



No.A.12011/1/2015-PD/HFW/Vol-IV  
OFFICE OF THE PRINCIPAL DIRECTOR  
HEALTH & FAMILY WELFARE DEPARTMENT  
GOVERNMENT OF MIZORAM



Dated Aizawl, the 7<sup>th</sup> June, 2023

To,

1. Director of Health Services
2. Director of Hospital & Medical Education

Subject: *Exemption from payment for treatment of Rare Diseases- regarding*

With reference to the above subject, copy of Ministry of Health & Family Welfare's D.O. letter No.11037/91/2021-Grants (RD) dt. 21.04.2023 alongwith its enclosure, Ministry of Finance, Department of Revenue's Notification, exemption of payment for treatment of Rare Diseases is enclosed herewith.

In this regard, you are requested to take necessary action in publicizing and displaying the provisions contained in the Notification on the Notice Board of Hospitals/Institutes and uploading in the department's website.

*Encl: As Above*

Yours faithfully,

(Dr. P.C. LALRAMLIANA)  
Principal Director  
Health & Family Welfare Deptt.  
Mizoram: Aizawl.  
Dated Aizawl, the 7<sup>th</sup> June, 2023

Memo No.B.12011/1/2015-PD/HFW/Vol-IV

Copy to:

*Website Manager, DHS for favour of kind information and necessary action.*

Principal Director  
Health & Family Welfare Deptt.  
Mizoram: Aizawl.



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण  
निर्माण भवन, नई दिल्ली - 11  
Government of India  
Ministry of Health & Family  
Nirman Bhavan, New Delhi

रोली सिंह, भा.प्र.से.  
**Roli Singh, I.A.S.**

अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)  
Additional Secretary & Mission Director (NHM)

D.O. No. 11037/91/2021-Grants (RI)  
Dated: 21<sup>st</sup> April 2023

*Dear Colleague,*

The National Policy for Rare Diseases (NPRD-2021) has been notified in March 2021, and the policy document can be accessed at <https://main.mohfw.gov.in/documents/policy>. The policy aims at lowering the incidence and prevalence of Rare Diseases based on an integrated and comprehensive preventive strategy encompassing awareness generation, screening and counseling programme. In terms of Para 6.2 of the policy, the Rare Diseases are categorized under 3 groups by experts based on their clinical experience and treatment availability.

The Department of Revenue, Ministry of Finance, vide their Notification No. 02/2022-Customs dated 01.02.2022 had given exemption from payment of Basic Customs Duty for drugs or medicines used in the treatment of Rare Diseases when imported by Centres of Excellence (CoEs), specified in NPRD, 2021, or any person or institution, on recommendation of any Centre of Excellence listed in NPRD, 2021, certifying that the person (by name) for whom the drugs or medicines are imported, is suffering from a Rare Disease (to be specified by name) and requires the drugs or medicines for the treatment of the same.

In continuation of the above mentioned Notification, Department of Revenue, Ministry of Finance, vide Notification No. 17/2023-Customs dated 29<sup>th</sup> March, 2023 (copy enclosed), has now provided full exemption from payment of Basic Customs Duty (BCD) on all Drugs, Medicines or Food for Special Medical Purposes (FSMP), specified in 'List 38', imported for personal use for treatment of rare diseases identified and categorized under National Policy for Rare Diseases (NPRD), 2021. This exemption will result in substantial cost savings, and provide much needed relief to the patients.

In order to avail this exemption, the individual importer has to produce a Certificate of Recommendation for exemption from the payment of customs duty in the "Form for Drugs/Medicines/FSMP used for the treatment of Rare Diseases covered under List 38 of the Notification dated 29.03.2023" certified by the Director General or Deputy Director General or Assistant Director General, Health Services, New Delhi; Director of Health Services of the State Governments or the Chief Medical Officer/Civil Surgeons of the Districts.

I would request you to give adequate publicity about the provisions contained in the above mentioned Notifications, upload the same on appropriate websites of the States/UTs, besides displaying prominently on the Notice Board of Hospitals/Institutes to enable the patients and their kin to benefit from the latest notification.

