

MAHARASHTRA AUTHORITY FOR ADVANCE RULING
GST Bhavan, Old Building, 1st floor, B-Wing, Room No.107, Mazgaon, Mumbai - 400010.
(Constituted under Section 96 of the Maharashtra Goods and Services Tax Act, 2017)
BEFORE THE BENCH OF

- (1) Shri. D. P. Gojamgunde, Joint Commissioner of State Tax, (Member)
(2) Ms. Priya Jadhav, Joint Commissioner of Central Tax, (Member)

ARN No.	AD271222028889R
GSTIN Number, if any/ User-id	27AADCP2043E1ZT
Legal Name of Applicant	M/s. PPD Pharmaceutical Development India Private Limited
Registered Address/Address provided while obtaining user id	101 A Wing, Fulcrum, Hiranandani Business Park, 1 st , Sahar Road, Andheri (East), Maharashtra, Mumbai Suburban, 400099.
Details of application	GST-ARA, Application No. 94 Dated 21.12.2022
Concerned officer	MUM-VAT-E-704, Nodal-7
Nature of activity(s) (proposed/present) in respect of which advance ruling sought	
A Category	Service Provision, Service Recipient
B Description (in brief)	The Applicant is desirous to know if they can take credit of Integrated Goods and Services Tax ("IGST") and credit of tax paid for Customs House Agent ("CHA") Services while importing the sample drugs, in terms of section 16(1) of the CGST Act?
Issue/s on which advance ruling required	➤ Admissibility of input tax credit of tax paid or deemed to have been paid
Question(s) on which advance ruling is required	As reproduced in para 01 of the Proceedings below.

NO.GST-ARA- 94/2022-23/B- **213** Mumbai, dt. **30/04/2025**
PROCEEDINGS

(Under Section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

The present application has been filed under Section 97 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017 [hereinafter referred to as "the CGST Act and MGST Act" respectively] by M/s. PPD Pharmaceutical Development India Private Limited, the applicant, seeking an advance ruling in respect of the following questions.

- a. Whether the Applicant is entitled to take credit of Integrated Goods and Services Tax ("IGST") paid by the Applicant under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the Integrated Goods and Services Tax Act, 2017 ("the IGST Act") while importing the sample drugs, in terms of section 16(1) of the CGST Act?
- b. Whether the Applicant is entitled to take credit of IGST paid by the "logistics service provider" [under DDP (Delivered Duty Paid) model of shipment] under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the IGST Act while importing the sample drugs, in terms of section 16(1) of the CGST Act, where the Applicant is the Importer on Record?

- c. Whether the Applicant is entitled to take credit of Central Goods and Services Tax ("CGST") paid by the Applicant under section 7 r/w section 9 of the CGST Act for the services of Customs House Agent received by the Applicant, in terms of section 16(1) of the CGST Act?

At the outset, we would like to make it clear that the provisions of both the CGST Act and the MGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to any dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provision under the MGST Act. Further to the earlier, henceforth for the purposes of this Advance Ruling, the expression 'GST Act' would mean CGST Act and MGST Act.

1. FACTS AND CONTENTION - AS PER THE APPLICANT:

- 1.1. The Applicant is a Company, registered under the Companies Act, 1956 and is engaged in monitoring and managing the clinical trial process undertaken by hospitals / clinics ("Sites") and Doctors ("Investigators") in India. The Applicant has obtained registration under the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "the CGST Act").
- 1.2. The PPD group, of which the Applicant is an affiliate, is a Clinical Research Organization and provides clinical research services to pharmaceutical and biotech companies ("Sponsors") on a global basis. These clinical trial management services comprise of consultancy, project management, data collection and specialist ancillary services. A Sponsor who wishes to conduct clinical trial study for a novel drug approaches the PPD group companies in the US or UK ("PPD Global"). These companies would then refer this work to the PPD Group affiliates in respective regions to procure services of hospitals and clinics to undertake the clinical trials and manage / monitor such clinical trials. For such services to be undertaken in India, the Applicant in India is approached by PPD Global, for which it is paid by PPD Global in convertible foreign exchange on a cost-plus basis.
- 1.3. The primary responsibility of the Applicant would be to monitor the clinical trials conducted by the hospitals / clinics for Sponsors under the defined protocol, including provision of administration and support services as per the arrangement between the Sponsor and PPD Global. In addition to the above, the Applicant would also be involved in providing other services to PPD Global such as 'Global Clinical Data Management Services', 'Global Biostatistics and Programming Services' and 'Clinical Shared Service Centre'.
- 1.4. As stated above, the hospitals and clinics would be conducting clinical trials using investigational products ("IP"), comparator drugs and ancillary products / equipment for use in the clinical trials (collectively referred to as "sample drugs"). The said sample drugs would be imported into India either from the Sponsors or through logistic service providers. It should be noted that the Applicant does not take title to the IP at any time during the course of the clinical trial; title remains at all times with the sponsor. Similarly, the Applicant rarely takes title to the comparator drugs and ancillary supplies when it imports them into India Applicant rarely takes title to the comparator drugs and ancillary supplies when it imports them into Indian.
- 1.5. The import of the sample drugs for the purpose of clinical trials in India would be in pursuance of the license issued by the Drug Controller General of India ("the DCGI") in the name of the Applicant, being the person responsible for monitoring the clinical trials in India. The License, inter-alia, authorises the licensee i.e. the Applicant in the present case to import the sample drugs from the specified foreign manufacturer



(Sponsor) for conducting clinical trials. Further, the license also contains the details of the hospitals / clinics where the trial is proposed to be conducted. Needless, to say that it is only the Applicant who is authorised to import the sample drugs by virtue of the license issued by the DCGI.

