

The Ruling of the Ministry of Finance, no. 011-00-64/2014-04 of 5 January 2015

1. The place of supply of services of clinical trial of drugs is considered to be the place where the service recipient performs its activities or has a permanent establishment for which the service is provided, or the place where the service recipient has its headquarters or place of residence. In this regard, the supply of services of clinical trial of drugs provided by a VAT payer to a foreign entity, i.e. to an entity that has no headquarters or a permanent establishment for which the service is provided, or residence in Serbia (hereinafter: the foreign entity), is not subject to VAT, while supply of these services provided by a VAT taxpayer to a local entity (an entity that has its headquarters or residence in the territory of the Republic of Serbia), is subject to VAT in the prescribed manner. In both cases, the VAT taxpayer who provides the services concerned has the right to deduct input VAT on that basis, provided that the prescribed conditions are fulfilled.

However, when a VAT payer, in accordance with a contract with a foreign entity, organizes the clinical trial of drugs performed by healthcare institutions in the Republic of Serbia (e.g. the clinical centers) in the manner that a service contract on clinical trial of drugs is concluded between a healthcare institution and a VAT payer – organizer of the clinical trial of drugs, in such case the service provided by that VAT payer to a foreign entity is not considered as a service of clinical trial of drugs or intermediary service related to clinical trial of drugs. In this regard, the supply of services referring to organization of clinical trial of drugs in the Republic of Serbia provided to a foreign person by the VAT payer – organizer of the clinical trial of drugs, is subject to VAT at the general VAT rate of 20%, taking into account that the place of supply of the these services is considered to be the place where service provider performs its activities, in this case in Serbia, and a VAT payer has the right to deduct the input VAT on that basis (e.g. VAT charged by the healthcare institution for supply of services of clinical trial of drugs).

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The provisions of Article 3 of the Law on Value Added Tax ("Official Gazette of the Republic of Serbia", no. 84/2004, 86/2004 - corr., 61/2005, 61/2007, 93/2012, 108/2013, 6/2014 – adjusted RSD amount, 68/2014 - other Law 142/2014 and 5/2015 – adjusted RSD amount – hereinafter: the VAT Law) provides that the supply of goods and services performed for consideration by a taxpayer in Serbia, within its business operations, as well as the import of goods into Serbia is subject to VAT.

In terms of the VAT Law, the supply of services includes all operations and actions, performed and taken within the business operations, which do not constitute the supply of goods referred to in Article 4 of the VAT Law (Article 5 paragraph 1 of the VAT Law).

The place of supply of services is the place where a service provider conducts its business. If the services are supplied through a permanent establishment, the place of supply of services is considered to be the location of that permanent establishment (Article 12 paragraphs 1 and 2 of the VAT Law)

Notwithstanding the provisions of Article 12 paragraphs 1 and 2 and according to Article 12 paragraph 3 point 4) sub-point (9a) of the VAT Law, the place of supply of services is considered the place where the service recipient conducts its business or has a permanent establishment for which services are rendered or the place in which the service recipient has its headquarters or residence, if services are related to the clinical trial of drugs and medical devices.

In accordance with Article 14 of the Law on Drugs and Medical Devices ("Official Gazette of the Republic of Serbia" No. 30/2010 and 107/2012, hereinafter the Law on Drugs), a drug is a product that is put on the market having a specific strength, pharmaceutical form and packaging containing a substance or combination of substances which proved to have the characteristic of treating or preventing disease of

humans or animals, as well as a substance or combination of substances which may be used or applied to humans or animals, either for the purpose of restoring, improving or modifying physiological functions by pharmacological, immunological or metabolic action or for setting up a medical diagnosis.

Clinical trial of drugs is an examination performed on humans as to determine or confirm the clinical, pharmacological or pharmacodynamic effects of one or more drugs tested, and/or as to identify any adverse reactions to one or more drugs tested, and to test the absorption, distribution, metabolism and excretion of one or more drugs, in order to determine their safety and efficiency (Article 59 paragraph 1 of the Law on Drugs).

2. In accordance with Article 33, paragraph 1 of the VAT Law a small taxpayer is considered to be an entity supplying goods and services in the territory of Serbia and/or abroad and generating less than RSD 8,000,000 of total turnover of goods and services in the preceding 12 months, or who, at the startup of its business, has estimated that in the following 12 months its total turnover will not exceed RSD 8,000,000. The provisions of Article 33, paragraph 6 of the VAT Law provide what is considered to be total turnover of goods and services referred to in the same Article paragraph 1 of the VAT Law (goods and services referred to in Article 28, paragraph 1, point 1) and 2) of the VAT Law, except for the supply of equipment and real estate for performance of business activity). According to Article 33, paragraph 3 and Article 38, paragraph 2 of the VAT Law, the small taxpayer may opt to pay VAT by submitting a registration form in accordance with the VAT Law. By opting for VAT payment, the small taxpayer shall attain and exercise all the rights and obligations provided under the VAT Law. Therefore, for example, the small taxpayer who exclusively supplies goods and services abroad (pursuant to Article 11 and 12 of the VAT Law) shall be entitled to opt for VAT payment (i.e. to become a VAT payer) and in this case, among other things, has the right to deduct the input VAT in accordance with the VAT Law.