Central Sector Scheme for Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy Drugs

The scheme aims at developing safety monitoring mechanism for Ayurveda, Siddha, Unani and Homoeopathy drugs and surveillance system to check the veracity of misleading advertisements of AYUSH.

1. Preamble:-

i). Pharmacovigilance refers to a continuous post-marketing monitoring system to systematically document the safety profile of a medicine. As defined by the World Health Organization, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems.

ii). The Ayurveda, Siddha, Unani and Homoeopathic drugs are regulated in the country in accordance with the exclusive provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder. Similarly, Sowa Rigpa drugs are yet to be brought under the regulatory control. The quality issues of these drugs are raised from various sources and it is felt necessary in the interest of public health to oversee the impact of AYUSH drugs consumed by the people from the prospective of their safety profile. Dissemination and advertisement of improper drug information is also a matter of concern that needs to be addressed with a systematic surveillance and regulatory action.

iii) In view of the above, it is intended to develop a system of safety monitoring and surveillance of adverse reactions and advertisements of ASU&H drugs. Accordingly, proposed scheme of Pharmacovigilance has been envisaged towards detection, assessment, understanding, prevention and regulatory action of adverse events and misleading advertisement of ASU&H drugs.
2. Aims and Objectives of the Scheme:

The purpose of the Pharmacovigilance initiative for ASU&H drugs is to collect, collate, and analyze data to establish evidence for clinical safety of the ASU&H drugs in a scientific manner for documenting clinical evidence of safety of these drugs and undertake surveillance of advertisements of these drugs.

The scheme aims at- (i) inculcating the reporting culture among the consumers as well as ASU&H practitioners to facilitate documentation of Adverse Drug Reactions (ADRs) and instances of misleading advertisements of Ayurveda, Siddha, Unani & Homoeopathy drugs; (ii) developing a system-wise database of Adverse Drug Reactions of ASU & H drugs; and (iii) evolving evidence based recommendations regarding the clinical safety and improper advertisements of ASU&H drugs for regulatory actions.

3. Structural Framework:

There shall be a three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs).

The All India Institute of Ayurveda shall be the National Pharmacovigilance Co-ordination Centre for the implementation of the National pharmacovigilance program for ASU&H drugs. The NPvCC will receive inputs in terms of suspected ADRs from the Intermediary Pharmacovigilance Centres (IPvCs), which will initially include:

i. National institute of Ayurveda, Jaipur.
ii. Institute of Post-Graduate Training and Research in Ayurveda (IPGT&RA), Jamnagar.
iii. National Institute of Unani Medicine, Bengaluru.
v. National Institute of Homoeopathy, Kolkata
and later on more such capable institutions can be identified and included as Intermediary Pharmacovigilance Centres (IPvCs). Peripheral Pharmacovigilance Centres (PPvCs) will be identified on the basis of their infrastructural and functional capability to take up the responsibility of safety monitoring of ASU&H drugs and reporting of their ADRs. The Peripheral Pharmacovigilance Centres (PPvCs) will operate under the purview of concerned Intermediary Centre.

4. Operational Guidelines:

a) The National Pharmacovigilance Co-ordination Centre (NPvCC) in consultation with the concerned Intermediary Pharmacovigilance Centre (IPvC) will identify the Peripheral Pharmacovigilance Centres (PPvCs) on the basis of following criteria:

i. AYUSH teaching hospital recognized under IMCC Act / HCC Act / similar Regulatory body; or NABH accredited / Government ASU&H healthcare facility, healthcare facilities of the Research Councils under Ministry of AYUSH;

ii. Technical competence and wherewithal to undertake surveillance and reporting requirements;

iii. Institutions / Organizations having credible outcomes on similar projects would be given preference.

iv. Any AYUSH institution that has obtained funding from any Ministry/Department of the Central Government and UCs are settled and no adverse remarks are reported.

AYUSH institutions/centres fulfilling the above criteria can also apply to the concerned Intermediary Pharmacovigilance Centre (IPvC) for inclusion as Peripheral Pharmacovigilance Centres (PPvCs).

b) The National Pharmacovigilance Co-ordination Centre (NPvCC) as well as the Intermediary Pharmacovigilance Centres (IPvCs) will also undertake documentation and reporting of the ADRs.
c) An Intermediary Pharmacovigilance Centre (IPvC) shall have 10-20 Peripheral Pharmacovigilance Centres (PPvCs) under its purview. The Intermediary Pharmacovigilance Centre (IPvC) shall receive the information through the Peripheral Pharmacovigilance Centre (PPvC) as well as directly from the consumers, practitioners, industry and other stakeholders regarding any suspected Adverse Drug Reactions in the prescribed format and regarding misleading advertisements of Ayurveda, Siddha, Unani and Homoeopathy drugs on regular periodicity. Each Intermediary Pharmacovigilance Centre (IPvC) shall co-ordinate and receive inputs from Peripheral Pharmacovigilance Centres (PPvCs) selected from amongst recognized educational institutions; licensed ASU&H pharmacies; or accredited / Government approved ASU&H healthcare facilities, hospitals, practitioners, and other stakeholders.

