Special Features

Current status of pharmacovigilance in India

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Earlier in 2015, the Drugs Technical Advisory Board (DTAB), which advises the Central and state governments on technical matters pertaining to drug regulations, recommended mandating pharmaceutical companies to report adverse effects of marketed drugs. Further, DTAB re-insisted on its 2011 recommendation for pharmacovigilance cells managed by a trained medical officer or pharmacist to be set up in all pharma companies. It also emphasized on sensitizing medical practitioners across the country by involving the Medical Council of India (MCI) and on training medical reps for collecting adverse event reports from doctors. DTAB has called for setting up a panel to draft pharmacovigilance guidelines for India to streamline the participation of all stakeholders.

Moreover, the Health Ministry approved in March 2015 the 'Materio Vigilance Programme of India' (MvPI) which would monitor Medical Device associated Adverse Events (MDAE) and be coordinated by the Indian Pharmacopoeia Commission (IPC) in collaboration with the Central Drug Standard Control Organisation (CDSCO). MvPI cells are to be established initially in 10 medical colleges in order to monitor the benefit-risk profile of medical devices. Similar programmes for Biovigilance and Haemovigilance were launched in 2012. While these are welcome moves, it makes sense for us to look back from where we have come this far and look forward to where we need to go, to be on par with global standards of drug safety.

From being a buzzword to a familiar term among healthcare professionals, Pharmacovigilance in India has grown considerably in the recent years. The introduction of a Pharmacovigilance system in India faced several roadblocks when it was started first in the year 1986 and then in the year 1997. Later, in November 2004, CDSCO launched the National Pharmacovigilance Programme (NPP) with the objective of fostering a reporting culture amongst the healthcare professionals across India. Contrary to the overwhelming expectations from the policymakers, the programme was not received well and eventually did not progress. Ultimately, in July 2010, NPP was renamed the Pharmacovigilance Programme of India (PvPI) and the new programme was commenced by CDSCO. From April 2011, IPC, Ghaziabad took over as the National Coordinating Centre (NCC) for PvPI with adverse drug reactions (ADRs) being reported from all across the country to NCC-PvPI. Under PvPI, various medical colleges began to function as Adverse drug reaction Monitoring Centres (AMCs) for collecting suspected ADR reports and forwarding them to NCC for further analysis. As of 2015, a total of 150 AMCs have been established across the country. Of late, PvPI has also included some large private hospitals as AMCs, which is a commendable step.

As a result, India became the first country to report over one lakh individual case safety reports (ICSRs) to Vigiflow, Uppsala Monitoring Centre's (UMC) web-based pharmacovigilance system. Further, India is currently the 7th largest contributor to the UMC's international drug safety database (Vigibase). Adding another feather to India's cap is the UMC's completeness score of 0.94 out of 1 assessed for Indian ICSR's, positioning India among the top-rankers in the completeness score criterion.

Recent initiatives undertaken by PvPI include the provision of a toll-free number and introduction of AE reporting forms in six regional languages to encourage consumer reporting. Global pharmaceutical companies and the pharmacovigilance outsourcing industry have shown interest to work with PvPI which was quite evidently felt in the recently concluded symposium "Comprehensive Pharmacovigilance for India - The Road Ahead" organized by the Pharmacovigilance Working Group (PVWG) of the Indian Society for Clinical Research (ISCR) and held in Mumbai in December 2014.

It is worth mentioning that the pharmacovigilance outsourcing industry in India has grown by leaps and bounds in the past 8 years, with the number of pharmacovigilance professionals in the country amounting to almost 15,000 people. Ranging from basic case processing activities to complex functions such as signal detection and analysis; the spectrum of pharmacovigilance capabilities available in India has been expanding. With India now being looked upon as the preferred destination for global pharmacovigilance services, it is quite logical to expect our knowledge to be utilized for our country too.

For an effective pharmacovigilance system to take shape, it is of immense importance that a pharmacovigilant culture is inculcated right from the student days. It is no exaggeration to state that the MCI mandate for all medical colleges to have a pharmacovigilance department has been a key reason for the success achieved by PvPI so far. With the emergence of the Pharm D (Doctor of Pharmacy) course in the recent years, the concept of clinical pharmacy has been redefined. The active presence of Pharm D graduates either in a hospital setting or in a drug safety surveillance unit has obviously added a lot of value from the patient safety perspective. The conduct of a "Pharmacovigilance Training Course" organized by the International Society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre in collaboration with JSS School of Pharmacy at Mysore in January 2015 stands testimony to the growing interest of the academic community in advancing Indian pharmacovigilance.

Despite all these laudable achievements, to be content with this pace of growth in pharmacovigilance for such a large population like India is unacceptable. The manpower shortage at CDSCO, the general tendency of the pharma industry to view investments for compliance as a burden and the inadequate levels of pharmacovigilance awareness among healthcare professionals are challenges which need to be overcome. Submission of Periodic Safety Update Reports (PSURs), which currently is almost the only post-marketing drug safety obligation for pharma companies in India, has received lukewarm response from the industry which allege a delay in acknowledgment of reports by the regulatory authority. Also with the info from PSURs flowing into CDSCO channel and with PvPI not being part of the flow, a significant amount of info goes unnoticed, thereby resulting in a less informed decision made on the drug's safety profile. Furthermore, the emergence of a purposeful regulatory action following the collection of PSURs is yet to be seen. With the highest degree of global expertise prevalent in the pharmacovigilance outsourcing industry in India, PvPI/CDSCO taking the help of this industry to analyze and derive meaningful conclusion from the collected data will be the easiest and quickest way for Indian pharmacovigilance to gain impetus.

Standard guidelines for pharmacovigilance in India, inspired by the good pharmacovigilance practices devised by EMA, will truly serve the purpose of ensuring safety of our patients. With the emerging regulatory agencies in the Middle East and North Africa (MENA) region adopting the European system of pharmacovigilance, Indian pharmacovigilance has got a lot of catching up to do with respect to evolving and implementing robust drug safety regulations in the country. For pharmacovigilance as a practice to be inculcated amongst consumers and healthcare professionals alike, a highly skilled, committed and enterprising network of expertise at various levels, with a well-defined mission is vital. The focus must always be directed towards establishing a unique drug safety ecosystem in India by leveraging the global pharmacovigilance knowledge base within India for the evolution of Indian pharmacovigilance, for which the baby steps seem to have been taken with the recent developments at DTAB and the Health Ministry.

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