Pharmacovigilance is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects associated with the usage of pharmaceutical products. This term covers both the clinical trial and the post-marketing phases. Though western countries have major achievements in the field of pharmacovigilance to their credit, India is yet to catch up. This review article provides a brief overview about the current situation and the future prospects of pharmacovigilance in India. Author has analysed importance of implementing proper pharmacovigilance in the Indian context and highlighted the academic advantages enjoyed by pharmacovigilance-compliant drug companies in India, as opposed to the others in the country.

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History of Indian Pharmacovigilance

The first recognised attempt to start pharmacovigilance activities in India dates back to 1986, when a formal Adverse Drug Reaction (ADR) monitoring system with 12 regional centres for a population of 50 million each, was proposed. However, the system did not come into existence. In 1997, India joined the World Health Organization’s ADR Monitoring Programme based in Uppsala, Sweden. The Uppsala Monitoring Centre (UMC) maintains an international database of suspected adverse drug reaction reports from all over the world to support good decision-making regarding the benefits and risks of treatment options for patients taking medicines. The WHO programme consisted of three centres in India for ADR monitoring. However, India’s contribution to the database was meager and the scheme too did not succeed. The major reason was the absence of adequate ADR monitoring systems and also the lack of knowledge of reporting suspected ADRs among healthcare professionals and consumers in the country. It is worth mentioning that the advantages of reporting suspected ADRs were not comprehended by most of the Indian pharmaceutical companies as the industry itself was then almost exclusively generic and had not adopted the well-developed pharmacovigilance systems of the innovator companies, probably due to paucity of compulsion from the Indian regulators.

National Pharmacovigilance Programme

After the attempts in 1986 and 1997 were found to be unsuccessful, the National Pharmacovigilance Programme for India was floated with sponsorship from the World Health Organization (WHO) and funding from the World Bank. The programme was inaugurated on 23rd November 2004 and became operational on 1st January 2005. It was overseen by the National Pharmacovigilance Advisory Committee based in the Central Drugs Standard Control Organisation (CDSCO), New Delhi. The programme had three broad objectives: The short-term objective was to foster a reporting culture, the intermediate objective was to involve a large number of healthcare professionals in the systems in information dissemination and the long-term objective
was for the programme to be a benchmark for global drug monitoring. Under the programme, 26 peripheral centers, five regional centres and two zonal centres were established. The peripheral centres would record the Adverse Events (AE) and send to the regional centres. They in turn would collate and scrutinise the data received from the peripheral centres and submit to the zonal centres. The zonal centres would analyse the data and submit consolidated information to the National Pharmacovigilance Centre, which would be shared with the WHO. The zonal centre also planned to provide training, general support and coordinate the functioning of the regional centres. But unfortunately, even this much-expected programme did not progress further, contrary to the expectations.

Pharmacovigilance Programme of India

Recognising the need to re-conceptualise the national pharmacovigilance programme, the framework of the subsequent programme was formulated with more forethought. The programme was renamed the Pharmacovigilance Programme of India (PvPI). The CDSCO, Directorate General of Health Services under the aegis of the Ministry of Health and Family Welfare, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad initiated this nation-wide pharmacovigilance programme for protecting the health of the patients by assuring drug safety. The programme is being coordinated by the Indian Pharmacopeia commission, Ghaziabad as a National Coordinating Centre (NCC). The centre will operate under the supervision of a Steering Committee which has the Drug Controller General of India (DCGI) as its ex-officio chairman and the Officer-in-Charge (New Drugs), CDSCO, New Delhi as its ex-officio Member Secretary. The goal of the PvPI is to ensure that the benefits of use of medicines outweigh the risks and thus safeguard the health of the Indian population. The PvPI has been operational from mid July 2010. The governance structure, five-year programme roadmap along with the targets for each year and the programme communications are illustrated in the schematic sketches provided below.
Current Trends

In recent times, pharmacovigilance has started gaining importance in the media as the number of stories on drug recalls increases.

Since clinical trials involve only smaller numbers and selected groups of patients, less common adverse events are often unknown at the time when a drug enters the market.

Also, use of drugs in organ-impaired patients and use in special populations like pregnant women and children are not studied extensively in clinical trials because of ethical limitations.

