THE AUTHORITY ON ADVANCE RULINGS
IN KARNATAKA
GOODS AND SERVICE TAX
VANIJYA THERIGE KARYALAYA, KALIDASA ROAD
GANDHINAGAR, BENGALURU – 560 009

Advance Ruling No. KAR ADRG 122 / 2019
Dated: 30th September,2019

Present:

1. Sri. Harish Dharnia,
   Addl. Commissioner of Central Tax , ... Member (Central Tax)

2. Dr. Ravi Prasad M.P.
   Joint Commissioner of
   Commercial Taxes . . . . Member (State Tax)

1.	Name and address of the applicant	M/s PAREXEL International Clinical Research Pvt. Ltd. Bay Area, Ground Floor, COWRKS, RMZ ECOWORLD, Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bengaluru 560103
2.	GSTIN or User ID	29AADCP9318C1ZD
3.	Date of filing of Form GST ARA-01	13.08.2018
4.	Represented by	Sri K Sivarajan, Chartered Accountant
5.	Jurisdictional Authority – Centre	Pr Commissioner of Central Tax, Bangalore East
6.	Jurisdictional Authority – State	LGSTO-015, Bengaluru
7.	Whether the payment of fees discharged and if yes, the amount and CIN	Yes, discharged fee of 1. Rs.5,000-00 under CGST Act vide CIN RBIS18062900306234 dated 21.06.2018 2. Rs.5,000-00 under KGST Act vide CIN RBIS18062900306052 dated 21.06.2018

ORDER UNDER SECTION 98(4) OF THE CENTRAL GOODS AND SERVICE TAX ACT, 2017 AND UNDER SECTION 98(4) OF THE KARNATAKA GOODS AND SERVICES TAX ACT, 2017

1. M/s PAREXEL International Clinical Research Private Limited, (called as the 'applicant' hereinafter), having GSTIN number 29AADCP9318C1ZD, has filed an application for Advance Ruling under Section 97 of CGST Act, 2017 read with Rule 104 of CGST Rules 2017, under Section 97 of the KGST

Act, 2017 read with Rule 104 of KGST Rules 2017, in FORM GST ARA-01 discharging the fee of Rs.5,000-00 each under the CGST Act and the KGST Act.

2. The Applicant is a Private Limited Company and is registered under the Goods and Services Act, 2017. The applicant has sought advance ruling on the following questions:

a) Determination of liability to pay tax on the co-ordination services provided by the company to its affiliates outside India?

b) Determination of liability to pay tax on "Pass Through" expenses charged by the Company to its affiliates located outside India?

3. The applicant furnishes some facts relevant to the stated activity:

a. The applicant states that PAREXEL International Corporation (USA) (the Parent Company of the applicant) is a leading Contract Research Organisation (CRO), providing a broad range of expertise in clinical research, medical communications, consulting and advance technology products and services to the worldwide pharmaceutical and biotechnology companies alternatively known as "Sponsors". For coordinating the clinical trial activity conducted in India, PAREXEL Prime (i.e. the entity which has executed the contract with the Sponsor – typically a PAREXEL entity in US, UK, Germany, Japan or Ireland) has entered into an agreement with the applicant.

b. The applicant states that he is engaged in coordinating clinical trial services in India for its affiliates (all the affiliates are hereinafter collectively referred to as PAREXEL Group). The key functions carried out by the applicant while providing the services are: Study initiation (Project Management), Project Monitoring, Compliance and Regulatory affairs.

c. Apart from the above, the applicant also provides Project Management Services to Indian Companies/ Sponsors and has been discharging the GST liability on the consideration received for these services.

4. The applicant states that the PAREXEL Prime typically enters into a contract with the Sponsor (the developer of drug) for undertaking the clinical research services (hereinafter referred to as CRS or "study") and outsources a part of its activities to the applicant if the CRS are intended to be performed in India. In this connection, the applicant provides the following services:

(a) The applicant co-ordinates and monitors the clinical trial services which includes the following:

i. Assistance in obtaining regulatory approvals for undertaking the clinical trials in India on behalf of the sponsor
ii. Identifying the sites available and suitable for the study based on the "approved site data" maintained by PAREXEL affiliates and other Project Management services
iii. Monitoring the activities of the sites undertaken for the study
iv. Assistance in compliance by way of inspection and audit of sites.

