INTRODUCTION
Pharmacovigilance has tremendous growth over the past 10 years. For example in Africa, in 2000 there were five countries with good Pharmacovigilance capacity, while at the end of 2010, this figure rose to 34 today 134 countries participate in the programme. Every country need Pharmacovigilance centre because there are differences between countries (even regions within the countries) in the occurrence of adverse drug reaction and other drug related problems. Data derived from pharmacovigilance centre within a country or region may encourage national regulatory decision-making. When information from a region itself is not available, it may take longer before a problem becomes known to drug regulatory authorities, physicians, pharmacists, patients and pharmaceutical companies.

Pharmacovigilance is a process that needs time, vision, dedication, expertise and continuity. A governmental department (health authority, drug regulatory agency) can be a good host for pharmacovigilance centre. However any department in a hospital or academic environment, working in clinical pharmacology, clinical pharmacy, clinical toxicology or epidemiology may suitable starting point for pharmacovigilance. The reporting of adverse drug reaction may start locally, perhaps in one hospital, then extend to other hospitals and family practices in the region, and progress step by step into a national activity. Pharmacovigilance centre is needed for the prevention of drug induced human suffering and to avoid financial risks associated with unexpected adverse effects. In conclusion, pharmacovigilance centre is necessary for continuous monitoring of marketed medicines in every country.

Keywords: Pharmacovigilance.

ABSTRACT
Pharmacovigilance has been tremendous growth over the past 10 years. For example in Africa, in 2000 there were five countries with good Pharmacovigilance capacity, while at the end of 2010, this figure rose to 34 today 134 countries participate in the programme. Every country need Pharmacovigilance centre because there are differences between countries (even regions within the countries) in the occurrence of adverse drug reaction and other drug related problems. Data derived from pharmacovigilance centre within a country or region may encourage national regulatory decision-making. When information from a region itself is not available, it may take longer before a problem becomes known to drug regulatory authorities, physicians, pharmacists, patients and pharmaceutical companies.

Pharmacovigilance is a process that needs time, vision, dedication, expertise and continuity. A governmental department (health authority, drug regulatory agency) can be a good host for pharmacovigilance centre. However any department in a hospital or academic environment, working in clinical pharmacology, clinical pharmacy, clinical toxicology or epidemiology may suitable starting point for pharmacovigilance. The reporting of adverse drug reaction may start locally, perhaps in one hospital, then extend to other hospitals and family practices in the region, and progress step by step into a national activity. Pharmacovigilance centre is needed for the prevention of drug induced human suffering and to avoid financial risks associated with unexpected adverse effects. In conclusion, pharmacovigilance centre is necessary for continuous monitoring of marketed medicines in every country.

Keywords: Pharmacovigilance.
New Pharmacovigilance Programme for India\textsuperscript{9,10}. Recognizing the need to restart the national pharmacovigilance programme (NPVP), in a brainstorming workshop jointly organized by Dept of Pharmacology, AIIMS and CDSCO in late 2009, the framework of the new programme was formulated. The programme now rechristened as the Pharmacovigilance Programme for India (PvPI) is scheduled to be operational from mid July 2010.

Framework of new programme

The programme is envisaged to be rolled out in three phases. Phase I would include 40 ADR monitoring centres (AMC) and will be rolled out in 2010. The programme would be expanded in phase II to include up to 140 MCI recognized medical colleges by 2011. Phase III would ultimately cover the healthcare system by 2013. Phase I will be further divided into phase Ia and Ib. Phase Ia will involve upgrading 10 centres in terms of infrastructure (computer and auxiliary). Phase Ib will include the rest of the 40 centres by end of 2010. The centres for phase Ia have been shortlisted based on letter of intent received from interested faculty, duly forwarded by the head of the institution. The AMCs will get operational and logistic support from their respective zonal CDSCO centres, situated at Ghaziabad, Kolkotka, Mumbai and Chennai. The zonal CDSCO centres will be under administrative control of the CDSCO headquarter at New Delhi.

The coordinating centre of PvPI will be housed at Dept of Pharmacology, AIIMS, New Delhi and will provide technical support to the CDSCO headquarter. All the centres under the programme will function in accordance with the protocol and SOPs developed by expert committees.

