

**THE AUTHORITY FOR ADVANCE RULING
IN KARNATAKA
GOODS AND SERVICES TAX
VANIJYA THERIGE KARYALAYA, KALIDASA ROAD
GANDHINAGAR, BENGALURU - 560 009**

**Advance Ruling No. KAR ADRG 24/ 2020
Dated : 23-04-2020**

Present:

1. Dr.M.P.Ravi Prasad
Addl. Commissioner of Commercial Taxes Member (State Tax)
2. Sri.Mashhood Ur Rehman Farooqui,
Joint Commissioner of Central Tax, Member (Central Tax)

1.	Name and address of the applicant	M/s DKMS BMST Foundation India, New Thippasandra Main Road, HAL 3 rd Stage, Bengaluru, Karnataka - 560 075
2.	GSTIN or User ID	29AAGCB4824Q1Z2
3.	Date of filing of Form GST ARA-01	29.11.2019 revised on 28.02.2020
4.	Represented by	Sri.Ravi Banthia, Chartered Accountant and Duly Authorised Representative
5.	Jurisdictional Authority - Centre	-----NA-----
6.	Jurisdictional Authority - State	Assistant Commissioner, VAT Sub- Office, LVO-045A, Bengaluru
7.	Whether the payment of fees discharged and if yes, the amount and CIN	Yes, discharged fee of Rs.5,000-00 under CGST Act vide CIN No. RBIS19112900465544, dtd. 29.11.2019 and Rs 5,000-00 under SGST Act vide CIN No. RBIS19112900434846 dtd 26.11.2019

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

1. M/s DKMS BMST India Foundation, having GSTIN number 29AAGCB4824Q1Z2, have filed an application for Advance Ruling under Section 97

of the CGST Act, 2017 read with Rule 104 of CGST Rules, 2017 and 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/- each under the CGST Act and the KGST Act.

2. The applicant is a company registered under the provisions of the Goods and Services Act, 2017. The applicant states that they are a not for profit organisation facilitating the treatment of blood cancer and other blood disorders by promoting awareness and encouraging people to register as a potential blood stem cell donors as well as facilitating the process of blood stem cell donations.

3. The applicant has sought advance ruling in respect of the following questions:

1. *Whether in the facts and circumstances of the case, DKMS BMST Foundation India is liable to pay Integrated Goods and Services Tax on the Human Leukocyte Antigen ('HLA') testing services performed by the overseas laboratory outside India on the Human Buccal Swabs sent by DKMS-BMST from India?*

Later at the time of personal hearing, he has modified the question and sought the advance ruling on the following questions:

1. *from the overseas laboratory falls under the definition of health care services by a clinical establishment, thereby exempt from the tax leviable thereon and accordingly not taxable in the hands of DKMS-BMST/*

Notwithstanding the outcome of Question 1, whether in the facts and circumstances of the case, DKMS BMST Foundation India ('DKMS BMST') is liable to pay Integrated Goods and Services Tax on the testing services performed by the overseas laboratory outside India on the Human Buccal Swabs sent by DKMS BMST from India?

4. The applicant furnishes some facts relevant to the stated activity.

a. The applicant states that they are a joint venture of two reputed non profit organisations, BMST (Bangalore Medical Services Trust) and DKMS, one of the largest international, not for profit blood stem cell donor centres in the world. DKMS-BMST is a company incorporated under section 8 of the Companies Act, 2013, and has obtained certificate of incorporation ('COI')



bearing certificate no. U74900KA2015NPL082065 dated 6th of August, 2015.

- b. DKMS-BMST is a charitable organisation and has obtained certificate w.r.t. section 12-AA(1)(b) of the Income Tax Act, 1961 and an approval under section 80G(5)(vi) of the Income Tax Act, 1961.
- c. A 'prior permission' under Foreign Contribution Regulation Act ('FCRA'), 2010 to receive foreign contribution is provided to a not for profit organisation. DKMS-BMST, being a not for profit organisation, has received a 'prior permission' under FCRA,2010 for the receipt of foreign contribution in the nature of cash donations / funding by way of foreign share capital from DKMS, Germany. The permission was granted in August 2017 and is valid for a period of 5 years.
- d. DKMS-BMST facilitates the treatment of blood cancer and other blood disorders across the globe by promoting awareness and encouraging people in India to register as potential blood stem cell donors as well as facilitating the process of blood stem cell donations for donors identified in India. Given that DKMS-BMST is a not for profit organisation, it recovers minimal from the patients and thus to continue its operations, it receives cash and kind donations from entities in India and outside.
- e. With more than 1300 persons succumbing to cancer every day in India, it has become one of the major causes of death occurring in the country due to communicable and life-style ailments. As per data of the National Cancer Registry Program of the India Council of Medical Research (ICMR), the estimated mortality rate due to cancer saw an increase of six per cent approximately between 2012 and 2014. Every five minutes, someone in India is diagnosed with Blood cancer or other blood related disorders. Blood Cancer accounts for 8% of all new cases of cancer diagnosed in India. For these diagnosed, their lives will be irrevocably changed. Some will need months of intensive therapies and others will need lifelong treatment. Studies suggest that India ranks 3rd highest in reported cases of Blood Cancer, after the US and China and affects more than 70,000 men and



women in the country. This growing burden is a serious concern for public health administrators in India.

f. The aim of DKMS-BMST is to improve the situation of patients suffering from blood cancer and other blood disorders in India and throughout the world, by raising awareness about blood stem cell transportation and registering potential blood stem cell donors. Blood cancers (like leukemia, lymphoma, myeloma, myelodysplastic syndrome and myeloproliferative disorders) is one of the most common cancers and affects the production of blood cells and their many functions, such as fighting off infections or preventing serious bleeding. Most of these cancers start in the bone marrow where blood is produced.

g. The stages of blood cancer are divided on the basis of metastasis. There are different scales to determine different stages, according to the symptoms and rate of metastasis. Mainly the stages of blood cancer have been divided into four parts:

(i) Stage 1: The blood cancer 1st Stage includes the enlargement of the lymph nodes. This happens because of the sudden increase of the number of the lymphocytes. The risk at this stage is very low as the cancer is not yet spread or affected any other physical organ.

