pharmaceutical Company Limited.

USFDA has been recalled Omontys on 23.02.2013 due to reports of anaphylaxis, a serious and life threatening allergic reaction and instruct to the health care providers to stop the using of Omontys. The FDA also asks health care professionals and consumers to report any adverse reactions with this drug through FDA's Med Watch Program

(Ref:http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm340899.htm).

Thirty-fifth annual meeting of National Pharmacovigilance Centers at Brazil

Brazil hosted the thirty-fifth annual meeting of representatives of National Pharmacovigilance Centers participating in the WHO Programme for International Drug Monitoring on 11-14 Nov 2012. In this meeting working groups discussed the building capacity for the monitoring of adverse events following immunization (AEFI). The group agreed that effectiveness and safety of vaccines might vary across countries and made some recommendations are following:

1. WHO to improve the availability of background data in low and middle income countries (LMIC) by pooling placebo data from clinical trials.
2. National centers and countries to improve collaborations between medicines and vaccines PV systems; and share experiences on the introduction of new vaccines in their settings.
3. Both national centers and WHO to:
   - Offer more training and build capacity in vaccine PV, especially in LMIC
   - Translate the 'online' WHO vaccine PV course into more languages
   - Develop and implement new methodologies in AEFI data collection, causality assessment and signal detection Apart from this working groups also discussed various other pertinent issues in Pharmacovigilance (Ref: WHO Pharmaceuticals Newsletter No. 1, 2013)

National News

- **Permission/ license will be treated as cancelled if manufacture fails to launch their product for marketing within a period of six months from date of issued**

As per Schedule Y, Periodic Safety Update Reports (PSURs) of new drugs are required to be submitted to regulatory authority for assessing the safety and efficacy in post marketing scenario. But it has been noticed that the manufacturers do not launch the product as well as not submit the required PSURs after years of getting approval from regulatory authority. Therefore assessment of safety and efficacy of such new drug in post marketing scenario remains incomplete.

In a circular dated January 10, 2013 to all State Drug controllers, the DCG(I) indicated that permission/ license will

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be treated as cancelled if manufactures fails to launch their product for marketing in the country within a period of six months from obtaining the permission/ license from CDSCO
(Ref: http://www.cdsco.nic.in/cancellation_of_permission.pdf)

- **Safety and efficacy of the FDC of Flupenthixol + Melitracen on Indian population-under vigilance**

Flupenthixol + Melitracen tablet was approved by CDSCO in 1998 as a Fixed Dose Combinations (FDC) for manufacturing and marketing in the country. However question has been raised on the safety and efficacy of this drug internationally. The Drugs Regulatory Authority of India has been decided that the issue of safety & efficacy of the FDC is under examination in consultation with the expert committee.

In a circular dated January 10, 2013 to all States/UTs Controllers, the DCG(I) has requested to instruct the manufacturers of the FDC of Flupenthioxol + Melitracen to establish safety and efficacy of drug within 6 months, failing which the drug would be considered for being prohibited for manufacture and marketing in the country.
(Ref: http://www.cdsco.nic.in/to_established_the_safety.pdf)

- **Safety and efficacy of Fixed Dose Combinations (FDCs)**

To maintain the Safety and efficacy of FDCs, the office of the DCG(I) issued a circular dated 15 January 2013 to all state/UTs Drugs Controllers that if any license approved by State Licensing Authorities before 01.10.2012 without the permission of DCG(I), the State Drugs Controllers requested to ask to the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing such FDCs will considered for being prohibited for manufacturing and marketing in the country.As regards the new FDCs which licensed by the State Licensing Authorities after 01.10.2012 without approval of DCG(I), the same will be considered for being prohibited for manufacturing and marketing in the country
(Ref:http://www.cdsco.nic.in/Approval_of_the_safety_and_efficacy_of_FDC.pdf)

- **Analgin, Dextropropoxyphene, and Tolperisone are under safety review**

The Indian drug regulatory authority, CDSCO has started to review of Analgin, Dextropropoxyphene, and Tolperisone (FDC) because the issues rose against the safety of these drugs by nationally and internationally. In this regard NCC has submitted the Individual Case Safety Reports with respect to Analgin, Dextropropoxyphene and Tolperisone to CDSCO for regulatory interventions.

