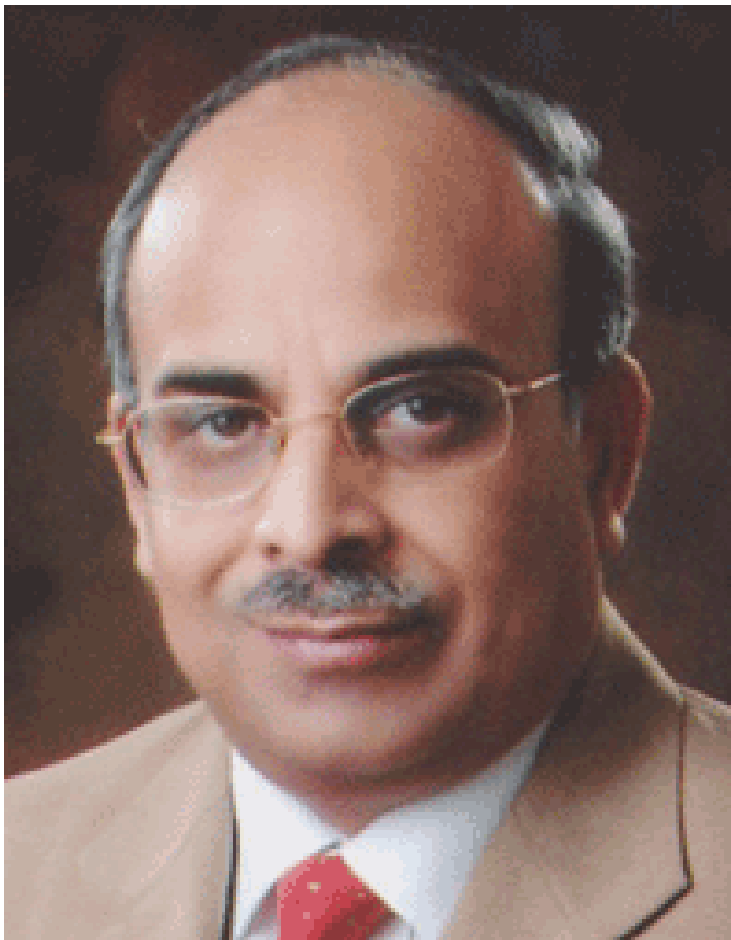


'Drug development approvals shouldn't be with DCGI'

29 April 2013 | News | By Rahul Koul Koul

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"It is very saddening to find that after year's wait for approvals, one is given only few minutes to put the case before the DCGI officials," said Dr Jitendra Verma, , managing director, Lifecare Innovations, Gurgaon, while expressing his disappointment at the functioning of the regulator. "I feel that the drug development should no longer be the part of it as it is a research activity. The Directorate of Health Services and the Biotechnology Regulatory Authority of India (if it has mandate and if it is passed in the parliament) must take the responsibility as we cannot simply sit on crucial decisions just because of manpower issues," he told BioSpectrum over phone.

Dr Verma believes that it is not appropriate to just keep watching the country's drug regulations in shambles. As per him, "The premier agencies such as Indian Council for Medical Research (ICMR) and Department of Biotechnology (DBT) have enough competencies available to deal with these issues. Yet today we remain helpless as the DCGI office doesn't have adequate qualified manpower to take decisions within the time."

His reaction has come only a month after Dr Rajesh Jain, managing director, Panacea Biotec, who too expressed his disappointment on the state of affairs at the DCGI office. Speaking at the foundation day celebrations event of Biotechnology Industry Research Assistance Council (BIRAC) at New Delhi on April 22, Dr Jain had mentioned, "We were upbeat when in December 2012, we were given permission for phase I trials for our one of the vaccines. However, after that we have been flooded with multiple notices seeking information again and again. Trials have been stopped as the investigators from our partner that belongs to US, are afraid to go any further. And as if that was not enough, there is a new rule of forming new ethical committees. We have been running pillar to post but DCGI doesn't speak to us. There is no clarity. This is very unfortunate" he had said.

Recently during a workshop on regulatory changes, organized at Jamia Hamdard University, various industry experts had expressed their resentment against what they called lack of clear decision making on the part of DCGI's office. Notwithstanding the criticism, the DCGI, Dr G N Singh in his recent conversation with BioSpectrum had admitted that there are challenges but he had also maintained that efforts are on to build the required manpower and infrastructure in due time to mitigate the concerns.