(ii) Stage 2: In the blood cancer 2nd Stage, spleen, liver and lymph nodes get enlarged. It is not necessary that all these organs get affected at the same time; however, this stage includes one of these organs for sure. The growth of the lymphocytes is very high in this stage.

(iii) Stage 3: In the blood cancer 3rd Stage, anemia develops in the third stage and above-mentioned organs are still found enlarged. It is sure that more than two organs get affected in this stage.

(iv) Stage 4: The blood cancer 4th Stage is the last stage with the highest risk ratio. The rate of blood platelets starts falling rapidly. The cancerous cells start affecting the lungs including the other organs which already started getting affected in the earlier stages. Anemia, in this stage, is more likely to be acute.



h. Treatment for blood cancer depends on the type of cancer, the patient's age, how fast the cancer is progressing, where the cancer has spread and other factors. While some of these treatments offer the opportunity to control or cure blood cancer, many of them are associated with shorter and longer term side effects. Some common blood cancer treatments include:

(i) Intensive treatment / high intensity treatment: Intensive treatment means strong treatments and for blood cancer, this often means using strong drugs to try and kill cancer cells or stop them from spreading. The main types of intensive treatment for blood cancer are:

(a) Standard dose or high dose chemotherapy: using cell-killing drugs with the aim of killing cancerous cells and stopping them from multiplying;

(b) Stem-cell transplant: having high doses of chemotherapy to kill the abnormal cells in your bone marrow or lymph nodes, then receiving new blood stem cells (either your own or from a donor), through a drip. The aim is for these new stem cells to start producing healthy blood cells;

(c) Some types of biological therapy / immunotherapies / monoclonal antibodies: drugs that encourage the patient's immune system to fight cancerous cells;

(d) Radiotherapy: using high energy rays to kill cancer cells in a particular area (mostly to treat lymphoma);

(e) Surgery: rarely, the patient may be offered a splenectomy (removing of spleen).

(ii) Non-intensive / low intensity treatment: Non-intensive treatments such as lower-dose chemotherapy are usually gentler and cause fewer side effects. In most cases, these treatments won't cure the cancer but they may help to keep the person in remission or manage his symptoms for a good length of time. These gentler treatments



may be used over a longer period of time to keep cancer under control. Types of lower intensity treatment for blood cancer include:

- (a) Low dose chemotherapy: using cell-killing drugs with the aim of killing cancerous cells and stopping them from multiplying;
- (b) Some biological therapies / immunotherapies / monoclonal antibodies: drugs that encourage the patient's immune system to fight cancerous cells.

i. Many patients suffering from blood cancer and other blood disorders need a blood stem cell transplant to survive. For a stem cell transplant, the primary step is finding a matching donor. Only about 30% of the patients in need of a stem cell transplant as life-saving treatment, are able to find a sibling match. The rest 70% depend on finding a matching unrelated donor. Currently, 7 out of 10 blood cancer patients in India are unable to find a compatible donor within the family and are likely to find an unrelated matching blood stem cell donor. The odds are even lower for those with diverse ancestry. This can change by registering more potential blood stem cell donor.

j. In some cancers, such as certain leukemias, multiple myeloma, and some lymphomas, a stem cell transplant can be an important part of treatment and often their only chance of survival. A high dose of chemo works better than standard dose to kill cancer cells but high doses can also kill all the stem cells and cause bone marrow to completely stop making blood cells, which are required to be alive. Given the same, a stem cell transplant is a better way in many cases as the transplanted stem cells replace the body's stem cells after the bone marrow and its stem cells have been destroyed by treatment. Transplant lets doctors use much higher doses of chemo to try to kill all of the cancer cells. A stem cell transplant from another person can also help treat certain types of cancer in a way other than just replacing stem cells. Donated cells can often find and kill cancer cells better than the immune cells of the person who had the cancer ever could.

k. The need for stem cell transplant depends case wise and the health status of the patient, but mostly doctor recommends stem cell transplant seeing the



long-term effects and better quality of life in such patients. Most of the patients living with blood cancer would require a stem-cell transplant in life for a longer survival.

1. A successful blood stem cell transplant needs a perfect HLA tissue match i.e. a 10/10 match which increases the chance that the patient's body will accept donated cells as its own and not fight them. Patients and donors of Indian origin have unique HLA characteristics that are severely under-represented in the global database, which makes the probability of finding a suitable donor very difficult.
- m. The applicant works on finding a HLA-matched donor for every patient in need of a transplant. As Indian patients mainly require an Indian tissue match, the applicant focusses on increasing the awareness and on encouraging many more people in India to register as a potential blood stem cell donor. It maintains a register or database of donors, including but not limited to HLA typing data required for donor and patient matching.
- n. With the help of upsurge in the details of potential donors in the global database, the chances of patients finding a suitable match increases to a large extent, thereby, increasing the chances of blood cancer treatment. It is also pertinent to note than the entire purpose of the said database is assisting in treatment of patient's blood cancer and other blood disorders.
- o. After, a donor has been identified as a match, because, he/she has the same tissue type as a patient in need of a transplant, the applicant facilitates the process leading to blood stem cell donation. It provides comprehensive post-donation support and monitors the short- and long-term health of adult unrelated volunteer donors who have provided hematopoietic stem cells.
- p. To allow a donor patient matching and facilitate the process leading to blood stem cell donation, the applicant procures certain goods and services from India/ outside India. One such service is the HLA testing service, which is procured by the applicant in India from DKMS Life Science Lab GmbH in Germany (hereinafter referred to as 'LSL DE').



- q. HLA testing, also known as HLA typing or tissue typing service, is a DNA test that identifies transcriptions of antigens on the surface of cells and tissues. It is used to match a transplant recipient with a compatible donor.

HLA testing Services involve currently the following kinds of testing:

- a. General Testing of HLA-A, -B, -C, -DRB, -DOB, -DPB
- b. Blood Group Testing
- c. CCR5 Testing
- d. KIR Testing
- e. CMV IgG Antibody Testing.

The applicant has entered into an agreement with LSL DE to provide the said laboratory testing services to the applicant.

