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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

आयुर्वेद, सिद्ध, सोवा-रिग्पा, यूनानी और होम्योपैथी प्रणालियों के लिए फार्माकोविजिलेंस केंद्र - सेवा आवश्यकताएँ

Draft Indian Standard

Pharmacovigilance Centre for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy (ASU & H) systems — Service Requirements

ICS 03.120.10

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FOREWORD

(*Formal Clause would be added later*)

Pharmacovigilance is the scientific discipline focused on minimizing the risks of drug-related harm to patients. While traditional Indian medicine systems have been practiced for centuries, the globalized world has brought increasing scrutiny regarding their clinical safety. A common misconception is that all naturally derived drugs are inherently safe. Traditional medicine itself recognized the toxicity of Various formulations & procedures and mentioned specific processing for their safe use.

Concerns also arise from the concomitant use of Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy (ASU & H) medicines with conventional drugs, possibly leading to drug interactions. A majority of reported adverse events associated with herbal or traditional products are often attributable to inappropriate usage, or lack of adherence to recommended guidelines.

Pharmacovigilance serves as critical public health function by monitoring and mitigating the risks associated with medicines, including traditional ones. Given that many people use traditional medicines at some point their lives, pharmacovigilance is crucial for ensuring the safer and effective use of medicines for everyone. It encompasses the detection, assessment, understanding, and prevention of adverse reactions.

In developing this Indian Standard for Pharmacovigilance Centres, significant guidance was drawn from the guidelines of the Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) Scheme, a central sector scheme for promoting pharmacovigilance for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs, issued by the Ministry of Ayush, Government of India. Additional inputs were drawn from publicly available information in both print and electronic media. There is a scope for alignment with international pharmacovigilance frameworks such as the World Health Organization – Uppsala Monitoring Centre (WHO-UMC), and the International Council for Harmonisation – Guideline E2E on Pharmacovigilance Planning (ICH-E2E), with necessary adaptations to suit the unique needs of the ASU&H systems.

The criteria for minimum qualifications and experience of staff have been formulated based on the existing provisions for staffing at different levels of the pharmacovigilance network, for data collection, analysis, and reporting of adverse drug reactions (ADRs).

Draft Indian Standard

PHARMACOVIGILANCE CENTRE FOR AYURVEDA, SIDDHA, SOWA-RIGPA, UNANI, AND HOMOEOPATHY (ASU&H) SYSTEMS — SERVICE REQUIREMENTS

1. SCOPE

This standard specifies the minimum requirements for operations, infrastructure, performance benchmarking, and staff qualifications for pharmacovigilance centres of Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy (ASU&H) systems.

2. TERMINOLOGY

For the purpose of this standard, following terms and definitions shall apply.

2.1 Adverse Drug Reaction (ADR)
A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

2.2 Adverse event
Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

2.3 Audit
A systematic and independent examination (conducted by personnel, independent of the centre) of centre's activities and documents to determine whether centre's activities were conducted and the data were recorded, analysed and accurately reported.

2.4 Causality assessment
The process of evaluating the likelihood that an observed adverse event (AE) is actually caused by a specific drug.

2.5 Coordinator
Designated in-charge of a particular Pharmacovigilance centre.

NOTE- The person appointed as Coordinator shall possess the qualification and experience as specified in Table 1. The key responsibilities of the Coordinator are outlined under Clause 4.3.3.

2.6 Pharmacovigilance
The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problem.

2.7 Pharmacovigilance Centre
A designated unit, responsible for collecting, documenting, and reporting adverse drug reactions (ADRs) associated with Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy (ASU&H) medicines.

2.8 Serious Adverse Drug Reaction
A serious adverse reaction is any untoward medical occurrence that at any dose, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity is life-threatening nature.

2.9 Side Effect
An unintended effect of a pharmaceutical product that occurs at doses normally used in humans, which is related to the pharmacological properties of the drug, but is not necessarily harmful.

