

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

**RAJYA SABHA
UNSTARRED QUESTION No. 2024
TO BE ANSWERED ON 10th MARCH 2026**

HIGH COST OF RARE DISEASE DRUGS

2024. SHRI JAGGESH:

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

- (a) whether it is a fact that many essential and orphan drugs for rare diseases remain unaffordable despite existing price control and support mechanisms;
- (b) whether Government has undertaken any assessment of the financial burden faced by patients, particularly children, due to the high cost of such life-saving medicines;
- (c) whether steps are being taken to expand coverage under the National Policy for Rare Diseases and to bring more critical drugs under price regulation;
- (d) whether Government proposes further measures such as price caps, subsidies or public procurement to ensure affordable access to these drugs; and
- (e) the details in this regard?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SHRI PRATAPRAO JADHAV)**

(a) to (e) Most of the drugs required for treatment of rare diseases are prohibitive as they are imported from outside the country. National Policy for Rare Diseases (NPRD), 2021 facilitates financial and medical assistance of up to INR 50 lakhs per patient for treatment of identified rare diseases in the designated Centers of Excellence (CoEs). As per NPRD, rare diseases are categorized into three groups. Group I deals with the disorders amenable to one-time curative treatment with the average cost of treatment being INR 10-30 lakhs per patient. Group II deals with the diseases requiring lifelong treatment, with the average cost ranging between INR 50,000 to 3.50 lakhs per patient annually. Group III deals with the diseases for which specific treatment is available but require lifelong therapy, with the average cost being more than INR 50 lakhs to 8 crores per patient, annually or with the gene therapies ranging from INR 9 crores to 30 crores per patient. The National Pharmaceutical Pricing Authority (NPPA) regulates the prices of medicines as per the provisions of the Drugs (Prices Control) Order 2013 (DPCO, 2013) for formulations specified

in Schedule-I which is based on the National List of Essential Medicines (NLEM). However, NLEM does not have any separate therapeutic category of orphan drugs for rare diseases. Following measures have been taken to expand coverage under NPRD:

- Since the inception of NPRD in 2021, the number of rare diseases identified under the policy has risen from 51 to 63 on the recommendation of Central Technical Committee for Rare Diseases (CTCRD) and the number of CoEs has also risen from 8 to 15.
- NITI Aayog constituted a Committee for 'Drugs and Dosage Forms for Rare Diseases: Engagement with Manufacturers' to fast track indigenous development and marketing of identified orphan drugs by engaging with domestic manufacturers. As a result, some Made-in-India drugs have become available at 1/10th of the price of the imported Reference Listed Drug (RLD).
- The Ministry of Finance provides exemption from Basic Customs Duty (BCD) and Integrated Goods and Services Tax (IGST) on most of the drugs, medicines and Food for Special Medical Purposes (FSMP), subject to extant rules.
- The Department of Pharmaceuticals has initiated implementation of 'Production Linked Incentive' scheme for pharmaceuticals which provides financial incentives to the manufacturers selected for domestic manufacturing of various product categories, including rare disease medicines.
