



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India

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| | | SOP No. | IPC/PvPI/TE/003 |
| Division | Training and Education | Revision No. | 00 |
| Effective Date | 01/11/2016 | Review Date | 31/10/2019 |

Title: SOP for Functioning of Core Training Panel

1.0 OBJECTIVE

To lay down a procedure for functioning of Core Training Panel (CTP).

2.0 SCOPE

This SOP shall be applicable for operational aspects of the Core Training Panel under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 All members of the quorum shall be responsible for the implementation of this SOP.
- 3.2 Training and Education division shall be responsible for Coordination with Core Training Panel.
- 3.3 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer In charge – Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 The CTP shall function under the aegis of IPC. The CTP shall perform the following activities:
 - a. Identifying Trainers for the training programme of Pharmacovigilance Programme of India.

| | Name | Designation | Signature | Date |
|-------------|--------------------|--------------------|--------------------|------------|
| Prepared by | Dr. Pooja Thota | S.A | <i>[Signature]</i> | 17/10/2016 |
| Reviewed by | Dr. Pawan K. Saini | Scientific officer | <i>[Signature]</i> | 18/10/2016 |
| Approved by | Dr. V. Kalaiselvan | PSO | <i>[Signature]</i> | 21/10/2016 |

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- b. To identify the zone wise training centres for imparting training to the technical personals/officials involved in ADR monitoring.
- c. Preparation of training modules and Training calendars
- d. Preparation and Amendments in Training Manual for PvPI Personnel
- e. Updating of tool kit.
- f. Participation and interaction with international Pharmacovigilance forums.

5.2 Quorum of the CTP

- 5.2.1 Minimum four members shall constitute a quorum including at least one clinician and one pharmacologist in the CTP.
- 5.2.2 The maximum number of members in the CTP shall be 13.

5.3 Constitution of the CTP

- 5.3.1 CTP shall be a multi disciplinary committee, constituted by Ministry of Health and Family Welfare, Government of India notification with representation of the following: clinicians, pharmacists, medical pharmacologists, public health experts, regulatory authority representative.
- 5.3.2 The member secretary shall be from the NCC and shall co-ordinate all activities of the CTP.
- 5.3.3 The chairperson shall be nominated by the Health Secretary, Ministry of Health and Family Welfare, Government of India.
- 5.3.4 Tenure of the committee will be three years. Special invitees e.g. subject experts may be invited to attend meetings but shall not have any voting rights.

| | Name | Designation | Signature | Date |
|-------------|--------------------|-------------|-------------|------------|
| Prepared by | Dr. Prasad Thota | S.A | [Signature] | 17/10/2016 |
| Reviewed by | Dr. Pawan K. Saini | S.O. | [Signature] | 18/10/2016 |
| Approved by | Dr. Kalaiselvan.V | PSO | [Signature] | 21/10/2016 |



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IPC/PvPI/TE/003

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5.4 Decision making

- 5.4.1 Decision shall be reached based on a majority vote of the CTP members, provided a quorum has been met.
- 5.4.2 The chair person shall not have veto powers.

5.5 Schedule of meetings

- 5.5.1 The CTP shall meet every six months and three times in first year of its constitution.
- 5.5.2 All members shall also sign a confidentiality disclosure agreement form before the start of a meeting.
- 5.5.3 If the members unable to attend the meeting then he/she shall give reason for not attending the meeting in writing before the start of every meeting.
- 5.5.4 Alternate members shall attend in the place of absent regular members in order to meet the quorum requirements.
- 5.5.5 The venue of the CTP meeting will be decided in the previous meeting and the Member Secretary would intimate the meeting details at least 15 days in advance.
- 5.5.6 The member secretary shall maintain records of all its meetings, correspondence and other proceedings for a minimum period of five years in the Training & Education division at NCC.

5.6 Communication of the meeting outcomes

- 5.6.1 Draft version of the minutes will be finalized by the Member Secretary in consultation with the chairperson and shall be circulated to all members of the CTP.
- 5.6.2 The members shall offer their comments within seven working days.

| | Name | Designation | Signature | Date |
|-------------|--------------------|-------------|-----------|------------|
| Prepared by | Dr. Anand Thota | S-A | | 15/10/2016 |
| Reviewed by | Dr. Pawan K. Saini | S.O. | | 18/10/2016 |
| Approved by | Dr. Kalaiselvan | PJO | | 21/10/2016 |



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5.6.3 The Minutes of meeting shall be finalized at the most within two weeks.

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 outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

- CTP : Core Training Panel
- IPC : Indian Pharmacopoeia Commission
- NCC : National Coordination Centre
- PvPI : Pharmacovigilance Programme of India
- SOP : Standard Operating Procedure

9.0 ANNEXURE: Not applicable

| | Name | Designation | Signature | Date |
|-------------|-------------------|-------------|--------------------|------------|
| Prepared by | Dr. Anand Thota | S.A | <i>Anand</i> | 17/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O | <i>Pawan</i> | 18/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | <i>Kalaiselvan</i> | 21/10/2016 |