

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

HAEMOVIGILANCE

HAEMOVIGILANCE PROGRAMME - INDIA

NEWSLETTER





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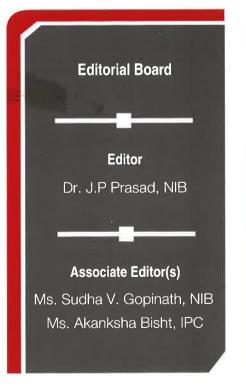
4th CME on Haemovigilance Programme at Goa Medical College, Bambolim, Goa





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 Products Administration practices.





Expert Reviewers ······

Dr. S.K.Gupta

Professor Emeritus & Head, Department of Clinical Research DIPSAR, Delhi University

Dr. Neelam Marwaha

Prof. & Head Transfusion Medicine, PGIMER, Chandigarh

Dr. Kabita Chatterjee

Incharge Blood Bank, AllMS, New Delhi

Dr. U. C. Dutta

Prof. & Head, Department of Pathology , In-Charge of Blood Bank, Guwahati Medical College & Hospital

Sh. Salim A. Veljee

Director, Food & Drugs Administration, Govt. of Goa

Dr. T.R. Raina

State Programme Manager, Blood Transfusion & Lab. Services, J &K

Dr. Joy Mammen

Professor Department of Pathology, Department of Transfusion Medicine, CMC, Vellore

Dr.G.N.Singh

Secretary cum Scientific Director, IPC and Drugs Controller General (India)

Dr. Surinder Singh

Director I/c,NIB, NOIDA

This newsletters is also available at our website: http://www.nib.gov.in

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Haemovigilance Programme - India

A centralized Haemovigilance Programme to assure Patient Safety & promote Public Health has been launched for the first time in the country on 10th Dec. 2012 in 90 Medical Colleges in the first phase, as a well-structured programme for monitoring Adverse Reactions associated with Blood Transfusion & Blood Products Administration. The number of centres covered under this programme at present is 101 and 413 Adverse Reactions Reports have been received. National Institute of Biologicals, NOIDA, Ministry of Health & Family Welfare (MoHFW), Govt. of India (Gol) is the Coordinating Centre for Haemovigilance. All the Medical Colleges, Institutes, Hospitals and Blood Banks of the country will be enrolled in this programme by the Year 2016. Haemovigilance Programme of India is targeting to become member of International Haemovigilance Network by end of the Year 2014.

Objectives-Haemovigilance Programme

- Monitor Transfusion Reactions
- Create awareness amongst health care professionals
- Generate evidence based recommendations
- Advise CDSCO for safety related regulatory decisions
- Communicate findings to all key stakeholders
- Create National & International Linkages

2nd Meeting of Haemovigilance Advisory Committee held on 27th Feb, 2013 at NIB, NOIDA

The second meeting of the Haemovigilance Advisory Committee was held on 27th Feb, 2013 at **National Institute of Biologicals, NOIDA.** The following Members/Special Invitees attended the meeting:

>>	Prof.(Dr.) S. K. Gupta	Chairperson
	Professor Emeritus & Head,	
	Department of Clinical Research, DIPSAR, University of Delhi	
>>	Dr. Surinder Singh	Member
	Director, NIB, NOIDA	
>>	Mr. P. Venkateshwarlu	Member
	Deputy Drugs Controller (I), CDSCO	
>>	Prof. (Dr.) Neelam Marwaha	Member
	Head, Department of Blood Transfusion, PGIMER, Chandigarh	
>>	Dr. R. N. Makroo	Member
	Director & Senior Consultant, Apollo Hospital, New Delhi	
>>	Dr. Kabita Chatterjee	Member
	In charge, Main Blood Bank, AIIMS, New Delhi	
>>	Prof. Joy Mammen	Member
	Department of Transfusion Medicine, CMC, Vellore	
>>	Dr. T. R. Raina	Member
	State Programme Manager, Blood Transfusion & Lab Services, J & K	
>>	Dr. S.B. Rajadhyaksha	Member
	Head -Department of Transfusion Medicine	
	Tata Memorial Cancer Hospital, Mumbai	
>>	Sh. Salim Veljee	Member
	Director, Food & Drugs Administration, Govt. of Goa	
>>	Dr.(Mrs.) Vanashree Singh	Member
	Director, Indian Red Cross Society, New Delhi	
>>	Dr. Shakti Kumar Gupta	Member
	Head, Department of Hospital Administration, AlIMS, New Delhi	
>>	Dr. Shobini Rajan	Member
	ADG, NACO	
>>	Dr. Madhur Gupta	Member
	Technical Officer WHO, WR Officer	
>>	Dr.V. Kalaisalven	Member
	Senior Scientific Officer	
	Indian Pharmacopoeia Commission	
>>	Dr. J. P. Prasad	Member
	Scientist-II & Head, NIB	
>>	Ms. Sudha V. Gopinath	Member
	Scientist-III, NIB	
>>	Ms. Akanksha Bisht	Member Secretary

