Getting the Deal Through – Life Sciences

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Archana Shanker and Devinder Singh Rawat talk about the key policy shifts proposed by the National Health Policy 2017, and the regulation of the pharmaceutical-healthcare relationship. Excerpts taken from the chapter published in Getting the Deal Through: Life Sciences. The Draft National Health Policy 2017 has been introduced in guiding the approach for addressing the health sector. The primary aim of the National Health Policy 2017 is to prioritise the role of the government in shaping healthcare systems. **What are the main rules and principles applying to advertising aimed at the general public?** There is no legislation that regulates direct marketing of medicinal products to the general public.; The direct marketing of prescription drugs (Rx) defined under schedules H and X of the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 is prohibited in India. However, over-the-counter medicinal products can be advertised by pharmaceutical companies. **Which authorities may grant marketing authorisation in your jurisdiction?** The Central Drug Standard and Control Organisation (CDSCO) is the national regulatory authority in India that evaluates the safety, efficacy and quality of drugs. The CDSCO is headed by the DCGI, which is an apex authority body under the MoHFW and is responsible for the approval of new drugs. **What rules are in place to counter the counterfeiting and illegal distribution of medicines?** Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to their identity or source. Counterfeiting can apply to both branded and generic products, and counterfeit products. The term 'counterfeit medicine' is not defined in the Drug and Cosmetics Act 1940. However, the terms 'misbranded drug', adulterated drug, and 'spurious drug' are defined under sections 17, 17A and 17B respectively of the Drugs and Cosmetics Act as types of 'counterfeit medicine'. *This chapter was published in Getting the Deal Through: Life Sciences 2018.*

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