INTRODUCTION

The World Health Organizations (WHO) defines pharmacovigilance as ‘the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem’. Pharmacovigilance aims mainly at detecting adverse events that were previously either unknown or poorly understood. The thalidomide disaster in 1961 resulted in the introduction of the International Drug Monitoring system by the WHO.[1] India launched its own Pharmacovigilance Programme with the mission to safeguard public health under the Ministry of Health and Family Welfare, Government of India in July 2010 with 22 adverse drug reaction (ADR) monitoring centres (AMCs), and the All India Institute of Medical Sciences, New Delhi as the national coordinating centre (NCC). To ensure implementation of this programme in a more effective manner, the National Coordinating Centre was later shifted to the Indian Pharmacopoeia Commission, Ghaziabad, (Uttar Pradesh), which has been functioning as the NCC for Pharmacovigilance Programme of India (PvPI) since April 2011.[2]

The mission of the PvPI is to safeguard the health of the Indian population by ensuring that the benefit of the use of medicines outweighs the risks associated with their use. The considerable social and economic consequences of adverse drug reactions (ADRs) need to be balanced against the positive benefit/cost ratio. The purpose of the PvPI is to collate and analyse and

Key words: Adverse drug reaction, local anaesthetics, Pharmacovigilance Programme of India
use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals (HCPs) and the public.

**PHARMACOVIGILANCE NETWORK IN INDIA**

To track ADRs in the Indian population, at present, 250 AMCs are established under NCC-PvPI; all these AMCs are either medical colleges and hospitals or public health programmes, district hospitals or corporate hospitals. These AMCs collate, analyse and submit the ADRs to the NCC.²,³

NCC-PvPI has established a nationwide network with a different genre of HCPs and is trying to stretch its reach to each and every corner of the country. Several innovative methods have been introduced for reporting ADRs such as Helpline Number-1800 180 3024 (toll-free), mobile application and consumer direct reporting to report ADRs associated with treatment therapies. ADRs may be known or unknown, serious or non-serious and frequent or rare. They can be reported by filling the suspected ADRs reporting form [Figures 1 and 2] that can be submitted to a nearby AMC (list of AMCs available at www.ipc.gov.in) or directly to the NCC-PvPI.²,³ The accumulated information through various channels is put into the database, wherein they are analysed for further assessment and then finally sent to the WHO-Uppsala Monitoring Centre (UMC). The collected information helps in detecting and thereby reducing the risks associated with the drugs. The data can also be used as evidence for laying down recommendations by national regulators i.e. Central Drug Standard Control Organization. Reporting of the ADRs also helps to assess the risk-benefit ratio, update prescribing information leaflet and promote rational use of medicines. The reporter will not have to face any legal action for reporting ADR, and patient information is kept confidential.

All adverse experiences with medications should be reported. If the HCP is not certain whether the patient’s symptoms are related to the drug, it is better to report it as an ADR. An ADR is a serious ADR if the patient outcome is either death, or if the event is life-threatening, results in hospitalization or prolongs stay in hospital, or leads to significant, persistent or permanent diability, or a congenital anomaly, or requires intervention to prevent permanent impairment or damage.

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**PHARMACOVIGILANCE FOR LOCAL ANAESTHETICS**

Local anaesthetics (LAs) are broadly used for local or regional anaesthesia techniques. Many new drugs have been launched into the market in recent years. Because of the development of regional anaesthesia techniques over the past few years, the use of LAs is increasing worldwide.⁷ However, prospective studies have provided evidence of significant patient morbidity and mortality associated with the use of these drugs.⁸ The most common ADRs are related to the pharmacological properties of these drugs, mainly the membrane stabilising effects.⁹ During the administration of LAs, there might be chances of faulty technique or regimen that may lead to severe ADR. These types of ADRs can be captured by the spontaneous reporting through a simple and effective reporting mechanism. Adverse reactions to LAs include complications related to the LA agent (e.g., LA systemic toxicity, allergic reactions
and neurotoxicity), those related to the nerve block procedure and those related to adjuvants added to the LA. In addition, LAs may be constituents in other oral or topical formulations.

