

AnnexureList of Authorized Pharmacovigilance Centres for ASU&H Drugs**A) National Pharmacovigilance Coordination Centre (NPvCC)**

1. All India Institute of Ayurveda, Gautam Puri, Sarita Vihar, New Delhi.

B) Intermediary Pharmacovigilance Centres (IPvCs)

1. National Institute of Ayurveda, Jaipur, Rajasthan
2. Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat
3. National Institute of Siddha, Chennai, Tamil Nadu
4. National Institute of Unani, Bengaluru, Karnataka
5. National Institute of Homoeopathy, Kolkata, West Bengal

C) Peripheral Pharmacovigilance Centres (PPvCs)Ayurveda

1. Central Ayurveda Research Institute for Cardiovascular Diseases, Delhi
2. Raja Ramdeo Anandilal Podar (RRAP) Central Ayurveda Research Institute for Cancer, RA Podar College, Worli, Mumbai
3. Regional Ayurveda Research Institute for Drug Development, Govt. Ayurvedic Hospital, Gwalior, MP
4. Rajiv Gandhi Government Post Graduate Ayurvedic College, Paprola, Himachal Pradesh
5. Uttarakhand Ayurved University, Dehradun, Uttarakhand
6. Shri Narayan Prasad Awasthi Govt. Ayurved College, Raipur
7. Bharati Vidyapeeth, College of Ayurved, Pune
8. Pt. Khushilal Sharma Government Ayurveda College and Institute, Bhopal
9. Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan
10. Madan Mohan Malviya Government Ayurved College, Udaipur, Rajasthan
11. Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi
12. Govt. Dhanwantri Ayurvedic Medical College, Ujjain, Madhya Pradesh
13. Institute of Medical Sciences, Banaras Hindu University, Varanasi
14. Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru
15. Central Ayurveda Research Institute for Drug Development, Kolkata
16. Shri BM Kankanawadi Ayurved Mahavidyalya, Belagavi, Karnataka
17. North Eastern Institute of Ayurveda and Homeopathy, Mawdiangdiang, Shillong, Meghalaya

18. Vaidyaratnam P.S.Varier Ayurveda College, Kottakkal, Kerala
19. Sri Dharmasthala Manjunatheshwara College of Ayurveda Hospital, Thanniruhalla, Hassan
20. Tilak Ayurveda Mahavidyalaya, Pune, Maharashtra
21. Govt. Ayurveda College, Bilaspur, Chhattisgarh
22. Government Ayurvedic College, Khadakpura, Nanded, Maharashtra
23. Govt Ayurved College, Raghuji Nagar, Nagpur, Maharashtra
24. SDM Institute of Ayurveda & Hospital, Bengaluru, Karnataka
25. JSS Ayurvedic Medical College and Hospital, Mysuru, Karnataka
26. Govt. Ayurveda College, Bangalore, Karnataka
27. JB Roy Ayurveda College, Kolkata, West Bengal
28. Amrita School of Ayurveda, Kollam, Kerala

Siddha

29. Siddha Central Research Institute, Arumbakkam, Chennai
30. Siddha Regional Research Institute, Puducherry
31. Siddha Regional Research Institute, Thiruvananthapuram
32. Government Siddha Medical College And Hospital, Palayamkottai, Tamil Nadu
33. AMO, Govt. Hospital (Siddha Wing), Perundurai, Erode.
34. Kulumani, Govt District HQ Hospital (Siddha Wing), Trichy
35. Government Siddha Medical College Arumbakkam, Chennai
36. Govt District HQ Hospital (Siddha Wing), Dindigul
37. Siddha wing Government Kamaraj Hospital, Chidambaram, Tamil Nadu
38. Government Villupuram Medical College and Hospital (Siddha Wing), Villupuram
39. Siddha Clinical Research Unit (functioning under CCRS), Karol Bagh, New Delhi
40. Govt. Hospital, Kamuthi, Ramanathapuram District, Tamilnadu
41. Govt. Theni Medical College Hospital (DSMO), Madurai District, Tamilnadu
42. Govt. Hospital, Kuzhithurai, Kanyakumari, Tamilnadu

Unani

43. Central Research Institute of Unani Medicine, Hyderabad
44. Central Research Institute of Unani Medicine, Lucknow, Uttar Pradesh
45. Regional Research Institute Of Unani Medicine, Mumbai, Maharashtra
46. Regional Research Institute Of Unani Medicine, Chennai, Tamil Nadu
47. Regional Research Institute of Unani Medicine, Srinagar, J&K
48. Regional Research Institute of Unani Medicine New Delhi
49. Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh, U.P.
50. Hakim Syed Ziaul Hasan Govt Unani Medical College & Hospital, Bhopal, M.P.
51. Dr. Abdul Haq Unani Medical College, Kurnool, Andhra Pradesh

52. Regional Research Institute of Unani Medicine, Kolkatta, West Bengal

Homoeopathy

53. Regional Research Institute of Homoeopathy, Dr. GGH Medical College
Campus, Gudivada , Andhra Pradesh
54. Dr. Anjali Chatterjee Regional Research Institute For Homoeopathy, Kolkata,
West Bengal
55. National Homoeopathy Research Institute in Mental Health - NHRIMH,
Kottayam, Kerala
56. Govt. Homoeopathic Medical College and Hospital, Bhopal , Madhya Pradesh
57. Regional Research Institute for homoeopathy, Navi Mumbai
58. Dr. D.P. Rastogi Central Research Institute for Homeopathy, Noida, Uttar
Pradesh
59. Regional Research Institute for Homoeopathy, Guwahati
60. Mahesh Bhattacharya Homoeopathic Medical College & Hospital, Howrah, West
Bengal
61. Sarada Krishna Homoeopathic Medical College, Kanyakumari, Tamilnadu
62. Father Muller Homoeopathy Medical College & Hospital, Mangaluru, Karnataka
63. Dr. Abhin Chandra Homoeopathic Medical College & Hospital, Bhubaneswar,
Odisha

Established Centers:

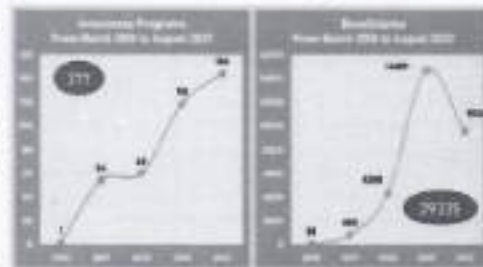


Following the eligibility criteria and having the approval of Project Approval Committee (PAC) and Project Sanctioning Committee (PSC); Peripheral Pharmacovigilance Centres (PPvCs) have been identified that function under the supervision of respective IPvCs. As on date, 96 PPvCs are functioning that are located across the country.

Conduction of training programs to generate human resource:

Since its inception, all the identified centres from different AYUSH specialties are involved in conducting awareness programs with an objective to disseminate the concepts of Pharmacovigilance in the AYUSH system and inculcate the reporting of suspected adverse drug reactions.

To date, 377 awareness programs on Pharmacovigilance have been organized by the identified centres, where about 29335 professionals belonging to various sectors have been trained.



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Z.25021/01/2017-DCC(AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
(AYUSH)

AYUSH Bhawan

'B' -Block, GPO Complex,
INA, New Delhi-110023

01, Nov. 2018

Subject:- Forwarding the minutes of the 2nd meeting of Project Sanctioning Committee (PSC) for the Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy drugs held on 23rd Oct 2018 - reg.

The undersigned is directed to forward herewith the minutes of the 2nd meeting of Project Sanctioning Committee (PSC) for the Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy drugs held on 23rd October, 2018 at 12:00 P.M under the Chairmanship of Secretary (AYUSH) for your information and compliance.

Shiela Tirkey

(Shiela Tirkey)

Under Secretary to the Govt. of India

To,

All members of PSC (As per list attached)

Copy to,

- 1) PPS to Secretary (AYUSH)
- 2) PPS to AS *24/11/18*
- 3) Director, All India Institute of Medical Sciences, New Delhi
- 4) Dr. D.C. Katoch, Advisor (Ayurveda)

Shiela Tirkey
24/11/18

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- 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.



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T-12012/1/2018-DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
(AYUSH)

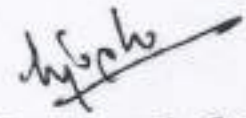
AYUSH Bhawan
'B' -Block, GPO Complex,
INA, New Delhi-110023
04th July, 2019

OFFICE MEMORENDUM

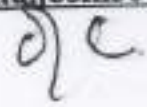
Subject: Minutes of the 4th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs-reg.