1.6. In this regard, the Applicant envisages following two routes for procuring the sample drugs:

A. in the first route:

- (i) the Applicant would file the bills of entry for home consumption under section 46 of the Customs Act, 1962 ("the Customs Act") for customs clearance upon payment of Basic Customs Duty ("BCD") under section 12 of the Customs Act, Integrated Goods and Services Tax ("IGST") under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the Integrated Goods and Services Tax Act, 2017 ("the IGST Act") and other applicable taxes and cesses, once the goods reach the customs frontiers of India
- (ii) For sake of clarity, it is stated that the bills of entry that would be filed under section 46 of the Customs Act would be in the name of the Applicant and the BCD and IGST would also be discharged / paid by the Applicant
- (iii) For carrying out the customs formalities, the Applicant would engage a Customs House Agent ("CHA") for their services upon which the CHA would charge the Applicant, GST as per section 7 r/w section 9 of the CGST Act at applicable rate (iv) Once the sample drugs are cleared from the Customs, the CHA or the logistic service provider would then dispatch the sample drugs directly to the identified location of the hospitals or the clinics. As we understand, in some cases upon the instructions of the hospitals / clinics, sample drugs would be sent to identified warehouses from where the sample drugs would be subsequently delivered to respective hospitals / clinics as and when the same is required for carrying out tests.



B. in the second route:

- (i) the logistics service provider would file the bills of entry for home consumption under section 46 of the Customs Act for customs clearance upon payment of BCD under section 12 of the Customs Act, IGST under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the IGST Act and other applicable taxes and cesses, once the goods reach the customs frontiers of India. However, the Applicant would continue to remain the importer on record, given that it is the Applicant only who can import the drug into India pursuant to the license issued by DCGI.
- (ii) For sake of clarity, it is stated that the importer on record would be the Applicant in bills of entry that would be filed under section 46 of the Customs Act, whereas the BCD and IGST payable on import would be discharged / paid by the logistics service provider/ PPD Global / Sponsor.
- (iii) This route is basically understood as Delivered Duty Paid Model of shipment wherein the supplier of goods agrees to bear all costs till the goods reach the destination. Under this model, the supplier undertakes to pay for the cost of all transportation, any loss due to damage during transit, and the payment of

customs duty, import tariffs, and other relevant charges till the subject goods reach the agreed upon destination.

- (iv) Once the sample drugs are cleared from the Customs, the logistic service provider would then dispatch the sample drugs directly to the identified location of the hospitals or the clinics. As we understand, in some cases upon the instructions of the hospitals / clinics, sample drugs would be sent to identified warehouses from where the sample drugs would be subsequently delivered to respective hospitals / clinics as and when the same is required for carrying out tests.

1.7. In terms of the agreement signed between PPD Global and the Applicant, the Applicant is expected to provide Clinical Trial Co-ordination and Support Services, comprising of the following key activities:

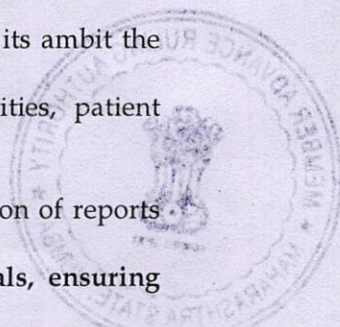
- Site / Investigator identification and qualification
- Pre-study activities
- Investigator's meeting and communications management
- Study monitoring
- As part of study monitoring, develop and maintain a system to ensure the study sites have adequate investigational product

1.8. Further, the scope of managing the clinical trials encompasses within its ambit the following functions:

- Identifying appropriate investigators by evaluating their facilities, patient population, fees payable for the services
- Ensuring the trial is conducted as per the Sponsor protocol
- Studying the results of the trials, involving analysis and submission of reports (which is the primary essence of the service rendered by PPD)
- Miscellaneous activities such as obtaining regulatory approvals, ensuring adequate investigational products, etc.

Therefore, what is apparent from the foregoing paragraphs is that as part of the activities of managing / monitoring the clinical trials undertaken by the hospitals / clinics, the scope of Applicant's service would include(s) co-ordinating and managing the supply of sample drugs to such hospitals / clinics, which includes importing the sample drugs into India.

- 1.10. Further, the Applicant, in terms of the said agreement, would be required to submit periodical reports / status of the clinical trials to PPD Global.
- 1.11. For the proposed services rendered by the Applicant, the Applicant would raise an invoice in terms of the agreement. The services proposed to be rendered by the Applicant is taxable services in terms of section 7 r/w section 9 of the CGST Act. Further, given that the services rendered by the Applicant fulfils all the conditions laid down by Section 2(6) of the IGST Act, the said services qualify as an export of services.
- 1.12. It may be noted that where the Applicant discharges the BCD and IGST itself, the BCD component will be considered as part of the cost base, per the agreement between PPD Global and the Applicant. Whereas, in the second scenario (i.e. under the DDP model), where the BCD and IGST is discharged by the logistics service provider / PPD Global / Sponsor, the BCD component will not be considered as part of the cost base.