Symposium cum Awareness Programme

A "National symposium on ADRs Monitoring and Pharmacovigilance was organized by Vardaan Welfare Society with technical support of Indian Pharmacopoeia Commission on 9th and 10th February 2013 at Ghaziabad. The symposium was focused on need of Pharmacovigilance in India as well as to create awareness among the healthcare professionals. Dr. G N Singh inaugurated the symposium and emphasized about the real need of Pharmacovigilance in India. NCC, PvPI officials participated and delivered talk on rational use of medicines and the current status of the Pharmacovigilance Programme of India.

Third Working Group Meeting of PvPI

The third Working Group of PvPI meeting was held on 29th January 2013 at CDSCO, Head Quarters, New Delhi under the chairmanship of Dr. G. N Singh.Professor S. K Gupta, Professor Y.K. Gupta, Dr. Surinder Singh, Dr. Parthasarathi, Dr. Bikash Medhi, Dr. Urmila Thatte and Dr. Sanjay Singh were participated to discuss various issues on PvPI.

Acknowledgements

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Important Activities under PvPI

WHO NRA Assessment in India-Report Closure Meeting was held on 5th April 2013 at CDSCO-HQ, New Delhi - Sh. Keshav Desiraju, Secretary, Dr. Jagadish Prasad, DGHS, Sh. R K Jain, Additional Secretary , DG, Dr. A K Panda, Joint Secretary-Regulation, Dr. G. N. Singh, DCG(I) from the Ministry of Health & Family Welfare, Government of India; Dr. Nata Menabde WHO representative to India, Dr. David Wood, WHO-HQ, Mr. Lahouari Belgharbi, WHO Team Leader-NRA Assessment, Dr. Surinder Singh, Director, NIB & Dr. Madhur Gupta, WHO-Country office (India) were participated

Shri. Keshav Desiraju, Secretary , MoHFW, Government of India is addressing in WHO NRA Assessment in India-Report Closure Meeting held on 5th April 2013 at CDSCO HQ. Dr. Jagadish Prasad, DGHS also in the picture

PvPI-Haemovigilance review meeting was held on 23.01.2013
Under the Chairmanship of Professor S.K. Gupta Advisor, PvPI & Dr. Surinder Singh, Director, NIB to review the progress of Pharmacovigilance & Haemovigilance Programmes for the Year 2012

Recognition of NCC-PvPI by WHO-NRA assessment Team
WHO NRA assessment in India and affiliated Institutions were held on 10-14 December 2012, as a part of this assessment first time NCC-PvPI, Vigiflow Vaccines-ADRs data was assessed by WHO-NRA Assesser Ms. Siti Asfijah Abdoellah (WHO-NRA/NADFC, Indonesia) at IPC & A.Visala (DDCI,CDSCO) Dr.Sujeet Kumar Jain (WHO-Country office India), Dr. Jyoti Joshi Jain (Senior Advisor- Immunization safety surveillance, ITSU) also visited IPC

A Premier Symposium on ADR Monitoring & Pharmacovigilance for Public & Health Care Professionals held on February 9th & 10th, 2013 at ALT Centre, Ghaziabad, India, in Technical collaboration with NCC – PvPI, with a dynamic presence of Dr. G.N. Singh (DCGI) & Dr. S. K. Gupta (Advisor, PvPI), Dr. K. Bangarurajan, DDC(I), Mr. S. L Nasa, Registrar Delhi Pharmacy council.

Two days workshop of CDSCO on Function to Pharmacovigilance including AEFI with WHO-HQ team-Dr. Patrick Juber, Dr. Stephane Guichard held on 28 & 29 January 2013 at CDSCO - HQ, New Delhi.

PMS Arts & Communications

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