d) The National Pharmacovigilance Co-ordination Centre (NPvCC) will undertake the pharmacovigilance activities under the guidance and technical support of W.H.O. collaborating centre for Pharmacovigilance- Indian Pharmacopoeia Commission and concerned programme officers of the W.H.O. Country Office. The National Pharmacovigilance Co-ordination Centre (NPvCC) in consultation with the Pharmacopoeial Commission of Indian Medicine and Homoeopathy (PCIM&H), if required, shall conduct the Causality Assessment of the signals received from the Intermediary Pharmacovigilance Centres (IPvCs) and intimate the Ministry of AYUSH regarding confirmed ADRs to enable suitable action.

5. Funding Pattern of the Scheme:

Financial assistance will be provided to the National Pharmacovigilance Co-ordination Centre (NPvCC) for implementing pharmacovigilance of ASU&H drugs, which in turn will disburse the required funds to the Intermediary Pharmacovigilance Centres (IPvCs) as well as the selected Peripheral Pharmacovigilance Centres (PPvCs) on approval of the project proposals on periodic intervals. Progress report and audited statement of expenditure shall be submitted by all centres to the National Pharmacovigilance Co-ordination Centre (NPvCC).
## Pattern of Financial Assistance

<table>
<thead>
<tr>
<th>Institution</th>
<th>Funding Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of AYUSH</td>
<td>Programme Management Unit (PMU)</td>
</tr>
<tr>
<td></td>
<td>Programme Manager-01&lt;br&gt;MD Ayurveda / Siddha / Unani / Homoeopathy &lt;br&gt;(@ Rs.65000/- per month)</td>
</tr>
<tr>
<td></td>
<td>Programme Assistant-01&lt;br&gt;Graduate in Ayurveda/Unani/Siddha/Homoeopathy&lt;br&gt;(@ Rs.40000/- per month)</td>
</tr>
<tr>
<td></td>
<td>Data Entry Operator -01&lt;br&gt;Degree Qualification&lt;br&gt;(@ Rs.20000/- per month)</td>
</tr>
<tr>
<td>National Pharmacovigilance Coordination Centre</td>
<td>Programme Management Unit (PMU)</td>
</tr>
<tr>
<td>(NPvCC)-01</td>
<td>Establishment Cost&lt;br&gt;One time grant for establishment of a Pharmacovigilance Centre towards purchase of office equipment&lt;br&gt;(@ 10,00,000/-)</td>
</tr>
<tr>
<td></td>
<td>Recurring Cost&lt;br&gt;Technical Programme Officer-02&lt;br&gt;MD (Ayurveda/ Siddha / Unani / Homoeopathy)&lt;br&gt;(@ Rs.50000/- per month)</td>
</tr>
<tr>
<td></td>
<td>Data Entry Operator -01&lt;br&gt;Degree Qualification&lt;br&gt;(@ Rs.15000/- per month)</td>
</tr>
<tr>
<td></td>
<td>CMEs and Awareness Programs&lt;br&gt;Organization of 2 to 3 Orientation workshops / CMEs at least twice in a year&lt;br&gt;(@ 10,00,000/-)</td>
</tr>
<tr>
<td></td>
<td>IEC Materials&lt;br&gt;One time grant for preparation, publication and distribution of IEC material (electronic &amp; print media) for spreading awareness about pharmacovigilance in ASU&amp;H drugs&lt;br&gt;(@ 5,00,000/-)</td>
</tr>
<tr>
<td></td>
<td>Contingency&lt;br&gt;One time grant towards contingency&lt;br&gt;(@ 5,00,000/-)</td>
</tr>
<tr>
<td>Intermediary Pharmacovigilance Centres (IPvCs)-05</td>
<td>Programme Management Unit (PMU)</td>
</tr>
<tr>
<td>Establishment Cost</td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>One time grant for establishment of a Pharmacovigilance Centre towards purchase of office equipment (@2,00,000/-per centre)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recurring Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme Associate-01 MD (Ayurveda/ Siddha / Unani / Homoeopathy) (@ Rs.40000/- per month)</td>
</tr>
<tr>
<td>Data Entry Operator -01 Degree Qualification (@ Rs.12000/- per month)</td>
</tr>
<tr>
<td>CMEs and Awareness Programs</td>
</tr>
<tr>
<td>Organization of 2 to 3 Orientation workshops / CMEs at least twice in a year (@ 5,00,000/-per centre)</td>
</tr>
<tr>
<td>IEC Materials</td>
</tr>
<tr>
<td>One time grant for preparation, publication and distribution of IEC material (electronic &amp; print media) for spreading awareness about pharmacovigilance in ASU&amp;H drugs (@ 2,00,000/-per centre)</td>
</tr>
<tr>
<td>Contingency</td>
</tr>
<tr>
<td>One time grant towards contingency (@ 2,00,000/-per centre)</td>
</tr>
</tbody>
</table>