The undersigned is directed to forward the minutes of the 4th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance of ASU & H drugs held on 24th May, 2019, under the Chairmanship of Sh. P. K. Pathak, Additional Secretary at Ministry of AYUSH for perusal and necessary action. All concerned are requested to send the action taken report on the decisions/recommendations of the Project Appraisal Committee within 15 days.

Enclosure:- As above



(Dr. Himanshu Joshi)
Research Officer (Ayu)
Email:- himanshu.joshi50@gov.in



To: All the participant of PAC (as per list)

Copy to:
1. PPS to AS
PA to Advisor (Dr. BCK) 4/7/19

Minutes of the 4th Meeting of Project Appraisal Committee (PAC) of AYUSH Pharmacovigilance Scheme held on 24th May 2019.

4th Meeting of the PAC of Pharmacovigilance Scheme was held under the Chairmanship of Shri P.K Pathak Additional Secretary on 24th May 2019 at 03:30 PM in the Ministry of AYUSH to review the progress of scheme implementation and appraisal of the proposals for the year 2019-20. Director AHA and National coordinator of the Pharmacovigilance Scheme from NPACC participated in the meeting. The list of participants is annexed.

2. The meeting started with welcome remarks from Dr D. C Katoch, Adviser (Ay.) and Head, Drug Control Cell and opening statement about the background of scheme implementation. The Chairman, Additional Secretary, Shri P.K Pathak in his remarks emphasized the need to fast track the reporting of adverse events of ASU&H drugs and instances of misleading advertisements and proactive performance of the pharmacovigilance centres in this regard by taking necessary actions in time bound manner. Subsequently, National coordinator of the Pharmacovigilance Program, Dr Gali presented the progress report and the agenda items were considered and discussed as under-

3. Agenda Item No.1: Minutes of the 3rd meeting of Project Appraisal Committee held on 2nd January, 2019 and Action taken report thereto.

PAC endorsed the minutes of the 3rd meeting of PAC held on 2.1.2019 and reviewed point-wise Action Taken Report. It was observed that CME programs have been conducted by all the intermediary centres, one advance training program organized at Indian Pharmacopoeia Commission, off late most of the peripheral centres started documenting ADRs and misleading advertisements, few centres were sluggish and yet to

recruit project staff. IEC materials developed and structural inputs of the pharmacovigilance website have been compiled after obtaining domain name from IPGTRA, Jamnagar. PAC emphatically pointed out the objective of streamlined implementation of the scheme for specified outcomes and recommended the following-

- i) In future PAC meetings, heads of Intermediary PharmacovigilanceCentres may also be called to present periodic progress reports.
- ii) The online portal www.ayushsuraksha.com should be consolidated shortly and operationalized within a month uploading IEC materials and reported instances of misleading advertisements and providing link with the AYUSH Ministry's and CDSCO's websites.
- iii) A brief note of progress of pharmacovigilance initiative along with IEC material may be sent to WHO Country and Regional Offices.
- iv) Warning may be issued to the non-performing peripheral centres for their closure, if they fail to recruit the project staff soon and undertake the intended work of pharmacovigilance and reporting of misleading AYUSH advertisements. Such centres are-CBP Ayurveda CharakSamsthan, Delhi; Govt. DhanwantariAyurved. College Ujjain; Ayurveda Department of Institute of Medical Sciences, BHU, Varanasi (Ayurveda); Pt. Khushilal Ayurveda College, Bhopal; Campus Ayurvedic College of Rajasthan Ayurveda University, Jodhpur; MMM Ayurveda College, Udaipur; andGovt District HQ Hospital (Siddha Wing), Trichy.
- v) NPvCC i.e. AIIA may at the earliest submit consolidated Expenditure Statement and UC along with achievement cum performance report to settle the grant accounts.

- vi) Trainings on AYUSH pharmacovigilance program may be clubbed with the training programs conducted by DCC and NMPB for the State regulatory personnel and other stakeholders.

4. Agenda Item No.2: Progress of implementation of Pharmacovigilance Scheme

Coordinator of NPACC explained the functionality status of 43 PPsCs and program implementation as under-

i) Functional Status of peripheral centres:

System	No. of Approved Peripheral Centres	Functionality	Status of Recruitment of Staff
Ayurveda	19	All centres are functional	Six centers are yet to recruit project staff.
Siddha	11	One centre- ATSVS Govt. Siddha Medical College. Kanyakumari not functioning.	One center is yet to recruit the project staff.
Unani	06	One centre- RRI, New Delhi not functioning properly due to manpower issue.	Two centers are yet to recruit the project staff.
Homoeopathy	07	All centres are functioning.	Recruitment of project staff done at all centers.

- 403
- ii) 88 ADRs and 1485 cases of misleading advertisements of ASU&H drugs have been reported till 24th May, 2019. Also the meetings of the Steering & Monitoring Committee and Technical Advisory Committee held at AHA.

In view of the need to expedite effective implementation of the pharmacovigilance initiative, PAC recommended following actions-

- i) Make all the existing PPvCs functional by issuing warning and bring the non-responsive centres to the notice of the Ministry.
- ii) NPvCC may regularly provide necessary details and copies of the reported misleading advertisements to the Ministry so that the same could be taken up with the concerned State Authorities and individual manufacturers/advertisers.
- iii) Preferably every State/UT should have minimum one PPvC of AYUSH and the existing centres need to be fully equipped and functional before new centres are considered for addition in the pharmacovigilance network.
- iv) A compact module of Pharmacovigilance initiative of ASU & H drugs and control of misleading advertisements may be prepared for inclusion in the CME programs funded by the Ministry of AYUSH and for distribution to AYUSH institutions.
- v) Report and recommendations of the Steering and Advisory Committees may be shared with the Ministry for information and consideration of action points.

5. Agenda Item No.3: Approval of New Peripheral Pharmacovigilance Centres

PAC observed that earlier 18 additional centres were approved for funding but their names & addresses were not known. NPVCC coordinator presented the list of 21 identified PPvCs and PAC recommended them for taking approval of the Project Sanctioning Committee as under-

Ayurveda

- 1. Tilak Ayurveda Mahavidyalaya, Pune (Maharashtra)
- 2. Govt. Ayurveda College, Bilaspur (Chhattisgarh).
- 3. SDM Institute of Ayurveda & Hospital, Bengaluru (Karnataka)
- 4. Govt Ayurved College, Raghuji Nagar, Nagpur (Maharashtra)
- 5. Government Ayurvedic College, Khadukpura, Nanded (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

- 10. M. B. Homoeopathic Medical College & Hospital, Howrah (West Bengal)
- 11. Sarada Krishna Homoeopathic Medical College, Kanyakumari (Tamilnadu)
- 12. Father Muller Homoeopathy Medical College & Hospital, Mangaluru (Karnataka).
- 13. Dr. AC Homoeopathic Medical College & Hospital, Bhubaneswar (Odisha)

Unani

- 14. Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh (U.P.)
- 15. Hakim Syed Ziaul Hasan Govt Unani Medical College & Hospital, Bhopal (M.P.)
- 16. Dr. Abdul Haq Unani Medical College, Kurnool (Andhra Pradesh).
- 17. Regional Research Institute of Unani Medicine, Kolkata (West Bengal).

Siddha

18. Siddha Clinical Research Unit (under CCRS), Karol Bagh, New Delhi (Delhi)
19. Govt. Hospital, Kamuthi, Ramanathapuram District (Tamilnadu)
20. Govt. Theni Medical College Hospital (DSMO), Madurai District (Tamilnadu).
21. Govt. Hospital, Kuzhithurai, Kanyakumari (Tamilnadu).

PAC suggested for identifying and including any more Peripheral Centre(s) for the approval of PSC on getting recommendation from relevant sources.

