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		SOP No.	IPC/PvPI/NHP/002
Section	National Health Programme (NHP)	Revision No.	00
Effective Date	01/06/2016	Review Date	31/05/2019

Title: SOP for Coordination between Pharmacovigilance Programme of India (PvPI) and National Health Programmes (NHPs)

1.0 OBJECTIVE

- 1.1 To lay down a procedure to monitor the Adverse Drug Reactions (ADRs) related to the drugs used in National Health Programmes.

2.0 SCOPE

- 2.1 This SOP shall be applicable to Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.
 3.2 NHP Section-Incharge shall ensure that this parent SOP has been reflected in the section.
 3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

- 4.1 Officer Incharge – Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 NCC-PvPI shall be responsible for coordination with all NHPs.
 5.2 Revised National TB Control Programme (RNTCP) is the collaborative Programme under NHP, Ministry of Health and Family Welfare, Government of India (MoHFW, GoI). It coordinates with PvPI for monitoring the safety of Anti Tubercular drugs.

	Name	Designation	Signature	Date
Prepared by	Mr. Vivek Dabas	Pharmacopoeial Associate		20/05/2016
Reviewed by	Dr Pawan K. Saini	Scientific officer		23/05/2016
Approved by	Dr. Kalai Selvan	PSO		24/05/2016



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- 5.3 National AIDS control programme (NACP) is the collaborative Programme under NHP, MoHFW, GoI. It coordinates with PvPI for monitoring the safety of antiretroviral drugs.
- 5.4 To monitor the possible recognition of adverse reactions due to Anti Tubercular, Antiretroviral, Bedaquiline or other drugs used in their respective programme through optimal use of Adverse Drug Reaction Monitoring Centers (AMCs), RNTCP/ART/BDQ./others NHP Centers.
- 5.5 A joint core committee including NHP, PvPI and AMC officials at state/districts level is set up for development of action plan for Pharmacovigilance Programme in India.
- 5.6 Both the organizations (NHPs and PvPI) shall hold consultations on planning and implementations of activities and jointly review the progress of activities.
- 5.7 Once the centers are identified, healthcare professionals from these AMCs shall be trained on basic concepts, terminologies and SOPs and also provide hands on training on ADR form filling, Vigiflow data entry and various other aspects of PvPI. All these NHP Centers (RNTCP/ART/BDQ) shall be provided with accessibility to VigiFlow for ICSRs processing.
- 5.8 Technical Associates who are working at AMCs shall coordinate with the RNTCP/ART/BDQ/others NHP centers for the ICSRs processing and communicating to NCC.
- 5.9 AMCs (RNTCP/ART/BDQ/other NHP Centers) shall be responsible for monitoring and processing both serious and non-serious ICSRs to NCC- PvPI as soon as possible.
- 5.10 Initially 17 RNTCP, 20 ART and 06 Bedaquiline Centers were identified in the first phase to monitor the safety of anti- tubercular/anti - retroviral drugs and Bedaquiline from the existing AMCs under PvPI across the India.
- 5.11 Central division of NHP (RNTCP/ART/BDQ/other NHP Centers) shall be approach NCC- PvPI or their regional centers/sites working as AMCs under PvPI for any ICSR follow-up.

	Name	Designation	Signature	Date
Prepared by	Mr. Vivek Dabas	Pharmacopoeial Associate		20/05/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		23/05/2016
Approved by	Dr. Karla Selvan	PO		24/05/2016

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6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.
- 6.2 Do not use adhesive tape or whitener on SOP.
- 6.3 Do not share the SOP information to outside the organization.

7.0 REFERENCES : In House

8.0 ABBREVIATIONS

GoI	:	Government of India
MoHFW	:	Ministry of Health and Family Welfare
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
AMCs	:	Adverse Drug Reaction Monitoring Centres
ICSRs	:	Individual Case Safety Reports
NHP	:	National Health Programme
QA	:	Quality Assurance
RNTCP	:	Revised National TB Control Programme
TB	:	Tuberculosis
NACP	:	National AIDS control programme
BDQ	:	Bedaquiline

	Name	Designation	Signature	Date
Prepared by	Mr. Vivek Dabas	Pharmacopoeial Associate	<i>[Signature]</i>	20/05/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	23/05/2016
Approved by	Dr. Kabir Lalwan	PdO	<i>[Signature]</i>	24/05/2016

