Announcement of the National Medical Products Administration, Ministry of Finance, and State Administration for Market Regulation on Rewards for Internal Informants Reporting Issues Concerning the Quality and Safety of Medicinal Products and Medical Devices[1]

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To further strengthen internal oversight of the quality and safety of the pharmaceutical and medical device industry, and to promptly identify and mitigate risks associated with medicinal products and medical devices, this announcement is issued in accordance with the Drug Administration Law of the People's Republic of China, the Vaccine Administration Law of the People's Republic of China, the Regulations on the Supervision and Administration of Medical Devices, the Interim Measures for Rewarding Reports of Major Violations of Laws in the Field of Market Regulation (SAMR Order No. 4 [2021], hereinafter the "Measures"), and other applicable laws and regulations.

1. Internal employees and relevant insiders of enterprises engaged in the research, development, production, and operation of medicinal products and medical devices, as well as those who use such products, providers of third-party platforms for the online trading of medicinal products and medical devices, and other organizations (collectively referred to as "enterprises and relevant entities") who report major violations of laws concerning the quality and safety of medicinal products and medical devices to the relevant regulatory department under their real names may be eligible for rewards from the regulatory department.

For the purposes of this announcement, "major violations of laws" refer to violations that are suspected of constituting a crime or that may result in administrative sanctions such as suspension of production or business operations, closure, revocation or cancellation of licenses, or the imposition of substantial fines or confiscation of property. If local regulations or local government rules contain specific provisions regarding major violations

1 Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

of laws, those provisions shall prevail. The determination of what constitutes a substantial fine or confiscation shall be made by the regulatory department at or above the provincial level in consultation with the finance department at the corresponding level, based on actual circumstances.

2. For the purposes of this announcement, “internal informants” include both internal employees and relevant insiders of enterprises and relevant entities. Internal employees are defined as individuals who have signed labor contracts with, or otherwise maintain de facto labor relations with, the enterprise or relevant entity. Relevant insiders include individuals who have terminated their labor contracts with the enterprise or relevant entity within the past year, those who maintain business connections with the enterprise or relevant entity relating to the quality and safety of medicinal products and medical devices, and temporarily employed personnel, among others.

3. The medicinal product regulatory department shall publicly disclose the 12315 reporting hotline, the 12315 reporting platform, correspondence address, report reception department, and other reporting channels at its offices or on its official website, ensuring open and accessible channels to promptly receive reports from internal informants. Enterprises and relevant entities are encouraged to prominently display these reporting channels at their research, development, production, operation, and usage sites.

4. Upon receiving a report from an internal informant, the medicinal product regulatory department shall handle it in accordance with the Interim Measures for Handling Complaints and Reports concerning Market Regulation, the Provisions on Administrative Sanctioning Procedures for Market Regulation, and other relevant regulations. Local authorities are encouraged to establish dedicated channels for handling internal reports according to local circumstances and to prioritize the investigation of reports that provide clues to major violations of law.

If an on-site investigation of the enterprise or relevant entity is conducted based on an internal report, or if the enterprise or entity is required to cooperate, the principle of necessity shall be observed, and efforts must be made to minimize or avoid disruption to the normal production and operations of the enterprise or relevant entity. Personnel involved in handling such cases must maintain confidentiality regarding state secrets, trade secrets, and personal privacy encountered during the investigation and enforcement process, in accordance with the law.

5. When the medicinal product regulatory department identifies any potential safety hazard related to medicinal products or medical devices, it shall promptly respond in accordance with the Medicinal Product Administration Law, the Vaccine Administration Law, the Regulation on the Supervision and Administration of Medical Devices, and other relevant provisions, as well as applicable emergency response plans. The department shall act in a timely manner to eliminate potential hazards, prevent the spread of harm, and promptly notify relevant entities or report the situation according to applicable regulations.

6. If the facts reported by an internal informant are verified to be true, the medicinal product regulatory department shall provide rewards to informants who meet the reward criteria. Determination of whether an internal informant qualifies for rewards, including the standard and conditions, shall be made through internal collective discussion by the regulatory department. In addition to material rewards, the informant may also receive a notice of commendation or other forms of recognition, with their consent.

7. Reward funds for reporting shall be included in the departmental budgets of medicinal product regulatory departments at all levels, in accordance with budget management procedures and relevant provisions, and shall be subject to supervision by the finance and audit authorities.

8. The medicinal product regulatory department responsible for investigating and handling a report, and for making the final decision on the case, shall notify the informant within 15 working days after the conclusion of the case. Procedures for granting rewards shall be initiated upon the informant's application.

9. An internal informant eligible to receive rewards must meet all of the following conditions:

(1) The report identifies a clear target and provides specific facts regarding the violation of law or clues to illegal or criminal activities, along with key evidence.

(2) The reported matter was previously unknown to the medicinal product regulatory department. (3) The investigation and handling of the reported matter has been completed, and the violator has either been subject to administrative sanctions by the medicinal product regulatory department or has been legally transferred to judicial authorities and held criminally liable.

10. Rewards for reporting shall be granted according to the following principles:

(1) Where two or more internal informants separately report the same matter based on the same clue, the reward shall be granted to the informant who submitted the report first. If an internal informant provides multiple clues to violations of law or reports multiple matters that are handled by the regulatory authority as one case, the reward shall be granted as a single case.

