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/80/2019
Dated: 24th September, 2019

Present:

1. Sri. Harish Dharnia,
   Additional 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 Asiatic Clinical Research Private Limited, 169/53, 14th Main Road, 1st Block East, Jayanagar, Bangalore 560 001
2.	GSTIN or User ID	29AAFCA0266N1ZE
3.	Date of filing of Form GST ARA-01	09.05.2018
4.	Represented by	Sri Lakshmikumaran and Sridharan Advocates,
5.	Jurisdictional Authority – Centre	Commissioner of Central Tax, Bangalore North.
6.	Jurisdictional Authority – State	LGSTO-020,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 HDFC18052900005346 dated 02.05.2018 2. Rs.5,000-00 under KGST Act vide CIN HDFC18042900435912 dated 30.04.2018

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

1. M/s Asiatic Clinical Research Private Limited, (hereinafter referred to as the 'Applicant'), GSTIN number 29AAFCA0266N1ZE, have filed an application for Advance Ruling under Section 97 of the CGST Act, 2017 read with Rule 104 of the CGST Rules 2017 and Section 97 of the KGST Act,

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

2. The Applicant is a private limited company engaged in the activity relating to the management of clinical trials on behalf of Asahi Kasei PharmaAmerica Corporation, USA (hereinafter referred to as AKPA). The applicant has sought advance ruling in respect of the following questions:

a) Whether the services provided by the applicant to the foreign client amounts to export of services and hence zero-rated under GST law; and
b) Whether the applicant acts as a 'Pure Agent' while receiving amounts from the foreign clients and passing it on to the Local Research Institutions.

3. The applicant states that Section 97(2)(b) of the KGST Act provides that the question in respect of which Advance Ruling is sought shall be inter-alia in respect of the taxability on goods or services or both of a transaction under the provisions of the GST Act. In the instant application for advance ruling, the applicant is seeking to determine the taxability of its transactions with the foreign sponsor and the local investigators. The applicant seeks clarity on whether it is exporting services in its transactions with AKPA and whether it acts as a pure agent between AKPA and the local investigators for the purposes of passing on their reimbursements.

4. Section 97 of the KGST Act, 2017 is as follows:

97. Application for advance ruling- (1) An applicant desirous of obtaining an advance ruling under this Chapter may make an application in such form and manner and accompanied by such fee as may be prescribed, stating the question on which the advance ruling is sought.
(2) The question on which the advance ruling is sought under this Act, shall be in respect of,
(a) classification of any goods or services or both;
(b) applicability of a notification issued under the provisions of this Act;
(c) determination of time and value of supply of goods or services or both;
(d) admissibility of input tax credit of tax paid or deemed to have been paid;
(e) determination of the liability to pay tax on any goods or services or both;
(f) whether applicant is required to be registered;
(g) whether any particular thing done by the applicant with respect to any goods or services or both amounts to or results in a supply of goods or services or both, within the meaning of that term.

The applicant contends that their application merits admissibility under Section 97(2) (b). The said provision relates to applicability of a notification issued under the said Act. The applicants question does not relate to applicability of a notification. Consequently the application does not survive under Section 97(2) (b) of the said Act. However the applicant has simultaneously, in their opening narration, stated that the question is in respect of taxability on goods or services or both of a transaction under the said Act. In this context we see that the applicant is duly registered under the KGST Act, 2017and is engaged in the supply of services from within the taxable territory as defined in the said Act. The Authority therefore considers

it appropriate to admit the Application under Section 97(2) (e) of the said Act and proceeds to examine the facts of the case.

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

a. The applicant states that they are engaged in providing global pharmaceutical development services including study management, clinical trial monitoring and other product development services in India. Asahi Kasei Pharma America Corporation, USA (AKPA) has filed an Investigational New Drug application with the United States Food and Drug Administration for the identified drug and has sponsored a clinical trial in India.

b. The applicant has entered into two main agreements with AKPA for the purposes of performing services related to study management and clinical trial monitoring:

1. Master Service Agreement: wherein the applicant is appointed by AKPA to undertake services required for conducting clinical trials for AKPA in India, in accordance with terms and conditions agreed upon in the Work Orders. Pursuant to Section 2 of the Master Services Agreement, the applicant has been entrusted with the responsibility to conduct clinical trials as the Clinical Research Organisation, on behalf of its principal, AKPA. Each Work Order includes detailed information concerning a given study, including a description of the specific services to be provided, project milestones and estimated time consumed to complete specific tasks.

2. Clinical Trial Agreement: This is a tripartite agreement between AKPA, the applicant and a Principal Investigator or an institution, which is typically a hospital conducting the clinical trial. Under this agreement, Institutions selected by the applicant and approved by AKPA agree to conduct the clinical trials in accordance with the terms and conditions of this agreement.

c. The applicant has entered into the Master Services Agreement on 23.05.2012 (hereinafter referred to as the 'Master Services Agreement' and copy of which is enclosed as Annexure 2) with AKPA wherein the applicant has undertaken to perform certain services required in relation to conducting the above mentioned clinical trials to be conducted in India on behalf of AKPA, in accordance with written work orders issued by AKPA from time to time.