(b) Apart from the above activities, the applicant undertakes the following functions:

i. Enters into contract with the investigators in India on behalf of the sponsors
ii. Receives and settles invoices from the investigators on behalf of the sponsor (these are reimbursed at actuals without any additional consideration by PAREXEL Prime)

For performing the above-mentioned services, the applicant invoices its affiliates on cost plus mark-up basis.

5. The applicant has provided the details of the activities performed by each of the parties involved as under:

Type of functions	**Sponsor**	**PAREXEL Prime**	**Applicant**	**Investigator (Hospital)**
Drug Development	Yes	-	-	-
Pre-clinical Trials	Yes	-	-	-
Study Protocol design for Clinical Trials				
Assistance in site feasibility – Project Management Services				
Preparation of plan for feasibility study	-	Yes	-	-
Providing the list of approved sites in India (Site Database)	-	Yes	-	-
Screening of the sites suitable for study based on parameters set by PAREXEL Group	-	-	Yes	-
Approval of sites for study	Yes	Yes	-	-
Concluding a contract with the approved sites for clinical trials on behalf of the Sponsor	-	-	Yes	-
Post feasibility Study Services – Regulatory Affairs and Compliance				

Obtaining regulatory approvals for undertaking clinical trials within India	-	-	Yes	-
Preparation of Investigation Brochure, Protocols and dossiers	Yes	Yes	-	-
Distribution of brochure and protocols to Investigators regarding the procedures of clinical trials	-	-	Yes	-
Making the drugs available to the Investigators	Yes	Yes	Yes	-
Conducting the Clinical Trials	-	-	-	Yes
Maintaining the Clinical study files along with the Case Report Forms	-	-	-	Yes
Site visit in India for collection of data	-	-	Yes	-
Follow up procedure and Monitoring the trials	-	-	Yes	-
Preliminary Compliance of data	-	-	Yes	-
Preparation of final trial reports	-	-	Yes	Yes

6. Regarding the determination of liability to pay tax on the coordination services provided by the company to its affiliates outside India, the applicant states that these activities done by them are in the nature of Project Management, Regulatory Affairs, Project Monitoring and Compliance activities.

6.1 The Project Management involves planning and integration service which includes serving as the primary resources and point of communication for sponsor/ project team, undertaking study/ site feasibility assessment, updating the sponsor and participation in telecom.

6.2 The Regulatory affairs involve assistance in getting regulatory approvals from DCGI, DGFT and ICMR for conducting clinical trials in India.

6.3 The Project Monitoring involves the monitoring team which supervised the clinical trial projects in India and respond to any critical incidents at the Investigator Site.

6.4 Compliance: This activity involves coordination of various audit activities of investigator sites as per protocol and other regulatory requirements like GCP Compliance review, IRB/EC audits, on-site investigator audits, drug accountability reviews, database audit, study document reviews.

For performing the above mentioned services, the applicant invoices its affiliates on a monthly basis, a fee comprising of total operating cost incurred by the company as increased by 15% mark-up.

7. Apart from the above services, the applicant acts on behalf of the sponsor and enters into contract with the investigators who perform the clinical trials in India and settles their invoices on behalf of the sponsor. These charges shall be reimbursed to the applicant at actuals (without any mark-up) and are named as "Pass through Expenses". In other words, pass through expenses are the reimbursements made to the applicant for the costs incurred by the applicant on behalf of the sponsors such as investigators fee, drug charges, laboratory fee, translation costs, etc.

The present application is filed to seek a ruling on the taxability of the above mentioned services under the GST provided by the applicant to its affiliates outside India.

