DABDAC/PVC/0125 .

NOTICE – First Meeting (Formation of Pharmacovigilance Cell)

Date: 13/12/2025

All faculty members and concerned staff are hereby informed that the first meeting for the formation of the Pharmacovigilance (PV) Cell will be held as per the details below:

Date: 23rd December 2025

Time: 11:00 AM

Venue: Principal's Chamber

Agenda:

- Formation of Pharmacovigilance Cell
- Appointment of PV Cell Members
- Introduction to Pharmacovigilance activities
- Planning initial SOP implementation
- Discussion on ADR reporting system in the institution

All the faculty members are requested to attend the meeting without fail.

Principal
Dr. Bhanudas Dere College of Ayurveda

Principal
Dr. Bhanudas Dere Foundation's
Dr. Bhanudas Dere College of Ayurved
Karhe,Tal.Sangamner, Dist. Ahilyanagar

Dr. Bhanudas Dere College of Ayurved Karhe
College Code AYU 0858

Pharmacovigilance Cell SOP (Standard Operating Procedure)

1. Purpose

To establish guidelines for the effective operation of the pharmacovigilance (PV) cell within SST Ayurveda Mahavidyalaya & Hospital, Sangamner.

2. Scope

This SOP applies to all personnel involved in pharmacovigilance activities within SST Ayurveda Mahavidyalaya & Hospital, Sangamner. Including:

Medical safety officers

Pharmacovigilance case handlers

Data entry personnel

Quality assurance personnel

3. Responsibilities

Medical Safety Officer:

Oversees the overall pharmacovigilance program.

Reviews and evaluates adverse event reports.

Pharmacovigilance Case Handlers:

Collects, verifies, and processes adverse event reports.

Maintains case files.

Data Entry Personnel:

Enters adverse event data into the pharmacovigilance database.

Ensures data accuracy and completeness.

Regulatory Affairs Personnel:

Manages regulatory submissions related to pharmacovigilance.

- Ensures compliance with regulatory requirements.

- **Quality Assurance Personnel:**
- Monitors the pharmacovigilance system for compliance with SOPs and regulations.
- Conducts audits and inspections.

4. Procedures

- **Adverse Event Reporting:**
- All adverse events associated with the organization's products (register clinical trials) must be reported to the PV cell.
- Reports should be submitted in a timely manner, using the appropriate reporting form.

Case Investigation:

- For serious or unexpected adverse events, a thorough investigation will be conducted.

- **Safety Assessment:**
- The safety assessment will evaluate the causal relationship between the adverse event and the product.
- Risk-benefit assessments will be conducted to determine if any regulatory actions are necessary.

- **Reporting to Regulatory Authorities:**
- Adverse events that meet the criteria for reporting to regulatory authorities will be submitted in accordance with local and international regulations.

- **Safety Signal Detection:**
- The PV cell will use data mining techniques and other methods to identify safety signals.
- If a safety signal is detected, a thorough investigation will be conducted.

- **Safety Communication:**
- If necessary, the organization will communicate safety information to healthcare professionals and patients.

Periodic Safety Update Reports (PSURs):

PSURs will be prepared and submitted to regulatory authorities as required.

5. Documentation and Record Keeping

For identifying ADR, to keep check on functioning of cell meeting of pharmacovigilance cell will be held with preintimated notice.

Quorum for meeting: 50% of members must attend.

Review and Revision

This SOP will be reviewed and revised periodically (once a year if needed) to ensure its continued effectiveness and compliance with evolving regulations.

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