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9.0 ANNEXURE(s):

Annexure I: List of ART Centres with coordinator detail under Pharmacovigilance Programme of India

Annexure II: List of RNTCP Centres with coordinator detail under Pharmacovigilance Programme of India

Annexure III: List of Bedaquiline Sites with coordinator detail under Pharmacovigilance Programme of India

	Name	Designation	Signature	Date
Prepared by	Mr. Vivek Dabas	Pharmacopoeial Associate	<i>[Signature]</i>	20/05/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	23/05/2016
Approved by	Dr. Kabirwan	PSO	<i>[Signature]</i>	24/05/2016



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National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I
List of ART Centres under Pharmacovigilance Programme of India

S. No	State	Centre Name	Centre-ID
1.	Andhra Pradesh	Andhra Medical College, King George Hospital (KGH), Jagadamba Area, KGH Down Road, Maharanipeta, Visakhapatnam- 530002	ART-KGH, Visakhapatnam
2.	Gujarat	BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016	ARTBJMC, Ahmedabad
3.		PDU Medical College, Civil Hospital Campus, Jam Nagar Road, Jam Nagar Road, Rajkot- 360001	ARTPDU, Rajkot
4.	Karnataka	JSS Medical College Hospital, Sri Shivarathreeshwara Nagar, Mysore-570015	ARTJSS, Mysore
5.		Karnataka Institute Of Medical Sciences, P. B Road, Vidyanagar, Hubli-580022	ARTKIMS, Hubli
6.		Bowring & lady Curzon hospital, Lady Curzon Road, Tasker Town, Shivaji Nagar, Bengaluru- 560001	COEARTBH, Bengaluru
7.	Maharashtra	BJ Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune- 411001	ARTBJMC, Pune
8.		Grant medical college & Sir JJ Group of Hospital, JJ Marg, Off Jijabhoy Road, Byculla Mumbai- 400008	ARTGMCJJ, Mumbai
9.	Rajasthan	SMS Medical College, Jawaharlal Nehru Marg, Jaipur- 302004	ARTSMS, Jaipur

	Name	Designation	Signature	Date	Page No.
Prepared by	Mr. Vinek Dabas	Pharmacopoeial Associate		20/05/2016	1 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.		23/05/2016	
Approved by	Dr. Kalaiselvan	PJO		24/05/2016	



National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I
List of ART Centres under Pharmacovigilance Programme of India

10.		Christian Medical College, Thorapadi P. O., Vellore-632002	ARTCMC, Vellore
11.	Tamil Nadu	Madras Medical College, E.V.R Periyar Salai, Park Town, Chennai-600003	ARTGMC, Chennai
12.		Government Hospital of Thoracic Medicine, Tambaram	ARTGHTM, Tambaram
13.		Telangana	Gandhi Medical College, Musheerabad, Secundrabad-500003
14.	Uttar Pradesh	Institute of Medical Sciences Banaras Hindu University, Varanasi- 221005	COEARTIMS, Varanasi
15.	West Bengal	School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata- 700073	COEARTSTM, Kolkata
16.	Chandigarh	PGIMER, Sector12, Chandigarh-160012	COEARTPGI, Chandigarh
17.	Delhi	All India Institute of Medical Sciences(AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi -110029	ARTAIIMS, New Delhi
18.		University College of Medical Sciences, adjacent to GTB Hospital, Dilshad Garden, New Delhi -110095	ARTUCMS, New Delhi
19.		VMMC & Safdarjung Hospital, Mahatma Gandhi Marg, Raj Nagar, Safdarjung, New Delhi - 110029	ARTVMMC, New Delhi
20.		Maulana Azad Medical College and associated Lok Nayak, Govind Ballabh Pant Hospital & Guru Nanak Eye Centre, 2, B.S.Z. Marg, New Delhi -110002	COEART MAMC, New Delhi

	Name	Designation	Signature	Date	Page No.
Prepared by	Mr. Vinek Dabas	Pharmacopoeial Associate		20/05/2016	2 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.		23/05/2016	
Approved by	Dr. Kalpana Chandra	P.S.O.		24/05/2016	