2.10 Signal
Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

3. GENERAL REQUIREMENTS

3.1 Basic Requirements

The compliance with the following general requirements shall be ensured for establishing and maintaining an effective Quality Management System (QMS) in Pharmacovigilance Centres:

a) A clear mandate for monitoring, collecting, documenting, and reporting adverse drug reactions (ADRs) and other safety-related issues pertaining to ASU&H medicines, formulations, and therapies in compliance with National Pharmacovigilance SOP's and WHO-UMC standards.
b) A dedicated team with requisite training in pharmacovigilance practices.
c) Infrastructure, including facilities for data entry, record keeping, storage, and secure access to reports, to support the pharmacovigilance activities.
d) Standard Operating Procedures (SOPs) for all key processes inclusive of standard casualty assessment tools as per Annex A.
e) Compliance with guidelines issued by the Ministry of Ayush or other regulatory authorities approved by Ministry of Ayush.
f) A risk management plan outlining procedure for identifying, evaluating, mitigating, and communicating product- or system-specific safety risks.

3.2 Internal and External Audit

The QMS shall incorporate clearly defined mechanisms for both internal and external audits to ensure continuous monitoring, compliance, and improvement.

a) The Pharmacovigilance Centre shall conduct periodic internal audits (at least once annually) to assess the conformity of its activities with the defined SOPs, national pharmacovigilance guidelines, and statutory obligations.
b) Internal audits shall be carried out annually by personnel who are independent of the function being audited. In case of potential conflicts of interest, third-party or independent audits may be conducted.
c) In addition to internal audits, the centre shall cooperate with external audits or inspections conducted by National Coordinating Centre, Ministry of Ayush or other regulatory authorities approved by the Ministry of Ayush.

d) Records of both internal and external audits, including responses and follow-up actions, shall be maintained as part of the QMS documentation.

4. INSTITUTIONAL PERSONNEL AND RESOURCES

Pharmacovigilance Centres shall ensure adequate institutional support, qualified personnel, and essential resources to carry out the functions effectively.

4.1 Organization/Institution

4.1.1 The Pharmacovigilance Centre shall be housed within a teaching institution recognized by National Commission for Indian System of Medicine (NCISM) or National Commission for Homoeopathy (NCH) or a research organization under Research Councils, after approval of authorities.

4.1.2 A formal institutional commitment shall be documented to offer administrative and technical support related to pharmacovigilance activities.

4.1.3 The head of the organization shall be responsible for the following;

a) Appointing a designated Coordinator for Pharmacovigilance centre;
b) Ensuring that adequate competent, trained, experienced and qualified manpower is available.
c) Clearly assigning, communicating, and ensuring understanding of roles and responsibilities across the centre's personnel;
d) Ensuring that the objectives established for all core activities are implemented and monitored;
e) Identifying and monitoring Key Performance Indicators (KPIs), such as the number of ADR reports received, the average turnaround time for causality assessments, the frequency and coverage of training sessions, the number of signals detected, and stakeholder feedback, to facilitate continuous quality improvement.

4.2 Facility and Resources

4.2.1 The minimum floor area of the dedicated workspace for pharmacovigilance operations shall not be less than 200 sq. ft. for a National Centre, 150 sq. ft. for an Intermediate Centre, and 100 sq. ft. for a Peripheral Centre.

4.2.2 Essential reference materials, such as the WHO safety guidelines, WHO benchmark documents and standard treatment guidelines shall be available for consultation.

4.2.3 Facilities shall include:

a) Adequate furniture and storage for documentation.
b) Secure computer systems with internet access for online reporting and communication.
c) Software/database systems for managing ADR records and generating periodic reports on monthly basis.
d) Backup and recovery mechanisms to safeguard electronic data.

4.2.4 The list of essential equipment required for the functioning of a pharmacovigilance centre is provided in Annex B.

4.3 Manpower

4.3.1 The minimum requirement of technical staff, along with the educational qualifications and experience shall be as given in Table 1.

4.3.2 The roles and responsibilities of each team member shall be clearly defined

4.3.3 The designated Coordinator should supervise activities such as ADR collection, assessment, database management, training, and reporting. Records of all activities shall be maintained and made readily available for review.

4.3.4 Sufficient backup personnel shall be identified in case of staff turnover, absence or upgradation/promotion to higher responsibilities.