Postmarketing pharmacovigilance gains much importance, since it uses tools such as data mining and investigation of case reports to identify the relationships between drugs and ADRs.

India is now coming to understand that the benefit-risk ratio of pharmaceutical products is a dynamic variable and that it has to be continuously monitored.

Early detection of signals from both clinical trials and post-marketing surveillance studies are done by global pharmaceutical companies in order to identify the risks associated with the medicinal products and effectively manage the risks by applying proactive risk management plans throughout the life cycle of the product.

Indian pharmaceutical companies with international presence have understood these changes in the global scenario and are also starting to apply the same strategies.

Signal detection and risk management have added new dimensions to the field of Indian pharmacovigilance and as evolving disciplines, they require ongoing refinement in order to increase their applicability and add value to the public health aspect in India.

With the Indian pharmaceutical industry entering into a good number of joint ventures with multinational pharmaceutical companies and considering the phenomenal increase in export of Indian-made drugs to the developed world, the pressure is mounting on the Indian pharmaceutical companies to invest in pharmacovigilance either by setting up their own team completely or outsourcing parts of it to contract research organisations.

Till recently, the Indian drug market has mostly seen the launch of only those products that were already approved and marketed in the regulated markets. For assessing the benefit-risk profile of a drug and to take appropriate corrective
actions, the Indian pharmaceutical companies as well as the regulators have been depending on the experiences gained from these markets.

Due to this reason, pharmacovigilance was considered to be non-vital and little emphasis was placed on establishing an India-specific pharmacovigilance system. However, with drugs getting global approvals almost simultaneously, the lead time Indian regulators used to get before deciding on the approval of a drug has decreased so much that the longer-term safety data from the regulated markets is no longer available.

The capability that Indian drug companies have built in getting close to bringing their own research molecules to the market has indicated that implementing sufficient internal pharmacovigilance standards to detect adverse drug events is something that they cannot ignore any more.

Moreover, with Indian companies launching biosimilars which cannot be considered as replicas of the innovators’ molecules due to their complex structure and high molecular weight, special pharmacovigilance planning is needed for this set of drugs.

With expansion of the medical devices market in India and augmented awareness of Adverse Events Following Immunisation (AEFI) through the media, the significance of the pharmacovigilance of medical devices and vaccines is now being realised. Thus, globalisation seems to have played a major role in breaking the ‘innovator company – generic company’ divide.

Another point to ponder is that most of the high-profile drugs that have been recently withdrawn were available in Indian market. In such cases, the Indian regulatory agency could not count on the experience of other regulated markets to assess the benefit-risk balance of the said drug.

In fact, we are not even sure as to whether those drugs harmed Indian patients to a lesser extent or if they did so more seriously. This point stresses the importance of developing our own adequately designed pharmacovigilance system for India. All these factors have drawn the attention of the Indian regulators and the pharmaceutical companies toward the inadequacy of pharmacovigilance systems in India.

The Future

Though the PvPI is a huge step forward in the right direction for accumulating Indian pharmacovigilance data, it is currently restricted to the approved medical college hospitals in India, public health programmes, and autonomous institutes like the Indian Council of Medical Research (ICMR).

The data received by PvPI is shared with the WHO through their VigiFlow and PaniFlow software but not shared with the concerned pharmaceutical companies, which misses the opportunity for understanding and managing the risks identified.

However, it is understandable that, being the beginning, it is not possible to set up a holistic pharmacovigilance system overnight and hopes are bright that the PvPI will become the centre of excellence for Pharmacovigilance in the Asia Pacific, as it targets, in due course.

It is strongly felt that, apart from the PvPI, Indian pharmaceutical companies also should educate all their staff on adverse event reporting and ensure that a proper pharmacovigilance plan is put in place for the products they market in India, as they do for their international operations in the regulated markets.

This will not only make them compliant with the DCGI’s regulations (especially when the submission of Periodic Safety Update Reports has been made mandatory by the DCGI) but also instill the confidence among healthcare professionals and consumers about the commitments of the pharmaceutical companies to pharmacovigilance. It will also help the pharmaceutical companies monitor their medicines for risk and to devise and implement effective risk management plans to define their use in difficult circumstances in India, as they do in the regulated markets. The DCGI could be the regulator for this system which, if implemented, will complement the PvPI and ensure that Patient Safety of the highest order gets established in India within the next few years.

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