ED/Complaint/223/2023
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement Division)

Dated: - 31 AUG 2023

Subject:- Voluntary Recall of Digene Gel manufactured by M/s Abbott India Limited, L-18 /19, verna Industrial Estate, Salcette, Goa-403722 -reg.

It was reported on 9th August 2023, that one bottle of Digene Gel Mint flavor batch no. 510303D7 used by Customer is of regular taste (sweet) and light pink colour whereas another bottle of same batch observed it was of white colour with bitter taste and pungent odour as per complaint. Accordingly, M/s Abbott India Limited, L-18 /19, verna Industrial Estate, Salcette, Goa-403722 vide letter no. AB/RA/EPD/078-2023 dated 11-08-2023, informed to this office for voluntary recall of impugned product Digene Mint flavor batch no. 510303D7 and Digene Gel orange having batch no. 500351D7, 500352D7, 500353D7, 500354D7 and voluntary stopped production of all variants of Digene Gel manufactured at their Goa facility. Further, M/s Abbott India Limited, L-18 /19, verna Industrial Estate, Salcette, Goa-403722 vide letter no. AB/RA/EPD/081-2023 dated 18-08-2023 intimated to this office regarding voluntary product **recall of all batches of Digene Gel of all flavors (Mint, Orange, Mix fruits flavor) which are within the self life and manufactured at Goa facility.** The impugned product may be unsafe and its use may result in adverse reaction.

Based on the above, the following advisory is provided:

a. **To doctors and Healthcare Professionals**: The doctors and healthcare professionals should carefully prescribe and educate their patients to discontinue the use and for reporting of any ADRs arising due to consumption of the said product. Healthcare professionals should promptly report any suspicious cases of adverse events linked to this product.
b. **To consumers and patients:** To discontinue the use of Digene Gel which are manufactured at Goa Facility.
c. **Wholesaler and Distributors** : The said impacted product with all batch numbers manufactured at Goa facility with in active shelf life to be removed from the distribution
d. **To Regulatory Authorities (All States/UTs Drugs Controllers and all Zonal and Sub-Zonal Offices of CDSCO):** Instruct your officers to keep strict vigil on the movement, sale, distribution, stock of the said drug products in the market, draw samples if said product lying in market and initiate necessary action as per the provisions of the Drugs and Cosmetics Act and Rules made thereunder.

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

Copy for information and necessary action:

- All Zonal/Sub-zonal offices of CDSCO.
- All State/UTs Drugs Controllers.
- All India Organization of Chemists and Druggists (AIOCD), 201, Safalya Building, Opp Jaigopal Industrial Estate, Dadar (W), Maharashtra 400028 (aiocd@aiocd.com)
- JS (R), Drugs Regulation Section, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
- CDSCO-IT Cell for publication on website.