6. Agenda Item No.04: Requirement of grants for the financial year 2019-20.

NPvCC Coordinator explained the financial proposal for the year 2019-20 and stated that total grant of Rs 2,58,80,000/- had been received from the Ministry since February, 2018 out of which Rs1,99,01,426/- disbursed/spent. Funds for salary of the project staff have been exhausted and balance amount of Rs 59,78,574/- will be spent need-wise under different heads by the time next installment of grant is received. Details of year-wise release of grant and expenditure at NPvCC are as under:

Financial Year	BE	Installment of grant /dated	Amount of grant released	Expenditure till date	Balance amount
2017-18	1,50,00,000/-	1 st /23.02.2018	1,40,00,000	1,99,01,426	59,78,574
		2 nd /27.03.2018	10,00,000		
2018-19	1,50,00,000/-	3 rd /28.05.2018	10,60,000		
		4 th /14.12.2018	98,20,000		

PAC showed its displeasure for not having submitted proper expenditure documents and directed NPvCC/AIHA to send at the earliest the UC of funds utilized so far in Form-12A alongwith audited Expenditure Statement as per GFRs and duly authenticated by Finance Officer/CA and countersigned by head of the institute. Further,

PAC appraised the proposal of financial requirement for eleven months (from May 2019 to March 2020) and recommended it for consideration in the next meeting of Project Sanctioning Committee as under-

Salary Component:

		Per month amount (@)	Monthly Expenditure	For 4 Months	For 11 Months
NPvCC					
1	Technical Program Officer (2)	a Rs 50,000/-	Rs 1,00,000/-	Rs 4,00,000/-	Rs 11,00,000/-
2	Data Entry Operator (1)	a Rs 15,000/-	Rs 15,000/- PM	Rs 60,000/-	Rs 1,65,000/-
IPvC					
1	Program Associate (5)	a Rs 40,000/-	Rs 2,00,000/-	Rs 8,00,000/-	Rs 22,00,000/-
2	Data Entry Operators (5)	a Rs 12,000/-	Rs 60,000/- PM	Rs 2,40,000/-	Rs 6,60,000/-
PPvCs					
1	Program Assistant (PA) (42)	a Rs 25,000/-	Rs 10,50,000/-	Rs 42,00,000/-	Rs 11,55,000/-
Total salary component needed for 2019-20 for existing 42 centres				Rs 57,00,000/-	Rs 1,56,75,000/-
If approval is accorded for 21 new peripheral centres then additional requirement for salary component from August 2019 onwards for 8 months.					Rs 42,00,000/-
Total salary component needed in 2019-20				Rs 57,00,000/-	Rs 1,98,75,000/-

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 Total funds requirement (anticipated expenditure) for Pharmacovigilance program implementation during the year 2019-20 will be as follows:

S. No.	Expenditure Head	Amount (for 11 months)	Already requested amount of funds for 4 months for existing 42 centres)
1.	Salary Component (of NPvCC, IPvCs, 42 existing PPvCs and 21 new PPvCs)	Rs 1,98,75,000/-	Rs 57,00,000/-
2.	Untied Funds (for entire year)	Rs 31,50,000/-	-
3.	One National Level Training Programs	Rs. 20,00,000/-	-
4.	For conduction of Steering and Advisory Committee Meetings	Rs. 7,00,000/-	-
	TOTAL	Rs 2,57,25,000/-	- Rs 57,00,000/-

Program Officer of the Pharmacovigilance scheme in the Ministry, Adviser (Ay), Dr D.C. Katoch informed that advance proposal of Rs 57.00 lakhs is being processed with the concurrence of Chairman, PSC and funds would be released after due approval of IFD. PAC recommended the financial proposal as above for consideration of PSC in its next meeting.

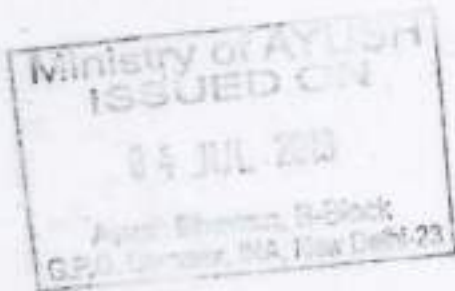
The meeting ended with vote of thanks to the Chair.

List of Participants

4th Meeting of PAC of Pharmacovigilance Scheme, 24th May, 2019

:

- ❖ Sh. P. K. Pathak, Additional Secretary, Ministry of AYUSH- Chairman
- ❖ Dr. D. C. Katoch, Advisor(Ayu.), Ministry of AYUSH
- ❖ Dr. Mohd. Tahir, Advisor(U), Ministry of AYUSH ✓ *Arshad 24/5/19*
- ❖ Dr. K.S. Sethi, Advisor(Homoeopathy), Ministry of AYUSH ✓ *Arshad 24/5/19*
- ❖ Mrs Shiela Turkey, Under Secretary, Ministry of AYUSH ✓ *Galib 24/7*
- ❖ Dr. Tanuja Nesari, Director, AIA - 19 443 | 2019
- ❖ Dr. Galib, National Coordinator, NPvCC, AIA - 19422 | 2019
- ❖ Dr. Himanshu Joshi, Research Officer, Ministry of AYUSH



Ministry of Ayush

Approved Minutes of the 1st Project Sanctioning Committee meeting for Central Sector Scheme of Ayush Oushadhi Gunvatta evam Utpadan Samvardhan Yojana (AOUGSY) Scheme

The first meeting of the Project Sanctioning Committee meeting (PSC) for AOUGSY Scheme was held under the chairmanship of Shri Rajesh Kotecha, Secretary (Ayush) on 09.03.2022 at 12 noon through video conferencing .List of participants is annexed.

At the outset , Dr Anand Gudivada, Advisor (Ay) Ministry of Ayush welcomed the Chairman and the members of the committee and thereafter briefly described about the background of first PSC meeting under AOUGSY scheme.

Dr Galib, Nodal officer for NPVcc, AIIA appraised the committee about the activity and achievements of Pharmacovigilance program held in the last two years. A brief note on existing structural hierarchy of pharmacovigilance centers was presented highlighting the synoptic statistics of reported misleading advertisements in these centers in the last six months and the awareness programs conducted under the scheme . The Chairman opined the need to outreach OPD's of the existing hospitals for sensitizing general public using IEC material about the ongoing program and that the National Commissions of respective system of medicine may be involved in this task.

(Action: AIIA to contact Chairperson NCISM and NCH for wider publicity).

In this context, DG-CCRAS has informed that awareness program is likely to be conducted in the last week of March, 2022 at Jamnagar to the State authorities and Print Media. The Committee suggested that awareness program needs to be given to electronic media also so as to sensitize them regarding the misleading advertisements casted in the electronic media.

The Chairman also suggested to draw these statistics thus obtained into a published clinical study. Agenda-wise deliberations and recommendations were made as under:

Agenda No 1: Approval and Grant in aid for Newly identified Peripheral Pharmacovigilance Centers (PPvC) under Pharmacovigilance of ASU&H drugs component of AOGUSY scheme.

The last meeting of PAC recommended the proposal of 25 newly identified PPvCs with a financial implication of Rs. 87.50 lakhs / year to be placed before PSC for approvals in accordance with the AOUGSY scheme guidelines.

Decision of PSC: The PSC noted the recommendation of PAC and approved the proposal with the following break up:

No of proposed centers	Financial involvement (per center / Year)	For 25 centers /year	
25	Rs 3,50,000/-	Rs 87,50,000/-	
Break-Up of proposed funds			
S.no	Designation	No of post	Salary/year
I.	Program Assistant	01	Rs 3,00,000 (@ Rs 25,000/ Month)

Agenda No 2: Approval for revision of pay structure and re-designation of technical officers under Pharmacovigilance of ASU&H drugs component of AOGUSY scheme.

The last meeting of PAC recommended the proposal for revision of pay structure and re-designation of technical officers to be placed before PSC for approvals in accordance with the Ayurgyan scheme guidelines and IFD concurrence.

Decision of PSC: The PSC noted the recommendations of PAC and approved the proposal, subject to revision of the existing AOGUSY scheme guidelines as per the due procedure and under following heads:

Existing designation, qualification, pay	Number	Proposed re-designation and qualification	Proposed pay
Technical Program Officer MD (A/S/U/H stream) Rs 50,000/- PM (Consolidated) provision of annual enhancement of 5% based on satisfactory performance	02	Research Associate Ph.D. in the concerned subject OR Post-Graduation in (A/S/U/H stream) OR Degree qualification in (A/S/U/H stream) with minimum 3 years research experience i.e. having worked for any research project funded by the Ministry of AYUSH, ICMR, CSIR, DST or equivalent organization	Rs 47,000 + HRA /month (in 1st Year) Rs 49,000 + HRA /month (in 2nd Year) Rs 54,000 + HRA /month (in 3rd Year)
Program Associate MD (A/S/U/H stream) Rs 40,000/-PM (Consolidated) provision of annual enhancement of 5% based on satisfactory performance	05	Research Associate Ph.D. in the concerned subject OR Post-Graduation in (A/S/U/H stream) OR Degree qualification in (A/S/U/H stream) with minimum 3 years research experience i.e. having worked for any research project funded by the Ministry of AYUSH, ICMR, CSIR, DST or equivalent organization.	Rs 47,000 + HRA /month (in 1st Year) Rs 49,000 + HRA /month (in 2nd Year) Rs 54,000 +HRA/month (in 3rd Year)
Program Assistant Graduate (A/S/U/H stream) Rs 25,000/month (Consolidated)provision of annual enhancement of 5% based on satisfactory performance	74	Junior Research Fellow Degree qualification in (A/S/U/H stream)	Rs 31,000 + HRA /month (1st, 2nd& 3 rd Years)

The additional financial implication is as follows:

Year	Proposed Expenditure	Existing Expenditure	Additional financial implication
Year 1	3,65,29,440/-	2,58,00,000	1,07,29,440
Year 2	3,67,33,920/-	2,58,00,000	1,09,33,920
Year 3	3,72,45,120/-	2,58,00,000	1,14,45,120

The Chairman desired that the proposal for revision of Scheme guidelines for the above proposal along with other necessary changes if any, may be submitted to the Ministry within two weeks from the date of issuance of the Minutes.

