File No. PMDSM-14011(13)/1/2026-eoffice (Comp. No. 35617)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Post Marketing Drugs Safety Monitoring Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Date:

To, 06 JUL 2026

All State/UT Licensing Authorities.

Subject: - Azithromycin related 'Fixed Drug Eruption (FDE)' - Recommendations for the change in Prescribing Information Leaflets (PILs)– regarding.

Sir,

The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), Ghaziabad, has forwarded recommendations arising from the assessment of Adverse Drug Reaction (ADR) reports pertaining to **Azithromycin** formulations, which was discussed in 27th Signal Review Panel dated 24th November, 2025. In the meeting, the PvPI has evaluated the Patient Population Incidence - Adverse Drug Reactions (PPIs-ADR) based on Individual Case Study Reports (ICSR) and made recommendation to CDSCO to take necessary measures to incorporate ***"Fixed Drug Eruption"*** as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the ***Azithromycin*** based medical products marketed in the country.

The aforementioned recommendations of NCC-PvPI were subsequently reviewed by the Subject Expert Committee (SEC) on (Antimicrobial & Antiparasitic) during its meeting held on 09.04.2026 at CDSCO-HQ, New Delhi. After detailed deliberations, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to incorporate **'Fixed Drug Eruption (FDE)'** associated with Azithromycin as ADR in the corresponding Prescribing Information Leaflet (PIL) of the drug.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of ***Azithromycin*** formulations under your jurisdiction to mention ***"Fixed Drug Eruption"*** as an adverse drug reaction in the Package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy for information & follow-up: -

1. All Zonal / Sub Zonal Offices of CDSCO.

Copy to:-

2. PvPI, Indian Pharmacopeia Commission, Ghaziabad.
3. PPS to DCG(I).
4. Website of CDSCO.