5. Regarding the question for the advance ruling, the applicant states as under:

5.1 On the background of the activities carried out by the applicant

- (a) The first and integral step of identifying the HLAs of potential donors by creating a registry/ database of potential donors: DKMS-BMST conducts various programs, campaigns, drives etc. to create awareness about the registry of potential blood stem donors maintained by it and the need for people to register with DKMS-BMST. Thus, in such awareness drives, educational drives etc., DKMS-BMST collects samples of buccal swabs / Human DNA from potential donors in India, marks each swab with a donor ID and sends these samples to LSL DE, Germany. To provide for the required HLA typing services, DKMS-BMST has entered into an agreement with LSL DE to conduct various kinds of HLA testing services. LSL DE performs tests on the samples received from DKMS-BMST. Once the tests are performed on the samples, the results of the same are shared by LSL DE through a software named DKMSOne India. DKMS-BMST shall download the said results from DKMSOne. Further, the results are also transferred to World Marrow Donor Association ('WMDA') and to HAP-E Search. While WMDA is a global organisation for anonymized listed donors where



physicians can search for a potential match for their patients from a worldwide database of donors maintained by many similar organisations like DKMS-BMST, HAP E Search is a program owned and operated by DKMS for physicians to search for a match for their patients out of the database maintained by DKMS worldwide. On both platforms (WMDA and HAP-E Search), the donors from India are marked as DKMS India donors and linked to DKMS-BMST and the HLA testing conducted by LSL DE, DKMS-BMST maintains a register or database of donors, including but not limited to HLA typing data required for donor and patient matching which proves to be an extremely important database for a patient suffering from blood cancer or any blood disorder.

(b) Facilitating the Blood Stem Cell Donation process: If the tissue type of a potential donor matches with that of a patient, the following services are provided by DKMS-BMST for potential donors:

- a. Confirmatory Typing (CT) and
- b. Work-Up (WU) process.

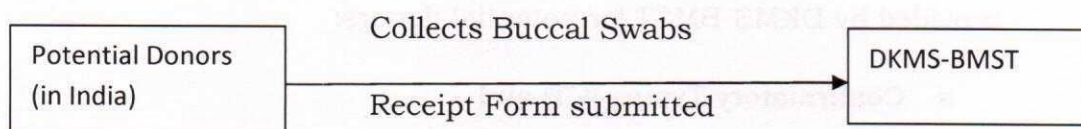
Confirmatory Typing Service: The HLA of the potential donor has to be confirmed again using a blood sample, which is taken from the donor. The donor's HLA is again tested and re-confirmed. As part of the CT services, DKMS-BMST re-sends the buccal swabs of the said donor to LSL DE to reconfirm the tests before the transplantation and the results of the same are uploaded on DKMSOne along with a doctor signed report. Invoices are raised by LSL DE to DKMS-BMST for such Confirmatory Typing Services as well. Given that DKMS-BMST is a not for profit organisation, it recovers negligible amount towards such HLA typing services received from its overseas laboratory.

Work-Up Service: Additionally, to rule out any infectious diseases, which could potentially put the patient's health at risk, the donor's blood is tested for any infectious diseases such as hepatitis etc. After that, once the patient's treating doctor selects the potential donor, the donor finally decides whether he / she would like to proceed with the blood stem cell donation. This is where the work-up process begins. DKMS-BMST

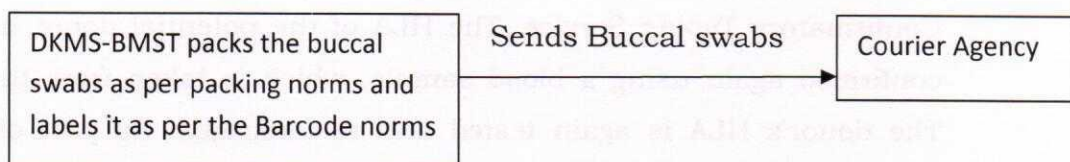


provides work-up services to transplant centres in India and outside. This includes the co-ordination between blood stem cell donor, the collection centre (medical facility where the blood stem cell collection takes place) and the transplant centre (medical facility where a patient receives a transplant from an unrelated donor). A medical assessment of the donor follows to ensure that there are no risks to the donor or to the patient. If there are no risks then the donor is cleared and if he/she still wishes to proceed, the patient shall be prepared to receive the potentially life-saving stem cells. In order to ensure that the donor is able to donate enough blood-forming cells for the transplant, he/she will receive daily G-CSF injections (naturally occurring growth factor) for five consecutive days before the donation. The procedure is as under:

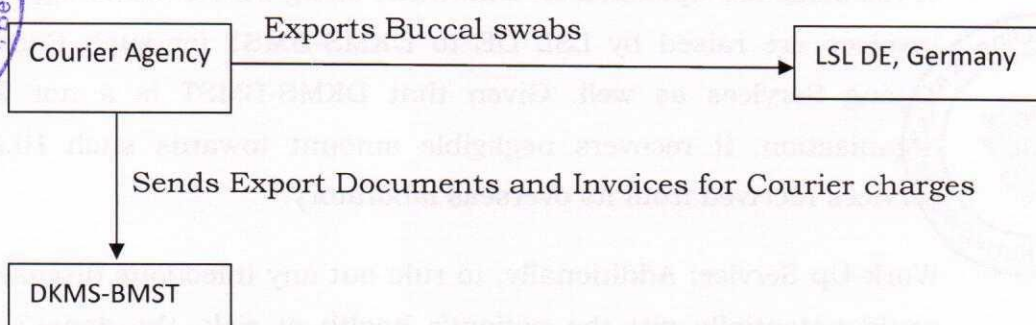
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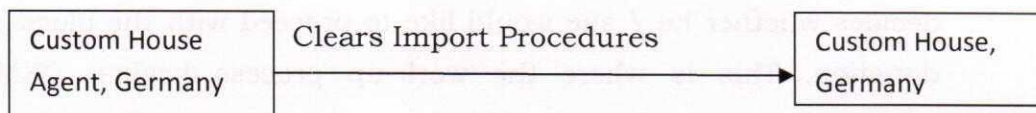
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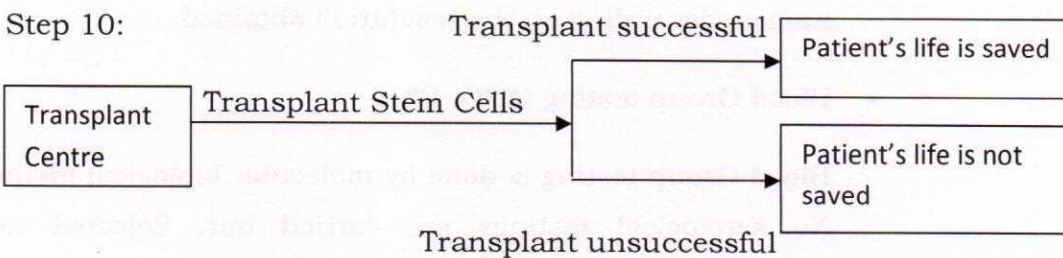
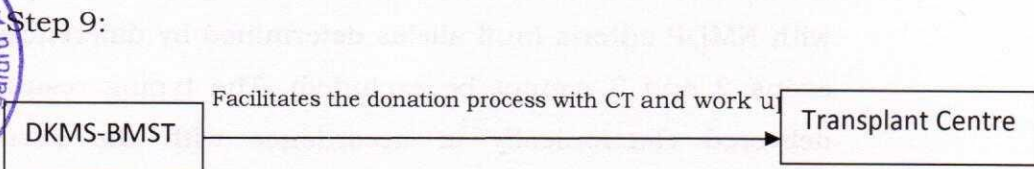
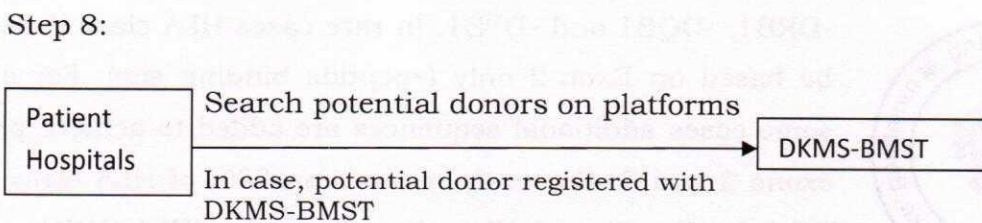
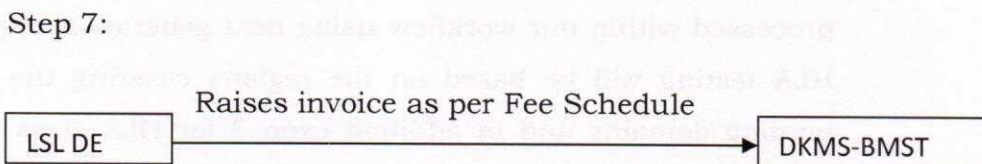
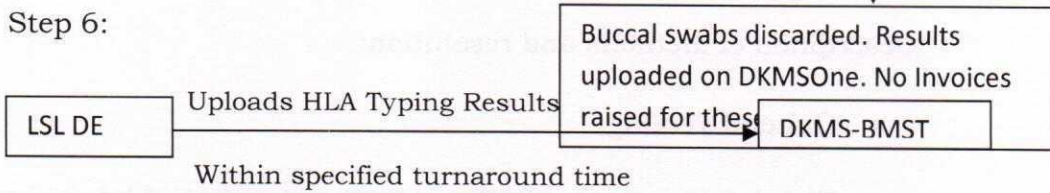
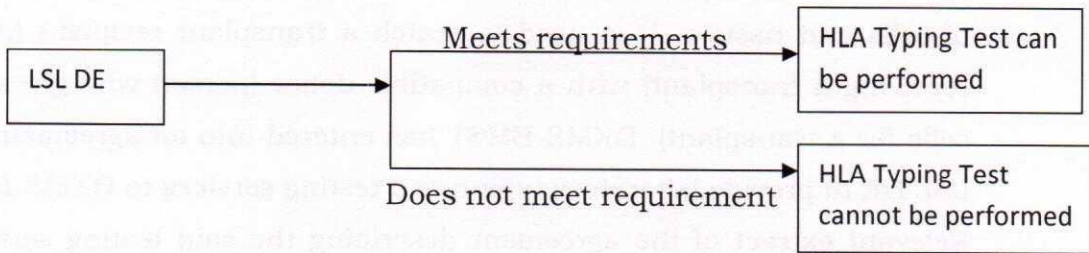
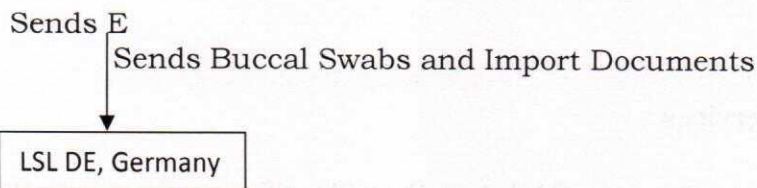


Step 3:



Step 4:





5.2. HLA Testing Services

5.2.1. HLA testing is a DNA test that identifies antigens on the surface of cells and tissues. It is used to match a transplant recipient (person receiving a transplant) with a compatible donor (person who gives their cells for a transplant). DKMS-BMST has entered into an agreement with LSL DE to provide laboratory typing and testing services to DKMS-BMST. Relevant extract of the agreement describing the said testing service is produced for reference:

“Description of methods and resolution:

- General Testing

The samples (except SSP and SBT of the clinical laboratory) will be processed within our workflow using next generation sequencing. HLA testing will be based on the regions covering the peptide-binding domains and in addition exon 3 for HLA class II genes. Therefore, regions sequenced are Exons 2 and 3 for HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1. In rare cases HLA class II results will be based on Exon-2 only (=peptide binding site). For class I in some cases additional sequences are added to achieve phasing of exons 2 and 3. Currently, more than 99% of HLA class I results (HLA-A, -B, -C) and HLA class II results (HLA-DRB1, -DQB1, -DPB1) can be delivered as high resolution results in accordance with NMDP criteria (null alleles determined by differences outside exons 2 and 3 cannot be excluded). The typing results will be delivered electronically in accordance with the current HLA nomenclature as G codes, multi-allele codes or (shortened) allele names, depending on the resolution obtained.