Agenda No 3: Grant in aid to financial support the functioning of Pharmacovigilance of AS U&H drugs component of AOGUSY scheme during F.Y 2022-23

The last meeting of PAC recommended the proposal of financial support of Pharmacovigilance component of AOGUSY scheme in accordance with the existing pay structure and existing centers for an amount of Rs.3.29 crores during F.Y. 2022-23 to be placed before PSC for approvals.

Decision of PSC: The PSC noted the recommendation of PAC and approved the proposal. The Committee also agreed to enhance 5% annually as per the existing guidelines of the Scheme :

Component	Finances
Salary Component for 1 NPvCC, 5 IPvCs and 74 PPvCs*	Rs 2,72,40,000
Office running, CME/Awareness and Contingencies (Rs 5 lakhs for NPvCC, 3 lakhs to each IPvCC)	Rs 20,00,000
United Funds for the existing 74 centers @ Rs 50,000/- per center	Rs 37,00,000
Total proposed expenditure for the existing structure	Rs 3,29,40,000

Break-up for the proposed salary component for the existing centers of 1 NPvCC, 5 IPvCs and 74 PPvCs for 2022-23

Designation	Number of posts	Salary Component	Salary / Month	For 12 months
NPvCC: Technical Program Officer	02	50,000/month	1,00,000/month	12,00,000/-
Data Entry Operator	01	20,000/month	20,000/month	2,40,000/-
IPvC Program Associate	05	40,000/month	2,00,000/month	24,00,000/-
Data Entry Operator	05	20,000/month	1,00,000/month	12,00,000/-
PPvCs Program Assistant	74	25,000/month	18,50,000/month	2,22,00,000/-

Total salary component needed for 2022-23 Rs 2,72,40,000/-

Break-up for the financial support against for office running, CME/awareness & contingencies for 2022-23

	Awareness Programs & IEC (Rs)	Establishment & Contingencies (Rs)	Total (Rs)
NPvCC	2,50,000/-	2,50,000/-	5,00,000/-
IPvC (for 5 centers)	7,50,000/-	7,50,000/-	15,00,000/-
Total			Rs 20,00,000/-

Agenda No 4: Grant in aid for recruitment of two consultants under Pharmacovigilance of ASU&H drugs component of AOGUSY scheme

The last meeting of PAC recommended the proposal of engagement of Administrative Consultant and Financial Assistant along with financial implications to be placed before PSC for approvals in accordance with Ministry's guidelines

Decision of PSC: The PSC noted the recommendation of PAC and approved the following proposal, subject to revision of the existing AOGUSY scheme guidelines as per the due procedure:

Number of proposed Consultants	Salary (Rs) (50,000/month/consultant)	Salary (Rs) (per year)
02	1,00,000/-	12,00,000/-

The Chairman desired that the proposal for revision of Scheme guidelines for the above proposal along with other necessary changes if any, may be submitted to the Ministry within two weeks from the date of issuance of the Minutes.

Agenda No 5: Ratification of earlier approved salary component for Pharmacovigilance of ASU&H drugs component of AOGUSY scheme for the FY 2021-22

The last meeting of PAC recommended the proposal for ratification of earlier approved salary component of Pharmacovigilance program during FY 2021-22 to be placed before PSC for approval:

Decision of PSC: The PSC granted ex post facto approval for the salary component of Pharmacovigilance program during FY 2021-22 as under:

Pharmacovigilance program	(for 12 months)
Staff Salary	Rs 2,72,40,000

Agenda No 6: Grant in aid for upgradation of existing State Drug Testing Laboratory (AYUSH), to Regional Drug Testing Laboratory (AYUSH) in Guwahati

The last meeting of PAC recommended the proposal to be placed before PSC for approvals, subject to restructuring of budget within the limits of existing AOUSSY scheme guidelines and liquidation of utilization certificate of previous funds provided to the unit through NAM.

Decision of PSC: The PSC noted the recommendation of PAC and approved the proposal subject to liquidation of utilization certificate of previous funds provided to the unit through NAM and also to conduct onsite monitoring visit and verification of the obsolete instruments requiring replacement as submitted by the State DTL with the following break up:

Revised Non recurring expenditure (in lakhs)	
Building renovation	21.50
Equipments	188.50
Total	210.00
Revised Recurring expenditure (in lakhs)	
Manpower for 05 years	67.20 (@13.44/Year)
AMC & chemical reagents, NABL Accreditation, misc.	22.80 (@4.56/Year)
Total	90.00
Total fund requirement from Central Government	300.00

Agenda No 7: Grant in aid for upgradation of existing State Pharmacy and State Drug testing laboratory in Jammu & Kashmir

The last meeting of PAC recommended the proposal to be placed before PSC for approvals, subject to restructuring of budget within the limits of existing AOGUSY scheme guidelines and liquidation of the pending utilization certificate of previous funds provided to the DTL through NAM.

Decision of PSC: The PSC noted the recommendation of PAC, approved the proposal subject to IFD concurrence and liquidation of pending U.C with the following break up:

Non recurring expenditure (in Rs)	
Building renovation	20.00 Lakhs
Computer, Printer	2.00 Lakhs
Machinery & equipment	85.51 Lakhs
Books	50,000
Monitoring of project	5,40,050
Total	1,13,41,050/-
Recurring expenditure (in Rs)	
Manpower	3.21 Lakhs
Raw material, chemical reagent	80.00 Lakhs
AMC	40,000
Packaging	80,000
Testing charges	5.00 Lakhs
Consumables	10.00 Lakhs
Monitoring of project	4,97,050
Total	1,04,38,050/-
Total (Non Recurring and Recurring)	217,79,100 (2.17 cr. approx)
Grant in aid for existing State Drug Testing Laboratory:	

Non recurring expenditure	
Building renovation	20.00 Lakhs
Equipment	74,58,400/-
Recurring expenditure	
Manpower	6,03,000/-
Total (Non Recurring and Recurring)	100,61,400 (100 cr. approx)

Agenda No 8: Grant in aid for existing State Drug testing laboratory of ASU&H in Mizoram.

The last meeting of PAC recommended the proposal of existing State DTL in Mizoram to be placed before PSC for approvals.

Decision of PSC: The PSC approved the proposal in accordance with the norms of the existing AOGUSY scheme guidelines with the following break up:

Recurring expenditure (in Lakhs)/year	
Manpower	14.82
Chemicals and reagents	0.38
Any other consumables	1.8
AMC	1.0
Total	18.00

Additional Agenda

The Advisor (Ay) appraised the PSC about the three regulatory training programs conducted under AOGUSY scheme during FY 21-22 with a budget of Rs 5.5 lakhs per each program as approved by IFD. the Committee was informed that other two training programs could not be conducted due to the Covid-19 restrictions.

The meeting ended with thanks to the Chair.

