

# Liability of Company Directors under Indian Drug Laws



**Nitin Potdar**  
M&A Partner  
J.Sagar Associates



**Sanjay Kumar**  
Pharma Counsel  
J.Sagar Associates

Covid-19 pandemic apart from disrupting lives and livelihoods, has caused a big dent into the very fabric of global business and industry, in an unprecedented manner. Healthcare has borne the most direct impact of this crisis, and Pharma being an integral part of the healthcare ecosystem, now faces the challenge of playing its part in building more resilience and equitability into health care solutions. According to the IQVIA's 2019 Global Use of Medicine 2019 report, the amount of money spent on buying medicines across the world may go beyond \$1.4 trillion by the end of 2021. So, whilst in this crisis we could see big and new opportunities we may also see serious regulatory challenges and unprecedented

claims from consumers. And when we talk any industry, the bug stops at the door of directors! Here I am attempting to articulate the role & responsibility of directors under the Indian Pharma Laws.

In the Pharmaceutical industry in India, liability may be imposed on Company Directors on the basis of several laws, such as the Drugs and Cosmetics Act, 1940 (“**D&C Act**”), Drugs and Magic Remedies Act, 1954 (“**DMRA**”), and Narcotic Drugs and Psychotropic Substances Act, 1985 (“**NDPS**”).

Liability of Directors has been defined under Section 34 of the D&C Act for violation of Chapter IV by companies, Section 9 of DMRA, and Section 38 of NDPS: Every person who, at the time the offence was committed, was in charge of the company and responsible for the conduct of its business as well as the company shall be deemed to be guilty of the offence. Under this rule, Directors can be held liable for any violation of the DMRA and Consumer Protection Act (CPA) for offences such as products being below standard quality or spurious, and being wrongfully labelled.

The only exception provided in Section 34(1) is that if such defaulter proves that the offence was committed without his/her knowledge, or had exercised due diligence to prevent the commission of such offence, then liability may be avoided under the Act.

The mandate of Section 34 of the D&C Act specifies that in the event the offence is committed by the company, the other categories of persons listed under the Section may also be held responsible in addition to the company. Therefore, to prosecute the other categories of persons as enumerated under Section 34 of the Act, the condition precedent is that such person must have been in charge of and responsible to the company for the conduct of its business. For that purpose, there should be specific averments made in the complaint against the accused, establishing that they were in charge and responsible to the company in the conduct of its daily business when the offence was committed.

The court in **Rajesh Kumar v. State of Jammu and Kashmir** found that the facts of the case failed to establish that the petitioners (Company Directors) were in charge of and responsible to the company for the conduct of its business. Thus, compliance with Section 34(1) of the Act was deemed unfulfilled. In the absence of any such averments, as required by Section 34(1) of the Act, the prosecution could not be launched.<sup>1</sup>

## When does Vicarious Liability arise?

Vicarious liability of a person for an offence committed by a company under the D&C Act arises if at the material time he/she was in charge of and also responsible to the company for the conduct of its business. Mere holding of office as Company Director does not necessarily mean that such person fulfils both the stipulated requirements for proven default, which thereby absolves him of liability. Conversely, a person, without being a Director, can be in charge of and responsible to the company for the conduct of its business and thus be liable for prosecution in the event of certain acts contravening the drug laws.

In the case of **State of Haryana v. Brij Lal Mittal**, the Supreme Court held that if the only allegation against the accused was that they were Directors of the manufacturing company, and that they were guilty of no other offence to indicate, even prima facie, that they were in charge of the company and also responsible for the conduct of its

business, then they could not be prosecuted for offences committed by the company.<sup>2</sup>

The Supreme Court in **Sunil Bharti Mittal v. Central Bureau of Investigation and Other** was faced with the issue of deciding when a Director/person in charge of the affairs of the company can be prosecuted for an offence committed by the company. The three-judge bench laid down that a Director can be prosecuted only if there is sufficient evidence of his/her active role coupled with criminal intent, or where the statutory regime itself attracts the doctrine of vicarious liability by specifically incorporating such a provision. The Supreme Court categorically laid down that, "When the company is the offender, vicarious liability of the directors cannot be imputed automatically, in the absence of any statutory provision to that effect." It was surmised that a cardinal principle of criminal jurisprudence is that no vicarious liability can be fastened to Directors unless the statute specifically provides for it.

### **Liability of Directors: Factors for consideration**

Sub-Section 2 of Section 34 of the D&C Act mandates that if the Director, manager, secretary, or any other officer of the company is shown to be an accused in the complaint, then it is obligatory on the part of the complainant to show that the offence is committed with the consent or connivance of the accused.

Merely holding of office by the said personnel is not sufficient to establish that the offence is committed with his/her consent or connivance in the absence of basic pleading in that behalf. Courts have held that the mere act of a complaint being filed against Directors does not require the said Directors to submit to prosecution at the complainant's behest.<sup>3</sup>

Under the Drugs and Cosmetics Rules, 1945, Rule 76 lists forms of licences for the manufacture of drugs specified in the Schedules as also conditions for compliance by applicants. For instance, the manufacture of drugs is to be conducted under the active direction and personal supervision of competent technical staff, including at least one full-time employee with the necessary qualifications prescribed under the Rules. However, though the entire responsibility of maintaining drug quality devolves on the competent technical staff, that alone is not sufficient to exonerate the company's Chairman or Managing Director from vicarious liability under Section 34 of the D&C Act.

Such grey areas of pinning responsibility for criminal offences place vicarious liability of Directors in uncertain domain in practice. It is therefore vital that the complaint clearly states the legal violation incriminating the accused Directors in terms of material evidence of culpable conduct, and acts of commission or omission.<sup>4</sup>

### **Fastening Responsibility**

Under the various provisions of the drug laws in India, Company Directors may be held liable for failure of the company's compliance with the drug laws pertaining to licenses, drug quality, etc. when they are bound by responsibility for such conduct. However, the D&C Act provides for an exception to such liability being borne by Directors when violations of the provisions are incurred without their knowledge or upon failure to stop such violation after having undertaken due diligence. If the conditions of Section 34 are fulfilled, liability may be imposed on the Directors under the D&C Act and other drug laws. When a Director is not party to a suit, but liability is sought to be imposed, the Director may challenge such a claim u/s. 482 of the Civil Procedure Code (CPC). Such controversial litigation needs to be avoided by early amendment of the vicarious liability provisions, clarifying the specifics that pin guilt of infraction of the drug laws.

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Views expressed are personal.

<sup>1</sup> Rajesh Kumar And Anr. vs State at Jammu and Kashmir, 561-A Cr.P.C. No.297/2016 & MP No.01/2016.

<sup>2</sup> State Of Haryana vs Brij Lal Mittal & Ors SC 1998.

<sup>3</sup> Bombay High Court in Ram Prakash Gulati. And others versus state of Maharashtra CRIMINAL APPLICATION (APPLN) NO.3684 OF 2009.

<sup>4</sup> Medipol Pharmaceuticals India vs State Of Gujarat R/SPECIAL CRIMINAL APPLICATION NO. 748 of 2018.