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Indian pharma: Raising barometer of success beyond generics

Ritul Bapna, B. P. Nagori, Vipin Mathur
Lachoo Memorial College of Science & Technology, India

Emergence of the Indian pharmaceutical industry on the global landscape as one of the biggest generic drug supplier was due to the Indian Patents Act, 1970 which allowed only process patents and no product patents for food, drugs and medicines. India being a member country of WTO signed TRIPS agreement and consequently amended its patent law in 2005 to allow product patenting in all fields of technology including pharmaceuticals. Post TRIPS era of product patentability has posed both opportunities and challenges in front of Indian pharma companies. In this new scenario, it takes away the freedom of Indian pharma companies to introduce generic versions of new chemical entities (NCEs) in the normal course before the drug's product patent expiry. However, since world's 10 biggest selling drugs are going to be off patent soon, it is going to create an estimated $250 billion worth of generic drug market till 2015. Although the generic industry will benefit in the short term but it will also see a slowdown in revenue growth after 2015 since R&D pipeline has dried up to a great extent and the number of NCEs has come down significantly. To cope up with these future pressures, Indian pharma companies definitely require to look beyond generics and should try other business options like building joint ventures, investing in lower risk research areas, developing skills in biotechnology based drug production, exporting to unregulated markets etc. This presentation analyses the impact of product patenting on Indian pharmaceutical industry and suggests some measures to tackle the possible challenges that the industry is expected to face in near future.

Biography

Ms. Ritul Bapna is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India.

Regulatory situation of herbal medicines

S.Haritha
JSS University, India

Herbal medicines which formed the basis of health care throughout the world since the earliest days of mankind are still widely used and have considerable importance in international trade. Recognition of their clinical, pharmaceutical and economic value is still growing, although this varies widely between countries. This article presents Regulatory situation of herbal medicines. It is essential to know what regulatory and legislative controls on the manufacture andsale of such herbal medicines exist or required to be implemented in various places around the world. The legal situation regarding herbal preparations varies from country to country. In recent years, many developed countries have shown growing interest in alternative or complementary systems of medicine, with a resulting increase in international trade in herbal medicines and other types of traditional remedies. The concern and difficulties related to the patenting of herbal medicines have precluded the financial incentives that could be provided to pharmaceutical industries. Regulations in countries for the assessment of the quality, safety and efficacy of medicinal plants, and the work of WHO in supporting the preparation of model guidelines in this field, have been helpful in strengthening recognition of their role in health care. It is hoped that assessment of these traditional remedies could become the basis for a future classification of herbal medicines, as well as for evaluative studies on their efficacy and safety, and their potential use in national health care systems in different parts of the world.

Biography

Iam S.Haritha currently pursuing her 2nd year M. Pharmacy in Pharmaceutical Regulatory Affairs from JSS University, Mysore. I have done my graduation in Vignan institute of Pharmaceutical Sciences. I have published 3articles in journals and have presented 8 posters at national level and has attended various National and International Conferences. My areas of interest are Regulatory Affairs, Intellectual property rights, Technology Transfer.

harithasuryadevara@gmail.com