- Blood Group testing (ABO, Rh)

Blood Group testing is done by molecular biological methods only. No serological testings are carried out. Selected exons are



sequenced by NGS. Testings achieved with this method have a high rate of concordance with serological testings. In rare cases serological and molecular biological testings differ due to changes outside of the sequenced regions. Submitted testings may only be used for donor pre-selection. The Contractor does not submit clinically applicable blood group testings. Testing results for blood groups can be obtained for approximately 90% samples.

- CCR5 testing

CCR5 is a cell surface chemokine receptor of leukocytes, eg. T-cells or macrophages. A 32 bp deletion in the corresponding gene leads to a truncated non-functional protein. To detect this 32 bp deletion, a 453 bp amplicon is generated and subsequently sequenced. Testings are reported as either WT (Wildtype) or Del32 for each copy designating a copy without or with deletion, respectively. Typing results for CCR5 can be obtained for approximately 96% of samples.

- KIR (Killer cell Immunoglobulin like Receptor) testing

We sequence exons 3, 4, 5, 7, 8 and 9 of the KIR genes to enable genotyping of the KIR genes at allelic resolution. Alleles differentiated only by sequence variation outside the sequenced exons cannot be distinguished. In addition some ambiguities arise due to the lack of phasing information between exons. Those remaining ambiguities will be reported as GL strings. In a small fraction of the genotyped KIR genes, the data quality is insufficient for reliable allele level genotyping. In those cases, only the presence or absence of a respective KIR gene is reported. In addition, for some samples no KIR genotyping result may be obtained. Overall, genotyping results for KIR genes can be expected for approximately 85% of the samples.

- CMV (Cytomegalovirus) IgG antibody testing (blood and swab based)



The Cytomegalovirus is widely spread in Europe. In most cases the infection does not break out due to generation of antibodies against the virus. During immunosuppression a CMV infection can be dangerous to patients who never had contact to the virus.

To detect anti-CMV-IgG, a sign of a previous or current CMV-infection, we perform an ELISA based on CMV surface protein coated microtiter-plates and anti-IgG conjugate. This assay delivers a positive or negative testing result for the sample. An ambiguous result which is not clearly positive or negative will be transmitted as "g" for grey-zone.

Swab samples with insufficient sampling material (IM) will be cancelled. These samples will not be charged, if the total quantitative share of such samples stays below 2.5%.

Testing results for CMV from swabs can be obtained for >75% of samples. About 2% of samples are here detected as false negatives. Testing results for CMV from blood can be obtained for approximately 98% of samples.



5.3. HLA Testing qualifies to be a 'service' under GST Law:

5.3.1 The applicant states that outset, he wishes to state that as per the section 2(52) of the CGST Act, 2017, goods means every kind of movable property other than certain exceptions. As per section 2(102) of the CGST Act, 2017, "services" means anything other than goods, money and securities. It is pertinent to note that HLA testing is a test performed in laboratories on the physical samples of swabs/ Human DNA to maintain a list of potential donors and execute the process of donation in case the samples of donor and done matches. Thus, it is a service performed by laboratories on the samples and hence HLA testing would fall within the definition of "service" as per the CGST Act, 2017.

5.4. HLA Testing -an integral part in the treatment of blood cancer and other blood disorder

5.4.1 Basis the background and above mentioned details, the applicant states that it is absolutely clear that the primary step of the donation process required for treatment of blood cancer and other blood disorders is identifying a donor. Now, to identify a donor, samples of potential donors would be required to be tested to classify those into specific categories as prescribed in medical terminology.

5.4.2 In the current scenario, the procedure of testing the samples of potential donors for further classification is entirely executed by LSL DE, Germany. The applicant states that it is pertinent to note that basis of such classification of HLA of potential donors into categories, the doctors, hospitals, transplant centres including the patients are able to conduct a search and find a suitable match. In case the said classification would not have been done, the patient would not have been able to find a suitable match in the limited life time available to them.

5.4.3 Further, the applicant reiterates that many patients suffering from blood cancer and other blood disorders need a blood stem cell transplant to survive. Only about 30% of the patients in need of a stem cell transplant as life-saving treatment, are able to find a sibling match. The rest 70% depend on finding a matching unrelated donor. Currently, 7 out of 10 blood cancer patients in India are unable to find a compatible donor within the family and are likely to find an unrelated matching blood stem cell donor. The odds are even lower for those with diverse ancestry. This can change by registering more potential blood stem cell donor.

5.4.4 A successful blood stem cell transplant needs a perfect HLA tissue match i.e. a 10/10 match which increases the chance that the patient's body will accept donated cells as its own and not fight them. Patients and donors of Indian origin have unique HLA characteristics that are severely under-represented in the global database, which makes the probability of finding a suitable donor very difficult.

5.4.5 DKMS-BMST works on finding an HLA matched donor for every patient in need of a transplant. As Indian patients mainly require an Indian tissue match, DKMS-BMST focusses on increasing the awareness and on



encouraging many more people in India to register as a potential blood stem cell donor. It maintains a register or database of donors, including but not limited to HLA typing data required for donor and patient matching.

5.4.6 With the help of upsurge in the details of potential donors in the database of donors, the chances of patients finding a suitable match increases to a large extent, thereby, increasing the chances of blood cancer treatment. It is also pertinent to note that the entire and the purpose of the said database is assisting in treatment of patient's blood cancer and other blood disorders.

5.4.7 Further, once the initial testing is done and upon finding a suitable match for the patient, the said step of reconfirming the samples of the identified donor and matching the same with the samples of the patient is also executed by LSL DE, Germany. Therefore, it is evident that the very first step and thereafter the re-confirmatory step, being one of the most important steps in the entire treatment process is being carried out of LSL DE, Germany through testing of the samples sent to DKMS-BMST.