Special Invitees

- Dr. Bikash Medhi, Additional Professor, Deptt. Of Pharmacology, PGIMER, Chandigarh
- Dr. Bharat Singh, Director, State Blood Transfusion Council GTB Hospital, New Delhi
- Dr. Ranjeet Singh Ajmani, Plasmagen Biosciences Pvt. Ltd, Bangalore
- Mrs. Karuna Kapoor, Baxter (India) Pvt. Ltd.

Scientific Assistant, Indian Pharmacopoeia Commission

• Dr. Zarin Bharucha, Consultant Expert Transfusion Medicine

Salient features of the meeting

- Demonstration of Haemo-Vigil Software prepared indigenously by IT Division of National Institute of Biologicals, NOIDA. Haemo-Vigil Software is available online at websites:
 - www.nib.gov.in, www.ipc.gov.in & www.cdsco.nic.in
- Finalization of Instruction Manual for Haemo-Vigil Software for online reporting of Adverse Reactions related Blood Transfusion & Blood Products Administration by Medical
- Colleges/Hospitals/Institutes/ Blood Banks. Instruction Manual for Haemo-Vigil Software is available on websites: www.nib.gov.in, www.ipc.gov.in & www.cdsco.nic.in
- Continuing Medical Education (CMEs) on Haemovigilance
 Programme in Medical Colleges all across the country to be organized in order to:
 - Create awareness about HaemovigilanceProgramme of India among

- the Medical fraternity
- >> Train the medical, nursing and technical staff of the medical colleges and the blood banks on Haemo-Vigil Software
- >> Facilitate the identification of needs, challenges and priority activities in implementation of Haemovigilance Programme

In the first phase following Medical Colleges were identified for organizing CMEs:

S.No.	Name of the Medical College	Date of CME		
1	Christian Medical College (CMC), Vellore ,Tamil Nadu	20 th April, 2013		
2	All India Institute of Medical Sciences (AIIMS), New Delhi	7 th May, 2013		
3	Govt. Medical College, Jammu, J & K	18 th May, 2013		
4	Goa Medical College & Hospital, Goa	29 th June, 2013		
5	PGIMER, Chandigarh	20 th July, 2013		











2nd Meeting of Haemovigilance Advisory Committee held on 27th Feb, 2013 at NIB

Launching of Haemo-Vigil Software

Haemo-Vigil, a software which is being used by the Medical Colleges/Institutes/Hospitals/ Blood Banks under Haemovigilance Programme to forward the data online in respect of Adverse Reactions associated with Blood Transfusion and Blood Products Administration to the National Coordinating Centre i.e. National Institute of Biologicals, NOIDA.

- The Software was developed in-house by three member team of IPC & NIB Information Technology Division.
- Haemo-Vigil was developed in less than two & a half months and was officially launched on 24th Jan, 2013 on the website of NIB.

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 th Nov, 2012
2	1st Meeting of Haemovigilance Advisory Committee : Offline Haemovigilance Software Demonstration was given	29 th Nov, 2012
3	As per feedback given by the Advisory Committee Software was modified	7 th Dec, 2012
4	Software given for Security Audit to External Agency	7 th Dec, 2012
5	Security Audit done by External Agency at 2 stage i.e. on: >> In-house local server of NIB >> Online Staging Sever of NIC	7 th Dec, 2012-14 th Dec, 2012 20 th Dec, 2012-1 st Jan, 2013
6	Security Audit Certificate was submitted to NIC	4 th Jan, 2013
7	Security Audit Done by NIC & certificate was forwarded to VPN support	11 th Jan, 2013
8	Haemo- Vigil software uplinked on NIB Website and was online available for the users.	24 th Jan, 2013



