Minutes of the 2nd meeting of Project Sanctioning Committee (PSC) for Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani and Homeopathic Drugs held in the Ministry of AYUSH on 23rd October 2018.

Second meeting of the Project Sanctioning Committee of Pharmacovigilance Scheme of ASU&H drugs was convened under the chairmanship of Secretary (AYUSH), Vd Rajesh Kotecha on 23.10.2018 at 12.00 hours to consider the proposals for the year 2018-19. Following were present in the meeting:

1. Sh. P. K. Pathak, Additional Secretary (AYUSH)
2. Dr. D. C. Katoch, Adviser(Ayurveda) & Head- Drug Control Cell (DCC)
3. Shri Raj Kumar, Deputy Secretary (IFD)- representative of FA.
4. Dr. Satya Pal Shani, Deputy Drug Controller, CDSCO- representative of DCG(I)
5. Dr. K.R.C Reddy, Director, PCIM&H
6. Dr. Galib, National Pharmacovigilance Coordinator, AllA, New Delhi.
7. Dr. Muzamil Rehman, Assistant Adviser (Unani), DCC
8. Dr. Sulochana Bhat, Assistant Director (Ayurveda), DCC
9. Dr. Pradeep Dua, Research Officer, DCC
10. Dr. Rajeshwari Singh, OSD to Secretary (AYUSH).

The meeting started with opening remarks from Adviser (Ayurveda), Dr. D.C. Katoch providing background of the implementation progress of the Central Scheme of Pharmacovigilance of ASU&H drugs since December, 2017, disbursement of funds to All India Institute of Ayurveda and summary of the activities undertaken so far at National, Intermediary and Peripheral Pharmacovigilance centres. Additional Secretary, Sh. P.K. Pathak briefed about the decision of Project Appraisal Committee taken in the meeting of 26th June, 2018 under his chairmanship to expedite the recruitment of program managers and utilization of funds at all the three levels of pharmacovigilance networks as disbursement of funds may not be considered as expenditure. Thereafter, the agenda items were presented and considered by PSC as follows:-
Agenda Item No. 01: Confirmation of minutes of the 1st Meeting of PSC of Pharmacovigilance Scheme held on 28th December, 2017.

PSC confirmed the minutes of the previous meeting as there were no comments/observations received from the members.

Agenda Item No. 02: Action Taken Report on the recommendations of PSC made in its first meeting on 28th December, 2017.

PSC noted and considered the actions taken by the Ministry and the Pharmacovigilance centres in implementing the decisions of the previous PSC meeting as follows:-

a) Sanctioned grant of Rs. 1,60,60,000 was disbursed to All India Institute of Ayurveda, New Delhi (the National Coordination Centre of the Pharmacovigilance Program) in three installments. Amount of Rs. 1.50 crore could be released in the financial year 2017-18 and the remaining amount of Rs 10.60 lakh in May, 2018.

b) Drug Control Cell of the Ministry engaged a Programme Assistant following the stipulated procedure of making contractual appointment to coordinate the implementation of pharmacovigilance program. However, the incumbent surrendered the assignment w.e.f. 17th July, 2018.

c) Required personnel/ Program Assistants have been appointed on contractual basis in the 38 centres out of 49 centres. Process of appointing required personnel is underway in remaining eleven centres.

d) Induction training of the concerned nodal officers/program coordinators of pharmacovigilance centres was conducted on 19th March, 2018 at AI&AA, New Delhi.

e) Press release for public awareness of the pharmacovigilance program of ASU&H drugs was made by Press Information Bureau (PIB) on 14th August, 2018.
f) The PAC has appraised the composition of various Committees proposed by the National Coordination Centre to operationalize the pharmacovigilance program and recommended for preparing standard protocol and reporting format for documentation of Adverse Drug Events/Reactions in consultation with Indian Pharmacopoeia Commission.

g) Monthly progress reports from all pharmacovigilance centres have been called for submission to the Ministry by 10th day of the succeeding month. The National Coordination Centre has started sending monthly reports of the progress in a prescribed format.

Considering the slow progress of scheme implementation, the PSC directed AIIA - the National Coordination Centre, to implement its recommendations effectively taking necessary actions in a time bound manner to achieve intended outcomes from the pharmacovigilance initiative and surveillance of misleading advertisements of ASU&H drugs.

Agenda Item No. 03: Requirement of grant for the financial year 2018-19.

