

Current Status of Adverse Drug Reactions Monitoring Centres under Pharmacovigilance Programme of India

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ABSTRACT

There are one hundred and fifty Adverse Drug Reactions Monitoring Centres (AMCs) across the country are functioning and reporting's Adverse Drug Reactions to National Coordination centre (NCC), Pharmacovigilance Programme of India (PvPI) at Indian Pharmacopoeia Commission (IPC), Ghaziabad. The AMCs are established to collate data on Pharmacovigilance and forward to NCC via online software (*VigiFlow*). The present AMCs are Medical Council of India (MCI) approved teaching hospitals and corporate hospitals. NCC is working with AMCs to coordinate with Pharmacy institutions to enhance ADRs reporting.

Keywords: Adverse Drug Reactions Monitoring Centres, Pharmacovigilance Programme of India, *Vigi Flow*. CDSCO. Indian Pharmacopoeia Commission.

INTRODUCTION

Indian Pharmacopoeia Commission (IPC), is functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) since 15th April 2011 under the aegis of Ministry of Health & Family Welfare, Government of India.¹ The major functions of NCC are to collect, collate and analyze Adverse Drug Reactions (ADRs) data to arrive at an inference to recommend regulatory interventions to Central Drugs Standard Control Organization (CDSCO), besides communicating risks to healthcare professionals and the public through PvPI-Newsletters.²⁻⁵ To collect the ADRs from patients ADRs monitoring centers (AMCs) are set up under NCC. The rationale for setting up the AMCs is to make it possible to identify rare ADRs that could not be found through clinical trial programmes.⁶ NCC provides the logistic support and manpower

to AMCs for their smooth functioning and reporting the ADRs

Procedure for the Selection of AMC

A 'Letter of Intent' is required to be submitted by the Head of the Institutions to participate in this nationwide programme to monitor drug safety. After examining the suitability, the concerned centre may be inducted as AMCs under PvPI. Subsequently NCC communicates the AMC details to WHO-Uppsala Monitoring Centre (UMC), Sweden to obtain *VigiFlow* (WHO-UMC owned online software) login details to upload ADRs (Figure 1).

Roles and Responsibilities of Personnel at AMCs

Each AMC under PvPI is assigned with a coordinator (department of pharmacology)

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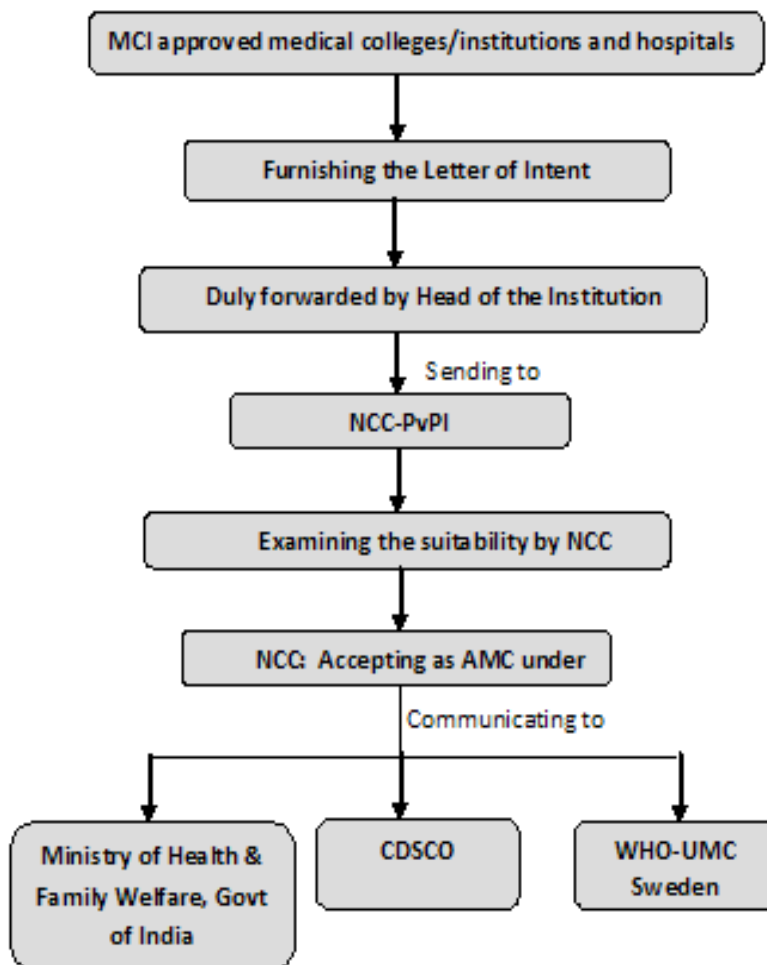


