Abstract

The distinct advantage of recombinant drugs and herbal drugs over the chemically derived drugs has led to their increased demand worldwide. Commercialization of these drugs is affected by the patenting status and the regulation type. In the post-TRIPs regime there is an increased need for innovation so that India can continue to be an important player in the world drug market. The challenge for drug development and commercialization in both these drug areas is the need to generate new innovations and to also comply with the differing regulatory standards for their approval across countries. It is from this perspective that the present study attempts to analyze the patenting activity to assess the innovation activity and the lacunae in the Indian regulatory approval process for marketing of these drugs. The patenting analysis reveals that more than half of the recombinant drug manufacturing companies in India are into new biological entities development. Patent landscape analysis indicates that modified proteins with enhanced efficacy and development of stabilized formulations are the current focus of innovations. Unlike the recombinant drug sector, in the herbal drug sector academic institutes as well as industry are the major assignees. Diabetes, cancer and inflammatory disorders are the major areas of innovations in both the drug sectors. Comparative GMP analysis reveals that Indian GMP in recombinant drugs lack critical aspects with respect to cell banking, fermentation or cell culture process, purifications, stability testing and validation process. With respect to submission, review procedures and timeline the analysis reveals that there is a need to merge the two separate review processes of GEAC and DCGI approvals. Defined timelines and transparency in review procedures need to be improved. In herbal drug sector it is observed that GMP compliance is not complete and implementation of current regulation is a major issue. Developing effective marker standards would help in raising the quality of herbal drugs. The study identifies a need to unify standards with respect to recombinant drugs as well as herbal drugs for their effective commercialization.

Key words:

Recombinant drugs, herbal drugs, regulation, GMP, intellectual property, patent analysis