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Government of India

Ministry of Finance

(Department of Revenue)

Notification No. 04/2019- Integrated Tax

New Delhi, the 30th September, 2019

G.S.R.....(E).- In exercise of the powers conferred by sub-section (13) of section 13 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), the Central Government, on being satisfied that it is necessary in order to prevent double taxation or non-taxation of the supply of a service, or for the uniform application of rules, on the recommendations of the Council, hereby notifies following description of services or circumstances as specified in Column (2) of the Table A, in which the place of supply shall be the place of effective use and enjoyment of a service as specified in the corresponding entry in Column (3), namely:-

Table A

Sl. No.	**Description of services or circumstances**	**Place of Supply**
(1)	(2)	(3)
1	Supply of research and development services related to pharmaceutical sector as specified in Column (2) and (3) from Sl. No. 1 to 10 in the Table B by a person located in taxable territory to a person located in the non-taxable territory.	The place of supply of services shall be the location of the recipient of services subject to fulfillment of the following conditions:- (i) Supply of services from the taxable territory are provided as per a contract between the service provider located in taxable territory and service recipient located in non-taxable territory. (ii) Such supply of services fulfills all other conditions in the definition of export of services, except sub- clause (iii) provided at clause (6) of Section 2 of Integrated Goods and Services Tax Act, 2017 (13 of 2017).

Table B

Sl. No.	**Nature of Supply**	**General Description of Supply**
(1)	(2)	(3)
1	Integrated discovery and development	This process involves discovery and development of molecules by pharmaceutical sector for medicinal use. The steps include designing of compound, evaluation of the drug metabolism,
2	Integrated development	

		biological activity, manufacture of target compounds, stability study and long-term toxicology impact.
3	Evaluation of the efficacy of new chemical/ biological entities in animal models of disease	This is in vivo research (i.e. within the animal) and involves development of customized animal model diseases and administration of novel chemical in doses to animals to evaluate the gene and protein expression in response to disease. In nutshell, this process tries to discover if a novel chemical entity that can reduce or modify the severity of diseases. The novel chemical is supplied by the service recipient located in non-taxable territory.
4	Evaluation of biological activity of novel chemical/ biological entities in in-vitro assays	This is in vitro research (i.e. outside the animal). An assay is first developed and then the novel chemical is supplied by the service recipient located in non-taxable territory and is evaluated in the assay under optimized conditions.
5	Drug metabolism and pharmacokinetics of new chemical entities	This process involves investigation whether a new compound synthesized by supplier can be developed as new drug to treat human diseases in respect of solubility, stability in body fluids, stability in liver tissue and its toxic effect on body tissues. Promising compounds are further evaluated in animal experiments using rat and mice.
6	Safety Assessment/ Toxicology	Safety assessment involves evaluation of new chemical entities in laboratory research animal models to support filing of investigational new drug and new drug application. Toxicology team analyses the potential toxicity of a drug to enable fast and effective drug development.
7	Stability Studies	Stability studies are conducted to support formulation, development, safety and efficacy of a new drug. It is also done to ascertain the quality and shelf life of the drug in their intended packaging configuration.
8	Bio-equivalence and Bio-availability Studies	Bio-equivalence is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If

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		two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same. Bio-availability is a measurement of the rate and extent to which a therapeutically active chemical is absorbed from a drug product into the systemic circulation and becomes available at the site of action.
9	Clinical trials	The drugs that are developed for human consumption would undergo human testing to confirm its utility and safety before being registered for marketing. The clinical trials help in collection of information related to drugs profile in human body such as absorption, distribution, metabolism, excretion and interaction. It allows choice of safe dosage.
10	Bio analytical studies	Bio analysis is a sub-discipline of analytical chemistry covering the quantitative measurement of drugs and their metabolites, and biological molecules in unnatural locations or concentrations and macromolecules, proteins, DNA, large molecule drugs and metabolites in biological systems.

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2. This notification shall come into force on the 1st day of October, 2019.

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