

Customs regulations newsletter (Pharmaceutical sector)

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The customs authorities inspect the legality of tax incentives upon importation of pharmaceuticals and medical purpose products into Ukraine

State Customs Service of Ukraine (hereafter - SCSU) emphasized the necessity to enforce the customs authorities' control over the legality of application of tax incentives during customs clearance procedures and subsequent use of pharmaceutical substances, pharmaceuticals and medical purpose products. SCSU addressed the relevant clarifications to the customs authorities in the letter No. 20/1-12/09050-EP of 16 September 2012. In particular, SCSU draws attention of the customs authorities to the following:

▶ **Designated usage of pharmaceutical substances by importers who are not actual manufactures of pharmaceutical products**

SCSU stresses that according to article 282 of the Customs Code of Ukraine customs duty exemption should apply to import of substances that are not manufactured in Ukraine, are classified under 28, 29, 30 tariff groups of Ukrainian Foreign Economic Activity Commodities Nomenclature (UFEACN), and are used exclusively to produce pharmaceutical products. The transactions on import of such products for other purposes (for example, for manufacturing of cosmetic goods) do not meet regulatory requirements, and, thus, are not subject to exemption from customs duties.

▶ **Availability of quality certificates issued by the pharmaceuticals' manufacturer and accuracy of information reflected in them**

SCSU underlines that according to article 17 of the Law of Ukraine “On pharmaceuticals” the import of pharmaceuticals to the territory of Ukraine is possible only if a manufacturer's certificate is in place. Also SCSU, referring to the clarifications of State Inspection on Quality Control of Pharmaceuticals, stresses that the information confirming clinical test results for prescribed characteristics should be specified in the mentioned certificates in an accurate manner.

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It is worth noting that if the customs authorities identify the improperly formalized certificates during the documentary audit, they could most likely insist on value added tax reassessments and payment of value added tax with respect to the products, imported in the past.

► **Compliance of imported medical purpose products with the requirements established by special List**

SCSU underlines that according to the Tax Code of Ukraine the transactions on import of goods of special purpose, medical purpose products for individual use, for disabled people and other socially vulnerable groups, according to the List approved by the Cabinet of Ministers of Ukraine are exempted from VAT.

However, there is a number of additional requirements with respect to certain medical purpose goods mentioned in the list, the compliance with which is mandatory for preferential treatment upon importation into Ukraine. In particular, the customs authorities should consider that certain products contained in the list must be designated exclusively for medical usage and have appropriate marking.

The Procedure to grant the storage facilities the "customs warehouse" status is approved

In order to implement the provisions of the Customs Code of Ukraine the Ministry of Finance of Ukraine issued the Order No.835 of 16 July 2012. This order approves the requirements to the equipping of customs warehouses, the procedure of their registration and the procedure of issuing, terminating and cancelling of the relevant permit that grants the right to open and operate the customs warehouse.

In spite of the fact that principal requirements to outfitting of customs warehouses were not changed comparing to the requirements effective before the new Customs Code of Ukraine took force, this order established certain additional requirement to outfitting of the customs warehouses' territory.

For example, this order envisages the necessity to file the conclusion of the sanitary-epidemiological station on lightening of the customs warehouse itself and near-by territory as well. Certain provisions of the order, in particular those dealing with goods accounting, remain unclear from a practical standpoint. Importantly, previously issued licenses granting the right to open and operate bonded customs warehouses, in fact, will be invalid starting 1 September 2012, and the entities-holders of such warehouses will have to reregister them according to the order.

The Order of the Ministry of Finance of Ukraine "On the Procedure on granting to the storage facilities "customs warehouse" status and on deprivation of such status" took force on 20 August 2012.

We will continue to monitor amendments and inform you of developments in customs legislation.

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