02. STATEMENT CONTAINING APPLICANT'S INTERPRETATION OF LAW

Statement with regard to Question No.1 and Question No. 2

- 2.1. With effect from 01.07.2017, the Goods and Services Tax laws came into force. The Central Goods and Services Tax Act, 2017 ("the CGST Act") and the Maharashtra Goods and Services Tax Act, 2017 ("the SGST Act") have subsumed the Value Added Tax laws, Excise laws, Service Tax, Entry Tax and other indirect taxes. On intra-state supply of goods and / or services, Central Goods and Services Tax ("CGST") is payable and on inter-state supply of goods and / or services, Integrated Goods and Services Tax ("IGST") is payable under the Integrated Goods and Services Tax Act, 2017 ("the IGST Act").
- 2.2. In terms of Section 7(2) of the IGST Act, import of goods is deemed to be inter-state supply of goods. Under sub-section (1) of Section 5 the IGST Act, IGST is payable on import of goods into India. Accordingly, Section 3 of the Customs Tariff Act, 1975 ("the Customs Tariff Act") was also amended with effect from 01.07.2017 and IGST became payable under subsection (7) of Section 3 of the Customs Tariff Act on import of goods into India.
- 2.3. Further, Section 20 of the IGST Act read with Section 16 of the CGST Act provides that IGST paid on import of goods can be utilized as the credit of the input tax if such imported goods are used in the course or furtherance of business. By virtue of Section 20 of the IGST Act, the provisions of the CGST Act relating to input tax credit would be mutatis mutandis applicable, so far as maybe, in relation to integrated tax. Section 20 of IGST and Section 16(1) of the CGST Act reads as follows:

Section 20 of IGST

SECTION 20. Application of provisions of Central Goods and Services Tax Act. – Subject to the provisions of this Act and the rules made thereunder, the provisions of Central Goods and Services Tax Act relating to, -

...

(iv) input tax credit

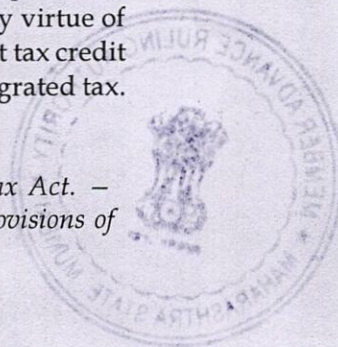
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shall, mutatis mutandis, apply, so far as may be, in relation to integrated tax as they apply in relation to central tax as if they are enacted under this Act.

... [Emphasis Supplied]

Eligibility of ITC under Section 16 of the CGST Act

- 2.4. Section 16 of the CGST Act is the primary provision governing the entitlement of ITC under the CGST Act. As per Section 16(1) of the CGST Act 'Every registered person shall, subject to such conditions and restrictions as may be prescribed and, in the manner, specified in section 49, be entitled to take credit of input tax charged on any supply of goods or services or both to him which are used or intended to be used in the course or furtherance of his business'.
- 2.5. The legislature in all its wisdom has enlarged the scope of credit in Section 16 of the CGST Act by using the term 'any supply of goods and services' in Section 16(1) of the CGST Act. Further, it also covers under its ambit the services which have been used and are also intended to be used in the course or furtherance of business.
- 2.6. The term 'goods' has been defined in Section 2(52) of the CGST Act, as under:
"(52) "goods" means every kind of movable property other than money and securities but includes actionable claim, growing crops, grass and things attached to or forming part of the land which are agreed to be severed before supply or under a contract of supply;"



2.7. Further, the term 'services' has been defined in Section 2(102) of the CGST Act, as under:

"(102) 'services' means anything other than goods, money and securities but includes activities relating to the use of money or its conversion by cash or by any other mode, from one form, currency or denomination, to another form, currency or denomination for which a separate consideration is charged;"

2.8. Further, the term 'business' as defined in Section 2(17) of the CGST Act is of wide amplitude. The relevant extract of the definition is reproduced hereunder:

"(17) 'business' includes –

- (a) any trade, commerce, manufacture, profession, vocation, adventure, wager or any other similar activity, whether or not it is for a pecuniary benefit;*
- (b) any activity or transaction in connection with or incidental or ancillary to sub-clause (a);*
- (c) any activity or transaction in the nature of sub-clause (a), whether or not there is volume, frequency, continuity or regularity of such transaction;*
- (d) supply or acquisition of goods including capital goods and services in connection with commencement or closure of business;*

....."

(emphasis supplied)

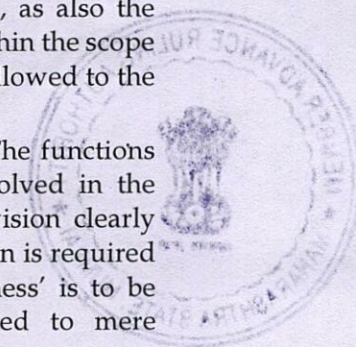
2.9. On a combined reading of Section 16(1) read with Section 2(17) and 2(102) of the CGST Act, it is evident that all goods and / or services used in activities in relation to or furtherance of business, whether used or intended to be used, as also the services availed prior to commencement of operations, are covered within the scope of Section 16(1) of the CGST Act, and therefore, credit on the same is allowed to the registered person.

The words 'in the course or furtherance' further widens the scope. The functions primarily encompass (surround) the entire gamut of activities involved in the process of manufacture of goods or provision of service. The provision clearly highlights the need of multifarious functions any business organization is required to undertake while pursuing their objectives. Thus, the term 'business' is to be understood as continuous activity and not confined or restricted to mere manufacture of the product or provision of a service.

2.11. The term 'input tax' has been defined in Section 2(62) of the CGST Act as under:

"(62) 'input tax' in relation to a registered person, means the central tax, State tax, integrated tax or Union territory tax charged on any supply of goods or services or both made to him and includes –

- (a) the integrated goods and services tax charged on import of goods;*
- (b) the tax payable under the provisions of sub-sections (3) and (4) of section 9;*
- (c) the tax payable under the provisions of sub-sections (3) and (4) of section 5 of the Integrated Goods and Services Tax Act;*
- (d) the tax payable under the provisions of sub-sections (3) and (4) of section 9 of the respective State Goods and Services Tax Act; or*
- (e) the tax payable under the provisions of sub-sections (3) and (4) of section 7 of the Union Territory Goods and Services Tax Act but does not include the tax paid under the composition levy;"*



2.12. It is evident that IGST paid on 'import of goods' is also covered under the scope of 'input tax', the credit on which can be claimed subject to compliance of conditions of Section 16 of the CGST Act.