List of Participants

Annexure - 1

1. Shri Raj Kumar , AS & FA, IFD
2. Dr.TanujaNesari , Director, AIIA
3. Prof. P K Prajapati, Director I/c PCIM&H
4. Dr. SubhashKaushik, DG CCRH
5. Shri RN Acharya,DG CCRAS
6. Prof.Asim Ali Khan, DG CCRUM
7. Dr . K. Kanakavalli , DG CCRS
8. Shri M.A Qasmi , Adviser (Unani) , Ministry of Ayush
9. Dr. Chinta, Deputy Adviser (H), Ministry of Ayush
10. Dr Suresh Kumar , Deputy Adviser (Ayurveda), Ministry of Ayush

11. Dr. Rachna Paliwal ,Assistant Adviser (H), Ministry of Ayush
12. G.V.R. Joseph (Guest), Joint Director I/e PCIM&H
13. Dr.Galib, Nodal officer for Pharmacovigilance program, NPvCC, AIIA
14. Shri SudiptRath,Nodal officer for Pharmacovigilance program IPvC, NIA
15. Dr Rama Kanta Sharma , Director (Ayush) , State of Assam
16. Dr. Mohan singh, Director (Ayush) State of J&K
17. Director (Ayush) State of Mizoram
18. Dr.Kumaran D, Research officer (Siddha) Ministry of Ayush
19. Dr.Shiddamallayya ,Research officer (Botany) ,CCRAS HQ
20. Dr. Neha Kalra, Research officer(H),Ministry of Ayush

Minutes of 7th Project Appraisal Committee Meeting of Pharmacovigilance Scheme virtually held at 2:30PM on 31.5.2021

7th PAC Meeting was held virtually under the Chairmanship of Shri P K Pathak, Special Secretary (SS), Ministry of Ayush on 31st May 2021 at 2:30 PM to review the progress of Pharmacovigilance scheme implementation. List of the participants is annexed.

The meeting started with welcome remarks by Dr J.L.N.Sastry, I/C Drug Control Cell followed by opening statement about the background and status of scheme implementation. The Chairman, in his remarks emphasized the need to hold the meeting of PAC on quarterly basis and implement the Pharmacovigilance activities in effective manner etc. He expressed his displeasure on poorly framed Agenda Items and directed NPvCC to exercise due diligence in preparation of Agenda items.

Thereafter, agenda-wise discussions proceeded as under-

Agenda Item No. 01: Confirmation of the Minutes of the 6th Project Appraisal Committee (PAC) Meeting held on 12th January 2021 and Action taken report thereto.

Minutes of the 6th PAC meeting held on 12th January, 2021 were confirmed. However, it was suggested by the Chair that the minutes are to be circulated among the committee members before finalizing their inputs, if any. Dr. Galib informed that there are 74 Peripheral Centers functioning across the country in majority of States/UTs. Program Assistants have been recruited in maximum of these centers and functioning in lines of the objectives of the program. PAC also noted the action taken report of previous recommendations and discussed the functional status of the Peripheral Pharmacovigilance Centres. In this regard Chairman, PAC specifically directed as under:

1. Pending UCs of Rs. 27.35 Lakhs from Financial Year 2019-20 should be settled within a 7 days.
2. Reporting of suspected Adverse Drug Reaction should be specific and to be augmented.
3. NPvCC should make it sure that the untied funds are being utilized as per the guidelines issued for the same. Chairman, PAC further directed that this should be taken as separate Agenda Item in the next meeting.

4. Details of publication by the Pharmacovigilance centres should be specific. Accordingly, details of publications by the pharmacovigilance centres are as follows:

National Pharmacovigilance Coordination Centre:

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- ii. A chapter *Pharmacovigilance for Indian Traditional Medicine* in association with IPC, Ghaziabad being published by SPRINGER Publishers, coordinated by University of Auckland
- iii. Invited article entitled *The challenges of implementing Pharmacovigilance in AYUSH Systems of Medicine* in a Commemorative Volume of 150th Birth Anniversary of Vaidya PS Varier Celebrations
- iv. Virtual workshop on Pharmacovigilance (PV) for Traditional Medicine (TRM) Products in the WHO South-East Asia Region (<https://apps.who.int/iris/handle/10665/340711>)
- v. Activity Report of Pharmacovigilance Program -upto June 2020

Intermediary Pharmacovigilance Centre - Jamnagar:

- i. KAP Study on the Pharmacovigilance concepts in the stakeholders of Gujarat

Intermediary Pharmacovigilance Centre - Jaipur:

- i. Impact of AYUSH Pharmacovigilance on Misleading advertisements.
- ii. Suspected ADRs in AYUSH Pharmacovigilance - Experiences of an Intermediary Pharmacovigilance Centre

Agenda Item No. 02: Status Report of System wise ADRs, Misleading Advertisements, COVID-19 Advertisements and awareness programs.

Dr. Galib provided information about the functioning and reporting culture and mentioned the reporting of 735 suspected ADRs, 13722 misleading advertisements and 184 COVID related misleading advertisements till date. However, during the reporting period of January to April 2021, he mentioned that the centres reported 128 suspected ADRs, 3038 misleading advertisements and 13 COVID related misleading advertisements.

In addition, it has also been mentioned that 1978 stakeholders from different sectors have been sensitized about Pharmacovigilance related aspects in 25 awareness programs during the reporting period.

Details of system wise ADRs Misleading Advertisements and COVID-19

Advertisements

	System	Number of IPvCs	Number of PPvCs	Number of Suspected ADRs		Misleading Advertisements		COVID-19 related Misleading Advertisements	
				Jan to Mar 21	April 21	Jan to Mar 21	April 21	Jan to Mar 21	April 21
1	Ayurveda	02	35	49	09	1607	337	4	9
2	Siddha	01	14	14	-	0223	-		
3	Homeopathy	01	13	31	00	0244	036		
4	Unani	01	11	23	01	0454	137		
5	Sowa-Rigpa	-	01	01	-	-	-	-	-
	Total	05	74	118	10	2528	510	4	9
				128		3038		13	

Dr Galib further said that about 62% of the received suspected ADRs are in POSSIBLE category, when preliminarily analysed following Naranjo's algorithm. He further emphasized that this finding is aligned with previous studies demonstrating that Casualty assessment results are often categorized as POSSIBLE, which is difficult to interpret clinically. In addition, about 29% are PROBABLE categories; while about 7% reports were incomplete and were unable to be analysed. About 87% of these suspected reactions were observed to be MILD in nature, while remaining were moderate. However, none of these reports are serious. None of the reactions required hospitalization, no fatality was noticed. All reports were non-serious in nature.

Chairman, PAC asked about the action taken and followup actions on the misleading advertisements reported. Dr.Galib informed that from January 2021 to April 2021, 3038 instances of objectionable advertisements were reported by centers to respective SLAs. About 64% of such advertisements were from Ayurveda, while 20%, 9% and 7% is shared by Unani, Homoeopathy and Siddha systems respectively. There are about 85 advertisements on which action has been taken by the State Licensing Authorities (SLAs) and majority of these are from NIA, Jaipur. Chairman, PAC directed, that respective PPvCs should send reminders to SLAs (enclosing the details of misleading advertisements) with a copy to Drug Policy Section, Ministry of Ayush to take actions on misleading advertisements.

Agenda Item No. 03: Presentation of Progress of the Pharmacovigilance

Scheme implementation by NPvCC and IPvCs:

Chairman, PAC directed in the PAC that a separate review meeting will be held in 2nd or 3rd week of June wherein NPvCC and IPvCC shall present the progress of implementation of the pharmacovigilance Scheme.

Agenda Item No. 04: Identifying New Centres:

A list of 24 centres has been submitted by NPvCC for possibility of designating as new Peripheral Centres. Chairman opined that in the current pandemic times, designating new centres may be considered later. After thorough assessment of performance of the existing centres, new centres may be identified on need basis.

Agenda Item No. 05: Communicating with CCIM for releasing advisories towards unethical practices by registered practitioners

It has been suggested that the NPvCC should directly communicate to CCIM to release suitable advisories against unethical practices by the registered practitioners. For such items, approval of PAC is not required.

Agenda Item No. 06: Releasing of News Letter

The agenda was discussed and suggested not to print the news letters. It was resolved in the meeting that digital version of news-letter should be released utilising the services of existing manpower..

Agenda Item No. 07: Revision of Pay Structure and nomenclature of the recruited man power

It was suggested to prepare a comprehensive agenda item justifying the proposed revisions and submit as a new agenda item in next meeting, keeping in view extant guidelines, their work profile and performance till now and pay structure of similarly placed employees in other Institutes/Schemes of Ministry of Ayush.

Agenda Item No. 08: Financial support facilitating the functioning

In the meeting Chairman appraised the budgetary provisions within the approved Scheme for FY 2021-22, whereas financial assistance for opening of designating new centres and recruiting administrative consultants was deferred considering the present pandemic situation. Further NPvCC was directed to resubmit the details of the break-up for various provisions as per

the approved scheme in accordance with budget allocation and the same should be reflected in the minutes.