Table 1 Requirement of technical staff and educational qualifications

(*Clause 4.3.1)*

Sl No	Level	Job role	Minimum Educational Qualification
(i)	(ii)	(iii)	(iv)
1	National, Intermediary and Peripheral Centres	Co-ordinator	Post-graduation in concerned Ayush system with basic training and understanding in pharmacovigilance or clinical research, working as Medical Officer / Assistant professor/Research Officer with minimum 5 years experience.
2	National and Intermediary Centres	Research Associate	Post-graduation in Ayush system with working knowledge in Computer.
3	Peripheral Centres	Junior Research Fellow	Under graduation in Ayush system with working knowledge in Computer.

4.4 Training and orientation

4.4.1 All personnel involved in pharmacovigilance shall undergo initial orientation training on pharmacovigilance concepts, SOPs, regulatory requirements, and ADR reporting mechanisms.

4.4.2 Periodic refresher training shall be conducted (at least annually) to update staff on changes in national guidelines, reporting formats, causality assessment methods, and any new digital tools.

4.4.3 Training shall be documented with pre/post evaluation to assess comprehension and effectiveness.

4.4.4 Records of all training sessions, attendance, and evaluations shall be maintained in an

auditable format and retained for a minimum period of five years.

4.4.5 Encouragement shall be given for staff to attend workshops, seminars, and webinars related to pharmacovigilance, safety monitoring, and quality systems.

5. ADR MONITORING AND REPORTING

The pharmacovigilance centre shall ensure effective monitoring and reporting, by following a systematic process for collecting, assessing, processing, and submitting reports.

5.1 Collection and processing of reports

5.1.1 The centre shall actively collect Suspected Adverse Drug Reaction (ADR) reports from various sources, including OPD/IPD services, health professionals, dispensaries, community outreach programs, public health programs and surveys.

5.1.2 ADR forms prescribed under the National Pharmacovigilance Programme for ASU&H Drugs shall be used for data collection. Digital formats or electronic data entry systems may also be utilized, for integration with OPD/IPD records.

5.1.3 A unique identifier (case ID) shall be assigned to each ADR report to ensure traceability.

5.1.4 Confidentiality and informed consent (if required) shall be ensured while collecting data, preferably using templates approved by Institutional Ethics Committees (IEC), where applicable.

5.1.5 Each received report shall be reviewed by a designated staff member for completeness and authenticity.

5.1.6 Incomplete reports shall be followed up for missing information within a reasonable time frame.

5.1.7 The centres shall periodically analyze accumulated ADR data for signal detection and emerging safety concerns, and report the findings to the higher center using algorithms/tools for signal detection.

5.1.8 All data shall be securely stored in digital or physical form, ensuring confidentiality.

5.2 Report Submission

5.2.1 Verified and assessed reports shall be submitted to the higher center as per the prescribed timeline given in table 2.

Table 2 Timeline for reporting ADRs
(*Clause 5.2.1)*

Sl No	**Type of ADR**	**Timeline for reporting**
(i)	(ii)	(iii)
1	Serious ADRs	Within 24 hours
2	Non-serious ADRs	At the earliest

5.2.2 Reports shall be submitted through the designated portal/email in prescribed formats following the timelines.

6. MANAGEMENT OF DOCUMENTS, RECORDS, AND DATA

The Pharmacovigilance Centre shall establish structured mechanisms for the development, control, storage, and retrieval of all documents, records, and data.

6.1 Policy and Procedural Documents

6.1.1 The Pharmacovigilance Centre shall develop and maintain Standard Operating Procedures (SOPs)**,** policies, guidelines, and manuals covering all key activities such as:

a) ADR collection and reporting
b) Causality assessment
c) Data management and quality assurance
d) Communication and escalation of serious adverse events
e) Confidentiality and ethical considerations
f) Internal audits and training
g) version control and review cycle tracking

6.1.2 Regular review and revision of SOPs (at least every two years) shall be ensured based on updated regulatory guidelines or feedback from audits.

6.2 Pharmacovigilance System Master File

6.2.1 The centre shall maintain a Pharmacovigilance System Master File which includes Organizational structure, key personnel with contact details, description of tasks, responsibilities, record of internal audits, training logs.

