

# UPDATE

### **ERGO** Analysing developments impacting business

### FIGHT AGAINST COVID-19: RELAXATIONS VIS-À-VIS IMPORTS OF OXYGEN, CONCENTRATORS, LIFE-SAVING DRUGS AND ALLIED PRODUCTS

#### 8 May 2019

India is fighting the second wave of the COVID-19 pandemic. Businesses, charitable institutions, public-spirited individuals as well as friendly nations are all doing their bit to mitigate the effects of this contagion.

To facilitate this fight, bottlenecks are being identified on a war-footing and several relaxations are being announced vis-a-vis the import of essentials like oxygen, concentrators, life-saving drugs, etc.

Notifications have been issued under the Customs Act, 1962<sup>1</sup> whereby the import of essential medicines and medical devices have been exempted from payment of Basic Customs Duty (BCD). An *Ad-hoc* exemption has also been granted from payment of applicable Integrated Goods and Services Tax (IGST) on import of essential medicines and medical devices,<sup>2</sup> subject to the fulfillment of specific conditions set out therein. The Ministry of Corporate Affairs also recently clarified that expenditures incurred on setting up of makeshift COVID-19 hospitals and temporary care facilities are eligible to be considered as corporate social responsibility activities.

Aside from executive actions, the judiciary is also seized of various aspects of this matter and both, the High Court of Delhi and the Supreme Court of India are hearing petitions *apropos* exemptions from GST for oxygen concentrators as well as life-saving drugs.

We have encapsulated key aspects in relation to imports and allied conditions, for ready reference. Any bottlenecks / impediments that need relaxation may also be brought to our notice so as to seek expeditious policy resolution.

#### I. Snapshot of key aspects vis-à-vis exemptions on imports:

		IMPORT DUTIES (BCD + IGST+ CESSES)			
DESCRIPTION OF IMPORTED PRODUCT	IMPORT POLICY - FREELY IMPORTABLE/ LICENSE NEEDED	BCD	IGST	Health Cess	Social Welfare Surcharge

<sup>&</sup>lt;sup>1</sup> Notification No. 27/2021 – Customs dated 20 April 2021 as amended by Notification No. 29/2021 – Customs dated 30 April 2021 and Notification No. 28/2021 – Customs dated 24 April 2021 (collectively, Exemption Notifications and individually, Notification No. 27/2021, Notification No. 28/2021, and Notification No. 28/2021).

<sup>&</sup>lt;sup>2</sup> Ad-hoc Exemption Order No. 4/2021 – Customs dated 3 May 2021.

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			(if ad-hoc exemption unavailable³)		
Remdesivir - Active Pharmaceutical Ingredients	An import license under Section 10 of the Drugs and Cosmetics Act, 1940 (D&C Act) read with Rule 24 of the Drug and Cosmetics Rules, 1945 (D&C Rules) is required.	0%	18%4	0%	0%
Beta Cyclodextrin ('excipient', SBEBCD) used in the manufacture of Remdesivir	No Objection Certificate is required from the Drugs Controller General of India.	0%	18% <sup>5</sup>	0%	0%
Injection Remdesivir	An import license under Section 10 of the D&C Act read with Rule 24 of the D&C Rules is required.	0%	5% <sup>6</sup>	0%	0%
	Further, small doses of injections can be imported in <i>bona fide</i> baggage of incoming passenger(s) for personal use without any license.				
Oxygen concentrators including flow meters, regulator, connectors, and tubings	No restrictions on import on payment of applicable duties. Duty free import as a "gift" of value up to INR 10,000 for personal use by individuals through post, courier, or e- commerce portals possible till 31 July 2021. <sup>7</sup>	0%	12% <sup>8</sup>	0%	0%
Medical oxygen	An import license under Section 10 of the D&C Act read with Rule 24 of the D&C Rules is required.	0%	12%9	0%	0%
Oxygen canisters, filling systems, tanks, cryogenic road transport tanks, and generators	These may require registration under the Gas Cylinder Rules, 2016. Extensions have been granted for existing licenses upto 30 June 2021 by the Petroleum and Explosives Safety Organisation.	0%	As per classification applicable	0%	O%

<sup>&</sup>lt;sup>3</sup> IGST would be leviable at these rates if the various conditions stipulated in the Ad-hoc Exemption Order No. 4/2021 – Customs dated 3 May 2021 are not fulfilled. Please see paragraph II below.