i. The activities of the applicant are illustrated through Work Order No.1 dated 01.07.2012 (hereinafter 'Work Order'), issued

to the applicant by AKPA. In pursuance of Section 2 of the Master Services Agreement, the applicant has been entrusted with the responsibility to conduct clinical trials in India as the Contract / Clinical Research Organisation (hereinafter referred to as the 'CRO') on behalf of its foreign principal, AKPA, or hereinafter referred to as the "Sponsor".

ii. The Work Order inter alia specifies the following:

a. Scope of Work: This section of the Work Order details the role and responsibilities of AKPA and the applicant, with respect to clinical trials. These include study documentation preparation, study startup, Enrollment, Treatment and Close-out, Trial Management, Safety, Regulatory and Quality Assurance.

b. Study Budget: It stipulates the estimated project costs that may be incurred by the applicant in conducting Project "ART 123" which is designated as "Phase –III Trials" in India for a duration of 39 months in 6+2 sites, with a patient strength of 60. The various heads of expenditure that could be incurred in the course of performing the clinical trials have been detailed in this section/

c. Study Timeline: Stipulates the different start dates (month/year wise) for undertaking the various activities that are listed under the scope of work section.

d. Payment Schedule: The schedule contains the payment / consideration that AKPA has undertaken to pay the applicant for the various activities outlined in the scope of work and study budget, unless otherwise agreed to in writing by both the parties in the form of a change order to the Project Addendum. In terms of the payment schedule, AKPA has agreed to pay the applicant a sum of $856,758 as 'Direct Fees'.

As per the said Work Order, AKPA pays the applicant 11.4% of the total contract value as upfront payment, 1.1% of the amount due on execution of Work Order No.1, 5% of the amount as backend payment and the remaining amount on monthly and milestone basis.

iii. In addition to the above, in terms of Clause 6.2 of the Master Services Agreement, AKPA shall reimburse the applicant for the

documented travelling and pass through expenses that are necessary and reasonably incurred in the performance of the services recognised under the Agreement.

iv. Clause 6.2 of the Agreement is being reproduced here for reference:

"AKPA shall in addition reimburse **Asiatic** for documented travelling and pass through expenses that are necessary and reasonably incurred solely in the performance of the Service and as the direct result of a request from AKPA provided that Asiatic obtains AKPA's written consent prior to incurring any expense in excess of $1000 of this expense was not already listed in the Payment Schedule under pass through costs as described in Section 6.1."

v. Accordingly, the 'Direct Fee' includes an estimate for "Pass Through" Costs or reimbursable expenses incurred by Asiatic on behalf of AKPA.

d. Clinical Trial Agreement or the 'Tripartite Agreement'

i. In addition to particular Work Orders issued to the applicant, for the purpose of conducting clinical trials in India, the Tripartite 'Clinical Trial Agreement' (CTA) has been entered into by AKPA, applicant and the identified institution / investigators.

ii. In terms of the CTA,

a. The clinical trial will be conducted by and under the directions of the specified researcher or the 'Principal Investigator' (hereinafter referred to a 'PI'). Further, the sponsor shall have the right to approve the inclusion of any co-investigators or sub-investigators (or 'other clinical investigators') recommended by the Principal Investigator, in accordance with the Sponsor's policy as stipulated elsewhere in the CTA.

b. The PI will use his best efforts to enroll the requisite number of patients in the Clinical Trial. In addition to strictly adhering to the Protocol, the PI is required to exercise his independent medical judgment as to the suitability of each patient for the trial. (clause 3.5)

c. While conducting the clinical trials, it is the responsibility of the PI to comply with all the applicable government laws, rules and regulations, including those under the FDA (clause 3.7)

d. The PI and the Institution will maintain complete and accurate records of the status and progress of the clinical trials, maintain a Clinical Investigator's Study Site Binder

with all the required documents and retain organized original patient, laboratory and drug inventory records relating to the clinical trial for not less that fifteen years as per Schedule Y of the Drugs and Cosmetic Rules, 1945 (Clause 4).

e. The PI is entrusted with the responsibility of submitting a final report of the trial to the Ethics Committee within one month from the completion of such trial (clause 5.5)

iii. The above clauses would show that the actual clinical trial is conducted by the researcher / Principal Investigator and that the applicant does not have any role in the actual clinical trial.

iv. Clause 6 of the CTA stipulates that during the course of the Clinical Trial on a regular basis, the PI / Institution will permit the applicant to inspect all records kept or made by the PI and the institution of the clinical trial, including original patient records and test reports. However, PI / Institution will not be required to disclose any information which would permit identification of a patient enrolled in, or a candidate for, the clinical trial.

v. It is also submitted that in terms of clause 8.5 of the CTA, all payments to be paid to PI / Institutions from the Sponsor shall be paid through applicant. Further, such payments have been identified as pass-through payments from the Sponsor to applicant to the PI or candidate. The applicant does not have any obligation under the CTA to the PI until such payments are released from AKPA. The CTA also prohibits the PI / Institution from charging any study subject (i.e patient) or third party payer for any materials or for study procedures for which payment by the Sponsor or applicant will be made under the CTA.

vi. Clause 8.5 of the Agreement is being reproduced herein, for the ease of reference:

