BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Malpractices in Indian drug approval system exposed

17 August 2012 | Analysis | By BioSpectrum Bureau

Drug approval in India: The major concerns

India received a lot of criticism in the past few months after a report exposed malpractices in the functioning of Central Drugs Standards Control Organization (CDSCO). The report by the parliamentary standing committee on health and family welfare

has come down heavily on the CDSCO for the discrepancies. However, there are other issues that need to be addressed in order to plug the gaps.

Where are all the regulators?
It is very easy to play the blame-game without getting to the crux of the issue as the lack of efficient manpower is a major concern in the regulatory scenario of the country. No action has been taken after the Mashelkar report was published describing the required infrastructure at the CDSCO.

Dr Krathish Bopanna, president, ISCR, and president and executive director, Semler Research Center said, "There do exist competent people capable of executing necessary decisions but they suffer from the lack of sufficient manpower and high workload. The CDSCO is very strong in terms of pharmaceutical manufacturing but is still ill-equipped to deal with the clinical and marketing aspects of drugs."

At the CDSCO, less-than-half of the 327 sanctioned posts, at the time of the report being released, were filled up. Also in terms of drug inspectors, there are only 846 instead of the required 1,349. More shockingly, the minimum prescribed academic qualifications for the post of DCGI is barely a Bachelor of Pharmacy (B.Pharm) degree, which well below the global standards. The 59th report of the parliamentary standing committee on the functioning of the CDSCO raises many such questions on the functioning and the decisions of the CDSCO.

Data exclusivity
There is a apprehension among MNCs that is preventing them from investing in trials in India. They fear that the lack of data protection will help generic companies to use their data in future. This concern needs to be addressed.

Mr Prashant Reddy, blogger at SpicIP, one of the most authoritative blogs on IP protection said that, "Data exclusivity remains a sticky issue. Since the Indian pharmaceutical industry is dominated by generic companies, who stand to be affected greatly if it comes into play, it will continue to be one."

In a nutshell, what it means is that MNCs that carry out clinical trials for their drugs in the country currently do not have exclusive rights over this data for a stipulated time, unlike some other countries. It does raise the question why MNCs would invest in carrying out trials if that data can be taken by other generic companies freely. This has certainly stopped them from adhering to the set rules for drug approvals.

The ripple effect
Along with the pharma industry, the next in line to be most affected by this report has been the CRO community. Mr Shoibal Mukherjee, chief medical officer, Quintiles India, and head, Asia Medical Sciences Group, said that, "In the last two years, there have been long delays in regulatory approval of clinical trial applications in India. Further, uncertainties relating to the regulatory environment in India have led to some sponsors excluding India from their global development plans. Consequently, we would not be surprised to find significant reductions in the annual number of clinical trial approvals in the last two-to-three years."

Dr Bopanna too added that there have been delays in approvals for clinical trials, "Currently, these approvals are taking more than six-to-eight months, and and with the release of this report, this delay might increase."

However, the critical issue is the follow through or the lack of it. The Mashelkar report in 2007 on the CDSCO had similarly provided recommendations for the revamp of the organization, though much was left to be desired with the action taken following that report. A three-member committee comprising Dr V M Katoch, secretary and DG, ICMR; Dr P N Tandon, president, National Brain Research Center; and Dr S S Aggarwal, former director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, have been set up to look into the report and suggest appropriate measures.

This happens to be crunch time for the Indian government to not just stop at acknowledging the report but also take some much needed definitive action by acting on its recommendations. As the deadline for the expert committee constituted for looking into the report draws to a close, the industry and general public alike wait for concrete action to be taken.