The PSC considered the proposals of AIIA vis-à-vis the recommendations of the Project Appraisal Committee meeting held on 26th June, 2018. Following proposals were approved-

i. Conduct of advance level training programme for the Coordinators/Nodal Officers of AYUSH pharmacovigilance centres at Indian Pharmacopoieia Commission, Ghaziabad with estimated financial implication of Rs. 7,57,500 as per the proposed break up. The training programme may be accomplished by February, 2019.

ii. Grant of Rs 18.00 lakh for four months to engage Program Assistants in 18 newly identified peripheral centres.
iii. Grant of Rs. 44.52 lakh for salary component of contractual manpower (2 Technical Program Officers & one Data Entry Operator (DEO) at National Centre, 5 Program Associates and 4 DEOs at Intermediary Centres and 30 Program Assistants at Peripheral Centres) for four months.

iv. Grant of untied funds of Rs 25,000 per peripheral centre for 42 existing peripheral centres and 18 new peripheral centres amounting to total of Rs. 15.00 lakhs. The guidelines for utilizing these funds may be prepared.

v. Conduct of National Workshop on Pharmacovigilance to be accomplished before 31st March 2019 with financial expenditure of Rs. 13.10 lakh as per the proposed break-up.

The summary of the approved proposals is as under:

<table>
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<tr>
<th>Training programme for the Coordinators/Nodal Officers.</th>
<th>Rs. 07.58 lakh</th>
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<tr>
<td>To engage Program Assistants in 18 newly identified peripheral centres for four months</td>
<td>Rs. 18.00 lakh</td>
</tr>
<tr>
<td>Salary component of contractual manpower for four months.</td>
<td>Rs. 44.52 lakh</td>
</tr>
<tr>
<td>Grant of untied funds to 60 peripheral centres at the rate of Rs.25,000/center</td>
<td>Rs.15.00lakh</td>
</tr>
<tr>
<td>National Workshop on Pharmacovigilance</td>
<td>Rs.13.10 lakh</td>
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<tr>
<td><strong>Grand Total</strong></td>
<td><strong>Rs. 98.20 lakh</strong></td>
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Agenda Item No. 04: Operational framework for Implementation of Pharmacovigilance Programme.

1) The PSC considered and approved the composition of following committees for developing a proper reporting system and monitoring of the progress of the pharmacovigilance programme.

Steering & Monitoring Committee
   i. Head, DCC, Ministry of AYUSH
   ii. Director/Coordinator from NPvCC i.e AIIA.
   iii. Coordinator from IPvCC
   iv. Representative from CDSCO
   v. Representative from IPC
   vi. Representative from PCIM&H

Technical Advisory Committee:
   i. Chairman of Scientific Body of PCIM&H
   ii. Chairmen of APC, UPC, SPC and HPC.
   iii. Head, DCC, Ministry of AYUSH
   iv. Representative from IPC
   v. Representative from CDSCO
   vi. Pharmacology expert from AIIMS/ICMR
   vii. Technical Officer dealing with medicines and pharmacovigilance in WHO country office
   viii. Director/Coordinator from NPvCC

Central Signal Detection & Causality Assessment Committee:
   i. Coordinator of NPvCC
   ii. AYUSH clinical expert
   iii. Pharmacy expert of AYUSH system
   iv. Pharmacology/Toxicology expert
2) The meetings of all the above 03 Committees shall be convened and facilitated by AIIA—the National Pharmacovigilance Coordination Center and their Terms of Reference (TORs) be specified accordingly. Henceforth the technical matters of the pharmacovigilance programme may not be brought to PSC.

3) The PSC considered the other related proposals under the Operational framework and recommended the following:-

a) The standard protocol and the Individual Case Safety Report format as proposed by the National Pharmacovigilance Coordination Center may be seen by the technical officers of the Ministry and finalized for adoption.

b) National Pharmacovigilance Coordination Center i.e AIIA may develop Web portal of AYUSH Pharmacovigilance programme and Pharmacovigilance Library by February 2019 taking the design/template and domain from IPGTRA Jamnagar in the name of www.ayushsuraksha.com for easy adoption.

c) Standard format and institutional mechanism for reporting of objectionable advertisements of ASU& H Drugs may be evolved and used for submission of reports to the State regulators and Central Authorities. The Pharmacovigilance Centers may issue initial notice to the defaulter as and when any misleading advertisement of ASU&H Drug in the electronic and print media comes is observed.

d) The individual CME Programmes at National AYUSH Institutes i.e intermediary Pharmacovigilance Centers may be organized by February 2019.

e) The matter of fixing the proportion of excipients in the ASU products may be taken up with PCIM&H to check the rampant proliferation of chemicals based products coming to the market.

The meeting ended with thanks to the Chair.