Accordingly, the revised proposal for financial support for 2021-2022 is as follows:

(A)	Salary Component	Salary Per Month	For 12 months
NPvCC			
Technical Program Officer (2)	@ Rs 50,000/- PM	Rs 1,00,000/- PM	Rs 12,00,000/-
Data Entry Operator (1)	@ Rs 20,000/- PM	Rs 20,000/- PM	Rs. 2,40,000/-
IPvCs(5)			
Program Associate (5)	@ Rs 40,000/- PM	Rs 2,00,000/- PM	Rs 24,00,000/-
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PPvCs(74)			
Program Assistant (74)	@ Rs 25,000/- PM	Rs 18,50,000/- PM	Rs 2,22,00,000/-
Total salary component for 2021-22			Rs 2,72,40,000/-

(B)	IEC Activities, Webinars, Office running, Management Unit, & Untied Funds	For existing centres	For 2021-22
NPvCC			
	IEC Activities, Webinars, Management Unit, Office running (1 NPvCC)	Rs 5,00,000/-	Rs 5,00,000/-
IPvCC (5 Centres)			
	IEC Activities, Webinars, Management Unit, Office running(5 IPvC)	Rs 2,00,000/- per IPvC	Rs 10,00,000/-
PPvCC (74 Centres)			
	Untied Funds (74 PPvC)	Rs 25,000/- per PPvC	Rs. 18,50,000/-
Total for 2021-22			RS. 33,50,000/-

	Component	Financial support for 2021-2022
1	Salary Component for NPvCC, 5 IPvC and 74 PPvC	Rs 2,72,40,000
2	IEC Activities, Webinars, Office running and Untied Funds (for all existing centres)	Rs 33,50,000
	Total	Rs3,05,90,000

Agenda Item No. 09: Any other item with the permission of the Chair.

NIL

The meeting was ended with a vote of thanks to the Chair.

LIST OF PARTICIPANTS

- Sh. P. K. Pathak, Special Secretary, Ministry of Ayush, Chairman
- Dr. Tanuja Nesari, Director, AIIA & Member Secretary, PAC
- Dr. J. L. N. Sastry, I/C Drug Control Cell, Ministry of Ayush
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T-12012/1/2019-DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
(AYUSH)

AYUSH Bhawan
'B' -Block, GPO Complex,
INA, New Delhi-110023
13th August, 2019

OFFICE MEMORENDUM

Subject: Minutes of the 3rd Meeting of Project Sanctioning Committee (PSC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs-reg.

The undersigned is directed to forward the 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, under the Chairmanship of Secretary (AYUSH) at Ministry of AYUSH for perusal and necessary action. All concerned are requested to send the action taken report on the decisions/recommendations of the Project Sanctioning Committee within 15 days.

This has the approval of the Secretary (AYUSH).

Enclosure:- As above



(K. B. Sinha)

Under Secretary to the Govt. of India

To,

- 1) Sh. Pramod Kumar Pathak, Additional Secretary, Ministry of AYUSH and Chairman, Project Appraisal Committee
- 2) AS&FA, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi-110011
Financial Advisor of the Ministry of AYUSH
- 3) Dr. D.C. Katoch, Advisor (Ay.), Technical Head of the Drug Control Cell
- 4) Dr. Eswar Reddy, DCG(I)
- 5) Dr. K. R. C. Reddy, Director, Pharmacopoeial Commission of Indian Medicine & Homoeopathy, Ghaziabad, U.P
- 6) Dr. Tanuja Nesari, Director, AIIA
- 7) Under Secretary (KBS) Ministry of AYUSH,
- 8) Dr. Galib, National Pharmacovigilance Coordinator, AIIA, New Delhi,
- 9) Prof. Rabinarayan Acharya- IPvC-IPGT&RA Jamnagar
- 10) Dr. R. Madhvan- IPvC-NIS, Chennai
- 11) Dr. M. Raja-IPvC, NIH, Kolkata
- 12) Dr. Mohd Aleemuddin-IPvC-NIUM, Bangalore
- 13) Dr. Sudipta Kumar Rath-IPvC-NIA, Jaipur

Copy for information to:-

- 1) PPS to Secretary (AYUSH), Ministry of AYUSH
- 2) PS to AS, Ministry of AYUSH
- 3) All the officers of Drug Control Cell, Ministry of AYUSH

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(I).
- e) Dr. K. R. C. Reddy, Director, PCIM&H
- f) Dr. Tanuja Nesari, Director, AIIA
- g) Sh. Kundan B. Sinha, Under Secretary, Ministry of AYUSH
- h) Dr. Galib, National Pharmacovigilance Coordinator, AIIA, 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 AIIA/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:-

(i) Agenda Item No. 01: Financial proposal for 2019-20.

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.

BE(2019-20)	Advance released on 11.06.2019	Proposed Demand for 2019-20	Approval granted	Funds Available & Deficit
1	2	3	4=2+3	5=1-2
Rs 1.80 Cr.	Rs 0.57 Cr	Rs 2.15 Cr.	Rs 2.72 Cr.	Rs 1.23 Cr. Deficit of Rs. 0.925 Cr.

(ii) **Agenda Item No. 02: Approval of New Peripheral Pharmacovigilance Centres**
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. GovtAyurved College, Raghujai 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, Kumool, (Andhra Pradesh)
4. Regional ResearchInstitute of Unani Medicine, Kolkatta, (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.

Email

Minutes of the 5th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs-reg.

From : DCC Ayush <dcc-ayush@nic.in>

Sat, Jul 04, 2020 11:42 AM

2 attachments

Subject : Minutes of the 5th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs-reg.

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T-12012/2/2020-DCC (AYUSH)

भारतसरकार

Government of India

आयुर्वेद, योग व प्राकृतिक चिकित्सा, यूनानी, सिद्ध एवं होम्योपैथी (आयुष) मंत्रालय
 Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and
 Homoeopathy (AYUSH)

**NBCC Office Block-3 (2nd Floor),
 East Kidwai Nagar, New Delhi-110023.**

OFFICE MEMORENDUM

Subject: Minutes of the 5th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance Program of ASU & H drugs-reg.

This has reference to the 5th Meeting of Project Appraisal Committee (PAC) for the Central Sector Scheme of Pharmacovigilance of ASU & H drugs held on 25th June, 2020, under the Chairmanship of Sh. P. K. Pathak, Additional Secretary at Ministry of AYUSH. In this regard, minutes of the meeting is hereby forwarded for perusal and necessary action. All concerned are requested to send the action taken report on the decisions/recommendations of the Project Appraisal Committee at the earliest and as per the directions of the PAC (Agenda-3 of the enclosed minutes), NPvCC and IPvCs are requested to make presentation for a special review meeting to be held in the third week of July, 2020.

Enclosure:-

1. Minutes of the 5th PAC
2. OM of even number dated 2nd July, 2020

---With regards---
(Drug Policy Section)

To:

All the participant of PAC (as per list)

Copy to:

- i. PPS to Secretary (AYUSH), Ministry of AYUSH
- i. PS to AS, Ministry of AYUSH
- ii. PPS to Advisor, Ayurveda, Dr. D.C. Katoch, Ministry of AYUSH

**Minutes_of_the_5th_PAC_Meeting_of_Pharmacovigilance_Scheme__held_o
n_25.06.2020.pdf**
380 KB

02_07_20_OM_Misleading_Advertisements.pdf
3 MB

Minutes of 5th Meeting of Project Appraisal Committee held on 25. 6.2020, 11:00 AM.

5th Meeting of PAC was held online under the Chairmanship of Shri P.K Pathak Additional Secretary (AS), Ministry of AYUSH on 25th June 2020 at 11:00 AM to review the progress of pharmacovigilance scheme implementation and appraisal of the proposals for the year 2020-21. Director AIIA and coordinators of National and Intermediary Pharmacovigilance Centres (NPvCC and IPvCs) participated in the meeting. The list of participants is annexed.

The meeting started with welcome remarks from Dr D. C Katoch, Advisor (Ayu.) and Head, Drug Policy Section followed by opening statement about the background and status of scheme implementation. The Chairman, Additional Secretary Shri P.K Pathak in his remarks emphasized the need to hold the meeting of PAC on quarterly basis (last week of every quarter), steer the pharmacovigilance activities in effective manner and instructed NPvCC to submit UC, expenditure statement, remaining balance etc of the funds sanctioned in the 2019-20 by 15th July, 2020 to liquidate the grant accounts. It was reiterated the need to assess the performance of existing PPvCs in respect of ADR reporting and monitoring of Misleading Advertisements. Thereafter, agenda-wise discussions proceeded as under-

Agenda Item No.1- Confirmation of the Minutes of the 4th meeting of Project Appraisal Committee held on 24th May 2019 and Action taken report thereto.