"All payments which are to be paid to investigative site from Sponsor shall be paid through Asiatic Clinical Research Pvt. Ltd. Institution and PI hereby acknowledge and agree that payments due under this agreement are pass-through payments from Sponsor and that Asiatic applicant shall have no payment obligations hereunder until such time as said payments are received by the applicant from sponsor. Asiatic shall exercise reasonable efforts to ensure timely receipt of pass through payments from Sponsor. It is expressly agreed between the parties that no payment of any form relating to the performance of the clinical trial, shall be made by sponsor directly to the Institution, the principal investigator or any trial site team

members. The Institution and Investigator will be responsible for making any payments in connection with the study to PI's employees or agents."

vii. The applicant submits that where the institutions / investigators raise the invoices for the services rendered by them, such invoices are directly raised in the name of applicant and the name of AKPA does not appear on the document.

viii. In the factual matrix discussed above, applicant is the organisation to whom the sponsor i.e. AKPA has entrusted the responsibilities of managing the conduct of the clinical trials in India, on behalf of AKPA.

ix. The applicant also submits they obtained the necessary approval from the Drugs Controller General of India to operate as a CRO in India as evident File No. CT/143/12-DCG(I) dated 20.08.2013 and the Clinical Trial Permission No. GCT/02/13.

x. The applicant submits that even though it is a commercial CRO, it is not authorised to undertake any of the functions entrusted to a qualified medical practitioner recognised as the 'investigator' and therefore, applicant is not authorised to administer the new drugs to human subjects, monitor their progress, control adverse effects, etc. The applicant can only monitor the functions entrusted to the investigators, encourage them to recruit more patients, upload information about the progress of the clinical trial as per the protocol and report to AKPA. Applicant cannot directly engage with the recruits or verify any document that would reveal their identity.

xi. The applicant submits that the applicant's role under the CTA is limited to two aspects –

1. Verification of records maintained by the PI and the institutions, monitoring the performance of such agencies with respect to the progress of the clinical trials; and

2. Passing the consideration received from AKPA to the investigators for the services rendered by the latter to AKPA.

xii. The applicant has tabulated and provided the details of the works and the same reads as under:

Sl. No.	Agreement	Parties to the Agreement	Payment Terms	Remarks
1	Master Services	AKPA and Asiatic	AKPA pays in pursuance to the	In this case, Asiatic receives

	Agreement		'Payment Schedule' of the Work Order. In addition, it also gives Asiatic 'pass through' expenditure.	consideration for the services it provides to AKPA, i.e. for managing the clinical trials undertaken through a PI.
2	Work Order	AKPA and Asiatic	The agreement specifies a budget including the costs for Study Document Preparation, Enrolment, treatment and close out costs etc. payable by AKPA to Asiatic	In this case, Asiatic receives consideration for the services it provides to AKPA.
3	Clinical Trial Agreement	Asiatic, AKPA and Institution / Principal Investigators	All payments to be paid to Institutions / Principal Investigators shall be paid through Asiatic from AKPA. Asiatic is not liable for any payment obligation towards the Institutions / Principal Investigators	In this case, Asiatic is not in receipt of any consideration, whereas it only passes on the cost to the Investigators / Institutions from AKPA.

6. In the backdrop of the above facts, the amounts received from AKPA by the applicant can be grouped under two categories viz., the consideration for the services of managing the clinical trial and the amount to be paid to the investigators who actually perform the trials.

7. The applicant states that he is of the view that the former amounts to export of service and in the latter the amount is related to the supplies of the investigators and the applicant merely acts as a pure agent. Hence the Applicant's transactions are not leviable to tax under GST acts.

8. Regarding the issue of the activities of Master Service Agreement and in support of its understanding that the applicant exports its services to AKPA and acts as a pure agent in the transactions between AKPA and the investigators, the applicant submits as under:

(a) In the factual matrix discussed above, Applicant is the Organisation to whom the Sponsor i.e. AKPA has entrusted the responsibilities of managing the conduct of clinical trials in India, on behalf of AKPA.

(b) Even though Applicant is a commercial CRO, it is not authorised to undertake any of the functions entrusted to a qualified medical practitioner recognised as the 'investigator' and therefore, the applicant is not authorised to administer the new drugs to human subjects, monitor their progress, control adverse effects etc.

(c) Section 7 of CGST Act defines 'Supply' to mean and include all forms of supply of goods or services or both such as sale, transfer, barter, exchange, license, rental, lease or disposal made or agreed to be made for a consideration by a person in the course or furtherance of business.

(d) The transaction between the applicant and AKPA is a supply of service from the applicant towards AKPA, for which it is in receipt of consideration on terms agreed upon. Therefore, as per Section 7 of the Central Goods and Services Tax Act 2017, the applicant is a supplier of service to AKPA, as it is a transaction of supply of service against a consideration, in the course or furtherance of business.

(e) As per the scope of work undertaken by the applicant under the Master Services Agreement / Work Order, the CRO is responsible for obtaining licenses for the import of new drugs from the concerned authorities including the Drugs Controller General of India, identifying investigators/ monitoring their activities in terms of uploading test results, encouraging them to recruit more patients etc. Thus, the activities of the applicant are in the nature of Project Management and not directly involving the clinical trial activity.

(f) Nowhere in the course of facilitating the trials, the applicant has access to the goods i.e. the imported drugs; neither does the applicant handle such goods nor does it perform any activity in relation to such goods. In fact, the regulatory compliance and other related activities as indicated above have to be undertaken prior to the import of the drug into India.