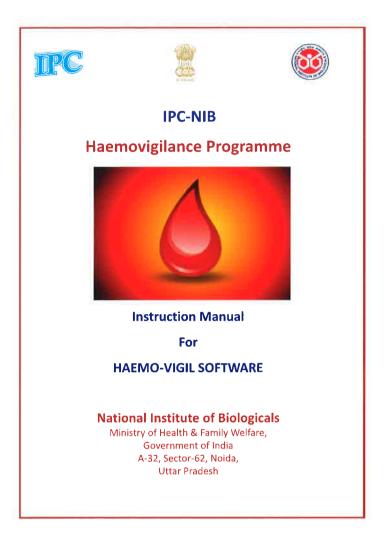
(From Left to Right: Ms. Akanksha Bisht, Mr. Deepak Mahajan & Mr. Sunish Singhal) Haemo- Vigil Software Developed by IPC- NIB: IT Team

Launching of Instruction Manual for Haemo-Vigil Software

- Instruction Manual for Haemo-Vigil Software was launched on 8th April, 2013 and is also available online on the website of NIB ,IPC & CDSCO i.e www.nib.gov.in, www.ipc.gov.in & www.cdcso.nic.in
- It is an essential tool to enable the user to enter the data in Haemo-Vigil Software which will aid in collation & analysis of the Adverse Reactions related to Blood Transfusion & Blood Products Administration as reported from all across the country.
- The following members of Core Group- Haemovigilance & IT Division of National Institute of Biologicals gave their contribution in preparing the Instruction Manual for Haemo- Vigil Software.

Core Group- Haemovigilance

- >> Dr. J. P. Prasad Scientist-II & Head, NIB
- >> Ms. Sudha V. Gopinath Scientist-III, NIB
- Ms. Akanksha Bisht Scientific Assistant, IPC Member Secretary-Haemovigilance Programme



IT Division (National Institute of Biologicals)

- >> Mr. Deepak Mahajan Computer Officer
- >> Mr. Sunish Singhal Technical Associate

1st CME on Haemovigilance held on 20th April, 2013 at Christian Medical College, Vellore











CME organized by CMC, Vellore in collaboration with State Drugs Control Department, Tamil Nadu, IPC & NIB, MoHFW, Govt. of India

The Programme was coordinated by

Dr. Joy Mammen, Professor, Dept. of Pathology, CMC, Vellore and
Dr. Manivannan, Deputy Drugs Controller, Bangalore, CDSCO



Mr. G. Selvaraj Director of Drugs Control Directorate of Drugs Control, Tamil Nadu

Haemovigilance program held at Christian Medical
College Vellore. I had an opportunity to highlight the
importance and need for the Haemovigilance in our State
as it has 281 blood banks both Private and Govt.
Institutions and 160 Blood storage centers and they
perform the blood and its components transfusion.
It would be a great honour, if these awareness ideas are
being enlighten to all our healthcare staff by our
Haemovigilance team, so that we would be able to
protect the health of our people.

2nd CME on Haemovigilance held on 7th May, 2013 at All India Institute of Medical Sciences (AIIMS), New Delhi











CME organized by All India Institute of Medical Sciences (AIIMS), New Delhi in collaboration with NIB & IPC, MoHFW, Govt. of India

The Programme was coordinated by

Dr. Shakti Kumar Gupta, HOD, Hospital Admin.,

Dr. Mahesh R, Assistant Professor and

Dr. Arvind Dhotre, Sr. Resident Administrator

Department of Hospital Administration, AllMS, New Delhi



Dr. Shakti Kumar Gupta Prof. & Head, Dept. of Hospital Admin. AllMS, New Delhi

Blood transfusion reactions though not a very common phenomena observed in any healthcare sector, but the implications associated with transfusion reaction are far too many. There are not only medical and ethical issues related to transfusion reaction, but with the growing concern for quality and patient safety, the adverse transfusion reaction becomes a matter of utmost importance for any healthcare setup.

Though globally there are various haemovigilance programmes, being conducted to record the adverse event following blood transfusion, but as far as India is concerned there is no Haemovigilance Programme to record such type of events.

National Institute of Biologicals under the able guidance of Dr. Surinder Singh has taken a pioneer step in this direction, by launching Haemovigilance programme for the whole country.