Figure 1: Process of induction of AMC's under PvPI.

and a Technical Associate responsible for its functioning. Their roles and responsibilities are:

- The designated Coordinator is responsible for the proper functioning of respective AMC. In absence of the coordinator, the designated deputy-coordinator is responsible for the smooth functioning of the centre.
- Other important responsibilities of coordinator is collection, checking completeness for a valid case, causality assessment and scrutinizing the ADRs reports as per SOPs
- The technical associate appointed is responsible for the collection and follow up of ADR reports, which have to be reported to the AMC coordinator, all the scrutinized and signed ADRs reports should be entered in *VigiFlow*. Every report has to be sent for the central assessment at NCC.
- The centre coordinator is responsible for sending the monthly reports of their AMC to NCC.
- Sensitization of the physicians/ healthcare professionals/ students/ patients of the catchment hospital for spontaneous ADR reporting by various mode (Lectures on ADR reporting, Email, telephone, pamphlet

and newsletter) has to be undertaken by the centre coordinator.

- Feedback to all healthcare professionals involved in reporting, to be sent by the AMC Coordinators.

Status of AMCs

At present ninety AMCs are established under different zonal offices of CDSCO (Figure 2). CDSCO provides administrative and technical support to the AMCs in their respective zone for the smooth functioning and reporting ADRs to NCC. Twenty two AMCs were functioning when the PvPI shifted to IPC and subsequently increased to sixty in first phase and to ninety in second phases. At present one hundred and fifty AMCs are functioning. All these AMCs are engaged to monitor and report ADRs to NCC via *VigiFlow*, a web-based Individual Case Safety Reports (ICSRs) management system that is specially designed for use by the authorized national centres in the WHO Programme for International Drug Monitoring. ICSR data can be manually entered into *VigiFlow* with support from the latest versions of terminologies such as the WHO Drug Dictionary and WHO-Adverse Reaction Terminologies.

