GOVERNMENT OF KERALA
HEALTH & FAMILY WELFARE(F) DEPARTMENT

No.921393/F1/2016/H&FWD Dated, Thiruvananthapuram, 28/10/2016

CIRCULAR

Sub:- H&FWD - Adverse Drug Reaction - Reg.

Pharmacovigilance tracking Adverse Drug Reaction (ADR) are an important component of ensuring drug safety in the State. It has been decided that ADR reporting has to reach 100% in Government hospitals. Therefore, hospitals shall take the following steps to ensure that reports are complied and sent to the Adverse Drug Reaction Monitoring Centres (AMCs).

1) Every hospital shall nominate a Nodal Officer for ADR reporting. Name, Phone Numbers and e-mail ID of the Nodal Officer shall also be intimated to the State Co-ordinator Dr.Ramani. P.T, Professor and HoD, Department of Pharmacology, Government Medical College, Thiruvananthapuram

2) Doctors, Administering Nurses and Pharmacists concerned shall inform Adverse Drug Reaction, if noticed, to the Nodal Officer who will in turn forward the same to the ADR monitoring centres.

3) Professor and HoD, Department of Pharmacology, Thiruvananthapuram will compile quarterly reports regarding ADR reported from the State and forward the same to the Director of Medical Education, Director of Health Services and to Government in addition to the usual practice of reporting ADRs to DGHS.

ADR form, write-up on Drug Reaction, contact details are attached as Annexure A, B & C respectively.

A. JAMES RAJ
Deputy Secretary to Government

To

The Director of Medical Education, Thiruvananthapuram.
The Director of Health Services, Thiruvananthapuram.
You are requested to upload the Circular on your website

The Director of Indian Systems of Medicines
The Indian Medical Association
The Qualified Medical Practitioners Association
All AMCs

Forwarded/By Order

Section Officer

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

1. Patient Name: 2. Age: 3. Sex: 4. Weight :

5. Name of suspected drugs:
Manufacturer, Batch No., Exp date:

6. Dose used: 7. Route used: 8. Frequency (OD, BD etc)

9. Therapy date Date started: Date stopped:

10. Indication:

11. Date of ADR started: Date of recovery (ADR):

12. Describe reaction/Problem:

13. Action taken: (Drug withdrawn/ dose increased/ dose reduced/ dose not changed/ not applicable/ unknown)

14. Reaction reappeared after reintroduction *(please tick):* Yes/No/ Effect Unknown;
Dose (If reintroduced):

15. Concomitant medical product – (dose, route, frequency, dates) (Exclude those used to treat reaction):

16. Relevant tests/lab data with dates:

17. Relevant medical/ medication history (allergies, race, pregnancy, smoking, alcohol use/hepatic/renal dysfunction etc.)

Seriousness of reaction: Yes/No; ☐ Death; ☐ Congenital anomaly; ☐ Life threatening; ☐ Disability; ☐ Hospitalization/Prolonged; ☐ Congenital anomaly; ☐ Required intervention to prevent permanent impairment /damage; ☐ Other (specify)

19. Outcome: ☐ Recovered; ☐ Recovering; ☐ Not recovered; ☐ Fatal; ☐ Recovered with sequelae; ☐ Unknown

20. Reporter Details: Name: Designation:

Phone: Signature:

Date of this report:

Ann: B

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector 23, Raj Nagar, Ghaziabad-201002
Tel: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage

Report non serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to [redacted] or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

[redacted]

(9:00 AM to 5:30 PM, Working Days)

No medicinal product is completely devoid of risk and a continuous monitoring of these products is required to ensure safety. The Pharmacovigilance Programme of India (PvPI) was launched in 2010 with the objective of safe & rational use of medicine. Indian Pharmacopoeia Commission (IPC) at Ghaziabad is functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) under the aegis of Ministry of Health and Family Welfare, Government of India. It collects and evaluates spontaneous reports of adverse reactions to medicines, vaccines, medical devices and herbal products from all Health Care Professionals (HCPs) & consumers/patient. The Medical Colleges and attached Hospitals are the cornerstone of PvPI. They act as Adverse Drug Reaction Monitoring Centres (AMC) which are responsible for collecting the Individual Case Safety Reports (ICSRs) in the Suspected Adverse Drug Reaction Reporting form. The ICSR data is then entered into the Indian patient safety database by using the Vigiflow software. Vigiflow also facilitate easy submission of Indian ICSRs to the WHO Global ICSRs Database, Vigi base. The PvPI data is utilised by Central Drug Standard Control Organisation (CDSCO) for the monitoring of drug safety information and implementation of required changes in the prescribing information/Package insert. The data analysed at NCC PvPI is communicated to the AMCs by periodic news letters. This data is useful in updating the knowledge associated with the use of medication in an Indian context.

Adverse reactions of drugs continue to remain as an important public health issue. Despite the increased incidence of ADRs, very few are curently being reported. Therefore all health professionals are requested to report suspected adverse drug reaction to the nearest AMC or directly to the National Coordination Center at pvpi.ipcindia@gmail.com or pvpi@ipcindia.net in the attached ADR reporting form. **Submission of an ADR report does not have any legal implication on the reporter and the confidentiality of the reporter will be maintained.**

In this context Kerala Government hereby entrust Professor & Head of the Department of Pharmacology, Government Medical College, Thiruvananthapuram as state level nodal officer in compiling the ADR statistics from various AMCs in Kerala.

