EDITORIAL

Involvement of Private Players in Pharmacovigilance Program of India: Data Reliability Will Be Under Question

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Pharmacovigilance or Adverse Drug Reactions (ADRs) monitoring is the pharmacological science related to the collection, detection, assessment, monitoring, and prevention of adverse effects or any other drug-related problem.[1] India is fast growing as a hub of clinical trials. This is reflected in the fact that the total number of applications received and processed at Central Drug Standard Control Organization (CDSCO) New Delhi has doubled from around 10,000 in the Year 2005 to 22,806 in Year 2009; with increase in New Drug Applications, global clinical trials, and market authorization of vaccine and biotech products from 1200, 100, and 10 in Year 2005 to 1753, 262, and 137 in the Year 2009 respectively.[2]

Such rapid introduction of new pharmaceutical products in the market poses new challenges for monitoring of ADRs in a thickly populated country like India. Before the actual marketing of any drug, the experience with the efficacy and safety of the drug is limited to the controlled clinical trials. During clinical trials only common adverse effects (AEs) of drugs are detectable. The AEs of drugs which take long time to appear or which appear with very low frequency (rare AEs) or which affect only a particular subset of patients (AEs due to pharmacogenetic variations) are not detectable during clinical trials. Moreover, the "controlled conditions" under which the drug is used during clinical trials are not always the same as "pragmatic conditions" under which the drug will be used in clinical practice. This mandates the continuous surveillance of the drug during post-marketing period, in order to have up-to-date comprehensive safety profile of the drug.[3] For any successful monitoring, data from different sources must be pooled and analyzed in a systematic and standard manner. Precisely to achieve this target, Pharmacovigilance Program of India (PvPI) was introduced by the Government of India.

The PvPI was started on July 14th 2010 by CDSCO. All India Institute of Medical Sciences (AIIMS), New Delhi was the designated National Coordination Centre (NCC) for monitoring ADRs.[4] To ensure implementation of this programme in a more effective way, the NCC was shifted from AIIMS to the Indian Pharmacopoeia Commission, Ghaziabad, on April 15th 2011. Since then, the NCC is operating under the supervision of Steering Committee to recommend procedures and guidelines for regulatory interventions.[5]

To implement this program, the ADR reports will be collected from Medical Council of India (MCI) approved private and government Medical Colleges and Hospitals, private hospitals, public health programs, and autonomous institutions (ICMR etc.).[5] The Medical Colleges are the corner stone of the PvPI. They act as ADR Monitoring Centres (AMCs) with responsibility of collection of ADR reports, perform follow up with the complainant to check completeness as per Standard Operating Procedures, entry of data into Vigiflow software, reporting to PvPI NCC through Vigiflow with the source data attached

with each ADR case and training / sensitization / feedback to physicians through newsletters circulated by the PvPI NCC.[2]

As on February 12th 2013, 90 Medical Colleges and Private Hospitals has been designated as AMCs;[6] while target was to register 200 Medical Colleges alone by financial year 2012-13. At the end of financial year 2013-14 a total of 300 Medical Colleges are to be registered as AMCs.[2] As on April 17th 2013, 355 Medical Colleges teaching MBBS course are present in India, with 161 in Government sector and 194 in Private sector.[7] There are few more institutes providing only post-graduate qualification like Post-graduate Institute of Medical Education and Research, Chandigarh. Thus it is very obvious that in order to achieve the target of registration of 300 Medical Colleges as AMCs, around 150 Medical Colleges in private sectors have to be registered.

Though no particular college or management is being pointed-out, it is an open-secret that the generalized data originated from many medical colleges is not genuine. In a very recent statement Karnatka State Medical Education Minister, S A Ramados has accused private medical colleges to pay Rs 500 per person to act as a patient and to produce them before the MCI committee. He further alleged that sometimes two to three hospitals exchange the patients just to satisfy the MCI norms.[8] Fake data is then generated to satisfy MCI norms. Other common practice, rather malpractice is of presenting fake faculty, hired for the day - during MCI inspections in private colleges. Even some of the government colleges are adopting unscrupulous methods. According to a news report Karnataka Government could not find faculty for six newly opened medical colleges due to mismatch of pay scales compared to private sector. As a stop-gap-arrangement, faculty was transferred from established medical colleges to the new colleges for MCI inspections only. Two of the three government run medical colleges in Chattisgarh were found unfit. In Madhya Pradesh, three of the six and in Karnataka four of the 10 government medical colleges were found unfit.[9]

Ironically, the Union Health and Family Welfare Minister in a written reply in Lok Sabha admitted of finding incidents of fake faculty in 17 medical colleges across the country. In some cases the faculty registered at medical college was not actually teaching there.[10] Though in some cases government and MCI has acted sturdily and has suspended some erring medical professionals;[11] the practice is hard to be curbed. As MCI has granted permission of starting medical colleges to the corporate houses, the over-all picture is bound to deteriorate.

The purpose of highlighting this well-known, on-going practice of presenting fake faculty and fake patients with fake generation of patient related data for the sole purpose of MCI inspections by the private medical colleges, and the policy of transferring faculty from one government medical college to another on the eve of MCI inspection by the government, is to raise a very important query – how reliable will be the ADR data generated from these sources? Is there any mechanism to stop filling of fake ADR reporting forms? Is there any counter-check mechanism? From my own experience, I know, currently the answers to all these queries are in negative. But as the speculations are rife, I hope soon some-sort of counter-check mechanism will be made operational, otherwise the whole exercise of starting PvPI will be an exercise in futile; and will ultimately become a tool to siphon program related funds.

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