(g) In terms of Section 13(3) of the IGST Act, the specific provision pertaining to 'services supplied in respect of goods which are required to be made physically available by the recipient of services' would not be applicable, as the applicant does not itself handle any of the drugs imported.

(h) In light of the fact that the transaction does not fall under Section 13(3)(a) of the IGST Act, or any other specific provision of the said Section 13, the default provision i.e. Section 13(2) of the IGST Act will apply to determine the Place of Supply of the services, as per which provision, the place of provision of service shall be the location of the 'recipient of service'.

(i) In the instant case, AKPA has its fixed establishment located outside India and, therefore, the place of provision of service is outside India.

(j) In this case, the applicant submits that the case of the applicant is solely reliant on the fact that it only manages and monitors the trial and does not provide the services itself. The clinical trials are only managed by the applicant and nothing more than that.

(k) 'Export of Services' is defined under Section 2(6) of the IGST Act, as the supply of any service when, -

i. The supplier of service is located in India;

ii. The recipient of service is located outside India;

iii. The place of supply of service is outside India;

iv. The payment for such service has been received by the supplier of service in convertible foreign exchange; and

v. The supplier of service and the recipient of service are not merely establishments of a distinct person.

(l) In the instant case, the applicant has submitted that these conditions are satisfied, as educed in the table below:

Sl No.	**Conditions to be satisfied for 'export of service'**	**Examination of the condition in case of Applicant**
1.	The supplier of service is located in India;	Applicant, the supplier of service is located in India
2.	The recipient of service is located outside India;	E.1 The recipient, AKPA, is located outside India
3.	E.1 The place of supply of service is outside India;	E.2 The place of supply of service, as examined above, is outside India
4.	E.1 The payment for such service has been received by the supplier of service in convertible foreign exchange; and	E.2 The payment terms and the invoices raised indicate that the payment of such service has been received by Applicant in convertible foreign exchange, in this case, US Dollars

5.	E.1 The supplier of service and the recipient of service are not merely establishments of a distinct person.	E.2 Applicant and AKPA are not merely establishments of distinct persons

(m) In light of the above, the applicant submits that the activities under the Master Services Agreement / Work Orders qualify as an export of service under the IGST Act.

(n) Therefore, the applicant submits that the services rendered by the applicant to AKPA under the Master Services Agreement / Work Order issued there under constitute export of service. As per Section 16 of IGST Act, this would constitute to be a zero-rated supply and therefore, the applicant would not be liable to pay IGST on the consideration comprising of the Direct Fee & the pass-through fee and seek refund of the unutilised input tax credit pertaining to such supplies.

9. Regarding the argument that the activity of the applicant is that of a pure agent between AKPA and the Investigators / Institutions, the applicant submits as under:

9.1 It is submitted that the consideration for Applicant undertaking monitoring of the trials / coordination with PI and institutions is included in the payment schedule within the work order itself. There is no separate consideration flowing for the aforesaid activity under the second agreement to the Applicant, as is evidenced in the Clause 8.5 of the Clinical Trial Agreement.

9.2 However, AKPA does not directly pay any institutions / investigators and the contractual responsibility rests solely with Applicant to make timely payments to the institutions / investigators.

9.3 Clause 8.5 of the Agreement is being reproduced herein, for the ease of reference:

> "All payments which are to be paid to investigative site from Sponsor shall be paid through Asiatic Clinical Research Pvt. Ltd. Institution and PI hereby acknowledge and agree that payments due under this Agreement are pass-through payments from Sponsor and that Asiatic shall have no payment obligations hereunder until such time as said payments are received by Asiatic from Sponsor. Asiatic shall exercise reasonable efforts to ensure timely receipt of pass through payments from Sponsor. It is expressly agreed between the parties that no payment of any form relating to the performance of the clinical trial, shall be made by sponsor directly to the Institution, the principal

investigator or any trial site team members. The Institution and Investigator will be responsible for making any payments in connection with the Study to PI's employees or agents."

9.4 Rule 33 of the Central Goods & Services Tax Rules, 2017 provides for the concept of Pure Agent, wherein it provides that 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.

9.5 For a service provider to be a pure agent, the following conditions are required to be satisfied in terms of the said Rule 33.

i. The supplier acts as a pure agent of the recipient of the supply, when he makes 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, "pure agent" means a person who -

i. 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;

ii. 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;

iii. does not use for his own interest such goods or services so procured; and

10. In the instant case, the applicant submits that the conditions prescribed for a pure agent are fulfilled as under:

No.	Condition in Rule 33	Examination of the condition in case of Applicant
1.	The supplier acts as a pure agent of the recipient of the supply, when he makes payment to the third party on authorization by such recipient;	Applicant makes payment to the Investigators on the authorization by AKPA, as is evidenced by Para 8.5 of the Clinical Trial Agreement
2.	The payment made by the pure agent on behalf of the recipient	Applicant also indicates separately the payment made by it to the

	of supply has been separately indicated in the invoice issued by the pure agent to the recipient of service; and	Investigator, on the invoice it raises to AKPA, who is the recipient of the service.
3.	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.	As can be seen by the nature of the contractual relation of Applicant and AKPA, which is bound by both the MSA and CTA, it can be said that the supplies provided by the Investigators i.e. conduct of the clinical trial, are in addition to the services it supplies on its own account i.e. the management of the clinical trial including obtaining various statutory approvals for AKPA, on its behalf in India.
"Pure agent" means a person who		
4.	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;	Applicant has entered into a contractual agreement with AKPA to act as his pure agent to incur expenditure or costs towards the conduct of clinical trials by the investigators
5.	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;	Applicant also neither intends to hold nor holds any title to the goods or services or both supplied by the Investigators
6.	Does not use for his own interest such goods or services so procured; and	Applicant also does not use for his own interest such goods or services so procured;
7.	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	Receives only the actual amount incurred to procure such goods or services of the investigators apart from the amount received for supply he provides on his own account

11. Accordingly, it is submitted by the applicant that this cost incurred by him, and reimbursed by AKPA as a pure agent, is excluded from value of supply and hence the applicant is not liable to discharge any GST on the amount received for payment to the Investigators.