(2) Where two or more internal informants jointly report the same case, the reward shall be distributed among them. The distribution shall be determined through mutual agreement; if no agreement is reached, the reward shall be divided equally.

(3) Internal informants reporting the same matter shall not receive duplicate rewards. If the same case is reported by two or more informants based on different clues, rewards shall be granted in accordance with the levels specified in the Measures, provided that the total amount shall not exceed the maximum standard for the corresponding reward level as set forth in Article 12 of the Measures.

(4) Where the final determination of violations is entirely inconsistent with the reported matter, no reward shall be granted. If the determination is partially consistent with the reported matter, only the portion consistent with the report shall be eligible for reward. If additional violations are uncovered beyond the matters reported, no reward shall be granted for those additional violations.

(5) Where a cross-regional report accepted by a superior regulatory authority is ultimately investigated and handled by two or more regulatory authorities separately, each regulatory authority shall grant rewards for the parts of the report verified within its respective jurisdiction.

11. Rewards granted to internal informants shall be determined in accordance with the relevant provisions of the Measures concerning their level and amount.

If a major violation of laws relating to the safety of medicinal products and medical devices reported by an internal informant results in death, serious disability, injury to multiple persons, significant property loss, adverse social impact, or other grave consequences, or if the report prevents the occurrence of such violations, eliminates major potential safety hazards, or substantially assists in the investigation and handling of major violations or criminal cases involving medicinal products and medical devices, the reward standards may be appropriately increased.

The maximum reward amount for each case shall be governed by the provisions of the Measures. The specific reward amount shall be determined by the medicinal product regulatory department responsible for granting the reward, in consultation with the finance department of the government at the corresponding level

12. Internal informants shall claim their rewards in person within 30 working days of being notified of the reward decision, presenting valid identification. If the reward is to be collected on the informant's behalf, the entrusted party must present a power of attorney issued by the informant, along with valid identification of both the informant and the trustee. In special circumstances, the collection period may be appropriately extended, but the extension shall not exceed 10 working days. Failure to claim the reward within the prescribed period without justified reason shall be deemed a voluntary waiver.

The medicinal product regulatory department shall streamline the procedures for reviewing and disbursing reward funds and minimize the collection of unnecessary personal information from internal informants. Internal informants shall cooperate in providing necessary personal details. Where an internal informant has specific requirements regarding the method of reward distribution, such requests may be considered at the discretion of the regulatory department.

13. Where an internal informant objects to the reward amount, he or she may, within ten working days from the date of receiving the reward decision, submit an application for review to the medicinal product regulatory department that issued the reward.

14. No reward shall be granted under any of the following circumstances:

(1) The report is filed by the infringed party, its authorized representative, or another interested party.

(2) The internal informant organized or principally committed the violation of law involved in the reported matter.

(3) The internal informant has already received remuneration or reward from another administrative authority or entity for the same reported matter.

(4) Other circumstances in which the granting of a reward is prohibited under applicable laws or regulations.

15. The medicinal product regulatory department shall adopt measures to strengthen the protection of internal informants' personal information and strictly limit access to such information. Without the consent of the internal informant, no information identifying the informant may be disclosed in any form.

Where personnel violate confidentiality obligations and unlawfully disclose the personal information of an internal informant, thereby causing adverse consequences, they shall be held accountable in accordance with the law and relevant disciplinary provisions.

16. Enterprises and relevant entities shall not retaliate against internal informants by rescinding or altering their labor contracts, or by any other means. Any party engaging in such conduct shall bear corresponding legal liability; where the conduct constitutes a crime, the offender shall be subject to criminal liability in accordance with the law.

Where an enterprise or relevant entity retaliates against an internal informant in a manner that amounts to refusal or obstruction of supervision and inspection, or through the forgery, destruction, or concealment of relevant evidentiary materials, the medicinal product regulatory department shall impose severe penalties in accordance with applicable laws and regulations.

17. Enterprises and relevant entities shall, in accordance with their actual circumstances, establish internal mechanisms for addressing issues related to the quality and safety of medicinal products and medical devices. They shall encourage employees to proactively identify and report potential safety risks and hazards, and shall voluntarily carry out self-inspections and corrective actions in an active, dynamic, and comprehensive manner, thereby enhancing the overall quality and safety standards of medicinal products and medical devices.

The legal representatives, principal responsible persons, directly accountable managers, and other responsible personnel of enterprises and relevant entities shall bear responsibility for safety management, promptly assess and verify identified potential risks, and, upon confirmation, take immediate remedial and preventive measures.

Enterprises and relevant entities are further encouraged to establish and improve internal incentive mechanisms to promote the reporting of safety risks, and to provide appropriate rewards to personnel who contribute to the identification and prevention of such risks.

18. Internal informants shall bear responsibility for the truthfulness of the information they provide. They shall not submit false or forged evidence, make false reports, or deliberately interfere with case-handling procedures.

Where an internal informant falsifies materials or conceals facts in order to obtain a reward, the medicinal product regulatory department is entitled to recover the reward funds. If an internal informant fabricates facts with the intent to defame others or engages in fraudulent conduct, he or she shall bear corresponding legal liability. Where circumstances are serious, the relevant authority shall impose joint disciplinary measures in accordance with applicable provisions; where the conduct constitutes a crime, the case shall be transferred to the judicial authority for criminal prosecution.

19. This Announcement shall take effect from the date of issuance.

National Medical Products Administration Ministry of Finance State Administration for Market Regulation

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