

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA  
UNSTARRED QUESTION NO.895  
TO BE ANSWERED ON 03<sup>RD</sup> DECEMBER, 2024**

**APPROVAL OF MONOCLONAL ANTIBODIES**

**895: SHRI HARIS BEERAN:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Central Drugs Standard Control Organisation (CDSCO) approved monoclonal antibodies for the treatment of various diseases in the country;
- (b) whether the biosimilars are approved for the original monoclonal antibodies and if so, the details thereof;
- (c) the names of monoclonal bodies approved by CDSCO from 1st January 2000 to 31<sup>st</sup> October 2024;
- (d) the disease for which it is approved, the name of the originator, and the price per SKU; and
- (e) the number of biosimilars if approved in the country, the names of biosimilar manufacturers and the price of biosimilar SKU?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SMT. ANUPRIYA PATEL)**

(a) to (e): Central Drugs Standard Control Organization (CDSCO) approves monoclonal antibodies as per the provisions of New Drugs and Clinical Trials Rules 2019 under Drugs and Cosmetic Act, 1940. The list of similar biologics/biosimilars including monoclonal antibodies, alongwith their indications, dosage form, strength, name of manufacturer/importer are available on the website of Central Drugs Standard Control Organization i.e <https://cdsco.gov.in/opencms/opencms/en/biologicals/>

National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals (DoP) fixes retail price of a new drug, as defined in DPCO, 2013, for existing manufacturers of scheduled formulation. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies. Manufacturers have to sell the formulation within the retail prices fixed by NPPA. The details of prices fixed by NPPA are available on the website of NPPA i.e., [www.nppaindia.nic.in](http://www.nppaindia.nic.in)

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