12. In the above factual position and based on the above submissions, the applicant has requested that a ruling may be given by this Hon'ble Authority for Advance Ruling stating that

i) the activity undertaken by the Applicant with AKPA qualifies to be an 'Export of Service', and that it acts as a pure agent in the case where it passes on costs to the Investigators

ii) No GST is payable on consideration received by Applicant as Direct fee and pass through fee and also on account of payment towards the PIs, as a pure agent.

13. Sri. G. Shivadass, advocate, M/s Lakshmikumaran & Sridharan, Advocates, appeared on behalf of the Applicant, on obtaining the authorization from the Applicant.

14. We have considered the submissions made by the Applicant in their application for advance ruling as well as the submissions made by their Authorised Representative, during the personal hearing. We have also considered the issues involved on which advance ruling is sought by the applicant and relevant facts of the issue involved.

14.2 The applicant is a contract research organization engaged in providing pharmaceutical development services. In the instant matter the applicant explains that they are providing Clinical trial management services to AKPA based in USA. These services involve representing AKPA before the statutory authorities for various approvals, planning of the trial, coordinating with the Investigators, closing the trial etc. The applicant receives certain predefined charges for performance of these activities. The applicant considers these services as export of services and therefore holds that they are not liable to pay GST. The applicant further emphasizes that the Clinical Trials are conducted by Principal Investigators or Institutions and their own role is limited to monitoring of the trial. In respect of these activities the applicant considers themselves as the pure agents of AKPA and therefore holds the belief that they are not liable to pay GST on the costs involved in the Clinical Trials.

14.2 The applicant has entered into a master service agreement, which is dated 23.05.2012, with the AKPA, USA wherein the applicant has undertaken to perform certain services required in relation to conducting clinical trials in India through the Institutions / Principal Investigators, in accordance with written work orders issued by AKPA from time to time.

14.3 Clinical Trials in India are governed by The Drugs & Cosmetics Act 1940 and The Drugs & Cosmetics Rules 1945. Rule 122 of The Drugs & Cosmetics Rules 1945 read with Schedule Y deal with the requirements and guidelines for obtaining permission to import new drugs and to undertake clinical trial of the same in India. In the instant case the **Clinical Trial**

Permission has been obtained by the Applicant vide permission GCT/02/2013 dated 20.08.2013, from the Drugs Controller General (India), Directorate General of Health Services, Government of India, subject to certain conditions, as enumerated at **(a)** to **(k)** in the said permission letter. Copy of the said letter has been furnished by the Applicant. The Directorate General of Health Services has accorded permission to the Applicant to conduct the clinical trial, as requested by the Applicant, as per the provisions of Drugs & Cosmetics Rules under the supervision of any of the approved investigators. In their 'Clinical Trial Permission' the competent authority has stated, inter alia, that '*...This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetic Rules under the supervision of the investigators mentioned below....*'. This enumeration is quite significant. The law recognizes the applicant as the entity engaged in the activity of Clinical Trials, albeit under the supervision of qualified and approved Investigators. All legal obligations and consequences arising out of the Clinical Trials rest on the applicant, as enumerated at (a) to (k) in the Permission letter. Further Rule 122 A requires that a licence has to be obtained from the competent authority for the import of new drug for clinical trial. Therefore anyone desirous of conducting Clinical Trials has to obtain permission to import the drugs also. The applicant has not clarified anything in this regard.

14.4 The Drugs & Cosmetics Act 1940, vide Section 12, stipulates that a licence is mandatory for import of new drugs and to undertake clinical trial of the same in India. In the instant case, the Applicant has not furnished copy of any such licence to import the drugs and also not furnished copy of any of the Bills of Entry showing the import of the drugs. However since the Clinical Trial Permission was granted under the provisions of the Drugs & Cosmetics Rules by the competent authority to the applicant only the applicant was eligible to obtain licence for the import of the drugs. In this regard we observe that though the applicant has stressed that they neither handle the new drugs nor perform any activity in relation to the same, they have also not submitted any documents like copy of the licence or the Bill of Entry to substantiate their claim of non-handling the import of new drugs. In the absence of documents to the contrary and in accordance with the provisions of the Drugs and Cosmetic Rules we are inclined to observe that the applicant was responsible for the import of drugs and their supply to the investigators. Having regard to the observation that the applicant is recognized as the person conducting the clinical trials and is licenced to import the new drugs for trials we now examine the agreements.