5.4.8 Therefore, the testing of samples provided by DKMS-BMST and creating a database upon classification of the HLA tests conducted is an inevitable step in the entire cycle of treatment of blood cancer / other blood disorders and without the said step, stem cell transplant required for treatment of blood cancer / other blood disorders would not have been possible.



6. For the first question, regarding the legal provisions classifying the said HLA testing service under the definition of Health Care Services provided by Clinical Establishment and therefore exempt from the levy of tax, the applicant states as under:

6.1 The section 2(47) of the CGST Act, 2017, defines "exempt supply" and as per section 11(1) of the CGST Act, 2017 the Government may issue notification exempting a goods or service from tax. As per entry no.74 of Notification No. 12/2017-Central Tax (Rate) dated 28.06.2017 and as amended from time to time, the services by way of health care services by clinical establishment, an authorised

medical practitioner or para-medics have been granted absolute exemption from the whole of taxes leviable thereon.

6.2 Paragraph 2 of the aforementioned notification also defines health care and clinical establishment as follows:

“(zg) ‘health care services’ means any service by way of diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicines in India and includes services by way of transportation of the patient to and from a clinical establishment, but does not include hair transplant or cosmetic or plastic surgery, except when undertaken to restore or to reconstruct anatomy or functions of body affected due to congenital defects, developmental abnormalities, injury or trauma.

(s) ‘clinical establishment’ means a hospital, nursing home, clinic, sanatorium or any other institution by whatever name called, that offers services or facilities requiring diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicines in India, or a place established as an independent entity or a part of an establishment to carry out diagnostic or investigative services of diseases;”

Hence the services by way of treatment or care for illness, injury, deformity, abnormality are covered under “health care services”. Also, hospitals, clinic, sanatorium or any other institution by whatever name called that offers services or facilities requiring treatment or care for illness, injury, deformity, abnormality is covered under “clinical establishment”.

6.3 In the instant case, the applicant states, LSL DE, Germany conducts the tests to identify and list potential donors which, as explained above, is an integral step in the entire process of treatment of an illness, injury, deformity, abnormality i.e. blood cancer and other blood disorders. The said laboratory tests the HLA of the samples provided for various potential donors under the Allopathy system of medicine in India. Given that without this test, the donation and therefore the treatment of illness would not be possible, hence the said HLA typing service providing by LSL DE would be classifiable as health care services.

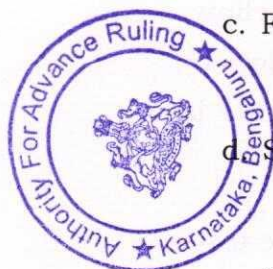
6.4 Further, as the laboratory in the instant case offers services requiring treatment for an illness, injury, deformity, abnormality under the allopathy system of medicines, recognised system of medicines in India, therefore, the said laboratory would qualify as a clinical establishment as per the definition provided in the GST Law.

6.5 The applicant also contends that the definition of “health care services” has been kept wide and doesnot specifically restrict any activity apart from certain exclusion, thereby extending the benefit of exemption for overall healthcare activities.

6.6 The applicant contends that since the said service of HLA typing would qualify as health care services provided by clinical establishment and hence exempted from taxes leviable thereon, the applicant shall not be required to pay taxes under reverse charge mechanism for services provided by overseas laboratory.

6.7 The applicant draws the attention to the ruling of this authority in the case of Sayre Therapeutics Private Limited and Matrix Imaging Solutions India Private Limited in support of his claim. He also draws reference to the following cases related to Service Tax era in support of his claim:

- a. Aditya Surgical Co. vs. State of Karnataka [2018(10) GSTL 284 (Kar)]
- b. Dr.Reddy’s Laboratories Ltd. vs CCE & C [2008(232) ELT 819 (Tri-Bang)]
- c. Flex Engineering Ltd. vs. Commissioner of Central Excise, U.P. [2012(278) ELT 153 (SC)]
- d. Sudarshan Chemicals Industries vs. Commissioner of Central Excise, Pune [2010(262) ELT 974 (Tri- Mumbai)]
- e. Aztecsoft Ltd. vs Commissioner of Central Excise, Bangalore [2012(26) STR 552 (Tri-Bang)]
- f. Micro Software Services Pvt. Ltd vs CST, Bangalore [2012(25) STR 369 (Tri-Bang.))
- g. Stag Software Pvt. Ltd v. Commissioner of Service Tax, Bangalore [2008(10) STR 329 (Tri-Bang.))



7. Notwithstanding the above, the applicant states that it is germane to note that in the instant case, the samples are made physically available by DKMS-BMST to LSL DE, Germany. LSL DE is providing testing services on physical product samples made available to them by DKMS-BMST after due examination and testing of these samples. Therefore, it is inferred that the said services of testing of samples, which are required to be physically made available by the service receiver to the service provider, are provided outside India i.e. Germany and therefore liable to tax. The applicant provides the facts, legal provisions and judicial precedence in support of the same:

7.1 Facts important for second question: Samples required to be made physically available by the applicant to LSL DE, Germany qualifies to be “goods” under GST Law:

7.1.1 In this context, it would also be important to determine as to whether the samples required to be made physically available by DKMS-BMST to LSL DE, Germany eg. Buccal swabs / Human DNA etc. can be considered as ‘goods’. A buccal swab, also known as buccal smear, is a way to collect DNA from the cells on the inside of a person’s cheek.

7.1.2 The applicant states that the samples required to be made physically available by DKMS form components of Human Blood (?) and the Human Blood and its components are listed as goods in the Notification No.02/2017-Central Tax (Rate) dated 28.06.2017.

8. Regarding the legal provisions not qualifying the said procurement of HLA testing service as a service, the tax on which is liable under reverse charge mechanism, the applicant states as under:-

8.1 As per section 5 of the IGST Act, subject to provisions of sub-section (2), tax shall be levied on interstate supplies of goods or services or both and as per section 5(3) of the IGST Act, 2017, the Government may exempt any transaction from tax. Section 7(4) of the IGST Act states that supply of services imported into the



territory of India shall be treated to be a supply of services in the course of inter-State trade or commerce and hence IGST would be levied on the said supply.

