

July 18, 2024

## Draft of the Drugs and Cosmetics (Compounding of Offences) Rules, 2023

On July 10, 2024, the Ministry of Health and Family Welfare ("**Ministry**") released the draft of the Drugs and Cosmetics (Compounding of Offences) Rules, 2023 ("**Draft Compounding of Offences Rules**") in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (the "**Act**"), in consultation with the Drugs Technical Advisory Board. The said Draft Compounding of Offences Rules will be taken into consideration on or after the expiry of a period of 45 days from July 10, 2024.

To gather feedback, the Ministry has invited objections and suggestions within the period specified above, which may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No 434, C wing, Nirman Bhawan, New Delhi - 110011 or emailed at [drugdiv-mohfw@gov.in](mailto:drugdiv-mohfw@gov.in).

The key highlights introduced by the Draft Compounding of Offences Rules are as follows:

### **I. Appointment of Compounding Authority:**

The Central Government and State Government may, by notification in the official gazette, appoint any person as the compounding authority under these Draft Compounding of Offences Rules. This Compounding Authority will exercise the powers and functions of the Central Government and State Government and take measures related to matters arising from these Draft Compounding of Offences Rules.

### **II. Form and Manner of Application:**

The applicant (Company or any person) may submit an application for compounding an offence under section 32(B) of the Act using Form-1, either before or after the initiation of prosecution. This application, accompanied by relevant information and documents, should be submitted to the compounding authority.

### **III. Procedure for Compounding:**

- a) Upon receiving the application, the compounding authority will request a report from the reporting authority (i.e., Licensing Authority, the Central Licensing Authority, the Central License Approving Authority appointed by the Central Government, or the Licensing Authority appointed by the State Government, under the Act and its rules which has jurisdiction over the location where the offence under the Act has occurred or is alleged to have occurred) in whose jurisdiction the offence occurred, based on the details provided in the application or any other relevant information needed to examine the application.
- b) The reporting authority must submit the requested report within 1 month or within an extended period allowed by the compounding authority, from the date of the receipt of communication from the compounding authority.
- c) After reviewing the application and the report, the compounding authority may either approve the application by specifying the

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compounding amount and granting immunity from prosecution or reject the application. However, before rejecting an application, the applicant must be given an opportunity to be heard, and the grounds for rejection must be stated in the order.

- d) It is pertinent to mention here that the applicant does not have an inherent right to have their offence compounded.

#### **IV. Immunity from Prosecution:**

The compounding authority may grant immunity from prosecution under the Act, if it is satisfied that the applicant has cooperated fully in the proceedings and has made complete and truthful disclosures regarding the case. This immunity, however, may be subject to conditions imposed on the applicant as deemed appropriate by the compounding authority.

#### **V. Withdrawal of Immunity from Prosecution:**

- a) Immunity granted to a person under this Draft Compounding of Offences Rules will be withdrawn if the person fails to pay the specified sum in the compounding order issued by the compounding authority under these rules within the given timeframe, or if they fail to comply with any other conditions associated with the granted immunity. In such cases, the provisions of the Drugs and Cosmetics Act, 1940, will apply as if no immunity had been granted.
- b) Additionally, the compounding authority may withdraw the granted immunity at any time if it is found that the person concealed material particulars or provided false evidence during the compounding proceedings. In this event, the individual may be tried for the original offence for which immunity was granted or any other offence related to the compounding proceedings. Consequently, the provisions of the Drugs and Cosmetics Act, 1940, will apply as if no immunity had been granted.

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## AWARDS & RECOGNITIONS



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