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LETTER TO EDITOR

Pharmacovigilance: Where do we stand?

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As per the World Health Organisation (WHO) - 'Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and the prevention of adverse effects or any other possible drug-related problems'[1]. The Uppsala monitoring centre (UMC) in Sweden which is an international arm of WHO for monitoring Adverse Drug Reactions (ADR), maintains an international database of ADR reports submitted by various national centres [2]. It has almost 78 countries participating and they submit ADR reports by means of a web based software called VIGIBASE. India joined hands with UMC in 1998, but till date, its contribution to the UMC database remains very meagre [3]. The questions which are arising are, whether the existing pharmacovigilance framework is performing to its full potential or whether it is only on paper and being health care professionals, are we significantly contributing to our country's pharmacovigilance?

With the ever rising Indian pharmaceutical industry touching a turnover of 89000 crores Rupees (US $18 billion) in 2009, as it caters to an exploding population of more than a billion, India now ranks 3rd in terms of the volume of drug production, thereby accounting for a total of 10% of the global volume. It also ranks 4th in terms of generics and 17th in terms of export bulk [4]. With all these big players in the generic market, India becomes a scary place when we find that there is absolutely no presence of pharmacovigilance in many of the pharmaceutical companies [5]. It is a matter of great concern, that with so many health care problems and diseases coupled with the trend of self medication being on the rise, where by people pop in drugs to cure themselves from illness and to keep themselves fit [6], we still do not have a properly functioning central pharmacovigilance cell [7]

The National Pharmacovigilance Programme

The Indian government had ambitiously launched the National Pharmacovigilance Programme on 23rd November 2004 along with the Central Drugs Standard Disease Control Organisation (CDSCO) and the Ministry of Health and Family Welfare. As per this program, 26 peripheral centres, 5 Regional Centres and 2 Zonal Centres were established. The Peripheral centres were to record the Adverse Events (AE) and send them to the Regional Centres. They in turn, would scrutinize the data received from the Peripheral Centres and submit them to the Zonal Centres. The Zonal Centres would then analyze the data and submit the consolidated information to the National Pharmacovigilance Centre [8]. The programme itself is struggling hard for its survival, after almost 5 years of its launch.

Various steps that can be taken to build the foundation of a robust pharmacovigilance in India:

1. Creating awareness about pharmacovigilance in health care professionals and the required training should be included in the undergraduate curriculum.[9]
2. Designing of proper Standard Operating Procedures (SOP) for various

aspects of the functioning of the pharmacovigilance cells.

3. Properly designed concise (non time consuming) ADR forms should be made available, which should not only be used by the national pharmacovigilance centres, but also by all registered hospitals (both private and government), teaching hospitals, Primary Healthcare Centres (PHCs) in rural areas and all practising general practitioners and physicians. Efforts should be made to create awareness in healthcare professionals regarding a downloadable format of the same ADR form which could be filled and submitted or can be dropped in drop boxes in the nearby centres available.

4. Procuring a software database or developing it in collaboration with IT professionals which could be accessed by all pharmacovigilance centres. Periodic auditing of the software database should be done.

5. The presence of properly functioning pharmacovigilance cells should be made mandatory in all medical colleges throughout the country and periodic inspections of these cells should be carried out, as recently proposed by DCGI.

6. More and more involvement of expert pharmacovigilance professionals from the industry arena in the functioning of the cells.

7. Intensive training should be imparted to all those professionals who are involved in the actual processing of the ADR reports.

Conclusion

For the safer use of drugs, there should be the presence of an efficient pharmacovigilance cell. India has to travel a long way to at least reach a benchmark which has been laid down by developed nations in the arena of pharmacovigilance [10]. An attempt has been made by the Indian government for laying the foundation of an efficient pharmacovigilance system which needs to be refined and unanimously supported by all healthcare professionals.

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