2.13. At this stage, it is also pertinent to note that the provisions section 16(1) employs two-fold conditions viz. tax ought to be charged on the input side (which is a given and undisputed fact) and secondly the goods or services which has suffered the tax ought to be used in the course or in furtherance of business. This means that, for the Applicant, to be eligible to take input tax credit of the IGST paid on the import of sample drugs, the same has to be used or should be intended to be used in the course or furtherance of its business i.e. the nexus/ connection between the sample goods and the output service rendered from these goods is required to be proved.

2.14. Applicant involves managing / monitoring the clinical trials in India undertaken by hospitals / clinics. For the purpose of undertaking the clinical trials, the hospitals / clinics need the sample drugs. As per the license issued by DCGI in relation to the clinical trials, it is only the Applicant who can import the sample drugs into India. Thus, the Applicant's scope of services encompasses within itself the activity of coordinating the supply of sample drugs to the hospitals / clinics conducting clinical trials.

2.15. Therefore, the IGST paid while importing the sample drugs is eligible as input tax credit in terms of section 16(1) of the CGST Act in as much as, the sample goods are used in course or in furtherance of business which is taxable.

2.16. Reliance is placed on the ruling of the Hon'ble Authority of Advance Ruling, Karnataka in the matter of **KARDEX INDIA STORAGE SOLUTION PVT. LTD.** reported in 2020 (35) G.S.T.L. 424 (A.A.R. - GST - Kar.). In the said matter the party sought advance ruling, inter-alia, seeking clarity with respect of eligibility of IGST, paid on import of goods which was further used in course and furtherance of business, as Input Tax Credit in terms of section 16(1) of the CGST Act. Answering in affirmative, the Advance Ruling Authority ruled as under (in verbatim):

"(1) The applicant is eligible to claim credit of IGST paid on import of goods as per Section 20 of the IGST Act, 2017 read with Section 16 of the CGST Act, 2017."

....

....

[Emphasis supplied]

2.17. In yet another case, the Hon'ble Authority of Advance Ruling, Rajasthan in the matter of **UMAX PACKAGING** reported in 2019 (20) G.S.T.L. 677 (A.A.R. - GST - RAJ) has ruled that credit of IGST is eligible to be input tax credit in terms of section 16(1) of the CGST Act. The relevant excerpt of the said ruling is as under:

"6. In view of the above stated facts, the applicant M/s. Umax Packaging, Jodhpur is eligible to claim the Input Tax Credit (ITC) of IGST paid on 'bill to ship to' model as per the relevant provisions of Section 16 and 17 of Chapter V of CGST Act, 2017."

2.18. In the erstwhile regime i.e. the Service Tax Regime, the Hon'ble CESTAT, Ahmedabad in the matter of **Alkem Laboratories limited** reported in 2022-VIL-790-CESTAT-AHM-CE has held that goods and material required for testing / clinical trials has direct nexus with the final products and therefore the taxes paid on the goods and material on the input side would be eligible to be CENVAT Credit. The relevant excerpt of the said ruling is reproduced hereinbelow for ready reference:

"10. Second issue involved in the present case is that whether the Appellant is entitled to Cenvat Credit in respect of inputs and packing materials used in the manufacture of medicament (exhibit batches) and the same is tested for trial and quality purpose and were destroyed / disposed off within the factory thereafter. We find that there is no



dispute in the facts that packaging / raw materials on which Appellant has claimed Cenvat credit has been used in process of manufacturing of medicaments for trial and testing purpose and quality purpose under the Drugs and Cosmetic Act, which was subsequently destroyed. On the basis of such testing / quality control process only the marketability of the product is ascertained. Accordingly, the raw materials / packaging materials which is used in manufacturing and which goes for testing / quality process are indeed the inputs which are used in or in relation to manufacturing of final products. The nature of products manufactured by the Appellant is such that it is a must / necessity that it needs testing and hence, the same forms an integral part of manufacture and without which it is not possible to manufacture the final products."

- 2.19. Further in *Thermax Culligan Water Technologies Ltd. v. Commissioner of Central Excise* [2014 (312) E.L.T. 148 - 2013-VIL-1812-CESTAT-MUM-CE] the Tribunal has held:

"5.3 As regards the demand on control samples of purified water, it is an admitted position that the samples had been drawn as per the norms fixed by the Food and Drugs Authorities. These were retained to test the shelf-life of the product of each batch and to analyse the customer complaints. Therefore, it cannot be said that the appellant had cleared the control samples for purposes other than those stipulated. There is also no evidence led by the Revenue to show that the appellant did not put to use the control samples by clearing them to customers.

- 2.20. In the case of *Commissioner of C. Ex., Ahmedabad-II Versus Cadila Healthcare Ltd.* 2013 (30) S.T.R. 3 (Guj.), the question before the Hon'ble Gujarat High Court was whether Cenvat credit on the service of technical testing and analysis could be allowed. In this context, the Court observed that the drugs manufactured by the assessee therein, by their very nature, required technical testing and analysis before entering commercial production, and that the final product could be manufactured only upon approval of regulatory authority after technical testing and analysis, and accordingly held that testing and analysis of trial batches was directly related to manufacture of final product.

- 2.21. It is submitted that while the judgement of *Cadila Healthcare (supra)* concerns with admissibility of credit on input services and not inputs (i.e. goods), it applies with equal force given that the eligibility criteria for both goods and services are the same under the provisions of CGST Act.

