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Health Ministry extends QR code-based drug product identification framework

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QR code-based authentication for inclusion of vaccines, antibacterial, NDPS and anti-cancer drugs



In a significant step towards strengthening the quality, safety and purity of India's pharmaceutical supply chain, the Union Ministry of Health and Family Welfare, Government of Ind,a has approved the Drug Rules, to expand the scope of Schedule H2 and bring additional categories of drugs under the QR code-based track and trace framework. Amendments have been notified in 1945.

Under the amended provisions, all vaccines, antimicrobial, narcotic and psychiatric drugs and all anti-cancer drugs covered under the Narcotic Drugs and Psychiatric Substances (NDPS) Act, 1985 have been included in Schedule H2 of the Drugs Rules, 1945.

As per this amendment, the manufacturers of these medicines will be mandated to print or affix the bar code or quick response (QR) code on the primary packaging label of the product or on the secondary packaging label if there is insufficient space. The QR code will store information that can be used to facilitate the authentication and verification of the product through software applications.

The QR code will include key product information, including the unique product identification code, generic and brand name, manufacturer's name and address, batch number, manufacturing and expiry dates, manufacturing license number, and where applicable, details of the accessories.

The QR code-based identification requirement was earlier applicable to the top 300 pharmaceutical brands in the country. The present amendment substantially expands its scope to include all vaccines, antimicrobial drugs, anti-cancer drugs and narcotic and psychiatric drugs, thereby widening the scope of detection and strengthening safeguards against the proliferation of spurious and substandard drugs.

The improved product identification framework will facilitate certification of drugs at various stages of the supply chain and enable better tracking and validation of pharmaceutical products. This measure is expected to strengthen regulatory oversight and aid efforts to curb the distribution of spurious drugs in the market. It will also contribute to the national fight against antibacterial resistance (AMR) by enabling better detection and monitoring of counterfeit and substandard antibacterial products.

Keeping in view the need to give adequate time to the industry and other stakeholders for implementation, the Ministry has prescribed phased timelines for compliance. The provisions relating to vaccines, narcotic and psychiatric drugs and anti-cancer drugs will come into effect from 1st July 2027, while those relating to antimicrobial drugs will come into effect from 1st July 2028.