Minutes of the 4th meeting of PAC held on 24th May, 2019 were confirmed since no comments received from any member. PAC also noted the action taken report of the previous recommendations and discussed the functional status of the Peripheral Pharmacovigilance Centres. National Co-ordinator Dr. Galib informed the house that 17 States/UTs are yet to have phramacovigilance centres and existing 62 PPvCs except that

114220/2020/DPS

of Banaras Hindu University, have appointed Program Assistants but reporting of ADRs, misleading advertisements is being carried out by the PPvC-BHU.

Agenda Item No. 02: Action Taken Report on the recommendations of the 3rd PSC:

Action Taken Report of the 3rd PSC held on 29th July, 2019 was presented in the meeting stating that an amount of Rs. 2.65 crore was released for pharmacovigilance activities in 2019-20. Discussing upon the method of fund transfer to the Peripheral Pharmacovigilance Centres, National Coordinator, Dr. Galib informed that funds to PPvCs are not being transferred through PFMS. In this regard, Chairman intervened that all the Pharmacovigilance Centers must be enrolled on the PFMS till **15th July** and funds should be transferred through PFMS only. It was informed that contract of the appointed DEO at NPvCC was renewed in April 2020 and after that salary is being paid as per the minimum wages norms. Regarding revision of ToRs/eligibility criteria of the Program Management unit (Program Manager and Program Assistant) to be recruited in the Ministry, Dr. D. C. Katoch, Advisor (Ay.) informed that due to constraint of space in previous office at AYUSH Bhawan and lockdown imposed due to COVID-19 outbreak, the file with the proposal of revised eligibility criteria has been submitted for getting approval of the Secretary (AYUSH)-Chairman PSC and thereafter would be forwarded for appraisal and concurrence of IFD. Recruitment process will be started after due approval of the same.

Agenda Item No. 3- Presentation of Progress of the Pharmacovigilance Scheme implementation by NPvCC and Intermediary Centres.

Dr. Galib, National Co-ordinator, NPvCC presented the progress of the Pharmacovigilance Scheme implementation and informed as under:

- Since January 2019, total of 416 Suspected ADR's (165 from Ayurveda, 61 from Siddha, 131 from Unani and 59 from Homoeopathy) have been reported till May, 2020. Causality analysis as per Naranjo Scale for reported suspected ADR's shows maximum reports in the probable category and a very few in the certain category.

Experts were nominated by the respective Central Councils of Homoeopathy, Unani and Siddha and from AIIA, New Delhi for the evaluation of Suspected ADR reports received. Evaluation of these reports in Homoeopathy and Siddha system was carried out at NPvCC, AIIA, New Delhi during December 2019. Evaluation of these reports in Ayurveda was carried in March 2020. Most of the reports were found to be non-serious and not directly related to the suspected drug.

- 6591 instances of misleading advertisements (4220 from Ayurveda, 1070 from Siddha, 728 from Unani and 573 from Homoeopathy) have been reported from August 2018 to May 2020 and 44 COVID 19 related misleading advertisements were reported in April 2020. Letters were sent to the editors of leading newspapers in Delhi by NPvCC citing misleading advertisements and urging them to stop publication of the same.

Thereafter, presentations were made by the Coordinators of the Intermediary Pharmacovigilance Centres. .

PAC raised concerns about underreporting of suspected ADRs and lack of follow up on the Misleading Advertisements escalated to State Regulators, Editors of the news papers and individual manufacturers. It was desired that NPvCC, IPvCs and PPvCs shall also send the reports through email on Misleading Advertisements to the concerned State Licensing Authority with a copy to State Health Secretary and Drug Policy Section of the Ministry and non-responsiveness or inaction of the State Regulatory Personnel on the reports of peripheral centres may be brought to the notice of Ministry. In this regard, Chairman, PAC directed to hold a special review meeting in the third week of July, 2020 involving participation and presentation from the NPvCC and IPvCs.

Agenda Item No. 04: Financial proposal for 2020-21(From June 2020 to March 2021-10 Months).

Dr DC Katoch and Dr Galib presented the financial proposal for the year 2020-21 and it was informed that total grant of Rs 5,23,36,587/- including Rs. 2,64,56,587 in 2019-20 had been released from the Ministry since February, 2018 under the pharmacovigilance scheme, out of which NPvCC and IPvC-IPGT&RA spent Rs. 4,78,45,519/- and unspent balance of Rs 44,91,068/- is available as on date in the account of National Pharmacovigilance Coordination Centre. UC of Rs. 15,00,000/- released to IPGT&RA, Jamnagar in September,2019 for National Conference of Pharmacovigilance has been submitted and UCs liquidated except for the funds released in the year 2019-20. Details of year-wise release of grant and expenditure are as under:

Financial Year	RE (in Rs.)	Instalment grant/dated	of	Amount of grant Released (in Rs.)	Expenditure till date (in Rs.)	Balance amount (in Rs.)
2017-18	1,50,00,000/-	1 st /23.02.2018		1,40,00,000	4,78,45,519/-	44,91,068/-
		2 nd /27.03.2018		10,00,000		
2018-19	1,09,00,000/-	3 rd /28.05.2018		10,60,000		
		4 th /14.12.2018		98,20,000		
2019-20	2,68,00,000/-	5 th /11.06.2019		57,00,000		
		6 th /20.09.2019		1,03,00,000		
				15,00,000(to IPGT&RA)		
		7 th /12.03.2020		89,56,587		

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PAC appraised the proposal of financial requirement for ten months from June 2020 to March 2021 and recommended it as under:-

A. Salary Component from June'2020 to March'2021 (10 Months)			
NPvCC	No.	Per Month (in Rs.)	For 10 Months (in Rs.)
(02) TPO @ 50000/- per month	2	50000	1000000
(01) DEO	1	20000	200000
IPvC (5)			
(05) Program Associate	5	40000	2000000
(05) DEO	5	20000	1000000
PPvC (63) *			
(63) Program Assistant	63	25000	15750000
Total			1,99,50,000
B.	Total Untied fund for 63PPvCs for 2020-2021 (@ 10,000/- per PPvC)		6,30,000/-
C.	11 New Peripheral Centres for 6 months		17,60,000
	i) Salary of 11 Program Assistants= Rs. 16,50,000		
	ii) Untied funds @ Rs 10,000 per centre= Rs 1,10,000		
D.	One National webinar on Pharmacovigilance (AYUSHSURAKSHA 2020) at NIUM, Bangalore		1,00,000/-
Total (A+ B+C+D)			2, 24, 40,000/-

It was recommended to deduct the unspent amount of Rs 44,91,068/- from the sanctioned amount of grant during 2020-21 and guidelines be made for activities to be done with untied funds. It was decided in the meeting that quarter-wise statistical information related to progress of implementation of Pharmacovigilance Scheme should be made available on the dedicated website of the Pharmacovigilance and a link of website should be made available on the Ministry's website and annual report of Pharmacovigilance program should be published along with the annual report of Ministry of AYUSH.

It was agreed in the meeting that NPvCC will provide specific activities-wise details of untied funds and the conference at NIUM, Bangalore may be in form of webinar with clear objectives and strict time frame involving participation from Pharmacovigilance Centers, Teaching Faculty and PG Scholars, State Government Regulatory personnel and other stakeholders of ASU&H sector.

Agenda Item No. 05: Approval of New Peripheral Pharmacovigilance Centres.