8. Regarding the nature of services and classification, the applicant highlights the relevant clauses in the agreement entered by the applicant with its affiliates in order to further understand the nature of services provided by the applicant and to understand the classification of the said services under the GST. The pertinent clauses highlighted are as under:

8.1 *"SCOPE OF WORK –*

1.1. PISPL (the applicant was named as "PAREXEL International Synchron Pvt Ltd" prior to change in name as PAREXEL Clinical) agrees to carry out the services with respect to arranging for, co-ordination and supervision of conducting clinical trials phase II – III of the specific types of medicines/ drugs as separately agreed by the parties. In particular, PISPL shall provide the services listed in "Appendix A (the services) to PIC (PAREXEL International Corporation).

2.1. PISPL shall not be an agent or partner of PIC. PISPL shall not enter into or execute any agreements, orders or any other commitments or otherwise obligate PIC in any manner.

APPENDIX A

The services to be provided by PISPL to PIC would include the following types of Services:

1. To obtain various regulatory approval from DGCA for conducting clinical trial in India and to submit the required data with DGCA time to time regarding the progress of clinical trial.

2. To carry out site inspection and site identification for carrying out clinical trials in India for conducting any new trials.

3. To coordinate with Ethical Committees of various investigators and obtain approval for conducting clinical trials in their organisations and provide all periodic updates with the Ethical Committee;

4. To conclude clinical study contracts with the independent investigators capable to carry out the trials according to the required standards and procedures

5. To control and monitor the clinical study process at various sites in India

6. To provide investigators the clinical trial protocol and support personnel with necessary information and training with respect to the procedures and the scope of clinical trials in progress.

7. To undertake periodical verification of the progress of clinical trials.

8. To pay visits to the hospitals and collect the study medication and addition materials, study documentation

9. To conduct the preliminary compilation of results

10. To assist in final elaboration of the outcome of tests

11. To conduct the additional activities of a technical nature necessary to perform the above activities, such as supplying the investigators with the appropriate forms and questionnaires for each phase of the research, ordering translations of the necessary documents and supplying the investigators with the study medication to be used exclusively within the trials.

12. To perform a feasibility study before commencing any new clinical trial activity in India and provide data to PIC based on the output of feasibility study

13. Overall coordination of clinical trials services as well as communication with PIC

14. Any other related activity as specified by PIC from time to time by way of a service order."

8.2 It is clear, according to the applicant, from the foregoing clauses that what is intended by the agreement is only co-ordination, study initiation and monitoring of clinical trials conducted in India and as these services are outsourced support services, these services are classifiable as "Business Support Services' with HSN 998311.

8.3 The relevant Central Product Classification for the services specified in HSN 998311 reads as under:

"83190 - Other management services, except construction project management services

This subclass includes

i. coordination and supervision of resources in preparing, running and completing a project on behalf of the client;

ii. project management services, which can involve budgeting, accounting and cost control, procurement, planning of time scales and other operating conditions, coordination of subcontractors' work, inspection and quality control, etc;

iii. project management services that include management and office management services, with or without the provision of their own staff;

This subclass does not include: - construction project management services"

8.4 The applicant states that from the above, it is clear that the services provided by way of co-ordination and supervision of a project on behalf of the client are classifiable as Business Support Services and in the instant case the applicant co-ordinates, monitors the clinical trial services in India on behalf of its affiliates. As the essential character of services being provided are in the nature of co-ordination and monitoring activities, according to the applicant, the services provided by them are to be classified as "business support services".

9. Regarding the taxability of the services provided by the applicant, the applicant states that in the GST regime, in order to determine the taxability of a transaction, it is important to refer to the definition of "Supply" (levy) and the place of supply provisions as applicable to the transaction. It is undisputed fact, according to the applicant, that the above mentioned services provided by the applicant qualify as "Supply" and therefore liable for GST. However, as these services are provided to the recipient outside India, before concluding on the taxability of the transaction, the relevant place of supply provisions of the GST Act are to be referred.

