

Notification by Ministry of Health and Family Welfare:

Feb 17, 2020: In a recent gazette publication, dated 11 Feb 2020, the Ministry of Health and Family Welfare (Department of Health and Family Welfare) notified about proposed changes in regulations to hold marketing companies accountable for drug product quality. This is in addition to current Drugs and Cosmetics Rules holding manufacturer of drugs responsible for product quality and liable to any consequential action in case of defects. To quote the notification – “Responsibility of marketer of the drugs - Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliance's along with the manufacturer under these rules.”

The publication further clarified that these rules may be called the Drugs and Cosmetics (Amendment) Rules, 2020. They are anticipated to come into force on the 1st day of March, 2021.

The proposed changes are being viewed as means to assert quality requirements in every stage of medicine-making. It is anticipated that the proposed changes shall impact domestic and multi-national pharmaceutical companies outsourcing production to third party entities.



<http://egazette.nic.in/WriteReadData/2020/216113.pdf>