

Tax & Legal Weekly Alert

June 28, 2019

In this issue:

New rules regarding the registration of entities that manufacture, import or distribute active substances used as raw materials for medicinal products for human use

On June 11, 2019, the Order no. 775/2019 (“**the Order**”) of the Ministry of Health on the registration of manufacturers, importers and distributors of active substances used as raw materials for medicinal products for human use was published in the Official Gazette, Part I, no. 473.

New criteria for the exemptions provided under the Agricultural Cooperative Law no. 566/2004

According to Order No. 1369/2019, published in the Official Gazette on June 12, 2019, the procedure for granting tax incentives for the electronic submittal of the “Unique tax return on income tax and social security contributions due by individuals”, as well as for the payment in advance of estimated tax liabilities for the year 2018 has been approved



New rules regarding the registration of entities that manufacture, import or distribute active substances used as raw materials for medicinal products for human use

The provisions of the Order have been issued for the implementation of Law no. 95/2006 on the health reform ("**Law 95/2006**"), which require importers, manufacturers and distributors of active substances that are established in Romania to register their activity with the National Agency for Medicines and Medical Devices ("**NAMMD**").

In this regard, the Order makes a distinction from the perspective of the due date in which the entities should submit the registration application with NAMMD, respectively:

- (a) the manufacturers, importers and distributors of active substances that already carry out such activities, are required to submit the registration application within a maximum term of 30 days as of the Order's entry into force – i.e. June 11, 2019. It is important to note that such entities are not required to cease their activity during the registration period.
- (b) the entities that intend to perform such activities following the Order's entry into force, shall submit the registration application within at least a 60 days term prior to the expected date of commencement of the activity. Law 95/2006 also provides this rule. Furthermore, in this case, the Order specifies, in addition to Law 95/2006, that NAMMD may decide to carry out an inspection following the submission of the registration application. Such inspection will be subject to the inspection tariff provided by Order no. 888/2014 approving the tariffs for the NAMMD activities.

The Order also establishes the administrative and technical documents that the entities are required to enclose to the registration application.

NAMMD shall submit with the European Medicines Agency the information regarding manufacturers, importers and distributors of active substances registered in Romania. Such information will be certified in the APIReg section of the EudraGMDP.

We mention that that the Order has entered into force on its date of publication in the Official Gazette of Romania – i.e. on June 11, 2019.

For further questions regarding the aspects mentioned in this alert, please contact us.



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New criteria for the exemptions provided under the Agricultural Cooperative Law no. 566/2004

On June 18, 2019, Order no. 203 / 2.287 / 1.809 (the “**Order**”) was published, establishing the criteria based on which the co-operating members would benefit from the exemptions provided under art. 76 par. (1) lit. e) of the Agricultural Cooperative Law no. 566/2004 (“**Law 566/2004**”).

According to the Order, no tax on buildings/land is due for the buildings/land owned and used in the agricultural activity if the co-operating members have sold at least 50% of their production by/to agricultural cooperatives defined according to Law 566/2004. The percentage of 50% refers to the fiscal year preceding the one for which the exemption is granted.

The buildings/agricultural land for which the exemption is granted are those held in the inventory/patrimony of the co-operating members. The buildings/land used in the agricultural activity include:

- Stores, silos, buildings for agrozootechnical activities held for rearing the animals, fishing, etc.;
- Productive agricultural land, land covered with forest vegetation, land occupied by construction and agrozootechnical installations, or any land exclusively used for agricultural activities.

In order to benefit from the exemption, the co-operating members should submit supporting documents to the local tax authorities, emphasizing that they have sold at least 50% of their production to the agricultural cooperative. The supporting documents are the followings:

- The certificate issued by the cooperative, attesting the quality of the co-operative member, the total quantity of production traded by/to the agricultural cooperative and the list of goods subject to the exemption;
- The affidavit of the co-operative member, mentioning the total quantity of production traded, the quantities traded by/to the agricultural cooperative and the list of goods subject to the exemption.

For further questions regarding the aspects mentioned in this alert, please contact us.



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The tax incentives are granted for fiscal obligations reported in the unique tax return for the estimated income and actually realized income for the year 2018.

The tax incentives are:

- a) 5% of the declared tax for the estimated income for the fiscal year 2018. This incentive is awarded if 95% of the tax on estimated income was paid prior to December 15, 2018;
- b) 5% of the declared tax for the income obtained in the fiscal year 2018. This incentive is granted provided that the following two conditions are cumulatively met:
 - The unique tax return was electronically submitted by July 31, 2018;
 - The difference between the declared tax for the income realized in 2018 and the value of the related incentive is paid until July 31, 2019. 95% of the fiscal obligation declared on the generated income was paid until July 31, 2019 (included).

The tax authority automatically allows the awarding of the incentives and shall subsequently issue a decision in this respect after July 31, 2019.

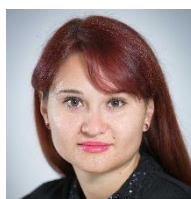
We would like to remind you that:

- The individuals are liable to submit the Unique tax declaration for year 2018 the latest by July 31, 2019;
- The related income tax must also be paid the latest by July 31, 2019.

For further questions regarding the aspects mentioned in this alert, please contact us.



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