8.2 Import of services have been defined in section 2(11) of the IGST Act as under:

'import of services means the supply of any service, where –

- (i) *the supplier of service is located outside India;*
- (ii) *the recipient of service is located in India; and*
- (iii) *the place of supply of service is in India;'*

The term India has been defined in section 2(56) of the CGST Act, 2017. In the instant case, the supplier of services i.e. LSL DE is located in Germany and hence the first condition is satisfied. Further, the recipient of services i.e. DKMS-BMST is located in India and hence the second condition is also satisfied.

8.3 Regarding the third condition, the provisions of section 13 of the IGST Act shall apply to determine the place of supply of services where the location of the recipient of service or supplier of service is outside India. The applicant submits that the goods are required to be made physically available by the recipient of service to the supplier of service. As per section 13(3) of the IGST Act, the place of supply of services shall be the location where the services are actually performed in case of services supplied in respect of goods which are required to be made physically available by the recipient of service to the supplier of services or to a person acting on behalf of the supplier of services in order to provide the services. In the instant case, the samples are made physically available by DKMS-BMST to LSL DE, Germany. LSL DE is providing the testing services on physical product samples made available to them by DKMS-BMST after due examination and testing of these samples. The testing activities that are carried out include General Testing, Blood Group Testing, CCR5 Testing, KIR Testing, CMV IgG Antibody Testing, etc.

8.4 The applicant states that as highlighted in the above process, the pre-requisite for conducting the HLA testing service is the samples of buccal swabs / Human DNA etc. Hence it is important for the DKMS-BMST to send the samples to LSL DE as LSL DE processes the samples received and provides details of whether a testing of the HLA can be performed on the collected samples. Once it confirms that the

testing can be performed, the samples undergo medical testing and thereafter a report is generated by LSL DE, Had DKMS-BMST not shared the physical samples, the testing by LSL DE could not have been possible.

8.5 The applicant states that the facts and situation in the present case clearly attract the provisions of section 13(3)(a) of the IGST Act and therefore it is inferred that the said services of testing of samples, which are required to be physically made available by the service recipient to the service provider, are provided outside India, i.e. Germany and therefore not liable to tax. Also on the basis of the above, the third condition is not fulfilled and hence the said purchase of HLA testing service is not an import of service under the provisions of GST. The applicant also reiterates that since the service received is not an import of service under GST, the provisions of section 7 and section 5 shall not be applicable and DKMS-BMST shall not be liable to pay taxes under reverse charge mechanism for the purchase of said service.

8.6 Assuming that in case there is a levy of IGST on such services received from outside India, it would result into a break in the value chain. As highlighted earlier, DKMS-BMST is not for profit organisation and hence, for the outward services i.e. Confirmatory typing service, work-up services etc. it recovers negligible amount from the patients. Additionally, the applicant also highlights that he does not charge any consideration for a lot of services provided by it in case the donation is not successful. It also does not recover any amount for the HLA Testing services performed for all potential donors. Its major source of funding is monetary donations received from entities in India and outside India. Given the same, the applicant does not have a substantial amount of taxes on its outward supply. Hence, in case IGST is leviable on such procurement of services, there would exist a huge blockage of Input Tax Credit which DKMS-BMST will not be able to utilise.

8.7 The applicant has taken the support of the following judgements and rulings in support of his claims:

a. Order of the Advance Ruling Authority of Maharashtra in the case of Behr-Hella Thermocontrol India Pvt Ltd,

b. Crompton Greaves Ltd vs CESTAT, Aurangabad [2016 (42) STR 306 (Tri-Mumbai)] -wherein it is held that the performance of testing services



provided by the foreign based entity where the testing is conducted in the foreign laboratory is entirely outside India and hence the appellant is not liable to service tax.

c. Total Oil India Ltd. vs CESTAT, Mumbai [2017(5) GSTL 209 (Tri-Mumbai)]

9. In view of all the above, the applicant argues that the tests conducted by the laboratory to identify and list potential donors is an integral step in the entire process of treatment of an illness i.e. blood cancer and other blood disorders and does not have any other use / purpose and hence the said laboratory HLA testing services would be classifiable as health care services provided by a clinical establishment and therefore exempt from taxes leviable thereon.

Further, the applicant argues that the services being provided by LSL DE would be provided outside India after making the goods physically available to the supplier of services who is located outside India and hence the place of supply of services should be outside India under section 13(3) of the IGST Act.

Under both circumstances, the applicant shall not be required to pay taxes under reverse charge mechanism. Further, considering that DKMS-BMST is a not for profit organisation, a levy of IGST on such procurement of service would result into accumulation of input tax credit and a break in the value chain and therefore, the said services should not be taxable in the hands of DKMS-BMST.



**PERSONAL HEARING: / PROCEEDINGS HELD ON 09.01.2020 AND
10.03.2020**

10. Sri Ravi Banthia, Chartered Accountant and the duly authorised representative of the applicant, appeared for personal hearing proceedings on 09.01.2020 and sought an adjournment to modify the questions as the same were not clear. Later, on 10.03.2020, he appeared and submitted the revised questions before this authority and reiterated the submissions made as narrated earlier.

FINDINGS & DISCUSSION

11. We have considered the submissions made by the Applicant in their application for advance ruling as well as the submissions made by the learned representative at the time of the personal hearing. We have also considered the issues involved, on which advance ruling is sought by the applicant, and relevant facts.

11.1 At the outset, we would like to state that the provisions of both the CGST Act and the KGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to such dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provisions under the KGST Act.

11.2 The issues involved in the above case are whether the HLA Typing Services obtained by the applicant from LSL DE falls under the scope of "health care services by a clinical establishment"?

11.3 The applicant collects the buccal swabs and samples from the potential donors of blood stem cells and sends the same to the foreign entity. i.e. LSL DE for HLA Typing which is required to be done as a prerequisite for any organ transplantation. It is similar to doing a blood group testing before collection of blood from any blood donor. The samples of the potential donors would be tested by the LSL DE at their laboratory in Germany and the results are posted onto a database with clear classification based on the alleles and the location of the donors. For this a consideration is charged to the applicant.