I have no doubt that National Institute of Biologicals (NIB) and Indian Pharmacopoeia Commission (IPC) will achieve their target of enrolling all the medical colleges of the

country by 2016 and will be able to establish National Centre of Excellence for Hemovigilance. I wish them good luck for all their future endeavors and hope that this pioneer step taken by NIB and IPC will pay rich dividends in the times to come and will lead to reduction in the numbers and severity of transfusion reaction.⁹⁹

3rd CME on Haemovigilance held on 18th May, 2013 at Govt. Medical College, Jammu, J & K









CME organized by PG Department of Transfusion Medicine, Govt. Medical College Jammu, ISBTI & JKSACS in collaboration with NIB & IPC, MoHFW, Govt. of India

The Programme was coordinated by

Dr. Vijay Sawhney, Head Transfusion Medicine,

GMC Jammu and

Dr.T.R. Raina, Secretary General, ISBT



Dr. Shashi Gupta Incharge, Principal & Dean Jammu Medical College, Jammu

Department of Blood Transfusion Medicine Govt.

Medical College Jammu in collaboration with National Institute of Biologicals, NOIDA organized a one Day CME on Haemovigilance Programme of India on 18th May 2013 in the college auditorium. A large no. of participants from different districts of Jammu including blood users and blood providers attended this programme. Subject experts of National and International repute highlighted the different aspects for implementation of Haemovigilance Programme at Institutional and National level to minimize the risks associated with blood transfusion reactions and enhancing blood safety. I am sure the interaction between panelists and delegates shall go a long way in understanding the concept of Haemovigilance.

4th CME on Haemovigilance held on 29th June, 2013 at Goa Medical College, Bambolim, Goa











CME organized by Directorate of Food & Drugs Administration and Goa Medical College & Hospital, Govt. of Goa in collaboration with NIB & IPC, MoHFW, Govt. of India

The Programme was coordinated by

Sh. Salim Veljee, Director,
Directorate of Food & Drugs Admin. Goa and

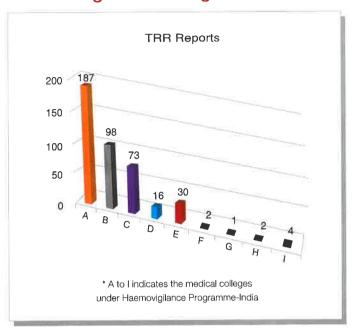
Dr. R.G. Wiseman Pinto, Prof. & HOD (Pathology),
Goa Medical College



Dr. V.N. Jindal Dean, Goa Medical College, Goa

Haemovigilance Programme all over the country. I am sure, this programme will go a long way in ensuring that the patients receiving blood or blood products are confident that they are in safe hands. Tracking of Adverse Reactions/Events will help in finding out the incidence and taking preventive steps. It is not a punitive action. Infact a country wide Haemovigilance network will help the blood banks to learn from each other and reduce or eliminate the errors in transfusion medicine. The software prepared by NIB for this will help the medical colleges in uploading any adverse events on the net. The initiative of NIB is worth appreciating. They have been conducting workshops all over the country to bring awareness amongst all medical personnel connected with transfusion medicine about the need to ensure safe methods of transfusion. Recently, one such workshop was conducted at Goa Medical College which was very informative. I Congratulate, the full team of NIB under the leadership of Dr. Surinder Singh who participated in this workshop.

Transfusion Reaction Reports (TRR) by Medical Colleges under Haemovigilance Programme



At present there are 413 reports in the database submitted via Haemo-Vigil Software by 9 Centers under Haemovigilance

Participation in DIA 2013, held in Bengaluru on 8-9th March, 2013

- The Drugs Information Association (DIA) India organized a 2-day seminar titled 'New Insights into Current Pharmacovigilance Challenges' from March 8 to 9, 2013 at the Vivanta by Taj - Yeshwantpur, Bengaluru.
- Participants were professionals with experience in clinical safety and who are involved in Pharmacovigilance, Clinical Research, Risk Management Compliance, Medical Information, Regulatory Affairs, Academia and Pharmacology.
- A key note on Haemovigilance and Biovigilance
 Programs of India was given by Dr.Surinder Singh,
 Director In Charge, National Institute of Biologicals
 followed by presentation on Haemo-Vigil Software by
 Ms. Akanksha Bisht, Member Secretary
 Haemovigilance Programme.
- The presentation was well appreciated by the audience & gave an insight into Haemovigilance Programme launched on 10th Dec, 2012.

