

# **HAEMOVIGILANCE PROGRAMME OF INDIA (HVPI) – ORGANIZATIONAL STRUCTURE**

**Presented by :  
Akanksha Bisht  
Member Secretary - HvPI**

**Indian Pharmacopoeia Commission  
Ministry of Health & Family Welfare, Govt. of India**



# Haemovigilance Programme of India- HvPI

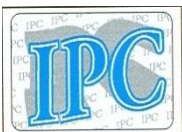
- **HvPI is a centralized, structured programme with defined responsibilities** launched in India on Dec 10, 2012 by Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India
- **Independent Programme** restricted to voluntary reporting of serious adverse reactions in recipients.
- Implemented under the broad ambit of Pharmacovigilance Programme of India with **dedicated budgetary provision- Rs 29.36 Crore (3.5 Million Euros approx.)** during 12<sup>th</sup> Five Year Plan (2012-2017)
- **National Coordinating Centre (NCC) for HvPI** is at National Institute of Biologicals (NIB), Ministry of Health & Family Welfare, Government of India





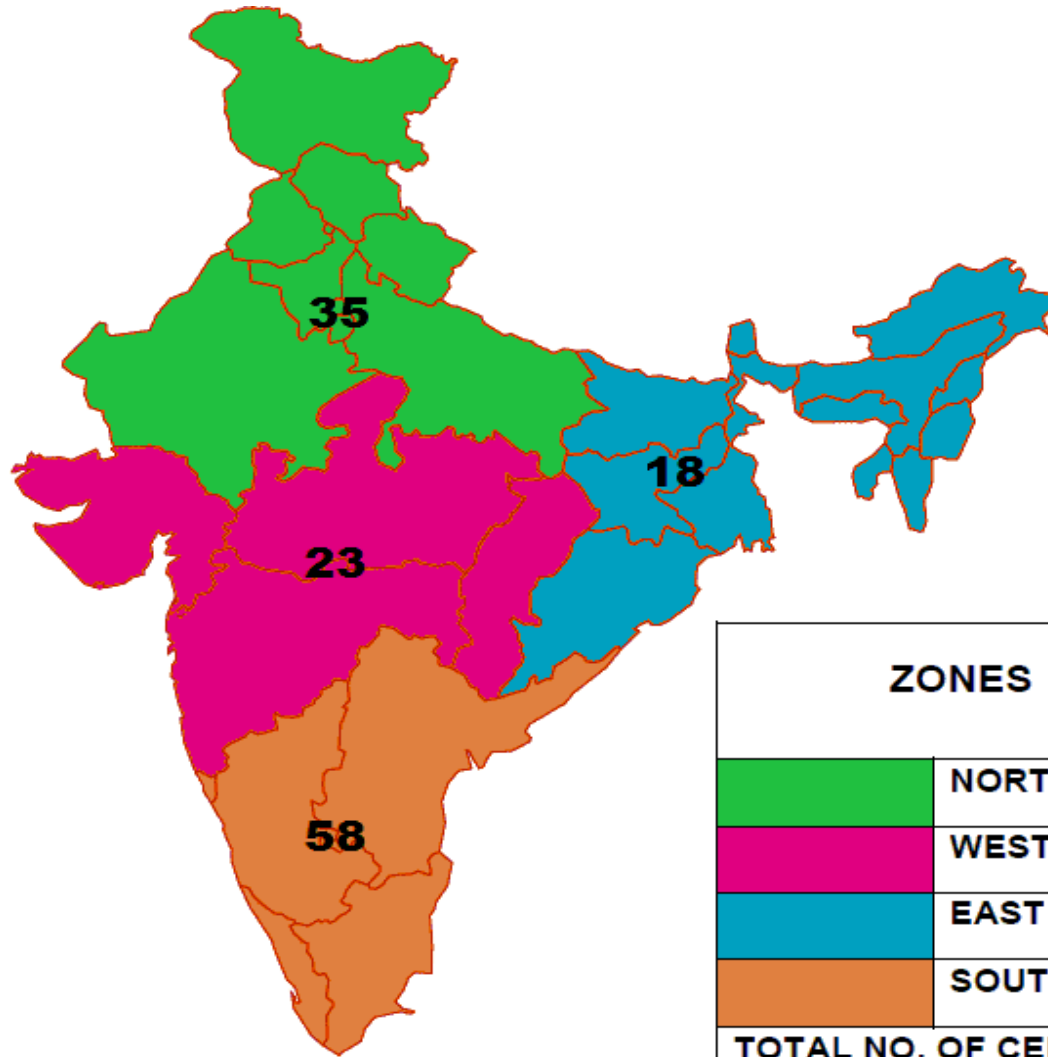
# Haemovigilance Programme of India- HvPI