9.1. The Place of Supply provisions under Section 13 of the IGST Act, as per the applicant, can be briefly tabulated as below:

Section	Conditions	Place of Supply
13(2)	Services should not have been specified in 13(3) to 13(13) – (General)	Location of the Service Recipient
13(3)	Services supplied in respect of goods which are required to be made physically available (or)	Location of performance

	Services supplied requires the physical presence of the recipient	
13(4)	Services in relation to Immovable Property	Location of immovable property
13(5) – 13(12)	Specified Services – (Not relevant in the instant case)	

9.2 The applicant states that the services provided by the applicant are not covered under Section 13(4) to 13(12). In order to conclude as to whether the supplies made by the applicant are "Performance based" or "Recipient based" services, the detailed provisions are extracted below:

Section 13 of the IGST Act provides that,

"....

13(2) the place of supply of services except the services specified in sub-sections (3) to (13) shall be the location of the recipient of services:
Provided that where the location of the recipient of services is not available in the ordinary course of business, the place of supply shall be the location of the supplier of services.

13(3) the place of supply of the following services shall be the location where the services are actually performed, namely:-
(a) Services supplied in respect of goods which are required to be made physically available by the recipient of services to the supplier of services, or to a person acting on behalf of the supplier of services in order to provide the services:

Provided .....

(b) Services supplied to an individual, represented either as the recipient of services or a person acting on behalf of the recipient, which require the physical presence of the recipient or the person acting on his behalf, with the supplier for the supply of services."

9.3. The applicant states that from the above the place of supply of a services can be "performance based" only when

(a) the services so provided are in respect of goods

(b) Such goods are required to be made physically available by the recipient of services to

a. the provider of service (or)

b. the agent of the supplier of service

(c) The service provided requires the physical presence of the recipient.

9.4. In the instant case, according to the applicant, the services provided by the applicant are in the nature of coordination services which neither require the physical presence of an individual (recipient) nor in respect of goods. These services are not related to goods and do not require such goods to be made available to the applicant in order to provide the services.

9.5 The applicant admits that it is an undisputed fact the clinical trials are conducted in India which are in respect of goods which are required to be made available by the recipient. However, it is important to note that the service of clinical trials is provided by the investigator to the sponsor and the applicant for the limited purposes, on behalf of the sponsor enters into an agreement with the investigator. A mere fact that the applicant has entered into an agreement with the investigator on behalf of the sponsor will not alter the nature of services provided by the applicant to its affiliates.

9.6. The applicant argues that as per Section 13(3) of IGST Act, the place of supply of services can be performance based only when such services require the physical presence of goods either to the supplier of services or his agent. In the instant case, the drugs are provided by the sponsor either to the investigator or to the applicant who in turn provides the same to the investigator. In this case, it is pertinent to note that the applicant is not an agent of the service provider being the investigator and therefore the conditions specified in Section 13(3) are not fulfilled.

9.7. The applicant also states that in most of the cases, the drugs required to conduct the clinical trials are directly provided to the investigator by the sponsor. The fact that the drugs are not received by the applicant proves that the applicant do not perform any services in relation to the goods. In this connection, the applicant refers to the Paragraph 5.4.1 of the Education Guide published by TRU, CBEC which reads as under (as the erstwhile law also had similar provisions):

" *5.4. Rule 4 – Performance based services*

5.4.1. What are the services that are provided "in respect of goods that are made physically available by the receiver to the service provider, in order to provide service? – sub-rule (1)
Services that are related to goods, and which require such goods to be made available to the service provider or a person acting on behalf of the service provider so that the service can be rendered, are covered here. The essential characteristics of a service to be covered under this rule is that the goods temporarily come into the physical possession or control of the service provider, and without this happening, the service cannot be rendered. Thus, the service involves movable objects or things that can be touched, felt or possessed. Examples of such services are repair, reconditioning, or any other work on goods (not amounting to manufacture), storage and warehousing, courier service, cargo handling service (loading, unloading, packaging or unpacking of cargo), technical testing/ inspection/ certification/ analysis of goods, dry cleaning etc. It will not cover services where the supply of goods by the receiver is not material to the rendering of the service e.g. where a consultancy report commissioned by a person is given on a pen drive belonging to the customer. Similarly, a provision of a market research service to a manufacturing firm for a consumer product (say, a new detergent) will not fall in this category, even if the market research firm is given say, 1000 nos. of 1 kilogram packets of the product by the manufacturer, to carry for door-to-door surveys.