14.5 The Applicant, through Master Services Agreement, has been appointed by AKPA, USA to undertake services required for conducting

clinical trials for AKPA in India. Also as admitted by the applicant, in terms of Section 2 of the said agreement the Applicant is responsible to conduct clinical trials as the Clinical Research Organisation, on behalf of AKPA, USA, in terms of work order. The Applicant is supposed to conduct the clinical trial as per the provisions of Drugs & Cosmetics Rules, under the supervision of the investigator/s, for which reason the applicant enters into tripartite agreement with Institution/Investigator, AKPA, even though the Applicant is solely responsible for the conduct of the clinical trial. It is pertinent to mention here that the Applicant obtains all the necessary approvals in India on their name for conducting the said clinical trials.

14.6 In view of the above, the applicant is licensed to import new drugs, on obtaining the necessary approval from the competent authority, which are tangible materials and use the same for conducting the clinical trials, through the investigator/institution. The total cost of the clinical trial i.e, Total contract value is paid by AKPA, USA to the Applicant and the applicant pays the required amounts to the investigator/institution, on obtaining the approval from the AKPA, USA. Further, in terms of clause 6.6 of the Master Services Agreement, the Applicant is responsible for all tax liabilities or similar contributions with respect to any amount paid. Therefore it is beyond doubt that the Applicant is responsible for conduct of the clinical trial in India. Also in terms of Attachment 1 to the work order i.e. Scope of work, the Applicant is responsible to complete drug accountability and to return the unused study drug from investigators.

14.7 In view of the above, it is clearly evident that the Applicant is providing service to AKAP, USA in the instant case. 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 contended that the services provided by them to the AKAP, USA 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 constrained to answer whether the activity undertaken by the applicant amounts to export or not.

15. The second issue before us to decide is whether the applicant acts as a Pure Agent while receiving the amounts from foreign client and passing on the local Reseach Institutions or not?

15.1 The Applicant, as discussed supra while discussing the first issue, is the licence holder for conducting clinical trial through any of the approved Investigator of an institution and also mandatorily obtain a licence to import the goods i.e new drugs meant for clinical trial in India. Therefore the applicant is the responsible person for the said clinical trial, being carried out through the investigator. The total contract value is paid to the Applicant on the basis of progress in the work i.e. clinical trial and the applicant pays the relevant amounts to the investigator / institute on the basis of completed work assessed by the applicant and approved by the AKAP, USA.

15.2 The concept of "Pure Agent" is explained under Rule 33 of CGST Rules 2017. The expression "pure agent", for the purpose of the said rule means ***a person who 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***. In the instant case, at clause 3.2 of the Master Service Agreement it is clearly mentioned that in no sense the Applicant shall be considered as an employee or agent of AKPA, USA. Therefore it seems that the first condition only is not fulfilled and hence the applicant is not liable to be considered as a pure agent of the recipient of the service i.e AKPA, USA.

15.3 A pure agent actually incurs the expenditure under the contractual agreement and then gets the reimbursement of the same. In the instant case the applicant is not incurring any expenditure but disbursing / paying the charges to the investigator / institution on the basis of the work progress assessed by the applicant and approved by the AKPA, USA.

15.4 The Master Services Agreement defines the following terms as under:

*(a) "**Materials**" – all tangible materials made available by or on behalf of AKPA to Asiatic or where the context admits generated by or on behalf of Asiatic in contemplation of prior or pursuant to this Agreement or in the course of performing the Service, including but not limited to, any drawings, documents, designs, models, records, reports, specifications, disks and tapes;*

*(b) "**Results**" – all knowhow, materials and other intellectual property generated or otherwise arising from services performed by Asiatic;*

*(c) "**Work Order**" – the written agreement between the Parties detailing the specific Service to be performed by Asiatic in connection with a particular study. Each Work Order shall include a*

description of the specific Services to be provided, the time lines to perform the Services, the costs associated with the Services and the related Payment Schedule and it specifically incorporates by reference the terms and conditions of this Agreement."

*(d) "**Service**" –the service participation and assistance of Asiatic in respect of AKPA's development projects and all such work undertaken by Asiatic for and at the request of AKPA as delineated in the Work Order under this Agreement and their amendments thereto.*

*(e) "**Study**" – the clinical trial of the investigational product or compound identified in the Work Order.*

15.5 Further, in para 2.1 of the Master Services Agreement, it is mentioned that each Work Order shall constitute a separate agreement, provided that the terms of the said agreement shall be incorporated in each Work Order by reference. Furthermore, in para 2.2, it is mentioned that Each Work Order will include detailed information concerning a given Study, including a description of the specific Services to be provided ("Scope of work"); project milestones, and estimated time consumed to complete specific tasks, either in parallel or sequential (each a "Project Timeline"); a detailed budget ("Project Budget"), wherein the budget will separately address the estimated pass-through costs and professional service fee; and a "schedule of payments" related to the Scope of Work, Project Timelines and the Project Budget ("Payment Schedule"); all of which will be signed by an authorised representative of each Party. Hence from the above, it is clear that each Work Order would constitute a separate contract within the framework or guidelines of the Master Services Agreement.

15.6 Further, the para 3.2 of the Master Services Agreement states that each Party shall be acting as an independent contractor and neither party is granted any right or authority to assume or to create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other party. Further in the same para, it is clearly stated that neither Party shall represent itself as the other Party's agent nor use the name of the other Party or any of its affiliates in any publication without the prior written consent of the other Party.

