GOVERNMENT OF INDIA
MINISTRY OF FINANCE
DEPARTMENT OF REVENUE
RAJYA SABHA
UNSTARRED QUESTION NO-855
ANSWERED ON – 11.02.2025

TAX ON LIFE SAVING DRUGS

855. SHRI BABUBHAI JESANGBHAI DESAI:
DR. K. LAXMAN:
SHRI BABURAM NISHAD:
SHRI BRIJ LAL:
SHRI IRANNA KADADI:
DR. PARMAR JASHVANTSINH SALAMSINH:
SMT. KIRAN CHOUDHRY:
DR. MEDHA VISHRAM KULKARNI:
SHRI NARHARI AMIN:

Will the Minister of **FINANCE** be pleased to state:-

(a) whether any steps have been taken to reduce import duties or taxes on life saving drugs for rare diseases;
(b) if so, the details thereof;
(c) whether GST exemptions are applicable for such imports; and
(d) if so, the procedure to avail such exemptions?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF FINANCE
(SHRI PANKAJ CHAUDHARY)

(a) to (c): (i) All drugs, medicines and Food for Special Medical Purposes (FSMP) used for the treatment of rare diseases listed in Annexure 'A' are exempted from basic customs duty and IGST, when imported by

1. individuals for personal use
2. by Centres of Excellence listed in Annexure B, or any person or institution recommended by any of the Centre of Excellence.

(ii) In Union Budget 2025-26, life-saving drugs or medicines at Annexure 'C' for rare diseases have been added to List 4 of notification No. 50/2017-Customs, which attracts Nil Basic customs duty.

(d): The procedure prescribed under notification No. 50/2017-Customs is as follows:

(i) For personal imports, the individual has to furnish a form (attached as Annexure ‘D’) certified by Director General or Deputy Director General or Assistant Director General, Health Services, New Delhi, Director of Health Services of the State Government or the District Medical Officer/Civil Surgeon of the district before Deputy Commissioner of Customs or the Assistant Commissioner of Customs at the time of clearance or gives an undertaking as acceptable to the Deputy Commissioner or the Assistant Commissioner to furnish the said certificate within such period as may be specified by the Deputy Commissioner or the Assistant Commissioner, failing which to pay duty leviable thereon.

(ii) For imports by any person or institution, there has to be recommendation by any of the Centre of Excellence listed in Annexure ‘B’, certifying that the person (by name) for whom the drugs or medicines [Drugs, Medicines or Food for Special Medical Purposes (FSMP)] are being imported, is suffering from a rare disease (to be specified by name) and requires these drugs or medicines [Drugs, Medicines or Food for Special Medical Purposes (FSMP)] for the treatment of said rare disease.

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Annexure A

1. Lysosomal Storage Disorders (LSDs)
2. Adrenoleukodystrophy
3. Severe Combined Immunodeficiency (SCID)
4. Chronic Granulomatous disease
5. Wiskot Aldrich Syndrome
6. Osteopetrosis
7. Fanconi Anemia
8. Laron's Syndrome
9. Tyrosinemia
10. Glycogen storage disorders (GSD) I, III and IV due to poor metabolic control, multiple liver adenomas, or high risk for Hepatocellular carcinoma, or condition of substantial cirrhosis or liver dysfunction, or progressive liver failure
11. Maple Syrup Urine Disease (MSUD)
12. Urea cycle disorders
13. Organic acidemias
14. Autosomal recessive Polycystic Kidney Disease
15. Autosomal dominant Polycystic Kidney Disease
16. Phenylketonuria (PKU)
17. Non-PKU hyperphenylalaninemia conditions
18. Homocystinuria
19. Urea Cycle Enzyme defects
20. Glutaric Aciduria type 1 and 2
21. Methyl Malonic Acidemia
22. Propionic Acidemia
23. Isovaleric Acidemia
24. Leucine sensitive hypoglycemia
25. Galactosemia
26. Glucose galactose malabsorbtion
27. Severe Food protein allergy
28. GH deficiency
29. Prader Willi Syndrome
30. Turner syndrome
31. Noonan syndrome
32. Acidemias, mitochondrial disorders

33. Acute Intermittent Porphyria
34. Wilson's Disease
35. Congenital Adrenal Hyperplasia
36. Neonatal onset Multisysteminflammatory Disease(NoMID)
37. Gaucher Disease Type I and III
38. Hurler Syndrome [Mucopolysaccharisosis (MPS) Type I]
39. Hunter syndrome (MPS II)
40. Pompe Disease
41. Fabry Disease
42. MPS IVA
43. MPS VI
44. Cystic Fibrosis.
45. Duchenne Muscular Dystrophy
46. Spinal Muscular Atrophy
47. Wolman Disease
48. Hypophosphatasia
49. Neuronal ceroid lipofuschinosis
50. Hypophosphatic Rickets
51. A typical Hemolytic Uremic Syndrome.

Annexure B

(1) AIIMS, New Delhi
(2) Centre for Human Genetics, Bengaluru
(3) Institute of Post Graduate Medical Education and Research, Kolkata
(4) King Edward Memorial Hospital, Mumbai
(5) Maulana Azad Medical College, New Delhi
(6) Nizam Institute of Medical Sciences, Secundarabad
(7) PGIMR, Chandigarh
(8) Sanjay Gandhi Post Graduate Institute of Medical Science, Lucknow.

Annexure C

1. Onasemnogene abeparvovec
2. Risdiplam
3. Spesolimab
4. Velaglucerase Alpha
5. Agalsidase Alfa
6. Rurioctocog Alpha Pegol
7. Idursulphatase
8. Alglucosidase Alfa
9. Laronidase
10. Olipudase Alfa
11. Agalsidase Beta
12. Imiglucerase

Annexure D

Form for Drugs/Medicines/FSMP used for treatment of Rare Diseases covered under S. No.607B of the Table.

Certificate No..... of ..... (year) Certified that the medicine.....(name of the Drug/Medicine/FSMP) to be used for the treatment of .....(patient name), is a Drug/Medicine/ Food for Special Medical Purposes (FSMP) used specifically for treatment of rare disease specified in List 38and exemption from the payment of customs duty is recommended.

Signature with date of Director General /
Deputy Director General /
Assistant Director General,
Health Services, New Delhi or
Director of Health Services or
District Medical Officer/Civil Surgeon