Minutes of the 3rd Meeting of Project Sanctioning Committee (PSC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs held on 29th July, 2019.

Third meeting of the Project Sanctioning Committee of Pharmacovigilance Program of ASU & H drugs was convened under the Chairmanship of Secretary (AYUSH), Vd Rajesh Kotecha on 29th July 2019 at 03:00 PM to consider the proposals for the Year 2019-20. Following attended the meeting:

a) Sh. P. K. Pathak, Additional Secretary (AYUSH)
b) Dr. D.C. Katoch, Advisor (Ayurveda) & Head- Drug Control Cell (DCC)
c) Shri Raj Kumar, Deputy Secretary (IFD)- representative of F.A.
d) Dr. Satya Pal Shani, Deputy Drug Controller, CDSCO- representative of DCG(l)
e) Dr. K. R. C. Reddy, Director, PCIM&H
f) Dr. Tanuja Nesari, Director, AllA
g) Sh. Kundan B. Sinha, Under Secretary, Ministry of AYUSH
h) Dr. Galib, National Pharmacovigilance Coordinator, AllA, New Delhi
i) Prof. Rabinarayan Acharya-IPvC-IPGT&RA Jamnagar
j) Dr. R. Madhavan- IPvC- NIS, Chennai
k) Dr. M. Raja- IPvC, NIH, Kolkata
l) Dr. Mohd. Aleemuddin –IPvC- NIUM, Bangalore
m) Dr. Sudipta Kumar Rath- IPvC-NIA, Jaipur
n) Dr. Himanshu Joshi, RO(Ayu), Ministry of AYUSH

2. The meeting started with welcome and opening remarks from Advisor (Ayurveda), Dr. D. C. Katoch providing background of the implementation progress of the Central Sector Scheme of Pharmacovigilance of ASU &H drugs since its inception on 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 and the recommendations of the previous PAC meeting held on 24th May, 2019. Additional Secretary, Sh. P. K. Pathak expressed the concern that Audited UC in Form 12-A as per GFR , Expenditure Statement etc are required from AllA/NPvCC to liquidate the grant funds released in 2017-18 and 2018-19 and settle the accounts.
3. It was informed that 137 ADRs (from January to June 2019) and 1426 instances of Misleading Advertisements (from August 2018 to April 2019) have been reported by the NPvCC and Ministry wrote letters to 15 State AYUSH Licensing Authorities, Editors of News Papers, Manufacturers 'Associations etc for taking necessary action in respect of misleading advertisements found violating the prohibitive provisions of the Drugs & Magic Remedies (Objectionable Advertisements), Act and Rules. In this regard, PSC endorsed the recommendations of last PAC meeting of 24th May, 2019; discussed the need of making swift and robust system of monitoring, reporting and taking actions and Chairman summed up the following directions-

i. Letter head in the name of Pharmacovigilance Program should be used for reporting the instances of misleading ASU&H drug advertisements to the State Authorities.

ii. Peripheral Pharmacovigilance Centres may be sensitized and their capacity built up about proper reporting of ADRs in the prescribed format with help from CDSCO.

iii. Dedicated website of Pharmacovigilance i.e. www.ayushsuraksha.com shall be made interactive and more functional in respect of issuance of notices & reminders to manufacturers violating the advertisement norms and ethics and for maintaining data base of misleading advertisements of ASU&H drugs.

3. Thereafter, the agenda items were presented and considered by PSC as follows:-


The PSC considered the financial proposal for the year 2019-20 vis-a-vis the recommendations of the Project Appraisal Committee meeting held on 24th May, 2019. Approval was accorded to the proposal of Rs. 2,72, 25, 000 for release of funds as per the following details-

a) Advance of Rs. 57.00 lakh already released to NPvCC on 11.06.2019 with the approval of Secretary and IFD on file for four months salary component of existing centres.
b) Rs. 1,41,75,000 for salary component of existing and 21 new peripheral centres.

c) Rs. 31.50 lakh as Untied Funds for 63 peripheral centres @ Rs. 50,000 per centre.

d) Rs. 20.00 lakh for conducting training programs of pharmacovigilance.

e) Rs. 7.00 lakh for conducting meetings of various Committees of the pharmacovigilance scheme.

f) Rs. 15.00 lakh for organising National Pharmacovigilance Conference, 8-10 November, 2019 at IPGTRA, Jamnagar. PSC also recommended to ensure participation of representatives/coordinators of all National, Intermediary and Peripheral Pharmacovigilance centres in the National Conference and approved that NPvCC may transfer required amount of funds to the Intermediary Pharmacovigilance Centre, IPGTRA-Jamnagar from the funds allocated for Training Programs for meeting expenditure on travel, accommodation etc of contractual technical staff of the pharmacovigilance centres going to be deputed to participate in the National Conference. IPGTRA, Jamnagar shall work out the proposal in this regard and send to NPvCC.