Hyperbaric lignocaine was used extensively for spinal anaesthesia several years ago. However, several reports implicated lignocaine as a possible cause of temporary and permanent neurologic complications after spinal anaesthesia. The risk of developing transient neurological symptoms after spinal anaesthesia with lignocaine was significantly higher than when bupivacaine, prilocaine or procaine were used.\[10,11\] Lignocaine is now not available for use in many countries. The American Society of Regional Anesthesia and Pain Medicine Practice Advisory on local anaesthetic systemic toxicity (LAST) assimilates and summarises current knowledge regarding the prevention, diagnosis and treatment of this potentially fatal complication.\[12\] A few literature reviews have also been published to manage LAST effectively.\[13\] The first analysis of safety profiles of LAs in a non-selected population, using data collected in a pharmacovigilance database was reported from the French Association of Regional Pharmacovigilance Centres.\[14\] Between 1995 and 2006, they identified 727 reports in which LA was suspected as the cause of 1157 different ADRs. Lignocaine (36.0%) and bupivacaine (35.4%) were most commonly involved. The most frequently reported ADRs were failure of the block (27.7%), neurological (22.1%), allergic (19.4%) and cardiovascular (15.3%) complications. Eight patients died. Twenty-two of 111 cardiovascular complications included cardiac arrest (three of which were fatal).

Thus, while while local and regional anaesthesia are generally safe, complications that occur may have significant morbidity or even mortality. If individual anaesthesiologists contribute data on ADRs to a pharmacovigilance programme, such uncommon but significant complications may be detected early and effective steps can be taken to avoid potentially harmful exposure of the population in future.

**SUMMARY**

ARs are reported from all over the country to NCC-PvPI, which also works in collaboration with the global AMC (WHO-UMC), Sweden and contributes to the global ADRs database. NCC-PvPI monitors the ADRs among Indian population and helps the regulatory authority of India (Central Drugs Standard Control Organization) in taking decisions for safe use of medicines. PvPI has become a formidable force at international level with the best pharmacovigilance practices including ADRs reporting and providing skill development. The Individual Case Safety Reports are collected/collated in a scientific way and analysed to facilitate appropriate decisions at CDSCO. Little is known about ADRs to LAs in India. All the HCPs are urged to report ADRs due to LA drugs, as they may contribute to the emergence of new disorders/reactions. Using information from reports of ADRs in the national pharmacovigilance database will lead to increased patient safety.

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**Conflicts of interest**

There are no conflicts of interest.
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Announcement

CALENDAR OF EVENTS OF ISA 2017

The cut off dates to receive applications / nominations for various Awards / competitions 2017 is as below. Hard copy with all supportive documents to be sent by Regd. Post with soft copy (Masking names etc.) of the same by E Mail to secretaryisanhq@gmail.com. The masked soft copy will be circulated among judges. Only ISA members are eligible to apply for any Awards / competitions. The details of Awards can be had from Hon. Secretary & also posted in www.isaweb.in

| Cut Off Date     | Name of Award / Competition                      | Application to be sent to       |
|------------------|--------------------------------------------------|---------------------------------|
| 30 June 2017     | Bhopal Award for Academic Excellence             | Hon. Secretary, ISA             |
| 30 June 2017     | Late Prof. Dr. A. P. Singhal Life Time            | Hon. Secretary, ISA             |
| 30 June 2017     | Rukmini Pandit Award                              | Hon. Secretary, ISA             |
| 30 June 2017     | Dr. Y. G. Bhoj Raj Award                         | Hon. Secretary, ISA             |
| 30 Sept. 2017    | Kop’s Award                                      | Chairperson, Scientific Committee ISACON 2017 |
| 30 Sept. 2017    | ISACON Jaipur Award                              | copy to Hon. Secretary, ISA     |
| 30 Sept. 2017    | Prof. Dr. Venkata Rao Oration 2017               | Chairperson, Scientific Committee ISACON 2017 |
| 30 Sept. 2017    | Ish Naranji Best poster Award                     | copy to Hon. Secretary, ISA     |
| 30 Sept. 2017    | ISA Goldcon Quiz                                 | Chairperson, Scientific Committee ISACON 2017 |
| 10 Nov. 2017     | Late Dr. T. N. Jha Memorial Award & Dr. K. P. Chansoriya Travel Grant | copy to Chairperson |
| 20 Oct. 2017     | Awards (01 Oct 2016 to 30 Sept 2017)             | Scientific Committee of ISACON 2017 |

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5. Public Awareness – City / Metro
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8. Membership drive
9. Proficiency Awards

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