6.2.2 The Pharmacovigilance System Master File shall be updated periodically and reviewed in alignment with the internal audit cycle, and shall be made available to relevant authorities or during audits.

6.2.3 Any transfer or delegation of responsibilities related to the Pharmacovigilance System Master File (PSMF) shall be properly documented. Access to the PSMF shall be controlled, and digital signatures may be used to ensure data security and traceability.

6.3 Records and Data

6.3.1 Data recording should be in adherence with ethical principles, including respect for patient autonomy, confidentiality, and informed consent, particularly in community-based data collection. In areas with low literacy, efforts shall be made to sensitize the community about the purpose of data collection and the importance of informed consent in an understandable manner.

6.3.2 The Pharmacovigilance Centre shall maintain secure and retrievable records of all reports, assessments, audits and communications**.**

6.3.3 For data reporting, the use of Application Programming Interfaces (APIs) or other digital tools for integration with centralized reporting systems is recommended.

6.3.4 ADR reports shall be preserved both in physical form and in digitized format.

6.3.5 Access to data shall be restricted to authorized personnel to maintain confidentiality**.**

6.3.6 Retention period for records shall comply with national regulatory requirements (at least 5 years). For digital records, it is recommended that storage be on secure servers approved or recognized by the Ministry or relevant authority, wherever feasible.

6.3.7 Centres shall track performance metrics such as report completeness rate, submission timelines, and training coverage to monitor system effectiveness. Dashboards or performance scoreboards may be developed to monitors these indicators.

6.4 Decision-Making and Action Based on Data

6.4.1 The Pharmacovigilance Centre shall ensure that data collected, assessed, and reported is systematically analyzed to support evidence-based decision-making.

6.4.2 Data shall be used responsibly for generating trend analysis, signal detection, and feedback reports.

6.4.3 Feedback mechanisms shall be established to disseminate pharmacovigilance findings to healthcare professionals, regulatory authorities, and the public, as appropriate. Where feasible, a yearly public ADR bulletin may be published to promote transparency and awareness.

ANNEX A
[*Clause* 3.1, (*d*)]

TEMPLATE FOR STANDARD OPERATING PROCEDURE (SOP)

Part I

1. Title:

[Insert SOP Title]

2. SOP Number:

[Unique identifier]

3. Effective Date:

[DD/MM/YYYY]

4. Version:

[Version number]

5. Review Date:

[DD/MM/YYYY]

6. Prepared by:

[Name, Designation]

7. Approved by:

[Name, Designation]

Part II

1. Purpose

Briefly state the objective of the SOP.

2. Scope

Define the processes, personnel, and systems the SOP applies to.

3. Responsibilities

List roles and their associated duties (e.g., Coordinator, data entry operator, assessors).

4. Definitions

Provide definitions for technical terms used (if any).

5. Procedure

Step-by-step actions to be followed, including timelines, tools/forms used, and responsible personnel.

6. Records and Documentation

Specify what records are to be maintained, format, responsible person, and retention period.

7. References

Mention any referenced standards, regulations, or guidance documents.

8. Annexures

Include any supporting forms or templates.

ANNEX B
(*Clause* 4.2.4)

LIST OF ESSENTIAL EQUIPMENT REQUIRED FOR THE FUNCTIONING OF A PHARMACOVIGILANCE CENTRE

The following is a suggested list of minimum equipment and facilities for operationalizing a Pharmacovigilance Centre for ASU&H.

S. No.	**Equipment/Facility**	**Specifications/Remarks**
(i)	(ii)	(iii)
1	Computer system with internet connectivity	Min. 1 unit; for data entry and communication
2	Secure data storage system (digital/physical)	For storing ADR reports and communications
3	Printer-cum-scanner	For documentation and reporting
4	Telephone/official mobile phone	For stakeholder communication
5	Lockable file cabinet	For storing physical records securely
6	Office furniture	Table, chair, visitor seating
7	Stationery and printing supplies	Registers, paper, pens, etc.
8	Notice board/display board	For displaying safety alerts/guidelines
9	First aid kit	For minor office-related emergencies
10	UPS/Inverter or Power backup	To ensure operational continuity

Note: Equipment may be upgraded or expanded based on workload and infrastructure.