News published in Daily Excelsior.com, The largest Circulated Daily of Jammu & Kashmir



Excelsior Correspondent

JAMMU, May 18: PG Department of Blood Transfusion Medicine, Gover-nment Medical College (GMC) Jammu in collaboration with National Institute of Biologicals (NIB), New Delhi IPC, JKSACS and ISBTI, organized a one-day CME for training on Haemovigilance Programme of India (HPI) in the College Auditorium, here today.

During the CME, subject experts of national and international repute deliberated upon the concept of the Haemovigilance Program of India to train the delegates,

Dr Vijay Sawhney, HoD, Blood Transfusion Medicine, GMC Jammu, welcomed the guests and the delegates. He elaborated various measures of Haemovigilance being adopted by the department.

Dr Shashi Gupta, Principal and Dean, GMC and Associated Hospitals Jammu, in her speech highlighted the importance of Haemovigilance for blood safety.

Director NIB. Surinder Singh, who is the son of the soil and has undertaken many important national and international assignments, told that a centralized Haemovigilance Program to assure patient safety was launched for the first time in the country on December 10, 2012 in 90 Medical Colleges in the first phase and GMC Jammu is one of these colleges.

Dr Akanksha Bisht, Member secretary, Haemovigilance Programme, demonstrated Haemovigilance software. It was followed by a panel discussion on Haemovigilance Program of India and International Haemovigilance network in which Dr TR Raina, Secretary General ISBTI, Member National Advisory Committee, Haemovigilance Programme of India, was the moderator.

A large number of delegates comprising Blood Providers, Blood users doctors, Postgraduates, technicians, nurses, and officers of administration section from GMC and Associated Hospitals attended the CME.

The CME ended with a vote of thanks by Dr Meena Sidhu, Assistant Professor, Blood Transfusion Medicine, GMC Jammu.

Transfusion Reaction Reporting Form (TRRF) for Blood & Blood Products



A) PATIENT INFORMATION

Indian Pharmacopoeia Commission-National Institute of Biologicals Ministry of Health & Family Welfare-Govt. of India

HAEMOVIGILANCE





* Mandatory Field

TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

For reporting of Transfusion Reactions by Healthcare Professionals

Patient	t initials* DC	B/Age in years*	Blood G	Group*	*****	Diagnosis	3	Hospital Cod	de No*
	al Admission No.*		Sex:*	F M					
Date &	Time of Transfusion*	Da	ate & Time of Re	action*		Date &	Time of Re	covery	<u>y.e.</u>
B) TR	ANSFUSION PRODU	CT DETAILS*							
- Components		Select Components	Unit Number (transfused)	Expiry Date			Batch Number	Indications	1*'time/Repeat Transfusion (No. of Repeats)
Whole	Blood								
	lood Cells								
	ets Apheresis ets Pooled/RDP								
$\overline{}$	it detergent (SD) Plasma								
FFP	en ninitata								
Any ot	recipitate her								
Blood Specify	Products (Please y)	Manufacturer		Batch Num	ber	Expiry Da	ite		
C) N	IATURE OF ADVERS	E REACTIONS	k						
S.No.		Reactions							Please Tick (✓)
1	Immunological Haemolys		patibility						
2	Immunological Haemoly	sis due to other allo-a	ntibodies						
3	Non Immunological Hear	molysis							
4	Transfusion Transmitted	Bacterial Infection							
5	Anaphylaxis / Hypersens	sitivity							
6	Transfusion Related Acu	le Lung Injury (TRAL	l)						
7	Transfusion Transmitted	Viral Infection (HBV)							
8	Transfusion Transmitted	Viral Infection (HCV)							
9	Transfusion Transmitted	Viral Infection (HIV-1	/2)						
10	Transfusion Transmitted	Viral Infection, other	(Specify)						
11	Transfusion Transmitted	Parasitic Infection (N	lalaria)						
12	Transfusion Transmitted	Parasitic Infection, of	ther (Specify)						
13	Post Transfusion Purpur	a							
14	Transfusion Associated (Graft versus Host Dis	ease (TAGv HD)						
15	Febrile Non Haemolytic	Reactions (FNHTR)							
16	Transfusion Associated I	Oyspnea (TAD)							
17	Transfusion Associated (Circulatory Overload	(TACO)						
18	Other Reaction (s)								
· '	O) OUTCOMES OF THE ADVERSE REACTIONS* E) REPORTER* Name and professional Address:								
1	Death following the adverse	reactions							
	Recovered with sequelae	片		Pin Coo	fe:		Email:		
•	Permanently disabled Unknown								
Any o	ther information			- /	SALITY		Date	of this report (DD/MM	MYYYY)