<sup>&</sup>lt;sup>4</sup> Serial No. 40 of Schedule III of Notification No. 1/2017 – Integrated Tax (Rate) dated 28 June 2017.

<sup>&</sup>lt;sup>5</sup> Serial No. 40 of Schedule III of Notification No. 1/2017 – Integrated Tax (Rate) dated 28 June 2017.

<sup>&</sup>lt;sup>6</sup> Refer Serial No. 180 of Schedule I of Notification No. 1 / 2017 – Integrated Tax (Rate) dated 28 June 2017.

<sup>&</sup>lt;sup>7</sup> Notification No. 4/2015-20 dated 30 April 2021 issued by the Directorate General of Foreign Trade.

<sup>&</sup>lt;sup>8</sup> Serial No. 219 of Schedule II of Notification No. 1/2017 – Integrated Tax (Rate) dated 28 June 2017 and Notification No. 30/2021 – Customs dated 1 May 2021.

<sup>&</sup>lt;sup>9</sup> Serial No. 57A of Schedule II of Notification No. 1/2017 – Integrated Tax (Rate) dated 28 June 2017.

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The licensing conditions, registration requirements or obtaining permissions as may be required under various regulatory statutes will have to be adhered to. Specifically, there is lack of clarity with respect to registration requirements *qua* oxygen concentrators under the Medical Devices Rules, 2017 which requires urgent clarifications from the statutory authority. Practically, however, we understand that the customs authorities are currently allowing clearance without insisting on such registration.

#### II. Key points vis-à-vis recent conditional exemptions from payment of IGST vis-à-vis such imports:

The *Ad-hoc* exemption from payment of IGST on imports is applicable for the medicines, equipments and medical devices covered under the aforementioned Exemption Notifications, subject to the fulfillment of the following conditions:

- the said goods have to be imported free of cost by a State Government, or any entity or relief agency or statutory body which is so authorised by the State Government;
- the goods so received have to be distributed for free subsequent to such import; and
- the importer has to furnish a certificate from a nodal agency prescribed by the State Government that the imported goods shall be distributed for free. Such certificate has to be furnished before the Deputy or the Assistant Commissioner of Customs. Within a period of six months or an extended period of nine months post import, the importer has to furnish a statement before the Deputy or the Assistant Commissioner of Customs detailing the goods distributed for free.

Considering the above, the following points emerge:

- while exemption from BCD has been announced and is not subject to any specific conditions, the exemption from IGST is subject to the fulfillment of the conditions mentioned above; and
- a critical condition to benefit from the exemption against payment of IGST is that the same has to be i) imported free of cost; and ii) distributed free of cost, subsequent to such import. Therefore, where the goods do not adhere to the aforesaid stipulations, the same would be subject to IGST as per the rate mentioned in the table above.

#### III. Areas where immediate policy intervention may be required from the Government:

Further policy intervention may be warranted in respect of the following aspects:

#### a. Relaxing the conditions vis-à-vis obtaining the exemption from payment of IGST

While the exemption from payment of BCD and IGST is a welcome step, the regulatory and procedural conditions stipulated for claiming exemption from IGST may act as a hindrance. The requirement for any entity or relief body to take permission from a nodal agency which have just been appointed may be a significant administrative hurdle.<sup>10</sup> The subsequent requirement of furnishing a statement indicating distribution of the goods so imported for free is an additional burden which may deter entities from undertaking such imports.