- **Blood is categorized as a drug** as per the Drugs and Cosmetics Act, Ministry of Health & Family Welfare, Government of India and Blood Banking services are regulated by the rules therein
- There are **2545 licensed blood banks**, most of these are hospital based. 981 (38.5% ) are in the Public Sector , the remaining 1564 are either in private hospitals or managed by charitable / voluntary organizations
- The average annual Blood collection is around **7- 8 million units**





# Centers under Haemovigilance Programme of India (HvPI)



ZONES		NO. OF CENTERS
	NORTH	35
	WEST	23
	EAST	18
	SOUTH	58
TOTAL NO. OF CENTERS		134



# Targets for Haemovigilance programme-India

## Initiation Phase

**FY-2012-13**

- Develop systems & procedures
- Develop software
- Enroll participants
- Start Data Collection
- Zonal workshops for awareness
- Publication of HV Newsletter

## Expansion & Consolidation Phase

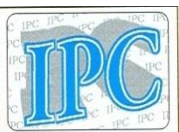
**FY 2013-15**

- Continue enrollment
- Training of staff
- Continue Zonal Workshops
- Publication of Newsletter
- Application for membership of IHN

## Expansion & Maintenance Phase

**FY 2015-17**

- Maintenance and optimisation
- Identify gaps & address through appropriate training
- Assess feasibility of donor vigilance
- Rapid alerts
- Epidemiological surveillance for TTIs





# Roles & Responsibilities of HvPI Units

## Medical Colleges/Institutions/Blood banks

- Collection and Causality assessment of Transfusion Reactions
- Data entry into **“Haemo-Vigil”** Software
- Transmission of data to HvPI – NCC , NIB

## HvPI- Haemovigilance National Coordinating Centre National Institute of Biologicals

- Review completeness of data Quality
- Preparation of SOPs, guidance documents & training manuals
- Publication of Haemovigilance Newsletter/ IEC Literature
- **Communicate recommendations of Haemovigilance Advisory Committee to IPC**

## PvPI, National coordinating Centre, IPC

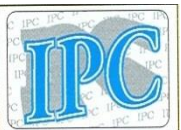
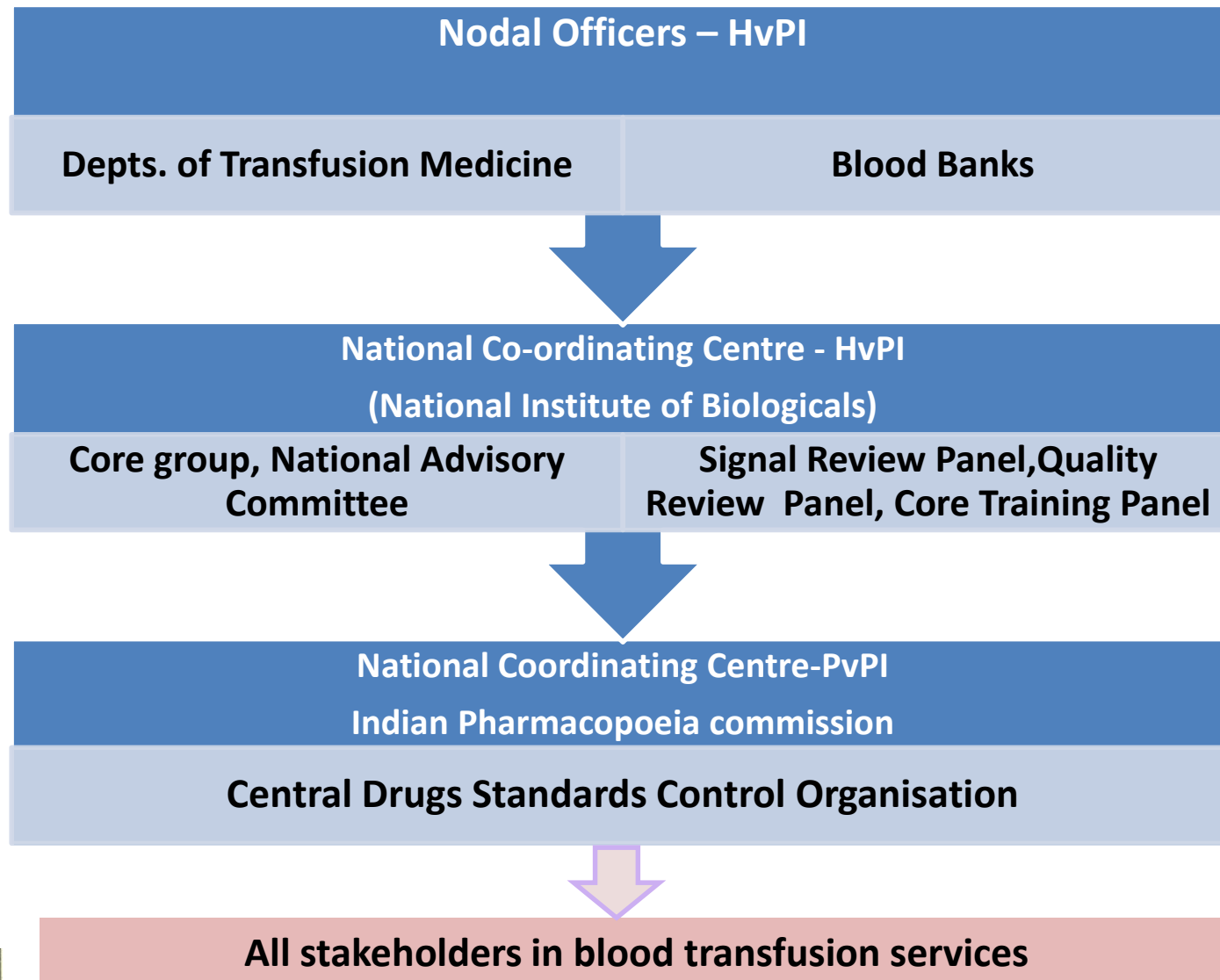
- **Forward recommendations of NCC to DCGI- CDSCO**

## DCGI- CDSCO

- Formulate safety related regulatory decisions
- Communicate Blood & blood Products transfusion safety related decisions to stakeholders



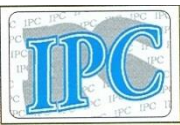
# Organisational structure for flow of information





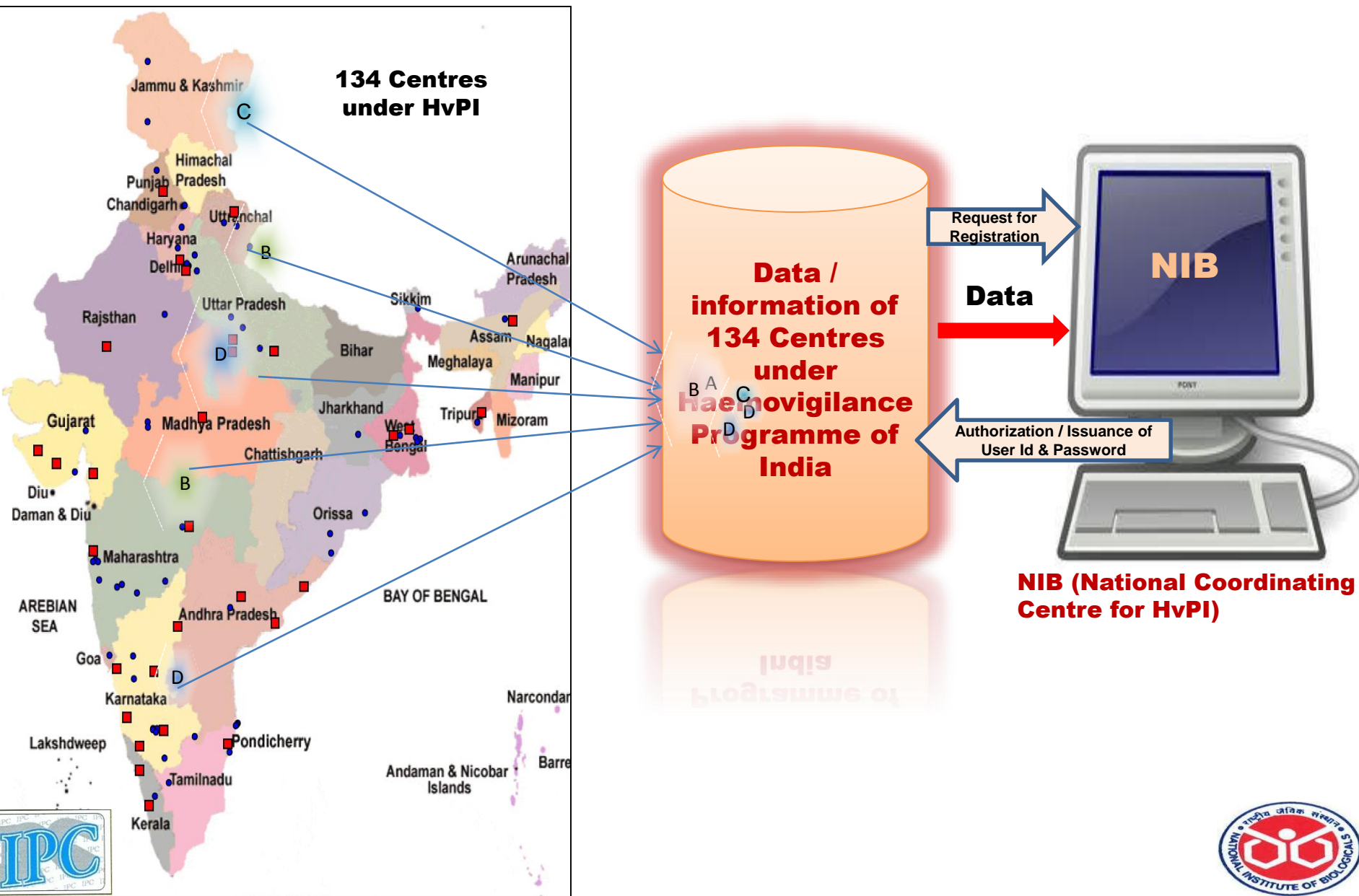
# Milestones in Development of Haemo- Vigil Software - IPC- NIB : IT Team

S.No	Milestones	Date
1.	Initiated software development for Haemovigilance by IT Division of NIB	15 <sup>th</sup> Nov,2012
2.	1st Meeting of Haemovigilance Advisory Committee : Offline Haemovigilance Software Demonstration was given	29th Nov 2012
3.	As per feed back given by the Advisory Committee Software was modified	7 <sup>th</sup> Dec 2012
4.	Software given for Security Audit to External agency	7 <sup>th</sup> Dec 2012
5.	Security Audit Done by External agency at 2 stage i.e. on : ✓In-house local server of NIB ✓Online Staging Server of National Informatics Centre (NIC)	7-14 <sup>th</sup> Dec 2012 20 <sup>th</sup> Dec 12- 1 <sup>st</sup> Jan 13
6.	Security Audit Certificate Submit to NIC	4th Jan 2013
7.	Security Audit Done by NIC & certificate was forwarded to VPN support	11 <sup>th</sup> Jan 2013
8.	VPN Certificate received & Haemo- Vigil software uplinked on NIB Website	24 <sup>th</sup> Jan 2013



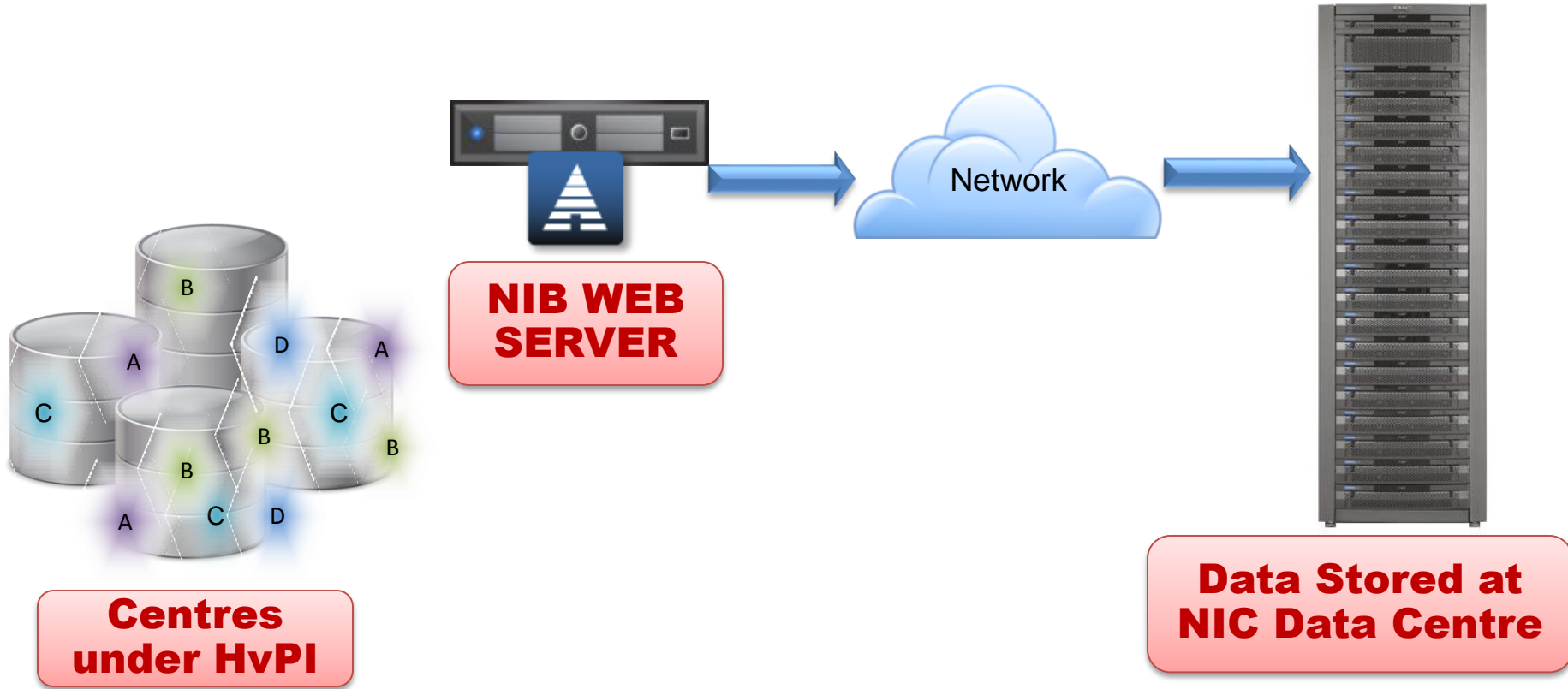


# Data Workflow





# Data Workflow

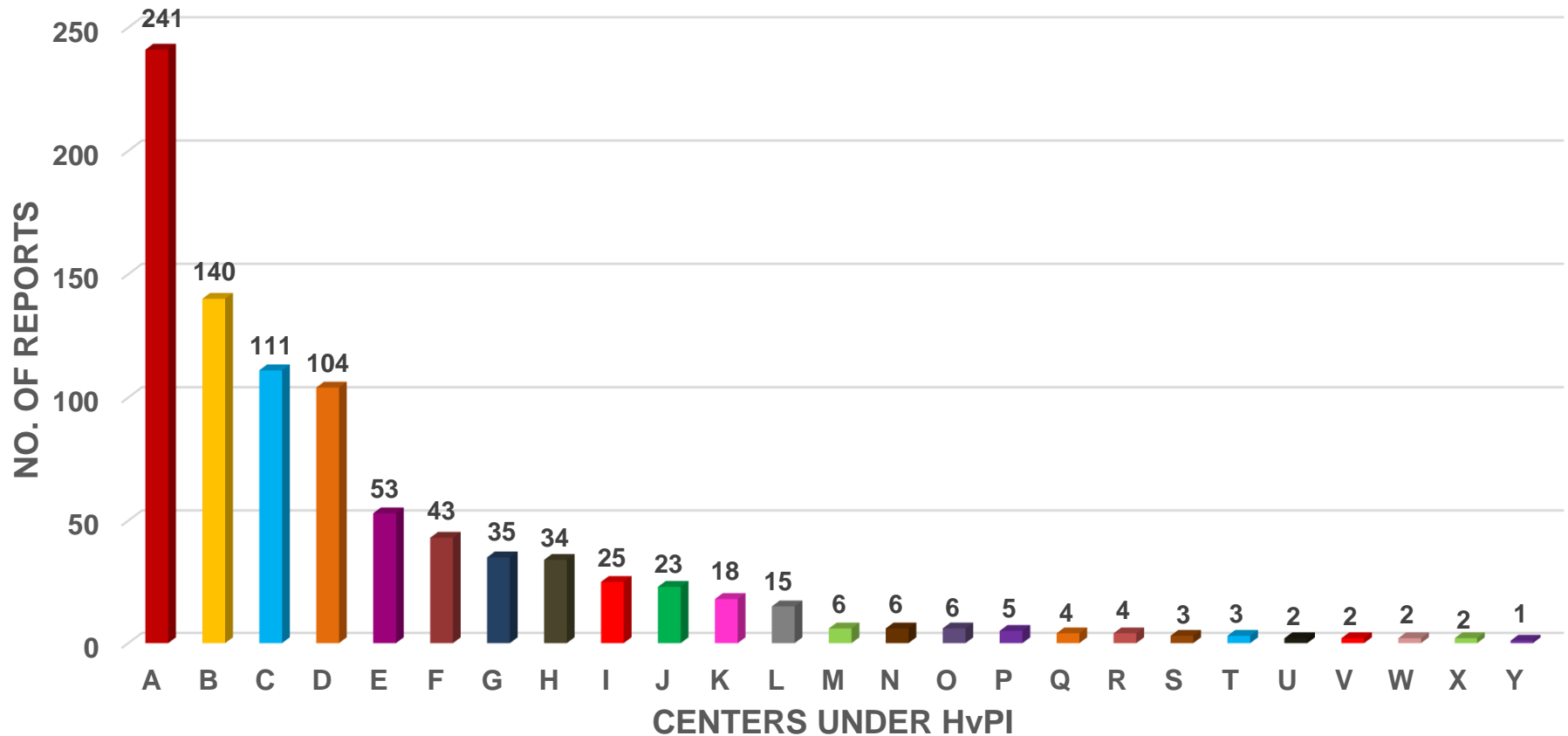




## TRRF's reported by Medical Colleges/Institutes/Hospitals/ Blood Banks



### TRANSFUSION REACTION REPORTS REPORTED BY THE CENTERS UNDER HvPI



**Total Reports Received=888**

# **IEC - Generating Awareness**



# IEC - Generating Awareness

**AJTS, Volume 7 Issue 1  
January-June 2013**

**1<sup>st</sup> HvPI Newsletter,  
Volume No.1, Issue 1,  
January-June, 2013**

**2<sup>nd</sup> HvPI Newsletter,  
Volume No.1, Issue 2,  
July-December, 2013**

## Hemovigilance Program-India

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<sup>1</sup>National Institute of Biologicals, Noida, Ministry of Health and Family Welfare, Government of India  
<sup>2</sup>Department of Transfusion Medicine, Postgraduate Institute of Medical Education and Research, Chandigarh, India

### Abstract:

A centralized hemovigilance program to assure patient safety and to promote public health has been launched for the first time in India on Dec 10, 2012 in 61 medical colleges in the first phase along with a well-structured program for monitoring adverse reactions associated with blood transfusion and blood product administration. National Institute of Biologicals (NIB) will be the National Coordinating Centre for Hemovigilance. This program will be implemented under overall ambit of Pharmacovigilance Programme of India (PvPI), which is being coordinated by Indian Pharmacopoeia Commission (IPC). All medical colleges of the country will be enrolled in this program by the year 2016 in order to have a National Centre of Excellence for Hemovigilance at NIB, which will act as a global knowledge platform.

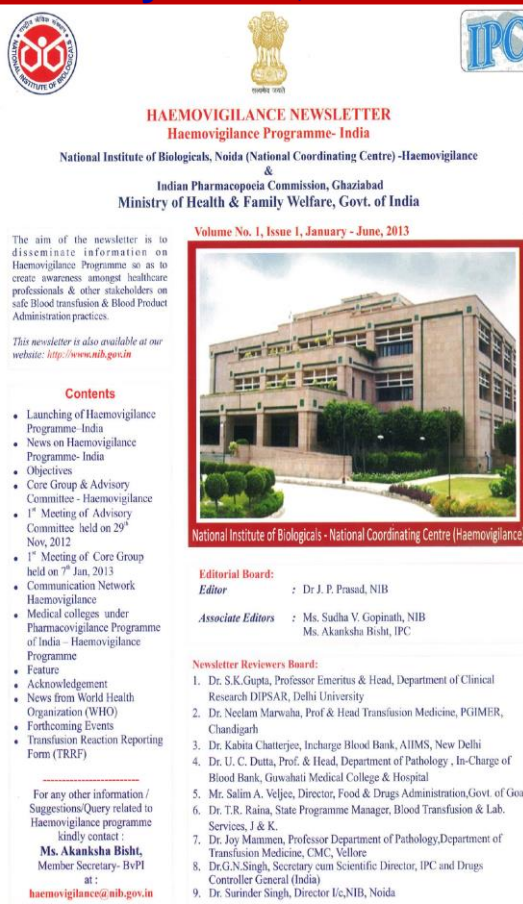
### Key words:

Hemovigilance, India, Medical colleges, Transfusion Reaction Reporting Form

### Introduction

Hemovigilance was first introduced in France in 1993 with mandatory reporting and in United Kingdom (UK) with first voluntary reporting system in 1996. Most of the developed countries like

phase, and optimization phase. A core group to coordinate the activities of hemovigilance between the medical colleges and National Coordinating Centre at IPC has been constituted. Furthermore, an advisory committee has also been constituted to a finalize hemovigilance-Transfusion Reaction Reporting Form (TRRF) to be introduced in the



**HAEMOVIGILANCE NEWSLETTER**  
Haemovigilance Programme- India  
National Institute of Biologicals, Noida (National Coordinating Centre) -Haemovigilance  
&  
Indian Pharmacopoeia Commission, Ghaziabad  
Ministry of Health & Family Welfare, Govt. of India

Volume No. 1, Issue 1, January - June, 2013

The aim of the newsletter is to disseminate information on Haemovigilance Programme so as to create awareness amongst healthcare professionals & other stakeholders on safe Blood transfusion & Blood Product Administration practices.

