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PvPI-Frequently asked questions

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Q1: What is Pharmacovigilance?

Ans: Pharmacovigilance, as defined by the World Health Organization, is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

Q2: What is the Scope of Pharmacovigilance?

Ans: The scope of Pharmacovigilance extends to include Modern medicines, the medicines of herbal origins/ traditional /complementary medicine, biological products including blood product, vaccines, similar biologics and safety of the medical device.

Q3: What is an Adverse Event (AE)?

Ans: An adverse event is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does necessarily have to have a causal relationship with treatment.

Q4: What is an Adverse Drug Reaction (ADR)?

Ans: It is a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of a disease or for modification of physiological function of the body.

Q5: What is a serious ADR or a Serious Adverse Event (SAE)?

Ans: A serious adverse event or serious adverse reaction is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in [patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity or
- Is a congenital anomaly or birth defect

Q6: Who can report an Adverse Drug Reaction?

Ans: All healthcare professionals including clinicians, dentists, pharmacists, nurses etc, and non-healthcare professionals (patients/consumers) etc can report ADRs.

Q7: Why to report ADR? What type of Adverse Drug Reaction should be reported?

Ans: As a healthcare professional and citizen of India its moral responsibility to report adverse reaction associated with pharmaceutical products to safeguard public health and help in improving patient safety.

PvPI encourages reporting of all types of suspected adverse reactions with all pharmaceutical products irrespective of whether they are known or unknown, serious or non-serious and frequent or rare.

Q8: What is the Pharmacovigilance Programme of India (PvPI)?

Ans: The Pharmacovigilance Programme of India is a flagship drug safety- monitoring programme of Government of India which collects, collates and analyses drug-related adverse events generally received through various adverse drug reaction monitoring centres. The vision of PvPI is to improve patient safety and welfare in the Indian population by monitoring drug safety and thereby sensitizing the stakeholders regarding reducing the risk associated with the use of medicines. There are 250 ADR Monitoring Centres under PvPI including 21 Revised National Tuberculosis Control Programme (RNTCP) centres and 20 Anti- Retroviral Therapy (ART) centres for AIDS control. The RNTCP centres include six centres for monitoring Bedaquiline centres, too.

Q9: How do we report ADRs through PvPI?

Ans: If there is any suspicion that an adverse event or adverse reaction has occurred, the health care professionals attending to the patient, can fill up the suspected ADR form or if a patient suspects that he/she has experienced an ADR can report to the nearest ADRs Monitoring Centres (AMCs) under the Pharmacovigilance Programme of India (PvPI). The details of AMCs are given on the website of IPC i.e. www.ipc.gov.in

Healthcare professionals can fill in the "Suspected Adverse Drug Reaction Reporting Form" by clicking the following link http://www.ipc.gov.in/PvPI/adr/ADR%20Reporting%20Form.pdf and Similarly Consumers can fill in the MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS) by clicking the following link http://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/430-adr-reporting-form-for-consumers-in-hindi-other-vernacular-languages.html is available for consumers and send it to nearest the Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordinating Centre (NCC) PvPI. You can directly mail the form to pvpi@ipcindia.net or ipclab@vsnl.net.

Toll-free helpline number (1800-180-3024) can also be used to directly report an ADR.

You can also report Adverse Drug Reaction through "ADR PvPI" Mobile app (Android version) by it from Google play store.

Q10: What are the timings to report an ADRs through helpline?

Ans: You can call on above helpline number to report ADR on all working days (Monday-Friday) from 9:00AM-5.30 PM. If a call is not responded then one can drop a voice message on voice recording system.

Q.11: What are the different recourse materials published by the NCC-PvPI?

Ans: To communicate the findings and regulatory status of medicine in India as well as globally to all stakeholders, NCC-PvPI publishes the newsletter i.e PvPI News Letter three issue in a year. NCC PvPI publishes also Guidance Documents for spontaneous adverse drug reaction reporting, a Performance report of Pharmacovigilance Programme of India and Pharmacovigilance guidance document for marketing authorization holder of Pharmaceutical Products.

Q12: Can Newsletter and other documents be downloaded from the website?

Ans: PvPI e-Newsletters can be downloaded from www.ipc.gov.in, under navigation, PvPI updates.

Q. 13: What is an Adverse event following immunization (AEFI)?

Ans: An Adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease