INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre - Pharmacovigilance Programme of India (PvPI)

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

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Ao for NA. CRR 9.12.16

File No. IPC/NCC-PvPI/ICMR/2016-17/05 **Date: 24-10-2016**

To,

Dr. Gangakhedkar
Scientist G & Director
National AIDS Research Institute (NARI),
Plot No 73, G-block, MIDC, Bhosari,
Pune, Maharashtra-411026

Subject: Recognition of National AIDS Research Institute (NARI) as PvPI Collaborating Centre for Monitoring the Safety of Anti-HIV/AIDS Drugs.

Sir,

Greetings from Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI)!

This is with reference to meeting on 'Optimizing safety of medicines through Research based Pharmacovigilance- ICMR institutions as PvPI Collaborating Centre' dated 28 July, 2016 held at ICMR (HQ), AIIMS Campus, New Delhi & further intent to participate in nationwide programme to monitor the safety of drugs.

It is my pleasure to inform you that Indian Pharmacopoeia Commission (IPC), National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI) has decided to accord recognition to your institution as PvPI Collaborating Centre for monitoring the safety of anti-HIV/AIDS drugs, which is a great privilege.

You are requested to comply with the terms of reference enclosed herewith.

Please accept our heartiest congratulations.

With Thanks and Regards

Yours faithfully

(Dr. G. N. Singh)
Secretary-cum-Scientific Director

Copy to:

1. Shri K. L. Sharma, JS (R), MoHFW, GoI, Nirman Bhawan, New Delhi
2. PS to DG, ICMR & Secretary, DHR, ICMR HQ, AIIMS Campus, New Delhi
3. PS to DCG (India), CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi
4. PS to Secretary-cum-Scientific Director, IPC, Raj Nagar, Ghaziabad

Recognition of National AIDS Research Institute (NARI) as PvPI Collaborating Centre for Monitoring the Safety of Anti-HIV/AIDS Drugs

Terms of reference

1. The Organization must acknowledge receipt of the recognition letter by stating that they will abide by the terms and conditions of recognition.
2. The Collaborating Centre shall nominate at least one person as coordinator/ focal person.
3. The Collaborating Centre shall be involved in focused monitoring of drugs of interest and shall not be involved in routine activities being done by ADR Monitoring Centre (AMCs) or Regional Centres.
4. The Collaborating Centre shall focus on their core areas of competence and take up research topics in pharmacovigilance.
5. The Collaborating Centre shall work on research based pharmacovigilance to optimize the safety of medicines. The research shall identify and address the gaps and needs that can be fulfilled by institution.
6. Technical support related to Pharmacovigilance activities may be provided by National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI).
7. The Collaborating Centre shall initiate research in pharmacovigilance activities as per their scope and expertise in the area of research.
8. The Collaborating Centre will be involved in analyzing and assessment of the ADR reports of specialized/focused drugs received by PvPI, in their specific area of expertise.
9. Funding for research on Pharmacovigilance- At present, the programme has no mechanism to fund research or logistic requirements etc. The institute/ researcher may apply to other funding agencies for this purpose.
10. The Collaborating Centre will submit concept note and phase wise plan of work on research based pharmacovigilance to NCC-PvPI.
11. The Collaborating Centre may take up any other assignment, which may be required from time to time.