| Peripheral Pharmacovigilance Centres (PPvCs)-50 |
| Programme Management Unit (PMU) |

<table>
<thead>
<tr>
<th>Recurring Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme Assistant-01 Graduate in Ayurveda/Unani/Siddha/Homoeopathy (@ Rs.25000/- per month)</td>
</tr>
<tr>
<td>Data Entry Operator -01 Degree Qualification (@ Rs.10000/- per month)</td>
</tr>
</tbody>
</table>

6. Structure of Proposals and Submission of Applications:

Along with the application for participating as a Peripheral Pharmacovigilance Centre (PPvC), a concept note of the proposal may be submitted to the Intermediary Pharmacovigilance Centre (IPvC). Such applications may be addressed to the Director of the Intermediary Pharmacovigilance Centre (IPvC) along with an Undertaking to the effect that physical and financial performance...
under the Pharmacovigilance initiative would be done in accordance with the approved norms and guidelines and documents & records as & when required would be submitted to the Intermediary Centre. The proposal must reflect clearly the available infrastructure in terms of space, equipments and manpower as well as the objectives, action plan, duration, mode of implementation; logistic requirements, milestones, deliverables & outcomes and broad budget breakup of the project as per the given funding pattern. The application should be forwarded with recommendation from the head of the applicant institution.

National Pharmacovigilance Co-ordination Centre (NPvCC) on receipt of applications from the Intermediary Pharmacovigilance Centres (IPvCs) along with their comments, will examine the proposal for the suitability and eligibility of the institution to become a Peripheral Pharmacovigilance Centre (PPvC) and with the approval of the Project Sanctioning Committee of the Ministry of AYUSH, shall declare it as a Peripheral Pharmacovigilance Centre (PPvC) under the Pharmacovigilance programme for ASU&H drugs for functioning as per the prescribed requirements.

7. Approval Process and release of funds:

Applications received under the scheme shall be processed at three levels as under:

Step-1
The National Pharmacovigilance Co-ordination Centre (NPvCC) will examine the proposals under the National Pharmacovigilance Program for ASU&H drugs. The proposal and concept note not found suitable as per the scheme’s guidelines i.e. proposals with major deficiencies in terms of objectives and eligibility criteria would be rejected and the applicant would be informed accordingly. The proposals found suitable will be placed for the consideration of the Project Appraisal Committee (PAC).

Step-2
Proposals found suitable in the initial examination, would be considered by the PAC and if needed, the applicant organization would be called for making a
presentation before the committee to explain the required details. The proposals with clearly defined deliverables, budgetary details and other requisite information would be recommended for consideration of the Project Sanctioning Committee (PSC).

Step-3
The proposals recommended by the PAC would be considered by the PSC for final approval and sanction. Installments of the sanctioned grant would be released only after liquidation of the Utilization Certificate of previous installment and acceptance of Annual Performance Report and approval of the PSC and the Integrated Finance Division (IFD) of the Ministry.

8. Project Appraisal Committee (PAC):-
Proposals found suitable by the National Pharmacovigilance Co-ordination Centre (NPvCC) would be subjected to consideration of Project Appraisal Committee (PAC) comprising of-

1. Joint Secretary dealing with drugs, Ministry of AYUSH-Chairperson
2. Director, National Pharmacovigilance Co-ordination Centre (NPvCC) for the Pharmacovigilance Program for ASU&H drugs-Member Secretary
3. Technical Head of the Drug Control Cell, Ministry of AYUSH-Member
4. Respective Advisor (Ayurveda/Siddha / Unani/ Homoeopathy)-Member
5. National Co-ordinator, Pharmacovigilance Programme of India-Member
6. Under Secretary dealing with the scheme in the Ministry of AYUSH-Member

This Committee will also evaluate the progress and achievement-cum performance reports and Utilization Certificates for making recommendations for release of the approved funds for the project. The Committee shall meet every three months to consider the annual proposals, supplementary proposals and review the progress of the ongoing projects.
9. Approval for funding the Projects

Project proposals recommended by the Project Appraisal Committee will be considered for approval of funding by the Project Sanctioning Committee (PSC) comprising of-

1. Secretary, Ministry of AYUSH-Chairperson
2. Financial Advisor of the Ministry of AYUSH or his nominee-Member
3. Chairperson of the Project Appraisal Committee-Member
4. Technical Head of the Drug Control Cell, Ministry of AYUSH-Member
5. Director, Pharmacopeial Commission of Indian Medicine & Homoeopathy-Member
6. DCG (I) or his nominee-Member-Member
7. Under Secretary dealing with the scheme in the Ministry of AYUSH-Member

The local transportation and sitting fee shall be paid to non-official members of the PAC and PSC as per approved norms.