This newsletter is also available at our website: <http://www.nib.gov.in>

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- Transfusion Reaction Reporting Form (TRRF)

For any other information / Suggestions/Query related to Haemovigilance programme kindly contact :  
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Volume No. 1 • Issue 2 • July-December 2013

**HAEMOVIGILANCE**  
HAEMOVIGILANCE PROGRAMME - INDIA  
**NEWSLETTER**

National Institute of Biologicals, Noida  
(National Coordinating Centre) -Haemovigilance  
&  
Indian Pharmacopoeia Commission, Ghaziabad  
Ministry of Health & Family Welfare, Govt. of India

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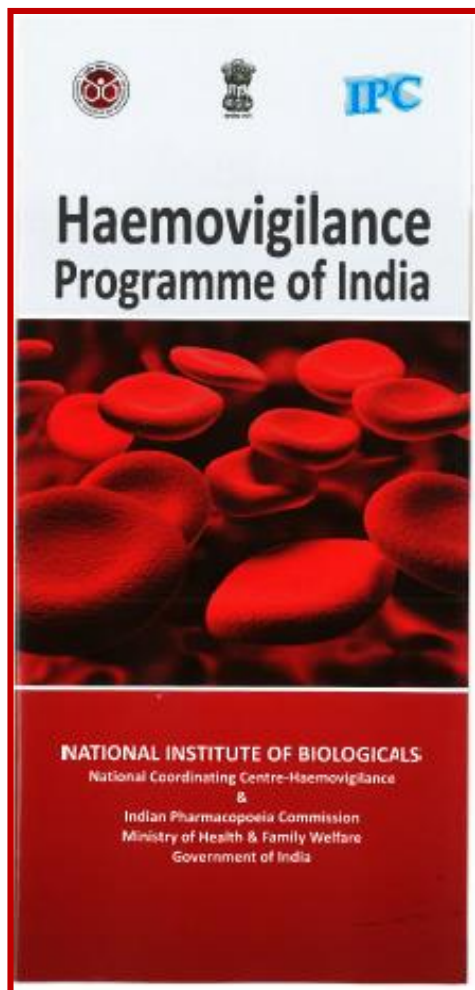
**IPC**