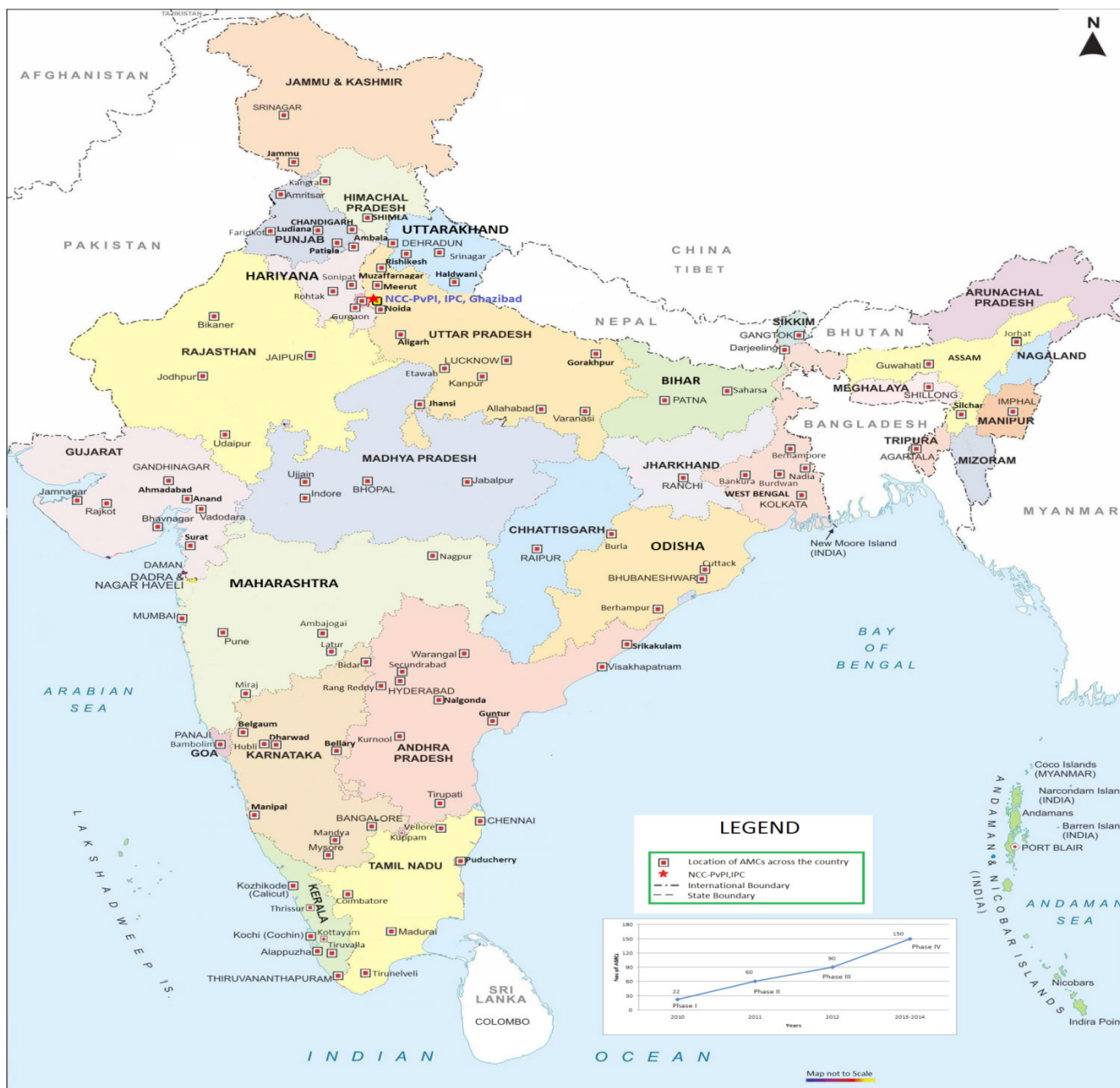


Figure 2: AMCs Network under PvPI

Regional Resource Centre for Training & Technical Support

In order to provide training and technical support to the newly inducted AMCs, four Training and Technical Support Centres at regional level were identified by NCC. These include Post Graduate Institute of Medical Education and Research, Chandigarh (North), JSS Medical College, Mysore (South), Institute of Post Graduate Medical Education and Research, Kolkata (East), Seth GS Medical College and KEM Hospital, Mumbai (West). The roles and responsibilities of these centres as follows:

- To provide basic concepts, terminologies and SOPs in Pharmacovigilance
- To provide hands on training and filling the ADRs and data entry in *VigiFlow*
- Interaction with the AMCs in their respective region on regular basis to resolve the technical issues

Future Plan

In a phase manner all MCI approved medical institutions will be enrolled in the programme and further it would be covered hospitals (govt. & private) and centres of public health programme located across India. Since

the data provided by the AMCs are going to contribute in the regulatory decision, NCC will implement 'PvPI inspection/audit' to the AMCs to ensure the quality of data and adequate training and technical exposure to the personnel involved in PvPI. NCC is closely working with the AMCs to coordinate with Pharmacy institutions particularly with Pharmacy Practice and PharmD departments to enhance the ADRs reporting culture.

CONCLUSION

At present, teaching and corporate hospitals have been identified as AMCs under PvPI. In future Pharmacy institutions may be enrolled in PvPI to enhance ADRs reporting. NCC is closely working with the AMCs to coordinate with nearby Pharmacy institution in reporting of ADRs.

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CONFLICTS OF INTEREST

Nil

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