15.6 As per para 3.6, the applicant is bound to arrange for qualified personnel to support its obligations under the Master Services Agreement and the key elements of the Services shall be performed by qualified and trained personnel as specified in the Work Order. Further it is also made clear that the applicant will delegate responsibilities of the study to Asiatic

personnel or AKPA approved subcontracted personnel and take ownership of the performance of their resources. Further, in para 3.7 it is made clear that any regulatory inspection of the applicant, conducted any regulatory authorities should be promptly notified to the AKPA and the applicant will have to consult with and allow AKPA to review and comment on any responses to such agency related to the inspection. Further any expenses related to such regulatory inspection or audit or any other action would be invoiced to AKPA as CO.

15.7 The para 5.1 of the Master Services Agreement makes it clear that the applicant acknowledges and agrees that

(a) all materials and all confidential information of AKPA received by the applicant and

(b) all results, improvements, ideas or information composed and generated by the applicant with respect to the assigned scope of work for the project

- shall be deemed to the exclusive property of AKPA.

15.8 Para 6, which relates to the Fees and Expenses, states that "in consideration of Asiatic performing the Services to AKPA's reasonable satisfaction which is judged and should be ascertained within a given point of time, AKPA agrees to pay to Asiatic pursuant to the "Payment Schedule" as set out in the Work Order. Further, the AKPA shall also in addition reimburse the applicant for documented travelling and pass-through expenses that are necessary and reasonably incurred solely in the performance of the Service and as the direct result of a request from AKPA provided that Asiatic obtains AKPA's written consent prior to incurring any expense in excess of $1000 if this expense was not already listed in the Payment Schedule under pass through costs as described in Section 6.1.

15.9 Coming to a sample work order provided by the applicant, it is seen that the work order refers to the Master Services Agreement. There is a separate scope of work, Study Budget, Study Timeline and Payment Schedule for each of the Work Orders thus making it a separate contract. The sample work order has the following tasks under the scope of work:

(a) Study Document Preparation – under this the applicant has the role of printing and distributing the documents and Study Reference Manuals and provide certain inputs to the AKPA to develop a plan

(b) Study Start up – under this the applicant facilitates execution of CDA distribution to sites, distributes, review and tract feasibility questionnaires sent to sites, to perform site qualification visits, to complete packet for final review of the AKPA, set up study wise and

individual investigator files for their region, etc. The applicant has to pay the sites monthly, once the invoice is approved by AKPA.

(c) Enrolment, treatment and close-out – The applicant is to perform interim monitoring visits and booster visits and report the results to AKPA and has to accompany AKPA personnel whenever they visit the sites. The applicant is also required to perform the close out visits, reconcile all hard copies of the study files and to complete the drug accountability from site to AKPA and the unused study drug shipment to depot would be the responsibility of the applicant and the applicant would transfer inventory and hard copies of the binders to AKPA.

(d) Trial Management – In this the applicant has to work with third parties and provide project communication and status reports to AKPA. They have to review trip reports before its submission to AKPA. The applicant will also be responsible for monitoring drug at the site and escalating any issues or concerns to AKPA.

(e) Safety – the applicant is required to review site's SAE submission documents to Sponsor, EC and CDSCO for initial and follow up reports and collate SAE causality assessment and relevant documents, prepare submission dossiers and submit it to CDSCO for initial and follow up reports, after obtaining prior approval of AKPA. They are also required to draft and collate SAE response documents to CDSCO queries. They are also required to generate annual study reports and collate supporting documents.

(f) Regulatory – The applicant is to act as AKPA's regulatory agent for India CDSCO for submission and follow up protocol approvals, site additional approvals, site deletion notifications, import permit approval, export permit approvals, audit response submission, CTA/financial notifications, EC approval notifications, notifications of revised IB, notification of DMC MON, notification of other country regulatory approvals for every protocol amendment, notification regarding insurance renewal, co-ordinate and facilitate unblinding requests and responses, facilitate regulatory inspections, any other correspondence.

15.10 Relating to invoicing and payments, the applicant would issue invoices as milestones are achieved to AKPA and the applicant would administer payments to Investigators on a monthly basis during the course of study and AKPA approval of payments would be required in advance of the applicant's payments issued to investigators. The most important part of the contract is the following, which is reproduced as it is:

"AKPA will pay Asiatic Seventy Five Thousand US Dollars ($75,000) upon receipt of invoice from Asiatic to facilitate prompt and timely payments to investigators. Concurrent with Asiatic's issuance of Investigator's payments, Asiatic will invoice AKPA for the same amount to insure the initial US $ 75,000 payment is replenished. If the balance is not sufficient to make timely payments to Investigators, Asiatic will request additional monies. If the balance is greater than needed, Asiatic will reduce the advance by requesting a lower replenishment amount. AKPA acknowledges and agrees that payments for Investigator's services are pass-through payments to third parties and are separate from payments to Asiatic's services. AKPA agrees that it will not withhold Investigator's payments except to the extent that it has reasonable questions about the services performed by a particular Investigator."