9.8. Based on the above, the applicant argues that rule 4 only contemplates a situation in which the goods are temporarily handed over to service provider for provision of services. The said paragraph of Education Guide also mentions that "it will not cover services where the supply of goods by the receiver is not material to the rendering of the service." In the instant case, the service of coordination do not require the physical presence of goods and therefore Section 13(2) which is akin to the Rule 4 of the Place of Provision of Services is not applicable to the applicant.

9.9. The applicant places reliance on the Advance Ruling given under the earlier law in the Steps Therapeutics Ltd 2017(49) STR 114 (AAR) where the applicant provides "clinical research services" which are similar to those of the services provided by the applicant. In the AAR it was concluded that –

"where only service of Clinical Research is provided, then such service would not be in relation to formulation provided by the service receiver located outside India, to the applicant. Hence, it would be not taxable under the Act in light of Rule 3 of the Place of Provision of Services (POP) Rules, 2012 as the applicant renders said services to its customers and the place of provision is located outside India".

9.10. Based on the above inferences the applicant submits that the place of supply provided by the applicant to its affiliates shall not be Performance based and therefore as per the general rule of Place of Supply provision, the place of supply for the said services shall be the "Location of Recipient". As the applicant provides services to its affiliates outside India, the place of supply shall be "outside India" and the transactions qualifies as "Export" subject to fulfillment of other conditions as specified in Section 2(6) of the IGST Act.

9.11. The applicant also clarifies that as mentioned above, though the company acts as on behalf of the sponsor and enters into contract with the investigators, it is important to note that this relationship is only for the limited purposes of "entering into the contract with the investigator" and "payment" thereof and no consideration is received by the company for acting as an agent of the sponsor except for the reimbursements of costs incurred by the company for acting as an agent of the sponsor except for the reimbursement of costs incurred by the company on behalf of the sponsor in the form of "pass through expenses" from its affiliates.

9.12. Furthermore, the applicant states that the contract entered by the applicant with the investigator clearly depicts the above relationship. The relevant extracts of the contract are provided below:

"Para 2 of the contract – PAREXEL is acting on behalf of the sponsor to arrange and administer a multi-centre study to clinically evaluate the study drug and has entered into an agreement with sponsor concerning the management, funding and administration of the study.

Section 4: Ownership rights – "All Study results obtained during the performance of the study shall be the property of "Sponsor".

Section 8.2 ; Relationship of Parties: The site shall perform its services under this agreement only as an independent contractor

for sponsor, and nothing contained herein shall be construed to be inconsistent with that relationship or status."

9.13. Based on the above, the applicant submits that he is not performing any clinical trial services and only arranges and administers the trials for which the place of supply shall be "location of recipient'.

As the applicant provides services to its affiliates outside India, the transaction shall qualify as "Export" subject to fulfillment of other conditions as specified in the Act.

10. Regarding the determination of liability to pay tax on the "pass through" provided by the company to its affiliates outside India, the applicant states he acts on behalf of the sponsor and enters into a contract with the investigators who performs clinical trials in India and settles their invoices on behalf of the sponsor. These charges shall be reimbursed to the applicant at actuals and are named as "pass through" expenses. As these expenses are in the nature of reimbursements made by the applicant, the applicant believes that the same cannot be included in the value of supply.

10.1. As per the Rule 33 of the CGST Rules 2017,

'Notwithstanding anything contained in the provisions of this Chapter, the expenditure or costs incurred by a supplier as a pure agent of the recipient of supply shall be excluded from the value of supply, if all the following conditions are satisfied, namely –

(i) The supplier acts as a pure agent of the recipient of the supply, when he makes the payment to the third party on authorization by such recipient;

(ii) The payment made by the pure agent on behalf of the recipient of supply has been separately indicated in the invoice issued by the pure agent to the recipient of service; and

(iii) The supplies procured by the pure agent from the third party as a pure agent of the recipient of supply are in addition to the services he supplies on his own account.