PSC noted accordingly the emerging budget utilization and deficit as under and recommended for NPvCC to first utilize the remaining balance of Rs 58.00 lakhs from the grants released till 2018-19 and submit the audited UCs, Expenditure Statements of 2017-18 and 2018-19 at the earliest.

<table>
<thead>
<tr>
<th>BE(2019-20)</th>
<th>Advance released on 11.06.2019</th>
<th>Proposed Demand for 2019-20</th>
<th>Approval granted</th>
<th>Funds Available &amp; Deficit</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4=2+3</td>
<td>5=1-2</td>
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<td>Rs 1.80 Cr.</td>
<td>Rs 0.57 Cr</td>
<td>Rs 2.15 Cr</td>
<td>Rs 2.72 Cr.</td>
<td>Rs 1.23 Cr. Deficit of Rs: 0.925 Cr.</td>
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PSC considered and approved the following 21 Peripheral Pharmacovigilance Centres:

**Ayurveda**
1. Tilak Ayurveda Mahavidyalaya, Pune (Maharashtra)
2. Govt. Ayurveda College, Bilaspur (Chhattisgarh)
3. SDM Institute of Ayurveda & Hospital, Bengaluru, (Karnataka)
4. Government Ayurvedic College, Khadakpura, Nanded (Maharashtra)
5. Govt Ayurved College, Raghuji Nagar, Nagpur (Maharashtra)
6. JSS Ayurvedic Medical College and Hospital, Mysuru, (Karnataka)
7. Ayurveda Department, Amrita Institute of Medical Sciences, Kochi (Kerala)
8. Govt Ayurveda College, Bangalore (Karnataka)
9. JB Roy Ayurveda College, Kolkata (West Bengal)

**Homoeopathy**
1. Mahesh Bhattacharya Homoeopathic Medical College & Hospital, Howrah (West Bengal)
2. Sarada Krishna Homoeopathic Medical College, Kanyakumari (Tamil Nadu)
3. Father Muller Homoeopathy Medical College & Hospital, Mangaluru (Karnataka)
4. Dr. Abhin Chandra Homoeopathic Medical College & Hospital, Bhubaneswar (Odisha)

**Unani**
1. Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh (U.P.)
2. Hakim Syed Ziaul Hasan Govt Unani Medical College & Hospital, Bhopal (M.P.)
3. Dr. Abdul Haq Unani Medical College, Kurnool, (Andhra Pradesh)
4. Regional Research Institute of Unani Medicine, Kolkata, (West Bengal)

**Siddha**
1. Siddha Clinical Research Unit of CCRS, Karol Bagh, New Delhi.
2. Govt. Hospital, Kamuthi, Ramanathapuram District (Tamilnadu)
3. Govt. Theni Medical College Hospital (DSMO), Madurai District (Tamilnadu)
4. Govt. Hospital, Kuzhithurai, Kanyakumari (Tamilnadu)
(iii) Agenda Item No. 03: Additional support at NPvCC

PSC considered the difficulties faced by NPvCC in handling grant accounts of the pharmacovigilance scheme for want of trained Accountant as explained by the Director, AIIA Prof. Tanuja Nesari. After detailed discussions in the light of scheme guidelines for engagement of contractual manpower, the Chairman decided to extend required manpower support of Program Assistant provided for the Ministry by hiring suitable expert on contract at approved norms to work in the NPvCC.

(iv) Agenda Item No. 04: Revision of Salary of Recruited Manpower

PSC discussed the remuneration rates of Data Entry Operators appointed on contract in National and Intermediary Pharmacovigilance Centres vis-a-vis the scheme guidelines. Considering the need to comply with the minimum wages norms of the Government for contractual manpower and on the suggestion of IFD representative, PSC agreed to pay remuneration to the Data Entry Operators engaged under the pharmacovigilance program in accordance with the extant minimum wages norms.

Agenda Item No. 05: Revision of ToRs of Programme Management Unit to be recruited in the Ministry

PSC considered the proposal of revising the eligibility criteria of qualifications and experience for hiring the services of Programme Manager and Programme Assistant on contract in the pharmacovigilance scheme handling unit of the Ministry. It was recommended to process the matter on file for approval of the revised norms and concurrence of IFD thereto.

The meeting ended with vote of thanks to the Chair and PSC members.