*with regards,*

Yours sincerely,  
*Roli Singh*  
(Roli Singh)

Encl: As above

Principal Secretary Health (all States/UTs)

PB of Principal Secretary  
Health & Family Welfare Deptt.  
Receipt No. 712  
Date 4/5/23

Joals DA  
940/SPB  
9/5/23

A/S (meeting)  
28/05/23  
S/S

B. of Addl. Secretary  
H & FW Deptt.  
Receipt No. 305  
Date 8/7/23

स्वच्छ भारत - स्वस्थ भारत

[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY,  
PART II, SECTION 3, SUB-SECTION(i)]

GOVERNMENT OF INDIA  
MINISTRY OF FINANCE  
(DEPARTMENT OF  
REVENUE)

Notification No. 17/2023-Customs

New Delhi dated the 29<sup>th</sup> March, 2023

G.S.R .....(E).— In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962) and sub-section (12) of section 3 of Customs Tariff Act, 1975 (51 of 1975); the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No. 50/2017-Customs, dated the 30<sup>th</sup> June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 785(E), dated the 30<sup>th</sup> June, 2017, namely :-

In the said notification,

I. in the Table, -

- (1) against S. No. 167A, in column (3), for the entry, the entry "Drugs, Medicines or Food for Special Medical Purposes (FSMP) used for treatment of rare diseases" shall be substituted;
- (2) against S. No. 403, in column (3), for the figures "2023", the figures "2024" shall be substituted;
- (3) for S. No. 460 and the entries relating thereto, the following S. Nos. and entries shall be substituted with effect from 1<sup>st</sup> April, 2023, namely: -

(1)	(2)	(3)	(4)	(5)	(6)
"460.	8446, 8448	The following goods (other than old and used) for use in the textile industry, namely: - (i) Shuttleless Ravier Looms (above 650 rpm); (ii) Shuttleless Waterjet Looms (above 800 rpm); (iii) Shuttleless Airjet Looms (above 1000 rpm); (iv) Parts and components for use in manufacturing of shuttleless looms:	Nil	-	-
			Nil	-	-
			Nil	-	-
			Nil	-	9

		<p>Provided that nothing contained in this S. No. shall have effect after the 31<sup>st</sup> March, 2025.</p>			
460A.	8445	<p>The following weaving machines (other than old and used), for use in the textile industry, namely: -</p> <ul style="list-style-type: none"> <li>(i) Carbon Fabric Weaving Rapier Looms;</li> <li>(ii) Biaxial and multiaxial weaving machines for manufacturing technical textiles;</li> <li>(iii) 3-D and block weaving machines for manufacturing technical textiles:</li> </ul> <p>Provided that nothing contained in this S. No. shall have effect after the 31<sup>st</sup> March, 2025.</p>	5%	-	-
460B.	8447	<p>The following knitting machines (other than old and used), for use in the textile industry, namely: -</p> <ul style="list-style-type: none"> <li>(i) Flat Knitting Machines (11 revolutions per minute or minimum speed of 0.3 Mts per sec);</li> <li>(ii) Warp Knitting Machines (Minimum working width of 60" and minimum speed of 500 RPM);</li> <li>(iii) Raschel Knitting Machines (Minimum working width of 60" and minimum speed of 500 RPM);</li> <li>(iv) Knitting machines for spacer fabrics:</li> </ul> <p>Provided that nothing contained in this S. No. shall have effect after the 31<sup>st</sup> March, 2025.</p>	5%	-	-