At this juncture, reference may also be made to the initiative undertaken by the State Government of Gujarat. Vide Resolution No. GST – 102021 – Tax – 1- GST Cell dated 1 May 2021, an incentive scheme whereby IGST paid on imports of specified COVID-19 treatment related products (*including products mentioned above*) by specified hospitals/institutions, would be reimbursed or an upfront payment would be made to them, subject to the conditions stipulated thereunder.

The High Court of Delhi is also seized with this issue and is actively considering the inter-play of Article 21 of the Constitution of India (pertaining to right to life) vis-à-vis customs duty exemptions. This would be a significant development for constitutional and taxation jurisprudence.

<sup>&</sup>lt;sup>10</sup> Instruction No. 9/2021 – Customs dated 3 May 2021 provided that all the States and Union Territories have been asked to create the nodal agency, at the earliest. Various state governments have notified the nodal authorities in pursuance of this instruction.

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#### b. Regulatory compliances under different statutes

As stated above, the import of COVID-19 treatment related products are subject to licensing or registration requirements. While it may not be feasible to grant relaxations vis-à-vis every product, considering the situation today, requirements under the D&C Act and Gas Cylinder Rules, 2016 must be relaxed to ease out administrative bottlenecks. A few relaxations have been granted by the Petroleum and Explosives Safety Organisation for cryogenic tankers and to the Gas Cylinder Rules, 2016.

#### IV. Other key aspects:

### a. Compliance with Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017 (Concessional Rate of Duty Rules)

Import of SBEBCD under Notification No. 27/2021 is exempt from payment of GST subject to an importer fulfilling the conditions stipulated under the Concessional Rate of Duty Rules, 2017 (Concessional Duty Rules). It may be noted that the Concessional Duty Rules have an in-built requirement of "actual user" condition, meaning that the benefit would be available only if the importer uses the products so imported at his own premises. Hence, post importation of SBEBCD, to be free from disputes at a later stage, the importer should consider using the same in manufacturing process at its own premises only.

The same is also true for import of goods mentioned at Serial No. 11 of Notification No. 28/2021. Serial No. 1 of Notification No. 28/2021 pertains to oxygen concentrators, flow meters, regulators, and tubings. Serial No. 11 pertains to parts which are imported in relation to the manufacture, transportation, distribution, or storage of goods mentioned at Serial No. 1 and the benefit would be granted only if the stipulations under Concessional Duty Rules are met. The customs authorities at a later stage, may raise questions on claims of exemption *qua* a product under Serial No. 1 and Serial No. 11, as the exemption under Serial No. 11 is conditional.

#### b. Possible implications which may arise out of financing arrangements for such imports

Owing to the regulatory stipulations, some companies / organisations may opt for third-party financing arrangements with holders of requisite licenses / registrations / permissions which may have GST implications as well as implications under Foreign Exchange Management Act, 1999. Any such arrangement must be carefully analyzed and structured.

#### c. Pertinent points under Legal Metrology laws

The Ministry of Consumer Affairs, Food and Public Distribution has issued an Advisory bearing number I-10/22/2020-W&M dated 28 April 2021 (Advisory dated 28 April 2021) whereby certain relaxations from the rigors of The Legal Metrology (Packaged Commodities) Rules, 2011 (Packaged Commodities Rules) have been granted.

Rule 6 of the Packaged Commodities Rules provided that any product which is imported and meant for sale must have specific declarations including but not limited to details of the importer, details of the manufacturer, details of the brand name, etc. However, the Advisory dated 28 April 2021 has provided that the import of medical devices like oxygen concentrators, oxygen filling tanks, nebulizers, etc. can be undertaken by complying with the rigors of Rule 6 of the Packaged Commodities Rules <u>subsequent to such import and before undertaking any further sale</u>.

In other words, the requirement for declarations stipulated under Rule 6 of the Packaged Commodities Rules can now be undertaken post the import (even without availing the "labelling in bond" option that has been hitherto available). This will certainly ease administrative burden and assist in faster clearance for such imports.

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