Explanation: For the purposes of this rule, the expression "pure agent" means a person who –

(a) Enters into a contractual agreement with the recipient of supply to act as his pure agent to incur expenditure or costs in the course of supply of goods or services or both;

(b) Neither intends to hold nor holds any title to the goods or services or both so procured or supplied as pure agent of the recipient of supply;

(c) does not use for his own interest such goods or services so procured; and

(d) receives only the actual amount incurred to procure such goods or services in addition to the amount received for supply he provides on his own account."

The applicant states since he has fulfilled all the conditions specified in rule 33 of the CGST Rules, the expenses incurred and recovered by the applicant may not be included in the value of services for the computation of taxes / availing the export benefit.

11. Sri Shivarajan, Chartered Accountant and duly authorised representative of the applicant appeared and made his submissions which is in line with the application filed. He has also made additional submissions which are as under:

11.1. The applicant is engaged in coordinating and monitoring clinical trial services in India. Typically these services involves activities in the nature of Project Management, regulatory affairs, project monitoring, compliance, etc.

11.2. As the essential character of services being provided are in the nature of co-ordination and monitoring activities, the applicant contends that the said services shall be classified under CPC 83190 which is akin to HSN 998319 and shall qualify as "exports" as the same are provided by the applicant to its affiliates outside India.

11.3 During the provision of the above mentioned services, the applicant acts on behalf of the sponsor and enters into a contract with the investigators who perform the clinical trial services. These charges are reimbursed to the applicant as actuals. In this connection, as PICRPL is acting as a "pure agent" of sponsor, the applicant contends that the said expenses incurred and recovered by the applicant may not be included in the value of services for computation of taxes / availing the export benefit.

12. The applicant also states that as mentioned in the application for advance ruling, he is engaged in co-ordinating and monitoring clinical trial services in India and for the provision of this service to its affiliates outside India, the applicant has entered into a contract and has agreed to provide

these services at a fee comprising of total operating cost incurred by the company as increased by 15% mark-up which shall be invoice monthly.

12.1. As per the contract, apart from the above services, the applicant is also required to enter into contract on behalf of sponsor with the investigators who perform the clinical trials in India and settle their invoices on behalf of the sponsor. These charges shall be reimbursed to the applicant at actuals (without any mark-up) and are named as "pass through expenses". In other words, pass through expenses are the reimbursements made to the applicant for the costs incurred by the applicant on behalf of the sponsors such as investigators fee, drug charges, laboratory fee, translation costs, etc. In this connection, the applicant submits that the services provided by the applicant are classifiable under HSN 9983 – Other professional, technical and business services (except research, development, legal and accounting services) which reads as under:

"998319 - Other information technology services n.e.c.
This subclass includes

i. coordination and supervision of resources in preparing, running and completing a project on behalf of the client;

ii. project management services, which can involve budgeting, accounting and cost control, procurement, planning of time scales and other operating conditions, coordination of subcontractors' work, inspection and quality control, etc;

iii. project management services that include management and office management services, with or without the provision of their own staff;

This subclass does not include: - construction project management services"

Based on the above, the applicant contends that it is clear that the services provided by way of co-ordination and supervision of a project on behalf of a client are classifiable under HSN 9983. In the instant case, the applicant co-ordinates and monitors the clinical trial services performed by the investigators on behalf of its affiliates.

12.2. As the essential character of services being provided are in the nature of co-ordination and monitoring activities, the applicant understands that the service provided by him are to be classified under HSN 9983 and accordingly be treated as "export of services" when the same are provided to affiliates outside India. He places reliance on the Advance Ruling given

under the Service Tax Law in the case of Steps Therapeutics Ltd wherein it was held that services qualify as "exports" when consumed outside India.

13. FINDINGS & DISCUSSION:

13.1 The documents produced at the time of hearing and later were verified and the drug development process involves the following steps

a. Discovery and Development
b. Pre-Clinical Research
c. Clinical Research
d. FDA Review
e. FDA Post market Safety Monitoring

The non-Clinical trials and Clinical Trials are conducted to test the efficacy and safety of the drugs tested.

