

GOVERNMENT OF INDIA
MINISTRY OF FINANCE
(DEPARTMENT OF REVENUE)
Notification No. 46/2021-Customs

New Delhi, the 30th September, 2021

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 30th 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 30th June, 2017, namely:-

In the said notification, -

(a) in the TABLE, for S. No. 607 and the entries relating thereto, the following S. No. and entries shall be substituted, namely: -

(1)	(2)	(3)	(4)	(5)	(6)
“607.	9804	The following goods, imported for personal use, namely: - (a) the life saving drugs or medicines (including diagnostic test kits) specified in List 4; (b) other life saving drugs or medicines, (c) life saving medicines for treatment of Spinal Muscular Atrophy or Duchenne Muscular Dystrophy, namely- (i) Zolgensma (Onasemnogene Aporavidine) (ii) Viltepso (Viltolarsen) (iii) any other medicine for treatment of the said diseases	Nil Nil Nil	- - Nil	- 16 16”;

(b) In the Annexure, -

(i) for Condition No. 16, the following condition shall be substituted, namely: -

“16.	If, - (a) the goods are imported by an individual for personal use; (b) it is certified in the Form as applicable and specified below, by the Director General or Deputy
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	<p>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>(1) Form for medicines used for treatment of Spinal Muscular Atrophy/ Duchenne Muscular Atrophy covered under sub-clause(iii) of clause (c) of S. No.607 of the Table. Certificate No..... of (year) Certified that the medicine.....(name of the medicine) to be used for the treatment of(patient name), is a life saving medicine used specifically for Spinal Muscular Atrophy / Duchenne Muscular Atrophy and exemption from the payment of customs duty and Integrated GST is recommended.</p> <p style="text-align: right;">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.</p> <p>or</p> <p>(2) Form for life saving drugs or medicines, not covered under (1) above, being imported under clause (b) of S. No. 607 of the Table.</p> <p>Certificate No..... of (year) Certified that the drug / medicine.....(name of the drug / medicine) to be used for the treatment of(patient name), is a life saving drug / medicine for.....(disease name) and exemption from the payment of customs duty is recommended.</p> <p style="text-align: right;">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.</p> <p>and</p> <p>(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.</p>
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(ii) in Condition No. 102, after item (iv), the following provisos and Explanation shall be inserted, namely: -

'Provided that goods may, instead of being re-exported out of India in terms of condition at (iii) above, be given on lease under a transaction covered by item 1(b) or 5 (f) of Schedule II of the Central Goods and Service Tax Act 2017, by lessor to another lessee in India, in which case, -

(a) the original lessee shall give an intimation to the commissioner of customs and get his bond discharged;

(b) the new lessee shall, by execution of bond, in such form and for such sum, as may be specified by the Commissioner of Customs, bind himself to comply with the conditions herein, as if he were the importer of the goods.

Provided further that in case of goods supplied by an SEZ unit to DTA under a transaction covered by item 1(b) or 5(f) of Schedule II of the Central Goods and Services Tax Act, 2017, where SEZ unit is liable to pay integrated tax on such transaction under the Integrated Goods and Services Tax Act, 2017, the lessee shall bind himself only with conditions (ii), (iii) and (iv) above.

Explanation. - In case of goods supplied by an SEZ unit (lessor) to DTA under a transaction covered by item 1(b) or 5(f) of Schedule II of the Central Goods and Services Act, 2017, -

(a) the “Commissioner of Customs” or the “Commissioner of Customs of the port of importation”, wherever they appear, shall mean “the Specified Officer” as defined in Special Economic Zone Rules, 2006;

(b) “Re-export” in item (iii) shall mean returning the goods to the lessor.’.

2. This notification shall come into force on the 1st day of October, 2021.

[F. No. 190354/206/2021-TRU]

(Rajeev Ranjan)

Under Secretary to the Government of India

Note: - The principal notification No.50/2017-Customs, dated the 30th day of 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 30th day of June, 2017, and last amended vide notification No. 44/2021-Customs, dated the 17th day of September, 2021 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 640(E), dated the 17th day of September, 2021