On presentation of the list of newly proposed 30 Pharmacovigilance Centers, PAC observed that new centres have proposed in most of the States where PPvCs are already functioning and contrary to the recommendations of the previous meetings, still 17 States/UTs namely Arunachal Pradesh, Bihar, Goa, Haryana, Jharkhand, Manipur, Mizoram, Nagaland, Punjab, Sikkim, Tripura, Andaman and Nicobar Islands, Chandigarh, Dadra and Nagar Haveli, Daman & Diu, Lakshadweep and Ladakh do not have any PPvC. Therefore, only eleven centres in these States were recommended to be established in 2020-21 with financial support for six months and it was advised to explore establishing PPvCs preferably in Government institutions in the remaining States/UTs of Punjab, Jharkhand, Mizoram, Dadra and Nagar Haveli, Daman & Diu and Lakshadweep. Following list of new centres was recommended-

AYURVEDA

- 1) Bharteeya Sanskrit Prabodhini Gomantak Ayurved Mahavidyalaya & Research Centre, Vajem, Shiroda- 403103, Distt. South Goa, Goa.
- 2) Shri Dhanwantri Ayurved College & Hospital, Sector.46-B, Chandigarh - 160 047.
- 3) Shri Krishna Govt. Ayurvedic College, Umri Road, KURUKSHETRA, Haryana.
- 4) Regional Ayurveda Research Centre (RARC), Dimapur, Nagaland
- 5) Regional Ayurveda Research Institute (RARI), Gangtok, Sikkim
- 6) Regional Ayurveda Research Institute (RARI), Itanagar, Arunachal Pradesh
- 7) ISM & Homoeopathy Hospital, Port Blair, Andaman and Nicobar Islands

HOMOEOPATHY

8. Regional Research Institute (H), Imphal, Manipur
9. Regional Research Institute (H), Agartala, Tripura

UNANI

10. Govt. Tibbi College, Patna, Bihar

SOWA-RIGPA

11. National Research Institute for Sowa-Rigpa, Leh, Ladakh

Agenda Item No. 06: Adjudication/ Performance Evaluation of Active Pharmacovigilance Centres

PAC appraised the proforma prescribing assessment criteria to evaluate the functionality/ performance of Pharmacovigilance centres and made following observations:

- The assessment shall be done from the date of inception of particular Pharmacovigilance Centre supported under the Scheme.
- NPvCC will relook the proforma and make it available in the website of Pharmacovigilance for making entries in online/digital format only.

Agenda Item No. 07: Utilisation of Unspent funds of 2019-20 in 2020-21:

It was decided to recommend for deducting the unspent funds of 2019-20 from the grant of funds sanctioned for 2020-21 and to process the matter on file after obtaining consolidated statement reflecting details of pending amounts with NPvCC and IPvCs.

Agenda Item No. 08: Revision of Salary of Recruited Manpower:

This matter was not recommended considering the Covid-19 situation in the country and its financial impact.

Agenda Item No. 09: Publication of Annual Report 2019-20 for Pharmacovigilance Program

PAC pointed out that there is no need to publish separate Annual Report of pharmacovigilance scheme implementation as the outcomes and outputs of the scheme are covered in the Annual Report of the Ministry. However, NPvCC may bring out quarterly bulletin of ASU&H pharmacovigilance activities, achievements and events including monthly reporting of ADRs and misleading advertisements and upload them in the website periodically.

Agenda Item No. 10: Setting up of Pharmacovigilance cell at all ASU & H Colleges/ Research Institutes.

PAC discussed in detail the proposal of setting up pharmacovigilance cells in all ASU&H college hospitals. It was found to be a welcome suggestion but providing support through the scheme to all the colleges may not be feasible and sustainable. Since the NCIM Bill and NCH Bill are in the Parliament, so the proposal should be taken up for consideration after the Bills are enacted and Commissions are set up. Meanwhile, CCIM and CCH may be approached for inclusion of pharmacovigilance modules in the UG and PG teaching and ADRs reporting and monitoring of advertisements by ASU&H colleges.

The meeting ended with vote of thanks to the Chair.



Online Meeting of PAC of Pharmacovigilance Scheme, 25.5.2020, 11.00 AM**List of Participants**

- ❖ Sh. P. K. Pathak, Additional Secretary, Ministry of AYUSH- Chairman
- ❖ Dr. D. C. Katoch, Advisor(Ayu.), Ministry of AYUSH
- ❖ Dr. S. R. Chinta, Deputy Advisor(Homoeopathy), Ministry of AYUSH
- ❖ Under Secretary (KBS) Ministry of AYUSH
- ❖ Dr. Tanuja Nesari, Director, AIIA
- ❖ Dr. Galib, National Coordinator, NPvCC, AIIA
- ❖ Prof. Rabinarayan Acharya- IPvC-IPGT&RA Jamnagar
- ❖ Dr. R. Madhvan- IPvC-NIS, Cherinai
- ❖ Dr. S.Paul -IPvC, NIH, Kolkata
- ❖ Dr. Mohd Aleemuddin-IPvC-NIUM, Bangalore
- ❖ Dr. Sudipta Kumar Rath-IPvC-NIA, Jaipur
- ❖ Dr Rachna Paliwal, Research Officer, Ministry of AYUSH
- ❖ Dr. Himanshu Joshi, Research Officer, Ministry of AYUSH
- ❖ Dr Rajnish Kumar Gautam, Research Officer, Ministry of AYUSH





F.No.-T.12012/2/2020-DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

AYUSH Bhawan, B Block
GPO Complex, INA, New Delhi-110023.

Dated: 2nd July, 2020

Office Memorandum

Subject: Actions to be taken on the instances of misleading advertisements of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs and related services reported by pharmacovigilance centres - reg.

Ministry of AYUSH has implemented a Central Scheme for Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy drugs aimed at monitoring and reporting adverse drug reactions (ADRs) and misleading/objectionable advertisements appearing in the print and electronic media. In this regard, a three-tier network of National, Intermediary and Peripheral Pharmacovigilance centres has been established as enclosed to undertake surveillance activities about ASU&H drugs across the country. More pharmacovigilance centres are added to the network from time to time.

Since enforcement of the provisions of the Drugs & Cosmetics Act, 1940 and Rules, 1945 and Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 pertaining to ASU&H drugs and related services is vested with the State Governments, it is requested to all the State Licensing Authorities / Drug Controllers for taking cognizance of the cases/instances brought to their notice by the ASU & H Pharmacovigilance Centres and initiate necessary action against the defaulters and alleged manufacturers/advertisers. Action taken report on case to case basis may be communicated to Ministry of AYUSH via email dcc-ayush@nic.in and to the respective pharmacovigilance centre.

Encl: List of pharmacovigilance centres

Dr D. C. Katoch

Adviser (Ay), Head- Drugs Policy Section.

To

All State Licensing Authorities/Drug Controllers of AYUSH

Copy to:

- i) State Principal Secretaries (Health/AYUSH) with a request for necessary direction to the concerned Licensing Authorities/ Drugs Control Officers.
- ii) All ASU&H Pharmacovigilance Centres.

7. List of other drugs used by the patient during the period of one month:

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Date of		Reason for use	Any unwanted occurrences
				Starting	Stopped / Continued		

8. Details of the drug suspected to cause ADR:

- Name of the drug:
- Manufacturing date and Expiry date (if available):
- Remaining pack / label (if available):
- Consumed orally along with (water / milk / honey / or any other)
- Whether any dietary precautions have been prescribed?
If yes, please specify:
- Whether the drug is consumed under medical supervision or used as self medication.
- Any other relevant information associated with drug use:

9. Management provided / taken for suspected adverse reaction

10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.		Reaction abated after drug stopped or dose reduced:		
		Reaction reappeared after re administration of drug:		
Was the patient admitted to hospital? If yes, give name and address of hospital				

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR:

12. Particulars of ADR Reporter:

Please tick: Patient / Attendant / Nurse / Doctor / Pharmacist / Health worker / Drug Manufacturer / Any others (please specify)

Name: _____

Address: _____

Telephone / E - mail: _____

Signature of the reporter: _____

Date: _____

Please send the completed form to: The centre from where the form is received or to
 The Coordinator, National Pharmacovigilance Coordination Centre (NPvCC)
 All India Institute of Ayurveda (AIIA), Mathura Road, Gautam Puri,
 Sarita Vihar, New Delhi - 110 076
 E-mail: pharmacovigilanceayush@gmail.com, ayush-pharmavig@aiia.gov.in

The ADR Probability Scale
 (Program Coordinator has to fill this scale)

Questions		Yes	No	Don't Know
1	Are there previous conclusive reports on the reactions?	+1	0	0
2	Did the ADR appear after the suspected drug was administered?	+2	-1	0
3	Did the ADR improve when the drug was discontinued a specific antagonist was administered?	+1	0	0
4	Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0
5	Are there alternatives causes that could solely have caused the ADR?	-1	+2	0
6	Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0
7	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
8	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
9	Was the adverse event confirmed by objective evidence?	+1	0	0
Total Score				

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

The Suspected Adverse Event	Grade - 1 (Mild)	
	Grade - 2 (Moderate)	
	Grade - 3 (Severe)	
	Grade - 4 (Threatening)	
The Suspected Adverse Event	Serious	
	Non-Serious	
The Suspected Adverse Event is due to	Physician	
	Patient	
	Drug	
	Other factors*	

Signature
Program Coordinator