- 2.22. The ratio of the aforesaid rulings would be applicable in the present case in so far as the propositions with regard to nexus of the input and output service is concerned.

The Applicant is in possession of documents required for availment of ITC

- 2.23. Further, as per Rule 36 of the Central Goods and Services Tax Rules, 2017, the relevant document for claiming input tax credit in case of IGST paid on imports is the bill of entry. The relevant rule is reproduced hereunder:

Rule 36:

The input tax credit shall be availed by a registered person, including the Input Service Distributor, on the basis of any of the following documents, namely,

(a)...

....

....

(d) a bill of entry or any similar document prescribed under the Customs Act, 1962 or rules made thereunder for the assessment of integrate tax on imports

....

- 2.24. In the instant case, with regard to the first question, the bill of entry is filed by the Applicant for purpose of import of sample drug and the payment of IGST is also done by the Applicant as the importer and in the course of and in furtherance of its

business of rendering services to PPD Global. Hence, the Applicant is eligible to the input tax credit of the IGST paid on the import of sample drugs.

- 2.24. With regard to the second question, the Applicant is the importer on record in the Delivered Duty Paid model of shipment for purpose of import of sample drugs. The sample drugs which suffer IGST is used in the provision of services to PPD Global. Hence, the Applicant is eligible to the input tax credit of the IGST paid on the import of sample drugs, even though the payment of IGST is discharged by the logistics service provider / Sponsor.

Statement with regard to Question No.3

- 2.25. The Applicant would be entitled to take credit of CGST paid by the Applicant under section 7 r/w section 9 of the CGST Act for the services of Customs House Agent received by the Applicant, in terms of section 16(1) of the CGST Act in as much as the CHA services would be received for procuring the sample drugs. As demonstrated in the foregoing paragraphs, where the goods imported itself could be considered to be in course of or in furtherance of business, the services received for procuring the subject goods would also be in course and in furtherance of business.

- 2.26. In paragraphs above, it is demonstrated as to how the custom clearance of the sample drugs is part of the taxable services rendered by the Applicant. For customs clearance, the services proposed to be received by the Applicant, in corollary is therefore in course of and in furtherance of business.

- 2.27. Even in the erstwhile regime, tax paid on the service of Customs House Agents was included in the definition of input services in rule 2(l) of the CENVAT Credit Rules, 2004 and accordingly tax paid on services of Customs House Agent was allowed as CENVAT Credit. Reliance is placed on **KEMWELL BIOPHARMA PVT. LTD.** reported in 2017 (47) S.T.R. 70 (Tri. - Bang.) and **CHAMUNDI TEXTILES (SILK MILLS) LTD.** reported in 2010 (258) E.L.T. 141 (Tri. - Bang.).

- 2.28. In light of the above, the Applicant is eligible to the input tax credit of the IGST paid on import of sample drugs as well as the CGST + SGST paid to the Customs House Agent.

- 2.29. Summary of Additional submission dated 06.08.2024

- As stated in the application, the hospitals and clinics conduct clinical trials using Investigational Products ("IP"), comparator drugs and ancillary products / equipment for use in the clinical trials (collectively referred to as "sample drugs"). The said sample drugs are shipped into India either from the Sponsors (Biotech and Pharmaceutical companies who own such sample drugs) who are resident outside of India, or a related party of PPD (currently PPD Ireland) on behalf of the sponsor.
- One of the routes through which the afore-said sample drugs are shipped into India is through the DDP incoterms model, which involves the following steps:
 - Logistics service provider files the bills of entry for home consumption under section 46 of the Customs Act
 - The Importer on record is the Applicant (i.e. PPD Pharmaceuticals Development India Private Limited) as mentioned in the bills of entry,
 - The customs duty is paid by the logistics service provider on behalf of the applicant as per the Customs law- Logistics service provider ensures customs clearance of the goods (sample drugs) and dispatches the sample drugs directly to the identified location of the trials / warehouses for storage.



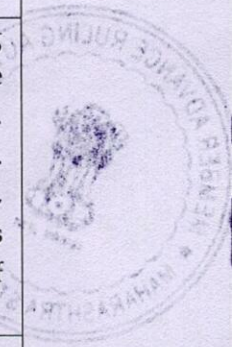
- Under the DDP model, the shipper of the goods undertakes to pay for the cost of all transportation, any loss due to damage during transit, and the payment of customs duty, import tariffs, and other relevant charges till the subject goods reach the agreed upon destination.
- The essential element of the entire DDP model is that the Applicant continues to remain the importer on record, given that it is only the Applicant who can import the drug into India pursuant to the license issued by the Drugs Controller General (India).
- The GST portal reflects the IGST paid (as part of the customs duty) on the import of sample drugs as credit available to the Applicant.

03. CONTENTION - AS PER THE CONCERNED OFFICER:

This office provide the facts in the case of M/s. PPD Pharmaceutical India Pvt. Ltd. holding of GSTN 27AADCP2043E1ZT, has filed Advance Ruling Application to your office.

The questions along with this office remark as below-

Sr.	Question	This office Remark
1.	Whether the Applicant is entitled to take credit of Integrated Goods and Services Tax ("IGST") paid by the Applicant under section 3 (7) of the Customs Tariff Act, 1975 r/w. section 5 (1) of the Integrated Goods and Service Tax Act, 2017 ("the IGST Act") while importing the sample drugs, in term of section 16 (1) of the CGST Act?	The Taxpayer Import the drug for Clinical Trial and provide the same to the hospitals free of cost. Hence, as per CBIC Circular No. 92/11/2019 dated 7 th March, 2019, the said ITC is ineligible as per section 17 (5) of CGST/MGST Act, 2017?
2.	Whether the Applicant is entitled to take credit of IGST paid by the "logistics service provider" [under DDP (Delivered Duty Paid) model of shipment] u/s. 3 (7) of the Customs Tariff Act, 1975 r/w. section 5 (1) of the Integrated Goods and Service Tax Act, 2017 ("the IGST Act") while importing the sample drugs, in term of section 16 (1) of the CGST Act? Where the Applicant is the importer on record.	Facts produced are incomplete. Hence can't be commented. It is hypothetical question.
3.	Whether the applicant is entitled to take credit of Central Goods and Services Tax ("CGST") paid by the applicant under section 7 r/w sec. 9 of the CGST Act for the service of Customs House Agent received by the applicant, in terms of section 16 (1) of the CGST Act?	Facts produced are incomplete. Hence can't be commented. It is hypothetical question.