So in addition to uploading of ADR data to NCC, the AMC coordinator in each centre shall email the ADR statistics to the state coordinator in the given address and in the prescribed format.

Sl. No.	Name of the Drug	Suspected ADR	Date of start of reaction	Outcome	Causality assesment	Seriousness

POLICY OF PHARMACOVIGILANCE PROGRAMME

Vision

To improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines.

Scope and Objective

- To create a nation-wide system for patient safety reporting
- To idenify and analyse new signal from the reported cases

- To analyse the benefit-risk ratio of marketed medications
- To generate evidence based information on safety of medicines
- To support regulatory agency in the decision making process on use of medications
- To communicate the safety information on use of medicines to various stakeholders to minimise the risk
- To emerge as a national centre of excellence for pharmacovigilance activities
- To collaborate with other national centres for the exchange of information and data management
- To provide training and consultancy support to other national pharmacovigilance centres across globe
- To promote rational use of medicine

Utilization of ADR Data

- ***Education :*** The information from PvPI data is useful in updating the knowledge associated with the use of medication to health care professionals.
- ***Drug regulation :*** After approval of a medicinal product, all available domestic and international safety information is continously monitored by the CDSCO and marketed authorisation holders. The PvPI data can be useful in review of product safety inforamtion and implementation of required changes in the prescribing information / pack insert
- ***Risk Management:*** The identification, assement, and prioritization of risk followed by coordinated and economical application of resources to minimize, monitor and control the probability and impact of unfortunate events is known to risk management.
- ***Signal generation and strengthening :*** A major aim of pharmacovigilance is the early detection of signals with regard to possible adverse reactions. A signal may be strengthened by further analysis can help the regulatory system in performing regulatory activities.

Confidentiality

The patient's identify is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. **Submission of an ADR report does not have any legal implication on the reporter and the confidentiality of the reporter will be maintained.**The data is uploaded through Vigiflow user name and password provided to each AMC by WHO.

Annexure

Contact Address : e-mail id : amcgmct@gmail.com
dr.pt.rami@gmail.com
Phone No : 0471 – 2528378 - Department of Pharmacology
9446593762 - Dr. Ramani – Professor & Head
09686330269 - Smt. Sabitha Raj – Pharmacovigilance Associate

The list of AMCs in Kerala are also enclosed.

LIST OF AMCs (Adverse Reaction Monitoring Centre)

- AIMS (Amritha Institute of Medical Sicences - Kochi
- AIMS (Amala Institute of Medical Sciences - Thrissur
- CMC (Co-operative Medical College) - Cochin
- GMC (Government Medical College) - Kottayam
- GMC (Government Medical College) - Kozhikode
- GMC (Government Medical College) - Palakkad
- GMC (Government Medical College) - Thiruvananthapuram
- PIMS (Pushpagiri Institute of Medical Sciences - Thiruvalla
- TDMC (Thirumala Devaswam Medical College) - Alappuzha
- SGMC & RF(Sree Gokulam Medical College & Research Foundation) - Thiruvananthapuram

Sl. No.	Name and Address of co ordintors of AMCs	E-mail	Mobile No.
1	Dr. Seema .P M Govt. Medical College P.O, Kozhikode-673008	seemapharmac@gmail.com	09497082050
2	Dr. Prabitha Govt. Medical College, Gandhinagar, Kottayam-686008	adrpharmac.mck@gmail.com	09447605340
3	Dr. Santosh Pillai Pushpagiri Institute of Medical Sciences and Research centre, Pushpagiri Medical College	pcm@pushpagiri.in	09447596426

	Hospital, Tiruvalla-689101		
4	Dr. Deepu jacob Chacko Amala Institute of Medical Sciences, Amala Nagar, P.O Thrissur-680555	vigil.amala@gmail.com	08157020222
5	Dr. Kala Kesavan Govt. T.D. medical college, vandanam, Alappuzha-688005	drkalakesavan@yahoo.co.in tdmcalappuzha@gmail.com	09847034504
6	Dr. Ramani P.T Dr. Annapoorna (Deputy coordinator) Government Medical College, Medical College PO, Thiruvananthapuçam-695011	dr.pt.rami@gmail.com amcgmct@gmail.com	09446593762 0471- 2528378
7	Dr. Thresiamma Thomas K Amrita Institute of Medical Sciences, Kochi, Kerala-68204	drthresiamma@aims.amrita.edu	09349503287
8	Dr S. N Veenasree Cochin Medical College, HMT colony P.D, kalamassery, Cochin-683503	veenabiju73@yahoo.com	09995446530
9	Dr. N. Sunil Government Medical College, Palakkad-678013	docsunil2005@yahoo.com	09645666189
10	Dr. P. Sobha Sree Gokulam Medical College & Research Foundation	sobhaent@gmail.com	09895885395