13.2 The Trials involve mainly two persons –
(a) a Sponsor – who is usually a pharma company. The sponsor may outsource the activity of trials to CROs
(b) CROs - are representatives of the Sponsor and are responsible for clinical trials.
(c) The Investigator is a person who conducts the trial and report the findings to the CROs or Sponsors.

The applicant company and all its affiliates is a CRO who has the contract of testing the drug and reporting the results to the Sponsor. The part of operations in India is done by the applicant and the agreement between the applicant and its parent affiliates govern the transactions between them.

13.3. The Agreement entered between the applicant and the PAREXEL International Limited (one of the foreign affiliate of the same group) which is produced as a prototype is verified and found that the applicant is sub-contracted a part of the work given to the main affiliate and the applicant performs certain services for and on behalf of the main affiliate on the terms set forth therein. Hence it is clear that the applicant is performing services for and on behalf of the affiliate situated abroad.

13.4 Further, it can be seen from the submissions made by the applicant that he enters into various agreements on behalf of the sponsor

with various investigators and payments are made by the applicant to the investigators. There is no privity of contract between the applicant and the sponsor and the power to enter into agreement with the investigators is derived from the agreement between the applicant and its foreign affiliate which in turn derives the power from the agreement entered between the sponsor and the foreign affiliate.

13.5. It is also seen that the applicant has entered into an agreement for Clinical Trial with the Investigators and it is clearly stated in the agreement that the applicant is entering the agreement on behalf of the Sponsor. It is clearly stated in the agreement that the Sponsor has requested the CRO to manage the Clinical Trial on its behalf in accordance with the Protocol for the Clinical Trial and had engaged the applicant as its representative in India and had authorized the applicant to

(a) liaise with the Indian regulatory authorities to obtain all approvals / permissions / licenses required for the performance of the Clinical Trial in India
(b) organize and conduct the Clinical Trial at selected sites in India
(c) enter into Clinical Trial Agreements with the participating sites on behalf of Sponsor
(d) make payments to the Institutions, and
(e) do such other things as may be required for conducting the Clinical Trial as per the applicable Laws in India.

13.6. The various clauses of the agreement show clearly that the applicant is acting as a representative of the sponsor in relation to the supply of services by the Investigators and the payments are made by the applicant.

14. Regarding the nature of service it is seen that the sponsor has entered into an agreement with the foreign affiliate of the applicant. The foreign affiliate has in turn entered into an agreement with the applicant. The applicant has further entered into an agreement with the investigator. The foreign affiliate is providing services to the sponsor as a CRO and the applicant is providing services to the foreign affiliate also as a CRO. There are two services which are involved in the above transaction, one the supply of drug testing services by the Investigator to the sponsor and the second the supply of CRO services to the foreign affiliate. It is also seen in the sample document provided by the applicant, that even this CRO services is again sub-contracted to one, M/s Ecron Acunova Limited.

14.1 It is seen in the para 19.4 of the agreement that the Institution and Investigator understand and agree that the agreement is being signed by CRO exclusively on behalf of and as an agent of Sponsor and for Sponsor's benefit and that CRO is not a party to this agreement. Upon request, CRO on behalf of Sponsor can provide a delegation of authority and/or power of attorney letter. Hence it can be presumed that that the applicant is signing the agreement on behalf of the Sponsor and not a party to that agreement and hence the agreement is actually between the Sponsor and the Investigator.

14.2 It is seen in the agreement that the payment of fees and expenses would be made by the Sponsor to the Institution solely and through the CRO, i.e. applicant's foreign affiliate, applicant and the subcontractor acting as go-betweens. The agreement also states in para 16.4 that the Institution and Investigator acknowledge and agree that CRO is the payment agent for Sponsor under the agreement and the CRO shall neither have any payment obligations nor be liable, in the event adequate funds are not made available by the Sponsor for payment. Hence the applicant is only a pass through for the Sponsor and there is no actual payment by the applicant from his own account to the investigator or institution.

