Rewards for Internal Informants Reporting Issues Concerning the Quality and Safety of Medicinal Products and Medical Devices

China - NMPA / SAMR / Ministry of Finance

Main information

Scope of Application:

Encourage whistleblowing by insiders and informants to competent authorities about serious violations committed by Pharma and MD companies about Quality and Safety of Drugs and MD

Effective Date:

May 29th, 2025

Related Provisions:

- Interim Measures for Rewards for Reporting Major Violations in the Field of Market Supervision – Notice SAMR and MOF no. 4/2021
- Labor Law / Labor Contract Law
- Personal Information Protection Law



Key Topics

Framework

- Encourage and Reward whistleblowing in pharmaceutical sector is disciplined by Chinese Law System since 2017. Reporting to authorities serious violations committed by Companies can be deemed as social duty. It is not mandatory unless the employee has specific obligations due to its role.
- The whistleblowing can be both by providing personal information of the informant, or anonymous. Only where the informant applies for reward, he/she must inform the Authorities about his/her personal information.
- The whistleblowing prevails over duty of confidentiality of employees or former employees.

What's new

- Compared to the Notice no. 4/2021, this new notice further strengthens
 procedures and protects whistleblowers from any potential negative
 consequence such as termination of labor contract, or violation of secrecy of
 his/her personal information.
- Employers shall not retaliate against internal informants by rescinding or altering their labor contracts, or by any other means.
- Without the consent of the internal informant, no information identifying the informant may be disclosed in any form.

Sensitive Factors

- Even former employees may be rewarded by the authorities
- Whistleblowing can be completely anonymous
- Informants providing true information may not be dismissed even though the whistleblowing causes losses to the Company

Drivers

- **Internal compliance:** The notice encourages companies to set up an internal preventive compliance system, to let the employees report potential deviations internally.
- Rewarding policy prevails over labor contracts: even though labor contracts prevent employees from whistleblowing, such prohibition is void where the information is shared with the competent authorities
- Surveillance on quality and safety prevails over losses caused to the Company: Chinese Courts usually support claim of unlawful termination of labor contract due to Labor Contract Law art. 39 (losses caused to the Company) where the loss is consequence of whistleblowing, provided that these parameters are met:
 - Authenticity: the information provided must be true, accurate and supported by relevant evidence, basic or full ones.
 - Appropriateness: the whistleblowing must be done to the authorities through the channels duly set up for this purpose.
 Public reporting can be deemed as appropriate where the Authorities did not respond in reasonable time and where are serious threats for public health.