Annexure-II
List of RNTCP Centres under Pharmacovigilance Programme of India

S. No	State	Centre Name	Centre-ID
1.	Andhra Pradesh	Guntur Medical College, Kanna Vari Thota, Guntur-522004	RNTCPGMC, Guntur
2.	Assam	Silchar Medical College & Hospital, Ghungoor, Silchar-788014	RNTCPSMCH, Silchar
3.	Chhattisgarh	Pt. JNM Medical College, Jail Road, Raipur- 492001	RNTCPPJNM, Raipur
4.	Gujarat	BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016	RNTCPBJMC, Ahmedabad
5.	Haryana	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak-124001	RNTCPPBDS, Rohtak
6.	Himachal Pradesh	Dr. Rajendra Prasad Govt. Medical College, Kangra, Tanda-176001	RNTCPRPMC, Tanda
7.	Karnataka	Karnataka Institute Of Medical Sciences, P. B Road, Vidyanagar, Hubli-580022	RNTCPKIMS, Hubli
8.	Kerala	Government Medical College, Medical College PO, Thiruvananthapuram-695011	RNTCPGMC, Trivanthapuram
9.	Madhya Pradesh	RD Gardi Medical College, Agar Road, Surasa, Ujjain - 456006	RNTCPRDGM, Ujjain
10.	Maharashtra	Government Medical College, Aundh Pune	RNTCPGMC, Pune
11.	Odisha	VSS Medical College, Burla, Sambalpur-768031	RNTCPVSSMC, Burla
12.	Punjab	Govt. Medical College Patiala, New Lal Bagh, Patiala-147001	RNTCPGMC, Patiala

	Name	Designation	Signature	Date	Page No.
Prepared by	Ms. Vivek Dabas	Pharmacopoeial Associate	[Signature]	20/05/2016	1 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	23/05/2016	
Approved by	Dr. Kavita Wari	PJO	[Signature]	29/05/2016	

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Annexure-II

List of RNTCP Centres under Pharmacovigilance Programme of India

13.	Rajasthan	Government Medical College, Jaipur	RNTCPGMC, Jaipur
14.	Tamil Nadu	Government Hospital of Thoracic Medicine, Tambaram	RNTCPGHTM, Tambaram
15.	Uttar Pradesh	S. N. Medical College, Agra	RNTCPSNMC, Agra
16.	West Bengal	R.G. Kar Medical College, 1, Kshudiram Bose Sarani, Kolkata-700073	RNTCPRGK, Kolkata
17.	Delhi	All India Institute of Medical Sciences(AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi -110029	RNTCPAIIMS, New Delhi

	Name	Designation	Signature	Date	Page No.
Prepared by	Mr. Vivek Dabas	Pharmaceutical Associate	<i>[Signature]</i>	20/05/2016	2 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	23/05/2016	
Approved by	Dr. Kabir Singh	PSO	<i>[Signature]</i>	24/05/2016	



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National Coordination Centre-Pharmacovigilance Programme of India

Annexure-III
List of BDQ. Centres under Pharmacovigilance Programme of India

S. No	State	Centre Name	Centre-ID
1.	Assam	Guwahati Medical College Guwahati	GMC (BDQ.) - Guwahati
2.	Gujarat	BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016	BJMC (BDQ.) - Ahmedabad
3.	Maharashtra	DPS KEM GTB Hospital, Sewri, Mumbai	KEM (BDQ.) - Mumbai
4.	Tamil Nadu	Government Hospital of Thoracic Medicine, Tambaram	GHTM (BDQ.) - Tambaram
5.	Delhi	Rajan Babu Institute of Pulmonary Medicine and Tuberculosis GTB Nagar Kingsway Camp	RBIPMT (BDQ.) - New Delhi
6.		National Institute of Tuberculosis and Respiratory Disease (Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases) Sri Aurobindo Marg, New Delhi-110030	NITRD (BDQ.) - New Delhi

	Name	Designation	Signature	Date	Page No. 1 of 1
Prepared by	Ms. Vinek Debis	Pharmacopoeial Associate	[Signature]	20/05/2016	
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	23/05/2016	
Approved by	Dr. Kalisekhar	PSO	[Signature]	24/05/2016	