10. Monitoring Mechanism:

To monitor the implementation of the scheme, the National Pharmacovigilance Co-ordination Centre (NPvCC) will establish key indicators to measure the efficiency of (i) process (ii) outcome and (iii) impact of the programme.

i. Process Indicators:
   a. Number of ADR monitoring centers participating in the National Pharmacovigilance programme for ASU&H drugs and the surveillance of advertisements of ASU&H drugs and practices
   b. Number of personnel trained in ADR Monitoring and surveillance of advertisements of ASU&H drugs and practices
   c. Funds budgeted for Pharmacovigilance Programme of ASU&H Drugs and funds spent
ii. Outcome Indicators:
   a. Number of ADR reports received in a year
   b. Number of ADR reports processed in a year
   c. Number of misleading advertisements of ASU&H drugs and practices reported and processed in a year

iii. Impact Indicators:
   a. Number of signals generated and confirmed
   b. Number of safety related alerts issued by the Ministry of AYUSH
   c. Number of misleading advertisements of ASU&H drugs and practices rectified or withdrawn

11. Management of the Scheme:

   Ministry of AYUSH will engage a Programme Manager with MD (Ayurveda / Siddha / Unani / Homoeopathy) and MBA / BBA / Post Graduate Diploma in Management, a Programme Assistant and a Data Entry Operator on contractual basis for the administration of the scheme, processing of proposals and related matters. The remuneration of all the staff appointed under the scheme would be reviewed as and when needed in consultation with the IFD.

12. Responsibilities of the Pharmacovigilance Centres:

   National Pharmacovigilance Co-ordination Centre (NPvCC):

   The NPvCC shall-
   (i). document and monitor the ADRs of ASU&H drugs
   (ii). seek Periodic Safety Update Reports (PSURs) from the ASU&H drug manufacturing companies for all the Patent & Proprietary (P&P) drugs
   (iii). Shall organize awareness building and capacity building workshops for the stakeholders
(iv). Scrutinize the project proposals of the Peripheral Pharmacovigilance Centres (PPvCs) in consultation with the concerned Intermediary Pharmacovigilance Centre (IPvC)

(v). conduct the causality assessment for all the signals regarding the ADRs of ASU&H drugs received from NPvCC, IPvCs as well as PPvCs for recommending necessary regulatory action by the Ministry of AYUSH

(vi). provide information to the end users through seminars, drug alerts and other means.

(vii). submit Annual proposals and the Supplementary proposals for seeking approval of the PAC and PSC.

Intermediary Pharmacovigilance Centres (IPvCs):
The IPvCs of the respective systems (Ayurveda/ Siddha/ Unani/ Homoeopathy) shall-

(i). document and monitor the ADRs of ASU&H drugs

(ii). collect the information regarding the ADRs of ASU&H drugs from the respective Peripheral Pharmacovigilance Centres (PPvCs)

(iii). report the ADRs of ASU&H drugs to the National Pharmacovigilance Centre (NPvCC) at regular intervals for causality assessment

(iv). organize awareness building and capacity building workshops for the stakeholders

(v). Scrutinize the project proposals received from the Peripheral Pharmacovigilance Centres (PPvCs) and forward the same to the National Pharmacovigilance Centre (NPvCC) along with comments.

Intermediary Pharmacovigilance Centres (IPvCs):
The IPvCs of the respective systems (Ayurveda/ Siddha/ Unani/ Homoeopathy) shall-

(i). document and monitor the ADRs of ASU&H drugs

(ii). report the ADRs of ASU&H drugs to the concerned Intermediary Pharmacovigilance Centre (IPvC) at regular intervals
In reference to the orders of the Government of India, Ministry of Finance, Department of Economic Affairs vide OM No. F.1 (8)-B (AC)/ 2017 dated 21st March, 2017, out of the allocated budget under the present scheme, ten percent (10%) of the amount would be used for infrastructure, manpower, consumables, awareness campaigns and other activities to accomplish the objectives of the Swachhta Action Plan (SAP).