Pharmacovigilance as an Indispensable Ingredient for India's Pharma Growth Formula

Dr J Vijay Venkatraman
Managing Director & CEO
Oviya MedSafe Pvt Ltd

India has always been an essential element in the global pharmaceutical milieu over the past several decades. This is not only because India is one of the largest producers and exporters of pharmaceuticals and vaccines but also because India is a huge market for all global pharma players given our status as the second most populous country in the world. Be it the global supply of Hydroxychloroquine in 2020 or Covishield in 2021, the COVID-19 pandemic has convinced the world about the inevitability of India in this context much more than ever before. While the future for Indian pharma industry is undeniably bright, India's current leadership position in the global Pharmacovigilance domain is a key strength that could and should be leveraged for our country to scale much greater heights during the period between 2022 and 2030.

Pharmacovigilance is defined by the World Health Organization as the science and activities relating to the

detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. Properly performed pharmacovigilance activities help in augmenting the benefits while minimising the risks associated with medicines. Although the pharma industry has been known to exist for centuries, it would not be an exaggeration to state that the emergence of Pharmacovigilance as a Science and consequently as a Regulation particularly in the past 60 years has made medicinal products much safer and more effective for the patients, thereby enhancing public confidence on the accountability of the industry. Hence, it has become increasingly important for pharma companies to focus on pharmacovigilance.

Pharmacovigilance became a buzzword in India about 15 years ago when it surprisingly turned out to be a promising unique vertical for Business Process Outsourcing companies and resulted in the hiring of Life Science professionals in large numbers. These companies were contracted by foreign multinational pharma giants for processing their voluminous drug safety data and then went on to quickly gain their confidence to the extent that end-to-end global pharmacovigilance operations of these clients started happening in India. Contract Research Organizations and exclusive Pharmacovigilance Service Providers also followed suit to join the bandwagon with even more specialised services. Some pharma majors, in addition to outsourcing to companies with teams based in India, also set up their own captive units in the country for carrying out their global pharmacovigilance activities. Motivated by these developments, Indian multinational companies, which had erstwhile outsourced their pharmacovigilance activities (for regulated markets) to service providers abroad, decided to either establish their global pharmacovigilance systems in-house or seek support from newer India-based service providers. On top of excelling in providing functional support in pharmacovigilance, India's time-tested proficiency in Information Technology was harnessed subsequently and that led to India becoming home to several multinational IT companies working on pharmacovigilance software databases initially and on cutting edge intuitive technological tools for pharmacovigilance later.

There was a time when pharmacovigilance was considered needed only for that part of the pharma industry which exported its products and in fact marketed them in developed countries (consequentially known as "regulated markets"). Over the past decade, regulatory reforms have happened throughout the world and we are now aware that not only the regulated markets have become more stringent in implementing their pharmacovigilance

regulations but the semi-regulated markets too have formulated regulations on the lines of the developed countries. Thanks to certain countries demanding a defined level of pharmacovigilance standard to be followed by the pharma company worldwide, it has become almost impossible for any ambitious pharma company to ignore pharmacovigilance even in unregulated markets. On a related note, the term 'unregulated markets' is becoming a misnomer, as almost every country in the world has some regulation for drug safety. Furthermore, even companies that wish to cater just to the domestic market are not exempt from pharmacovigilance, as India has begun demanding the implementation of pharmacovigilance requirements as in the local regulations since quite a few years. In fact, a specific Pharmacovigilance Guidance Document for Marketing Authorisation Holders of Pharmaceutical Products in India was notified and made effective since January 2018.

Another key driver that could be said to create peer pressure for pharmacovigilance in India is the active evangelization of the subject by several interested stakeholders. The fact that the Pharmacovigilance Programme of India (PvPI) has grown to cover a wide range of ADR Monitoring Centres throughout the length and breadth of the country, along with the proactive steps taken by the Indian Pharmacopoeia Commission (the National Coordination Centre of PvPI), speaks a lot about the commendable role of the governmental agencies. Although the Central Drugs Standard Control Organisation (CDSCO) is the national regulatory authority in India, PvPI also has a role in engaging with the industry and monitoring compliance with their pharmacovigilance obligations. In addition to these, professional associations with specific interest in pharmacovigilance such as the Pharmacovigilance Council of the Indian Society for Clinical Research (ISCR), Pharmacovigilance Standing Committee of the Indian Medical Association (IMA) Headquarters, International Society of Pharmacovigilance (ISoP), Drug Information Association (DIA), among others, keep emphasising the significance of pharmacovigilance through their awareness and advocacy initiatives. Last but not the least, the COVID-19 pandemic, especially the debates surrounding vaccine-associated adverse events, has heightened the awareness of pharmacovigilance among the public to levels never seen before. From a largely binary approach of "safe" versus "unsafe" drugs, the narrative has changed towards accepting that even good drugs may have adverse effects and that continuous monitoring of the benefit-risk balance is essential throughout the life cycle of any therapeutic product. All

these developments may not result in an overnight increase in ADR reporting rate but it is certain that the mindset change has begun and is here to stay and grow.

From the above, it is clear that pharmacovigilance as a 'need to have' compliance element is for real and not complying with it will directly impact the reputation and consequently the growth of the said pharma company. Not only that, prescribers and many consumers too have begun thinking seriously on whether the safety and effectiveness of the medicinal products they use are backed by solid evidence. Healthcare professionals outside the regulatory pharmacovigilance environment too have now understood that randomised clinical trials alone do not define the safety profile of a drug and the true safety profile of a drug will be known only when it is used in the population at large, which can obviously happen only in the post approval phase. This realisation could impart a sense of apprehension to pharma companies which still believe in the traditional thinking that pharmacovigilance is just a cost centre but it has been proven time and again that pharmacovigilance is a life-saving term insurance policy instead.

Moreover, the good news is that India has already cultivated enormous knowledge and versatile capability in pharmacovigilance which means that it is not difficult to adopt globally acceptable pharmacovigilance standards even in a comparatively smaller pharma company in the country. With the Indian innovation in play, numerous business models both in the outsourced pharmacovigilance services space and in the technology front have come into existence, thereby creating an environment that is conducive to compliance in a cost-effective manner. Many new age pharma companies have accepted this reality and have started building pharmacovigilance as integral components of the foundations of their organizations.

Looking at the future, it is evident that the foreseeable phenomenal growth of Indian pharma industry will in all probabilities involve more and more focus on product safety and effectiveness, as is the case throughout the world. Thousands of pharmacovigilance professionals based in India are the primary reason for our country to rightly and rightfully claim the title of the Mecca of outsourced global pharmacovigilance operations today. India achieved this distinction several years ago and this unparalleled capacity is waiting to be leveraged for the purpose of taking the already tall Indian pharma industry to much greater altitudes. ■