\textbf{TWO ZONAL CENTRES}

\begin{itemize}
  \item Dr. N. A. Kshirsagar, Seth Dean, Prof. head, and ME & H Coordinator, Zonal Pharmacovigilance Center, Department of Clinical Pharmacology, Seth G S Medical College and KEM Hospital, Parel, Mumbai- 400 012. dcpkem@vsnl.com avinasikhairnar@gmail.com njgogtay@hotmail.com
  \item Dr. Y K Gupta, Prof. & Head, Department of Pharmacology AIIMS, Ansari Nagar, New Delhi- 110029 ykg@hotmail.com
\end{itemize}

\textbf{FIVE REGIONAL}

\begin{itemize}
  \item Prof. Santanu Kumar Tripathi, Medical Supdt. Cum Vice Principal PGIMER - SSKM Hospitals, 244 AJC Bose Road, Kolkata 700 020 sskm_msvp@yahoo.com, pharmaintel@vsnl.com
  \item Dr. Urmila Thatte, Professor & Head, Dept. of Clinical Pharmacology TN Medical college & BYL Nair Charitable Hospital, 5th Floor, Old RMO Qtrs, ‘G’ Block, Dr. A. L. Nair Road, Mumbai Central, Mumbai 400008 Clinpharm@vsnl.net
  \item Dr. Meena Srivastava Professor and Head, Department of Pharmacology Indira Gandhi Govt. Medical College, Nagpur - 440 018 Res. 58, H.B. Puram, Shivangaon, Nagpur- 440 005 drmeenashrivastava@rediffmail.com
  \item Dr. Kamlesh Kohli Director Prof. & Head Department of Pharmacology, Lady Hardinge Medical College, Delhi University, New Delhi.
  \item Dr. C. Adithan Director-Professor, Department of Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry - 605006 jipgene@jipmer.edu
\end{itemize}
ADR reports will be collected at the AMCs. The PV staff at the AMCs will act as ADR monitors and will implement the ADR software. The coordinating centre will prepare a concentrated report of ADRs collected at defined time intervals. The coordinating centre will also implement and integrate PV activities into public health programmes involving mass usage of investigational drugs. Improve signal detection systems by development in the face of future challenges.

**Future Challenges of Pharmacovigilance**

Current pharmacovigilance systems need to be reviewed and developed further in the face of these important future challenges. The following summarize some of the priority areas that need to be addressed either at a national or international level:

**Detection of ADR:** Consider special activities and expertise required for the detection of safety concerns related to vaccines, biological, veterinary medicines, herbal medicines, biotechnology products and investigational drugs. Improve signal detection systems by...
facilitating the rapid availability of ADR data that may have international relevance.

**Assessment of ADR:** Foster collaborative links both at local and international level that could allow countries to assess and respond appropriately to drug safety crises. Consider methods by which information on local patterns of drug use can be integrated with pharmacovigilance information during assessment of benefit and harm at a national level.

**Prevention:** Integrate pharmacovigilance activities into national drug policies and the activities arising from these like standard treatment guidelines, essential drugs lists etc. Incorporation of pharmacovigilance principles into clinical practice and academic medicine. Improve regulation and pharmacovigilance of traditional and herbal medicines and develop systems which assess the impact of preventive actions taken in response to drug safety problems.

**Communication:** Improve communication and collaboration between the key partners in pharmacovigilance both locally and internationally. Different solutions are likely to be developed in different countries and regions, and the experience should be shared. Develop sustained and active relationships with the media in order to facilitate effective and accurate communication of drug information to the public. Encourage harmonization of drug regulatory and pharmacovigilance activities by incorporating the wider international community in the development of harmonization policies.

**CONCLUSION**

India is the fourth largest producer of pharmaceuticals in the world. Many new drugs are being introduced every year so every health care professional must have knowledge about the importance of ADR monitoring and pharmacovigilance. Government of India will make reporting of adverse reaction mandatory for medical colleges across the country. All medical colleges both private and public in the country will be required to monitor the effect of medicines given to their patients and report whether there is any adverse drug reaction. For improving pharmacovigilance in India, a new scheme introduced i.e. 24 hour telephone and online advice in which people can telephone a helpline to report suspected adverse drug reactions.

**REFERENCE**

2. http://www.pharmacovigilance.co.in/nppcentreslist.html
9. Dr. Y. K. Gupta, Ensuring Patient Safety - Launching the New Pharmacovigilance Programme of India, Pharma Times (August 2010) - Vol42 - No. 08