

/7/2023

**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**(Enforcement Division)**

Dated: - 05 SEP 2023

**Alert on falsified versions of Adcetris Injection (Brentuximab Vedotin) manufactured by M/s. Takeda Pharmaceutical Company Ltd. -reg.**

The World Health Organization (WHO) has informed about a safety alert identified with multiple falsified versions of Adcetris Injection 50mg (Brentuximab Vedotin) Mfg by M/s. Takeda Pharmaceutical Company Ltd. identified in four different countries including India. These products are most often available at patient level and distributed in the unregulated supply chains (mainly online). The products have been identified in both regulated and illicit supply chain, sometimes at patient levels as well. WHO has reported that there are at least 08 different batch numbers of falsified version in circulation namely Batch No.11980412 ED: 04/2024, 12188747 ED: 01/2025, 12188749 ED: 01/2025, 12200242 ED: 01/2025, 12202389 ED: 01/2025, 12203322 ED: 01/2025, 12310404 ED: 09/2025 and 512053 ED: 11/2024.

ADCETRIS (Brentuximab Vedotin) is a CD30-directed antibody-drug conjugate indicated for treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and systemic anaplastic large cell lymphoma.

Based on the above the following advisory is provided:

**a) To doctors and Healthcare Professionals:**


- i. The doctors and healthcare professionals should carefully prescribe and educate their patients for reporting of any ADRs.

**(b) To consumers and patients:**

- i. To be careful and only procure the medical products from authorized sources with proper purchase invoice.

**(c) To Regulatory Authorities (All States/UTs Drugs Controllers and all Zonal and Sub-Zonal Offices of CDSCO):**

- i. Instruct your officers to keep a strict vigil on the movement, sale, distribution, stock of the said drug products in the market, draw samples and initiate necessary action as per the provisions of Drugs and Cosmetics Act and Rules made thereunder.

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

Copy to:

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