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Spending on Post-Marketing Observational Study

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In an expanding pharmaceutical market, situations often arise when, to most efficiently sell a medicine that has been newly released into general circulation, the broadest possible data are needed concerning its properties, how effectively it acts on patients and the possible side effects. A company selling the product may obtain such information by conducting observational research or, as it is also known, post-marketing observational research of a medicine released onto the market. But the issue arises whether such research may be taken into consideration for tax purposes.

Let us say a pharmaceutical company that is not a manufacturer but an official distributor and/or an importer brings a new product onto the market. Legislation does not require the seller to conduct clinical trials of the new medicine. It establishes that the manufacturer may carry out such trials with respect to the medicine in question. The law is silent on whether the seller may conduct such trials. But it is in the seller's interest to obtain data on the medicine and on how it directly affects patients. The manufacturer and the seller have different objectives: The seller's is that of a marketing, rather than a scientific, nature. When observational studies are carried out, usually several objectives are met: The medicine becomes more prominent (the marketing purpose); data on its safety are obtained; and any positive results of such research can be used in publications to promote the medicine further.

But the tax authority may regard these observational programmes and clinical trials as one and the same thing. The tax authority may, therefore, refuse to allow the seller to deduct its expenditure on conducting such programs on the grounds that they are uncalled for, given that the seller or developer of the medicine conducts clinical trials.

In addition, there have been cases in which the tax authority has affirmed that a seller, which conducts observational research, has performed a service free of charge for a third party, i.e. the manufacturer of the medicine. This means that the seller cannot deduct its expenses

on conducting the research (Clause 16, Article 270 of the Russian Tax Code).

Neither claim has any legal grounds.

1) Under Clause 1, Article 252 of the Tax Code, expenses should be economically justified and supported by documentary proof.

The economic justification of research for a seller lies in selling a medicine more effectively by obtaining the highest possible degree of information on its properties, therapeutic properties, indications and so on.

A claim from the tax authority that a seller company's expenses on clinical trials are not justified is in essence an assessment of the economic reasonableness of the expenses. But the concepts of "reasonableness" and "economic justification" are different things. The tax authority is not competent to assess the reasonableness of expenses.

For expenses to be recognized for profit tax purposes, they must be incurred for the purpose of obtaining a profit. Moreover, whether expenses are justified is not determined by whether profit is received in a particular tax period, but by whether they are aimed at receiving a profit. This author, therefore, argues that expenses on observational research may be deducted even if they have not produced positive results.

The company must stipulate in internal documents (in the marketing, product sales and promotion policy; commercial policy, etc.) that it is attempting to increase sales volume by conducting observational experiments. This will help to justify the expenses incurred.

2) There is also no justification for the claim that conducting something akin to clinical trials constitutes a service provided free of charge to a manufacturer.

For it to be concluded that a party has received a service free of charge, it is necessary to have a direct expression of that party's intent. Such an expression of intent may be set out in an agreement between a seller and a manufacturer, where it is explicitly stated that the company is paying for research conducted on the manufacturer's behalf.

Russian court practice proceeds on the basis that a clear intention to transfer property as a gift is a necessary feature of a transfer of property free of charge.

Therefore, it is impossible to speak of a service being provided free of charge to the manufacturer if the above intention has not been established on the part of the seller company and the seller company needs the research on the application of the medicine to sell the product.

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