India’s Pharmaceutical Regulatory Framework

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Pravin Anand and Archana Shanker look at the regulatory framework governing India’s pharmaceutical market. India, the largest democracy in the world, has rightly been termed the 'pharmacy of the world'. The country's objective data speaks for itself. There are over 4,655 pharmaceutical manufacturing plants in India, including the world's third-largest in terms of volume and 14th in terms of value. In 2013, the domestic pharmaceutical marker stood at $16.4 billion and pharmaceutical exports at $15.6 billion. In view of the growing market and demand, the government has, from time to time, had to upgrade its regulatory framework. The Guidelines on Similar Biologics for regulating the approval process for biosimilars were introduced in 2012 by the Ministry of Health and Family Welfare, and a draft Drugs and Cosmetics (Amendment) Bill, 2015 was released so as to amend the Drugs and Cosmetics Act, 1940. The objective of the said bill is to introduce provisions for clinical trials and regulation of medical devices. The Central Drugs Standard Control Organisation took several initiatives in the year 2014 and of these stellar initiatives included the introduction of e-governance at CDSCO and a bill for clinical trials and medical devices based on the recommendations of the Prof Ranjit Roy Chaudhury Expert Committee. The CDSCO also issued 14 orders in July 2014 to ensure that data generated in clinical trials is authentic, while the rights of human subjects participating in the trial are well protected. *This chapter was published in The Life Sciences Law Review 2017.*