460C.	84	<p>The following goods (other than old and used), for use in the textile industry, namely: -</p> <p>(i) Industrial sewing machine (tariff heading 8452);</p> <p>(ii) Laser garment panel cutter (tariff item 8456 11 00);</p> <p>(iii) Whole garment making machine (knitted) (chapter 84);</p> <p>(iv) Ink Jet printing machines (tariff item 8443 39 10):</p> <p>Provided that nothing contained in this S. No. shall have effect after the 31<sup>st</sup> March, 2025.</p>	5%	-	-
460D.	84	<p>Machinery (other than old and used) for manufacture of non-wovens textiles, namely: -</p> <p>(i) Complete production lines for the production of following non-wovens, up to rolled goods preparation and packing, namely:</p> <p>(a) Needle punched non-wovens</p> <p>(b) Chemically bonded non-wovens</p> <p>(c) Thermally bonded non-wovens</p> <p>(d) Stitch bond non-wovens</p> <p>(e) Spun laced (hydro entangled) non-wovens</p> <p>(f) Melt blown non-wovens</p> <p>(g) Spun bond melt blown (SMS) non-wovens</p> <p>(ii) Machinery for finishing of all non-wovens;</p> <p>(iii) Machinery for converting non-wovens into made-ups:</p> <p>Provided that nothing contained in this S. No. shall have effect after the 31<sup>st</sup> March, 2025.</p>	5%	-	-
460E.	84, or any chapter	<p>Parts and components (other than old and used) for use in manufacturing of textile machineries (falling under tariff headings 8444, 8445, 8446, 8447, 8448, 8449, 8451, 8452):</p>	5%	-	9";

		Provided that nothing contained in this S. No. shall have effect after the 31 <sup>st</sup> March, 2025.			
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(4) against S. No. 563A, in column (3), in entry (ii), after item (g) and entries relating thereto, the following items and the entries relating thereto shall be inserted with effect from 1<sup>st</sup> April, 2023, namely: -

“(h) Flat Panel Detector, including Scintillators (9022 90 90);

(i) X-ray Tube (9022 30 00)”;

(5) against S. No. 564, in column (3), after item (g), the following items and the entries relating thereto shall be inserted with effect from 1<sup>st</sup> April, 2023, namely: -

“(h) Medical Grade Monitor (8528 59 00);

(i) Flat Panel Detector, including Scintillators (9022 90 90);

(j) X-ray Tube (9022 30 00)”;

(6) after S. No. 607A and the entries relating thereto, the following S. No. and entries shall be inserted, namely: -

(1)	(2)	(3)	(4)	(5)	(6)
“607B.	9804	Drugs, Medicines or Food for Special Medical Purposes (FSMP) used for treatment of rare diseases specified in List 38.	Nil	-	115”;

II. in the ANNEXURE,

(1) in Condition No. 112, for the words “drugs or medicines” at both places, the words “Drugs, Medicines or Food for Special Medical Purposes (FSMP)” shall be substituted;

(2) after Condition No. 114, the following Condition No. shall be inserted, namely: -

“115.	<p>If,-</p> <p>(a) the goods are imported by an individual for personal use;</p> <p>(b) it is certified in the Form as applicable and specified below, by the 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, in each individual case</p> <p style="text-align: center;"><u>(1) Form for Drugs/Medicines/FSMP used for treatment of Rare Diseases covered under S. No.607B of the Table.</u></p>
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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 38 and 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.

and

(c) the importer produces the said certificate to the Deputy Commissioner of Customs or the Assistant Commissioner of Customs, as the case may be, 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.

III. (1) in List 4, after item number 111 and the entries relating thereto, the following entry shall be inserted, namely: -

“(112) Pembrolizumab (Keytruda)”;

(2) after List 37 and the entries relating thereto, the following list and entries shall be inserted, namely: -

“List 38 (See S. No. 607B of the Table)

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 malabsorption
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 Multisystem inflammatory Disease (NoMID)
37. Gaucher Disease Type I and III
38. Hurler Syndrome [Mucopolysaccharidosis (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 lipofuscinosis
50. Hypophosphatic Rickets
51. Atypical Hemolytic Uremic Syndrome".



2. Save as otherwise provided, this notification shall come into force on 30<sup>th</sup> March, 2023.

[F. No. 334/05/2023-TRU]

(Amreeta Titus)

Deputy Secretary

Note: The principal notification No. 50/2017-Customs, dated the 30<sup>th</sup> June, 2017 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i), *vide* number G.S.R. 785(E), dated the 30<sup>th</sup> June, 2017 and was last amended *vide* notification No. 16/2023-Customs, dated the 3<sup>rd</sup> March, 2023, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 170(E), dated the 3<sup>rd</sup> March, 2023.