04. HEARING

Preliminary hearing in the matter was held on 29.05.2024. Mr. Mihir Deshmukh, Advocate appeared and requested for admission of the application. Jurisdictional Officer Mr. Murlidhar Bande, Deputy Commissioner of State Tax also appeared.

The application was admitted and called for final hearing on 20.03.2025. Mr. Mihir Deshmukh, Advocate Authorized Representative, appeared made oral and written submissions. Jurisdictional Officer Mr. Murlidhar Bande, Deputy Commissioner of State Tax appeared. We heard both the sides.

05. OBSERVATIONS AND FINDINGS:

We have gone through the facts of the case, documents on record and submissions made by both, the applicant as well as the jurisdictional officer.

5.1 The Applicant is a Company, registered under the Companies Act, 1956 and is engaged in monitoring and managing the clinical trial process undertaken by hospitals / clinics ("Sites") and Doctors ("Investigators") in India. The PPD group, of which the Applicant is an affiliate, is a Clinical Research Organization and provides clinical research services to pharmaceutical and biotech companies ("Sponsors") on a global basis. These clinical trial management services comprise of consultancy, project management, data collection and specialist ancillary services. A Sponsor who wishes to conduct clinical trial study for a novel drug approaches the PPD group companies in the US or UK ("PPD Global"). These companies would then refer this work to the PPD Group affiliates in respective regions to procure services of hospitals and clinics to undertake the clinical trials and manage / monitor such clinical trials. For such services to be undertaken in India, the Applicant in India is approached by PPD Global, for which it is paid by PPD Global in convertible foreign exchange on a cost-plus basis.

In terms of the agreement signed between PPD Global and the Applicant, the Applicant is expected to provide Clinical Trial Co-ordination and Support Services, comprising of the following key activities:

- Site / Investigator identification and qualification
- Pre-study activities
- Investigator's meeting and communications management
- Study monitoring
- As part of study monitoring, develop and maintain a system to ensure the study sites have adequate investigational product



5.3 Further, the scope of managing the clinical trials encompasses within its ambit the following functions:

- Identifying appropriate investigators by evaluating their facilities, patient population, fees payable for the services
- Ensuring the trial is conducted as per the Sponsor protocol
- Studying the results of the trials, involving analysis and submission of reports (which is the primary essence of the service rendered by PPD)
- Miscellaneous activities such as obtaining regulatory approvals, ensuring adequate investigational products, etc.

5.4 As per the arrangement between the Sponsor and PPD Global, The primary responsibility of the Applicant is to monitor the clinical trials conducted by the hospitals / clinics for Sponsors under the defined protocol, including provision of administration and support services.

5.5 The hospitals and clinics conducts clinical trials using investigational products ("IP"), comparator drugs and ancillary products / equipment for use in the clinical trials (collectively referred to as "sample drugs"). The said sample drugs would be imported into India either from the Sponsors or through logistic service providers.

5.6. The applicant imports the sample drugs for the purpose of clinical trials in India, being the person responsible for monitoring the clinical trials in India. He files the Bill of Entry for home consumption and pays Basic Customs Duty ("BCD"), Integrated Goods and Services Tax ("IGST") and other applicable taxes and cesses. For carrying out the customs formalities, the Applicant engages a Customs House Agent ("CHA") for their services upon which the CHA charges GST at applicable rate.

5.7 Once the sample drugs are cleared from the Customs, the CHA or the logistic service provider then dispatches the sample drugs directly to the identified location of the hospitals or the clinics for clinical trials.

5.8 As per the agreement, the Applicant have to co-ordinate and manage the supply of sample drugs to hospitals/clinics and is also required to submit periodical reports / status of the clinical trials to PPD Global. The services rendered by the Applicant are taxable services in terms of section 7 of the CGST Act.

5.9 From the submission, it is seen that, as per the applicant's agreement with PPD Global, applicant supplies sample drugs to hospitals/ clinics for clinical trials without any consideration. After getting clinical trial report, submit periodical reports / status of the clinical trials to PPD Global.

5.10 Based on above facts, applicant has raised following questions-

5.10.1 Whether the Applicant is entitled to take credit of Integrated Goods and Services Tax ("IGST") paid by the Applicant under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the Integrated Goods and Services Tax Act, 2017 ("the IGST Act") while importing the sample drugs, in terms of section 16(1) of the CGST Act?

a. To determine eligibility of Input Tax Credit of IGST paid by the applicant, we have to go through the provisions of Section 20 of IGST and Section 16(1) of the CGST Act which reads as follows:

Section 20 of IGST

SECTION 20. Application of provisions of Central Goods and Services Tax Act. – Subject to the provisions of this Act and the rules made thereunder, the provisions of Central Goods and Services Tax Act relating to, -

...

...

(iv) input tax credit

...

...

shall, mutatis mutandis, apply, so far as may be, in relation to integrated tax as they apply in relation to central tax as if they are enacted under this Act.