14.3 From the above, it can be concluded that the Clinical Testing Services is provided by the investigator and institution to the Sponsors and the CROs (including the applicant) are actually performing the Project Management function and for this the applicant is providing the project management service which is contracted between the CROs and also between the CRO and the sponsor.

15. Rule 33 of the Central Goods and Services Tax Rules states as under:

*"**33. Value of supply of services in case of pure agent.** – Notwithstanding anything contained in the provisions of this Chapter, the expenditure or costs incurred by a supplier as a pure agent of the recipient of supply shall be excluded from the value of supply, if all the following conditions are satisfied, namely, -*

(i) The supplier acts as a pure agent of the recipient of the supply, when he makes the payment to the third party on authorization by such recipient;

(ii) The payment made by the pure agent on behalf of the recipient of supply has been separately indicated in the invoice issued by the pure agent to the recipient of service; and

(iii) The supplier procured by the pure agent from the third party as a pure agent of the recipient of supply are in addition to the services he supplies on his own account.

Explanation. – For the purposes of this rule, the expression "pure agent" means a person who –

(a) enters into a contractual agreement with the recipient of supply to act as his pure agent to incur expenditure or costs in the course of supply of goods or services or both;

(b) neither intends to hold nor holds any title to the goods or services or both so procured or supplied as pure agent of the recipient of supply;

(c) does not use for his own interest such goods or services so procured; and

(d) receives only the actual amount incurred to procure such goods or services in addition to the amount received for supply he provides on his own account."

15.2 The agreement of Clinical Trial Services is verified and since the applicant satisfies all the conditions laid down in the Explanation to Rule 33, the applicant qualifies as a pure agent of the recipient of service, i.e. the Sponsor. He also satisfies all the conditions prescribed in rule 33 of the CGST Rules and hence the value of invoice raised by the applicant on the sponsor for making payment to the principal investigator and the institution would be excluded from the value of supply. **But this ruling has a caveat that this ruling is not a ruling on the nature of the supply of services by the principal investigator and the institution to the sponsor.**

16. On the question whether the Project Management Services provided by the applicant to the foreign affiliate is an export of services or not it is clearl that the Applicant is providing service to PAREXEL Prime located in the non-taxable territory. The location of the recipient of the service is outside India. The Applicant is supplying service in respect of the goods i.e. new drugs, which are physically made available to the investigator / institution who conducts the clinical trial, on behalf of the applicant, in order to provide the service. The Applicant contends that the services provided by them to the Parexel Prime amounts to export of services. In order to decide whether the said services amount to export or not, place of supply of service need to be determined. Section 97(2) of the CGST Act, 2017 empowers the Authority to give a Ruling on time and value of Supply. However it does not empower the Authority to examine the place of supply. In the absence of this provision

the Authority is not empowered to answer whether the activity undertaken by the applicant amounts to export or not.

17. In view of the foregoing, we rule as follows

RULING

1. The first question whether the services provided by the applicant to the foreign client amount to export of service cannot be answered as Section 97 of the CGST Act, 2017 does not empower the Authority to give Ruling on the Place of Supply of Goods or Services.

2. Regarding the "pass though expenses", the applicant acts as a "pure agent" in receiving amounts from the foreign clients and passing it on to the Local Research Institutions.

30/9/2019

(Harish Dharnia)
Member
MEMBER
Karnataka Advance Ruling Authority
Bengaluru - 560 009

(Dr.Ravi Prasad.M.P.)
Member
MEMBER
Karnataka Advance Ruling Authority
Bengaluru - 560 009

Authority For Advance Ruling ★ Karnataka, Bengaluru ★

Place: Bengaluru,
Date: 30.09.2019

To,

The Applicant

Copy to:

1. The Principal Chief Commissioner of Central Tax, Bangalore Zone, Karnataka.
2. The Commissioner of Commercial Taxes, Karnataka, Bengaluru.
3. Pr. Commissioner of Central Tax, Bangalore-East
4. The Asst. Commissioner, LGSTO-015, Bengaluru
5. Office Folder