11.4 It is no doubt that LSL DE is providing a service to the applicant as the applicant is liable to pay the consideration for the services provided. The contract agreement for the Laboratory Services entered between the applicant and the DKMS Life Science Lab GmbH (LSL DE) shows clearly that the LSL DE is providing laboratory typing and testing services to the applicant and the applicant is responsible to safeguard that import and export of the biological sample material sent from India to the LSL DE in Germany is in conformity with the applicable legislation. Further, the typing results on the basis of the physical samples sent



from India to Germany would be transmitted electronically by LSL DE to the applicant and the remaining sample material (blood, buccal swab) would be discarded after typing. An aliquot of extracted human DNA will be stored in the LSL DE for an undefined period unless the applicant notifies LSL DE otherwise and it is understood that these samples remain in the possession of the applicant. The contract also contains a Fee Schedule giving the consideration payable by the applicant for each workflow. Hence it is clear from the contract that the applicant is receiving services from LSL DE and there is a supply as per the scope specified in section 7(1) of the CGST Act, 2017.

11.5 It is also clear from the above contract that what is deliverable is a service and the same is a testing report in the form of HLA Typing Report and hence LSL DE is providing services to the applicant.

12. Regarding the question, whether this service is a “health care service” or not, the following are noticed :

12.1 “Health Care Services” are defined in paragraph 2 of the Notification No.12/2017- Central Tax (Rate) dated 28.06.2017 and the same is as under:

“(zg) “health care services” means any service by way of diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicines in India and includes services by way of transportation of the patient to and from a clinical establishment, but does not include hair transplant or cosmetic or plastic surgery, except when undertaken to restore or to reconstruct anatomy or functions or body affected due to congenital defects, developmental abnormalities, injury or trauma.”

The service of HLA typing is to identify the potential donors and is related directly to a transplantation to be done on a future date to a patient requiring such transplant. Analogous to testing of Blood Group, HLA typing identifies the alleles of the donor and these alleles are matched with the alleles of the recipient of transplant. The applicant gets the HLA of the potential donors typed and uploaded

to the databases for the doctors to identify the potential donors. Hence the service is to received only to shortlist the potential donors and increase chances of getting the perfect donors from a big list of potential donors and going through the entire process of testing ab initio and matching between the patient and the donor individually. This testing is sine qua non for any transplantation of an organ not restricted to blood stem cell transplantation and it is only a preponement of such testing or diagnosis of the potential donor to obtain the blood stem cells which is for the treatment. Other than for obtaining an organ from a potential donor, this HLA testing is not done for any other purpose in clinical set up and hence this is a for the treatment of an illness, the same is covered under "health care services" as per the definition given to it.

13. Regarding the issue whether the supplier of services is a clinical establishment, the term "clinical establishment" is defined in paragraph 2 of Notification No.12 /2017 -Central Tax (Rate) dated 28.06.2017 as under:

"(s) "clinical establishment" means a hospital, nursing home, clinic, sanatorium or any other institution by whatever name called, that offers services or facilities requiring diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicines in India or a place established as an independent entity or a part of an establishment to carry out diagnostic or investigative services of diseases,"

It is seen that the HLA testing involves various tests which are for the identification of the alleles of the donor cells and also the suitability of the potential donor for treatment of a patient of illness, i.e. blood cancer and other blood disorders. Hence any institution which does these investigative services would be covered under the definition of "clinical establishment" as contemplated in the said definition. Hence, the LSL DE is a clinical establishment under the meaning given to it.

14. By combined reading of the above, it is clear that the services obtained by the applicant from LSL DE in the form of HLA Typing Services would be "health care

services provided by a clinical establishment". Entry No. 77 of Notification No.09 /2017 -Integrated Tax (Rate) dated 28.06.2017 reads as under:

77.	Heading 9993	Services by way of- (a) health care services by a clinical establishment, an authorised medical practitioner or para-medics; (b) services provided by way of transportation of a patient in an ambulance, other than those specified in (a) above.	Nil	Nil
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Hence the services provided by LSL DE to the applicant in the form of HLA Typing would be covered under "Health Care Services by a Clinical Establishment" and hence is exempt from tax under the IGST Act.

15. Entry No. 1 of Notification No.10/2017 - Integrated Tax (Rate) dated 28.06.2017 specifies that in case of any service supplied by any person who is located in a non-taxable territory to any person other than non-taxable online recipient, the whole of integrated tax leviable under section 5 of the said Integrated Goods and Services Tax Act, shall be paid on reverse charge basis by the recipient of the such services. In this case, the tax liability, if any, would have to be paid by the recipient of service, i.e. the applicant. Since the service itself is exempt, the applicant is not liable to pay tax on the services obtained in the form of HLA testing and typing from LSL DE on reverse charge basis.

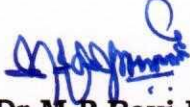
16. Regarding the applicability of tax based on the contention of the applicant that the entire service is provided outside India, the same is verified. The issue involves the determination of the place of supply which is outside the mandate provided to this Authority and hence no discussion is made on this issue.

In view of the foregoing, we rule as follows



RULING

1. The services of HLA Typing received by DKMS BMST Foundation India from the overseas laboratory is covered under the definition of "health care services by a clinical establishment" and thereby is exempted from IGST leviable thereon and accordingly not taxable in the hands of the applicant under reverse charge mechanism.
2. The applicant is not liable to pay Integrated Goods and Services Tax on the testing services performed by the overseas laboratory outside India on the Human Buccal Swabs sent by DKMS BMST from India and is already answered in para 1 above.



(Dr. M.P. Ravi Prasad)
Member

Karnataka Advance Ruling Authority

Bengaluru - 560 009

Date : 23-04-2020



(Mashhood Ur Rehman Farooqui)
Member

MEMBER

Karnataka Advance Ruling Authority

Bengaluru - 560 009



To,
The Applicant

Copy to :

- (i) The Principal Chief Commissioner of Central Tax, Bangalore Zone, Karnataka.
- (ii) The Commissioner of Commercial Taxes, Karnataka, Bengaluru.
- (iii) The Commissioner of Central Tax, Bangalore South Commissionerate, Bengaluru.
- (iv) The Asst. Commissioner, LGSTO-45 A, Bengaluru.
- (v) Office Folder.