Union Health Ministry Proposes Immediate Suspension of Manufacturing Licences for Drugs Found Not of Standard Quality on Specified Critical Parameters

Proposed Amendments to Drugs Rules, 1945 Aim to Strengthen Regulatory Oversight and Ensure Prompt Action Against Substandard Medicines

Manufacturing Licences of Drugs Found Deficient in Assay, Dissolution, Related Substances, Impurities or Sterility Proposed to be Suspended Immediately

Restoration of Suspended Licences to be Permitted Only After Verified Corrective and Preventive Action by Manufacturers

Enhanced Reporting Mechanism Proposed to Facilitate Timely Regulatory Coordination and Strengthen Accountability

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In a significant step towards strengthening the regulatory framework for ensuring the quality and safety of medicines in the country, the Union Ministry of Health and Family Welfare has proposed amendments to the Drugs Rules, 1945, to provide for immediate suspension of manufacturing licences in respect of drugs declared Not of Standard Quality (NSQ) on specified critical quality parameters.

The proposed amendments seek to enable prompt regulatory intervention upon detection of substandard medicines, prevent their continued manufacture and distribution, and strengthen the mechanism for ensuring compliance with prescribed quality standards, in the interest of patient safety and public health.

Under the existing provisions of the Drugs Rules, 1945, suspension or cancellation of a manufacturing licence is preceded by the prescribed regulatory procedure, including issuance of a show-cause notice. This may result in a time gap between the declaration of a

drug as NSQ and initiation of regulatory action. During this period, the concerned drug may continue to remain in circulation, posing potential risks to public health and making effective recall more challenging.

To address this regulatory concern, the Ministry has proposed a provision for immediate suspension of the manufacturing licence of the concerned drug by the Central Licensing Approving Authority or the State Licensing Authority, as the case may be, upon receipt of a Government Analyst's report declaring the drug as NSQ with respect to Assay, Dissolution, Related Substances, Impurities or Sterility.

These parameters are critical to determining the quality of medicines. The proposed provision aims to ensure that instances of non-compliance involving these specified parameters are met with prompt regulatory action, thereby minimising potential risks to patients.

The proposed amendment also provides for mandatory corrective measures before revocation of the suspension. The suspension shall continue until the manufacturer undertakes an effective Root Cause Analysis to identify the reasons for the quality failure and implements appropriate Corrective and Preventive Action (CAPA) to the satisfaction of the concerned Licensing Authority.

Revocation of the suspension shall be permitted only after implementation of the requisite corrective and preventive measures and their due verification by the Licensing Authority. This mechanism is intended to ensure that identified quality deficiencies are adequately addressed and necessary safeguards are put in place to prevent their recurrence.

To further strengthen regulatory coordination and facilitate timely action, consequential amendments have also been proposed to Form 13, relating to the test report of the Government Analyst.

Under the proposed mechanism, the Government Analyst's report would be endorsed to the Drugs Controller General of India (DCGI), the concerned State/UT Licensing Authority under whose jurisdiction the manufacturing site is located, as well as the manufacturer and marketer of the concerned drug.

The proposed arrangement is aimed at ensuring timely communication of NSQ findings to the relevant authorities and stakeholders, thereby facilitating coordinated regulatory action and strengthening accountability across the drug manufacturing and marketing chain.

The proposed amendments follow deliberations at the 65th meeting of the Drugs Consultative Committee (DCC), held on 20 December 2024, and recommendations of the 92nd meeting of the Drugs Technical Advisory Board (DTAB), held on 24 April 2025.

The amendments are expected to strengthen post-marketing regulatory surveillance, facilitate timely action against substandard medicines, promote greater accountability among manufacturers and marketers, and reinforce public confidence in the quality of medicines available in the country.

The initiative reflects the Government of India's continued commitment to strengthening the drug regulatory framework and ensuring the availability of safe, effective and quality medicines for the public.

The draft amendments have been notified for public consultation, inviting objections and suggestions from stakeholders and members of the public within 30 days from the date on which copies of the Gazette of India containing the draft rules are made available to the public.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall-C Wing, First Floor, Kartavya Bhawan-1, New Delhi – 110001, or sent by email to **drugsdiv-mohfw[at]gov[dot]in**.

The draft Gazette notification may be accessed through the official e-Gazette portal at:

https://egazette.gov.in/(S(tqlgzgdze5s0ylovnh4l0ej1))/ViewPDF.aspx

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