Eligibility of ITC under Section 16 of the CGST Act

As per Section 16(1) of the CGST Act 'Every registered person shall, subject to such conditions and restrictions as may be prescribed and, in the manner, specified in section 49, be entitled to take credit of input tax charged on any supply of goods or services or both to him which are used or intended to be used in the course or furtherance of his business'.

b. The applicant submits that the IGST paid while importing the sample drugs is eligible as input tax credit in terms of section 16(1) of the CGST Act in as much as, the sample goods are used in the course or in furtherance of business.

c. Jurisdictional officer has taken the view that as the drugs have been supplied free of cost to the hospital, input tax credit IGST paid on import of these drugs is not available u/s 17 (5) (h).

d. Sample drugs so imported by paying IGST under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the Integrated Goods and Services Tax Act, 2017 ("the IGST Act") and after clearance from the Customs, the CHA or the logistic service provider dispatches them on delivery challans directly to the identified location of the hospitals or the clinics for clinical trials. Neither any commercial invoice is raised nor any consideration is taken from hospitals or clinics where clinical trials are to be conducted. Thus, sample drugs are supplied by Sponsor from out-side of India, imported by the applicant and delivered free of cost to hospitals and clinics for clinical trials. DCGI (Drug Controller General of India) has issued the licence to applicant for import of new drugs or investigational new drugs for the purpose of clinical trial or bioavailability or bioequivalence study or for examination, test and analysis in FORM CT-17. Licence itself does not allow applicant to supply the sample drugs with consideration. Clause (h) of Section 17(5) is reproduced below-

(5) Notwithstanding anything contained in sub-section (1) of section 16 and sub-section (1) of section 18, input tax credit shall not be available in respect of the following, namely:-

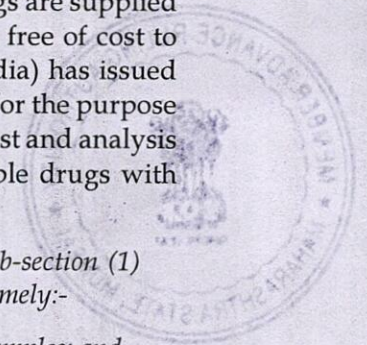
(h) goods lost, stolen, destroyed, written off or disposed of by way of gift or free samples; and

Goods or services that are supplied free of cost (without any consideration) cannot be treated as 'supply' as per Schedule I of the CGST Act, 2017 except for services mentioned in schedule I of the GST Act. Section 17(5)(h) of the CGST Act, 2017 restricts ITC on goods disposed off by way of gift or free samples.

e. Further, as per Circular No. 92/11/2019 - GST issued by the CBIC on 07th March 2019, any goods or gifts provided under the category of gifts, samples, and other related categories without consideration shall not become categorized as 'supply' as per the Act. Hence, the input tax credit shall also be not in respect of said goods. Clarification regarding free samples given in circular is reproduced here as-

"Free samples and gifts:

i. It is a common practice among certain sections of trade and industry, such as, pharmaceutical companies which often provide drug samples to their stockists, dealers, medical practitioners,



etc. without charging any consideration. As per sub-clause (a) of sub-section (1) of section 7 of the said Act, the expression "supply" includes all forms of supply of goods or services or both such as sale, transfer, barter, exchange, licence, rental, lease or disposal made or agreed to be made for a consideration by a person in the course or furtherance of business. Therefore, the goods or services or both which are supplied free of cost (without any consideration) shall not be treated as „supply" under GST (except in case of activities mentioned in Schedule I of the said Act). Accordingly, it is clarified that samples which are supplied free of cost, without any consideration, do not qualify as „supply" under GST, except where the activity falls within the ambit of Schedule I of the said Act.

ii. Further, clause (h) of sub-section (5) of section 17 of the said Act provides that ITC shall not be available in respect of goods lost, stolen, destroyed, written off or disposed of by way of gift or free samples. Thus, it is clarified that input tax credit shall not be available to the supplier on the inputs, input services and capital goods to the extent they are used in relation to the gifts or free samples distributed without any consideration. However, where the activity of distribution of gifts or free samples falls within the scope of „supply" on account of the provisions contained in Schedule I of the said Act, the supplier would be eligible to avail of the ITC".

g. Though section 16 (1) provides for eligibility of input tax credit in respect of goods or services to be used in the course or furtherance of business, subsection (5) of section 17 starts with non-obstante clause 'Notwithstanding anything contained in subsection (1) of section 16....' Hence, the drugs supplied are in the nature of free samples or supplies without consideration and input tax credit in respect of such goods would not be available u/s. 17 (5) (h) of CGST Act.

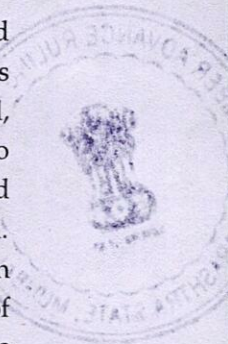
5.10.2. Whether the Applicant is entitled to take credit of IGST paid by the "logistics service provider" [under DDP (Delivered Duty Paid) model of shipment] under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the IGST Act while importing the sample drugs, in terms of section 16(1) of the CGST Act, where the Applicant is the Importer on Record?



a. Other way of import the sample drugs which is called as Delivered Duty Paid Model of shipment (this is proposed model) wherein the supplier of goods agrees to bear all costs till the goods reach the destination. Under this model, the supplier undertakes to pay for the cost of all transportation, any loss due to damage during transit, and the payment of customs duty, import tariffs, and other relevant charges till the subject goods reach the agreed upon destination.

b. The logistics service provider would file the bills of entry for home consumption under section 46 of the Customs Act for customs clearance. Upon payment of BCD under section 12 of the Customs Act, IGST under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the IGST Act and other applicable taxes and cesses, once the goods reach the customs frontiers of India. However, the Applicant would continue to remain as the importer on record, as the Applicant only who can import the drug into India pursuant to the license issued by DCGI.

c. This means the importer on record would be the Applicant in the Bill of Entry, whereas the BCD and IGST payable on import would be discharged / paid by the logistics service provider/ PPD Global / Sponsor. After clearance from the



Customs, the logistic service provider would dispatch the sample drugs on delivery challans directly to the identified location of the hospitals or the clinics for clinical trials. In this model also any commercial invoice would not be raised by the applicant. Applicant will not receive any consideration from hospitals or clinics where clinical trials are to be conducted. Here also sample drugs will be supplied free of cost to hospitals and clinics for clinical trials.