16. **Clinical Trial Agreement**:

16.1 On verification of the clinical trial agreement, it is seen that the agreement is entered between

(a) Asahi Kasei Pharma America Corp. (sponsor)
(b) Institution where the clinical trial is conducted
(c) Principal Investigator – who is conducting the trial
(d) The applicant

16.2 In this it is clearly mentioned that the applicant is the local contract research organisation (CRO) of the sponsor in India and working with the institutions and the respective investigators. The applicant would perform services related to the study management and monitoring of the Clinical Trial. Further, it is also mentioned that the institutions are selected by the applicant and are approved by the Sponsor. Further, it is stated that in the agreement that the Sponsor is and shall at all times remain the sole owner of the product. The sponsor would provide the institution with the required quantities of the product, at no charge, for the institution to conduct the Clinical Trial. The Institution shall maintain a stock account of the product and return any unused materials.

16.3 It is also clearly stated that the Principal Investigator and the Institution acknowledges that the Sponsor is the owner of the electronic Case Report Forms (eCRFs) and the final report is prepared by the Institution and all information contained therein. The eCRFs and final

report may be used by Sponsor in any manner whatsoever in compliance with all federal, state or local laws, rules and regulations.

16.4 The role of the applicant is only to inspect the records kept or made by Principal Investigators and Institutions of the Clinical Trial. The compensation is worked out as under:

(a) Maximum Payment per Patient: The applicant would pay the Principal Investigator or Institution the maximum payment per patient as per the agreed amount for each patient who completes the treatment and evaluations specified in the Protocol and for whom Principal Investigator completes that patient's (eCRF)

(b) Partial Payment: The applicant would pay Institution on a per visit basis in accordance with the budget attached as per the agreed amount for each patient and the payment is contingent upon completion of the eCRFs and acceptance by Sponsor.

(c) Payment: All Payments which are to be paid to investigative site from Sponsor shall be paid through the applicant. Institution and Principal Investigator acknowledges and agrees that payments due under this Agreement are pass-through payments from the sponsor and that the applicant shall not have any payment obligations hereunder until such time as said payments are received by the applicant from the Sponsor.

16.5 On analysis of the above terms of the contract, it is evident that the Principal Investigators and the Institutions are selected by the applicant and they are ratified by the Sponsor. What follows is the agreement between the Sponsor, Principal Investigator, Institution and the applicant and there is a contract for provision of service by the Principal Investigator and Institution to the Sponsor. The payment for the services is made by the Sponsor to the Principal Investigator and the Institution through the applicant. The applicant is only a pass through for the sponsor to make payments to the Principal Investigator and Institution as per the agreement.

17. In case of the services of clinical trial, the applicant is holding the money of the sponsor as advance and money is paid as per the milestones on the strength of invoices issued by the Principal Investigators and Institutions. The applicant issues invoices against the sponsor and collects the money and maintains a required balance project wise and makes the payments out of this fund as a pass-through, after approval of the sponsor.

17.1 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."

17.2 A close look at the various agreements brings forth the point that the applicant themselves do not conduct the actual clinical trials. The trials are conducted by Institutions and Principal Investigators. In respect of the payments to be made to these Institutions or Principal Investigators the agreement provides that the Sponsor shall make the payment to the applicant and the applicant will pass on the payment to the Institutions or Principal Investigators once the Sponsor is satisfied with the work.

17.3 The first condition for a pure agent, as indicated at (a) in Explanation to Rule 33 requires the applicant to incur expenditure or costs in the course of supply of the services. The agreement provides that the applicant will not make any payments to the service providers, i.e. the Institutions and/or Principal Investigators, till the Sponsor is satisfied about the quality of work done by the Institutions and/or Principal Investigators. The applicant receives the money and holds it back till the sponsor gives

clearance. Therefore the applicant does not incur any expenditure. The applicant receives the amount and then transfers it to the Institutions and/or Principal Investigators. The other three conditions required for a pure agent at (b), (c) and (d) are complied with by the applicant.

17.4 Taking into consideration the terms of the agreements and the facts of the case it is clear that when the applicant was engaged by the sponsor it was known to the sponsor that the applicant was not capable of conducting the clinical trials themselves and that the same would have to be carried out by a third entity. In other words the fact that the clinical trial services would have to be performed by another person was known to the service recipient. Accordingly after the Institutions and/or Principal Investigators were identified the tripartite agreement was prepared. The applicant receives the required amount and the same amount is transferred to the Institutions and/or Principal Investigators. This amount is besides the amount that the applicant receives for the services provided by them. The only infarction is that the pure agent is required to incur the expenditure and recover the same later and in this case the payment is made to the Institutions and/or Principal Investigators only after the same is received from the Sponsor. We see that this arrangement does not change the nature of a pure agent as long as the amount received is completely transferred to the Institutions and/or Principal Investigators for their services.

17.5 The on examination of the agreement of Clinical Trial Services 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. However 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.

18. 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. In respect of question 2 it is Ruled that the applicant qualifies to be a Pure Agent in receiving amounts from the foreign clients and passing it on to the Local Research Institutions, as provided in the agreements placed before the Authority.

24.09.2019

(Harish Dharnia)
Member (Centre)

MEMBER
Karnataka Advance Ruling Authority
Bengaluru - 560 009

(Dr. Ravi Prasad.M.P.)
Member (State)

MEMBER
Karnataka Advance Ruling Authority
Bengaluru - 560 009

Place: Bengaluru

Date: 24.09.2019

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. Commissioner of Central Tax, Bangalore-North
4. The Asst. Commissioner, LGSTO-020, Bengaluru
5. Office Folder

Authority For Advance Ruling ★ Karnataka ★