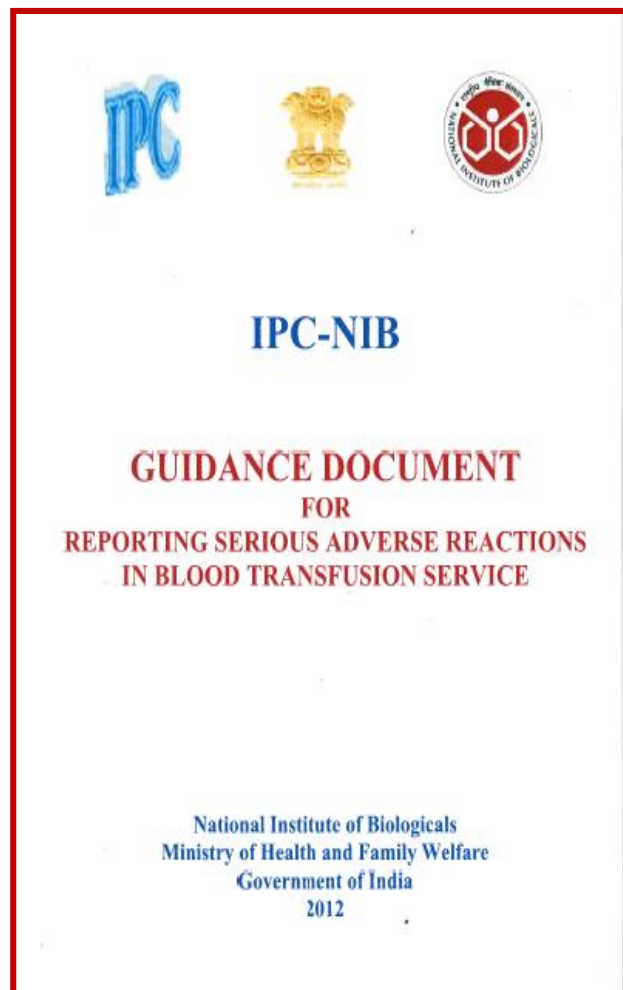


# IEC - Generating Awareness

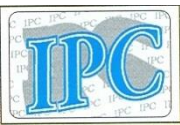
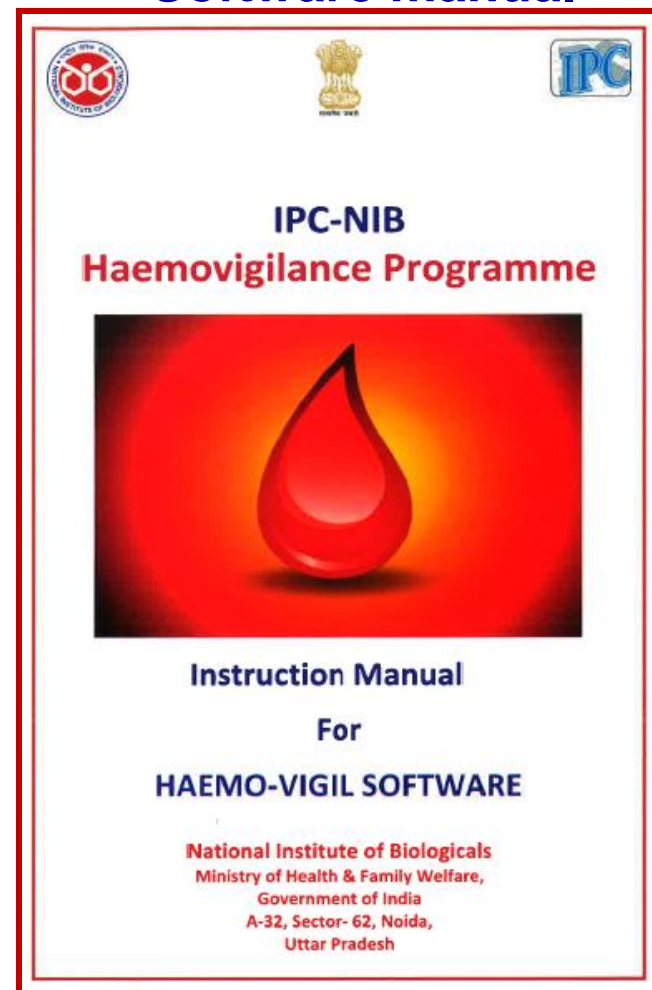
## HvPI Pamphlet



## Guidance Document



## Haemo-Vigil Software manual





# IEC - Generating Awareness

CMEs April 2013- January 2014

S.No.	Venue & Date	Facilitators
1	CMC , Vellore 20 <sup>th</sup> April 2013	Department of Transfusion Medicine Christian Medical College, Vellore
2	AIIMS, New Delhi 7 <sup>th</sup> May 2013	Deptt. Of Hospital Administration & Main Blood Bank, AIIMS
3	Jammu Medical College 18 <sup>th</sup> May 2013	Blood Transfusion & Lab Services, Jammu & Kashmir
4	Medical College, Goa 29 <sup>th</sup> June 2013	Directorate of Food and Drugs Administrator, Goa
5	PGIMER, Chandigarh 20th July 2013	Department of Pharmacology & Transfusion Medicine , PGI Chandigarh
6	NIMHANS, Bengaluru 28th September 2013	State Drugs Control Deptt, CDSCO and Deptt. Transfusion Med., NIMHANS
7	Srinagar, J & K 5th October 2013	Mission Director , National Rural Health Mission, J & K
8	Amrita Institute of Medical Sciences, Kochi, 9th Nov 2013	Department of pathology & Blood bank, AIMS, Kochi & CDSCO
10	PGIMER, Chandigarh 14th December 2013	Department of Pharmacology & Transfusion Medicine , PGI Chandigarh
11	CDSCO, Zonal Office Hyderabad 23 <sup>rd</sup> January 2014	CDSCO





# Roadmap : HvPI (Oct 2012- Jan 2014)

Year 2014  
member of IHN

Indigenous Software –  
Haemo-Vigil launched on  
24th Jan 2013 &  
1<sup>st</sup> Haemovigilance  
Newsletter published

Haemovigilance Programme  
launched on 10<sup>th</sup> Dec, 2012  
in 90 Medical Colleges  
across the country

TRRF & Guidance Document Finalized  
by Advisory Committee on  
7<sup>th</sup> Dec 2012

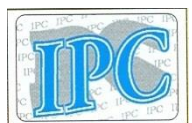
Core Group & Advisory Committee  
constituted in Nov, 2012

Decision to launch Haemovigilance  
Programme across the country on 26<sup>th</sup> Oct  
2012





**This is just the beginning,  
long way to go.....**





**For any query related to Haemovigilance Programme  
of India (HvPI) please feel free to contact :**



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Member Secretary – HvPI  
at**

**E-mail ID : [haemovigilance@nib.gov.in](mailto:haemovigilance@nib.gov.in)**





*Thank you  
for your attention*

