GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 846
TO BE ANSWERED ON THE 26th JULY, 2024

Medicines for Rare Diseases

†846 Shri Hanuman Beniwal:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has taken note that medicines for many rare diseases including Ducheme Muscular Dystrophy, Spinal Muscular Atrophy, Osteogenesis Imperfecta are very expensive in India or they have to be imported at expensive rates;
(b) if so, the details thereof;
(c) whether the Government has any plan to start the indigenous production of medicines including injections used for the prevention and treatment of such diseases which have to be imported at expensive rates;
(d) if so, the details thereof;
(e) whether the Government proposes to make such medicines available free of cost to poor patients until their indigenous production starts in the country; and
(f) if so, the details thereof along with the time by which it is likely to be done and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(MS. ANUPRIYA PATEL)

(a) & (b): As informed by the Department of Health & Family Welfare (D/o H&FW), the drugs for treatment of many rare diseases including Ducheme Muscular Dystrophy, Spinal Muscular Atrophy, Osteogenesis Imperfecta etc. are quite expensive. The cost of these medicines varies from few lakhs to Rs. 16 crore.

The National Pharmaceutical Pricing Authority (NPPA) has informed that formulations are mentioned in NLEM,2022 and Schedule-I of DPCO,2013 according to their therapeutic category. The formulations used for rare disease, including Ducheme Muscular Dystrophy, Spinal Muscular Atrophy, Osteogenesis Imperfecta, are not specifically mentioned in Schedule I of DPCO, 2013. A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation (branded or generic) launched by it. However, as per the DPCO,2013 the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum in the preceding 12 months. All price notifications for the formulations of which prices have been fixed by NPPA are available on NPPA web-site www.nppaindia.nic.in.

(c) & (d): In order to make the country Atmanirbhar in pharmaceuticals sector, the Department of Pharmaceuticals is implementing the Production Linked Incentive (PLI) Scheme for

Pharmaceuticals with a total financial outlay of Rs. 15,000 crore and scheme tenure up to FY 2027-28. The scheme provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The product Category 1 covers drugs such as bio-pharmaceuticals, complex generics, gene therapy drugs, complex excipients, Orphan Drugs etc. Under the scheme, total 8 products have been approved for manufacturing under the scheme. The approved orphan drugs under PLI scheme for Pharmaceuticals are as follows:

S. No.	Name of the product	Usage
1	Nitisinone	Treatment of hereditary Tyrosinemia type 1
2	Nusinersen	Treatment of Spinal Muscular Atrophy
3	Rufinamide	Treatment of Lennox-Gastaut Syndrome.
4	Sodium Phenyl Butyrate	Treatment of Urea Cycle Disorders
5	Tiopronin	Prevention of Cystine nephrolithiasis
6	Trientine Hydrochloride	Treatment of Wilson's disease
7	Eliglustat	Treatment of Gaucher’s disease
8	Cannabidiol	Treatment of Dravet-Lennox Gastaut syndrome

(e) & (f): Ministry of Health & Family Welfare launched National Policy for Rare Diseases (NPRD) in March 2021. Under NPRD, 2021, financial assistance upto Rs. 50 lakhs is provided to the patients suffering from any category of the Rare Diseases in any of the Centres of Excellence (CoEs) mentioned in NPRD, 2021.

Further, Department of Revenue provides -

(i) Full exemption from Basic Customs Duty (BCD) on Drugs or Medicines imported for persons suffering from rare disease and requires these drugs or medicines or Food for Special Medical Purposes (FSMP) for the treatment of rare disease, if imported by an individual, for personal use, for treatment of rare disease.

(ii) Integrated Goods and Services Tax (IGST) on medicines and FSMP used in the treatment of rare diseases enlisted under the National Policy for Rare Diseases (NPRD), 2021 have been exempted when imported for personal use subject to conditions.

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