5.10.3. Whether the Applicant is entitled to take credit of Central Goods and Services Tax ("CGST") paid by the Applicant for the services of Customs House Agent and Logistics services provider received by the Applicant, in terms of section 16(1) of the CGST Act?

- a. The Applicant is of the view of that he would be entitled to take credit of CGST paid by the Applicant under section 7 r/w section 9 of the CGST Act for the services of Customs House Agent received by the Applicant, in terms of section 16(1) of the CGST Act in as much as the CHA services would be received for procuring the sample drugs.
- b. Being importer, the applicant takes customs house agent services to clear the sample drugs and for his service, CHA raises an invoice by levying applicable GST. After clearance from the Customs, the logistic service provider dispatches the sample drugs on delivery challans directly to the identified location of the hospitals or the clinics for clinical trials. Here, any commercial invoice would not be raised by the applicant to the clinics to whom sample drugs are supplied for clinical trials. Applicant does not receive any consideration from hospitals or clinics where clinical trials are to be conducted. Here also sample drugs are supplied free of cost to hospitals and clinics for clinical trials.
- c. CHA services have been availed for clearance of the drugs imported by the applicant which are disposed of by delivering to the hospitals without charging any consideration. Thus, these goods acquire the colour of free samples. Further, Logistic services provider provides services for delivering these goods to the hospital and clinics. Thus, the services of CHA and logistic service provider are used to dispose of the drugs by supplying to hospitals without any consideration. Provisions of section 17 (5) (h) are reproduced as under.

Section 17

(5) Notwithstanding anything contained in sub-section (1) of section 16 and sub-section (1) of section 18, input tax credit shall not be available in respect of the following, namely:-;

(a).....

(b)....

(c)...

...

...

(h) goods lost, stolen, destroyed, written off or disposed of by way of gift or free samples;

Section 17 (5) not only overcomes provisions of section 16 (1), but it also provides that ITC shall not be available in respect of goods disposed of by way of gift or free samples.



Since, the drugs supplied to hospitals are without consideration and acquires the colour of free sample or gift, any input services provided in respect of such disposal of goods would also be covered by the provisions of section 17 (5) (h). Therefore, input tax credit in respect of the tax paid on CHA services or logistic services availed would not be available.

As per the West Bengal AAR ruling dated 18-Sep-2018, in case of M/s. Indian Oil Corporation the GST paid on railway freight related to the non-taxable supplies was held to be not eligible for Input Tax Credit (ITC). This ruling is further upheld in the AAAR ruling dated 08-Mar-2019.

Additionally, Circular 92/11/2019 as discussed above clarifies that free samples do not constitute a supply under GST, thereby not allowing for ITC on services used for such goods. Consequently, CHA charges, transportation attributable to free sample goods remain ineligible for ITC under current GST provisions.

06. In view of the extensive deliberations as held here in above, we pass an order as follows:

ORDER

(Under Section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

For reasons as discussed in the body of the order, the question is answered thus -

Question 1: Whether the Applicant is entitled to take credit of Integrated Goods and Services Tax ("IGST") paid by the Applicant under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the Integrated Goods and Services Tax Act, 2017 ("the IGST Act") while importing the sample drugs, in terms of section 16(1) of the CGST Act?

Answer: - Answered in negative.

Question 2: Whether the Applicant is entitled to take credit of IGST paid by the "logistics service provider" [under DDP (Delivered Duty Paid) model of shipment] under section 3(7) of the Customs Tariff Act, 1975 r/w section 5(1) of the IGST Act while importing the sample drugs, in terms of section 16(1) of the CGST Act, where the Applicant is the Importer on Record?

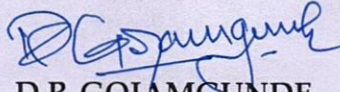


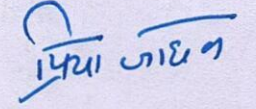
Answer: - Answered in negative.

Question 3: Whether the Applicant is entitled to take credit of Central Goods and Services Tax ("CGST") paid by the Applicant under section 7 r/w section 9 of the CGST Act for the services of Customs House Agent received by the Applicant, in terms of section 16(1) of the CGST Act?

Answer: - Answered in negative.




D.P. GOJAMGUNDE
(MEMBER)


PRIYA JADHAV
(MEMBER)

PLACE - Mumbai

DATE - 30/04/2025

Copy to: -

1. The applicant
2. The concerned Central / State officer
3. The Commissioner of State Tax, Maharashtra State, Mumbai
4. The Pr. Chief Commissioner of Central Tax, Churchgate, Mumbai
5. The Joint commissioner of State Tax, Mahavikas for Website.

Note: -An Appeal against this advance ruling order shall be made before The Maharashtra Appellate Authority for Advance Ruling for Goods and Services Tax, 15th floor, Air India Building, Nariman Point, Mumbai - 400021. Online facility is available on gst.gov.in for online appeal application against order passed by Advance Ruling Authority.