ADVICE ABOUT REPORTING

- Report adverse experiences with Blood Transfusion or Blood Products Administration
- Who Can Report?
 - Medical Colleges, Institutes, Hospitals and Blood Banks under Haemovigilance Programme of India
- Where to Report?
 - Please return the completed form to the nearest Medical Colleges, Institutes, Hospitals and Blood Banks under Haemovigilance Programme or to NIB Coordinating Center-Haemovigilance
 - A list of nationwide Medical Colleges, Institutes, Hospitals and Blood Banks under Haemovigilance Programme is available at: http://www.nib.gov.in
- What happens to the submitted information

- The causality assessment is carried out at Medical Colleges, Institutes, Hospitals and Blood Banks under Haemovigilance Programme
- The information collected in Transfusion Reaction
 Reporting Form (TRRF) will be forwarded to National Coordinating Centre-Haemovigilance NIB, through software (Haemo-Vigil) developed in house by NIB's IT division. This data will be collated & analyzed to identify trends, recommend best practices and interventions required to improve patient care & safety
- >> These recommendations will be forwarded to PvPI National Coordinating Centre IPC for onward transmission to Drugs

- Controller General (India), Central Drugs Standard Control Organization
- >> These recommendations will be used to formulate safety related regulatory decisions on Blood & Blood Products Transfusion which will be communicated to various stakeholders.
- >> The information is submitted to the Advisory Committee of Haemovigilance
 Programme constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required

TRANSFUSION REACTION REPORTING FORM (TRRF)

For VOLUNTARY reporting of Transfusion Reactions by health care professionals.

National Institute of Biologicals

National Coordinating Centre-Haemovigilance, NOIDA Ministry of Health & Family Welfare, Government of India A-32,Sector-62, NOIDA http://www.nib.gov.in



Confidentiality-----

The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

TRRF can be downloaded from the websites; www.nib.gov.in • www.ipc.gov.in • www.cdsco.nic.in

New Members of Haemovigilance Programme of India

Haemovigilance Programme of India was launched on 10th December 2012 in 90 Medical Colleges. The number of Centers have increased from 90 to 101 as on date which includes Medical Colleges, Institutes, Hospitals & Blood Banks.

New Members enrolled in Haemovigilance Programme – India are as follows:

Medical Colleges

Jamia Hamdard, New Delhi

- Government Vellore Medical College & Hospital, Tamil Nadu
- Coimbatore Medical College Hospital, Tamil Nadu
- Chengalpattu Medical College Hospital, Tamil Nadu
- Govt.Stanley Medical College & Hospital, Tamil Nadu

Hospitals

 Kokilaben Dhirubhai Ambani Hospital, Mumbai

Blood Banks

- · Lions Blood Bank, New Delhi
- Hospicio hospital South Goa District Blood Bank, Goa
- Apollo Victor Hospital Blood Bank, Goa
- SMRC Blood Bank, Goa.
- District Hospital North Goa Asilo Blood Bank, Goa

Forthcoming Events



3rd Advisory Committee meeting to be held on 11th September, 2013 at NIB, NOIDA

Second National Conference of ISTM Transmedoon to be held on 13-15th September, 2013 at Bengaluru





CME on Haemovigilance Programme to be held on 28th September, 2013 at National Institute of Mental Health & Neuro Science (NIMHANS), Bengaluru

The programme is being organized by NIMHANS in collaboration with State Drugs Control Department, Karnataka, NIB & IPC, MoHFW,Gol

CME on Haemovigilance Programme to be held on 5th October, 2013 at Srinagar.

"The programme is being organised by Mission Director, National Rural Health Mission, Jammu & Kashmir in Collaboration with NIB & IPC, MoHFW, Gol"





National Institute of Biologicals - National Coordinating Centre (Haemovigilance)

National Institute of Biologicals

Ministry of Health & Family Welfare Government of India

A-32, Sector-62, NOIDA, Uttar Pradesh

Email: haemovigilance@nib.gov.in

Tel: 0120-2400072, 2400022 Fax: 0120-2403014

For any other Information/Suggestions/Query related to Haemovigilance Programme kindly contact: Ms. Akanksha Bisht, Member Secretary- HvPl at: haemovigilance@nib.gov.in