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Via Leone Pancaldo 68, 37138 T: +39 045 8114111 - F: +39 045 8114390 The Budget Law 2018⁽¹⁾ introduced an important measure for pharmaceutical companies, which came into force on 1 January 2018.

Background

Pharmaceutical companies in Italy have to follow a system known as the 'payback' mechanism, which enables the Italian National Health Service to curb overspending and reduce budget overruns by requiring all of the players in the supply chain to pay back a certain amount if national ceilings on expenditure on drugs in community pharmacies (community budget) and hospital settings (hospital budget) are not respected. This system has operated since 2008 for expenditure through private distribution channels (community pharmacies) and since 2013 for expenditure in hospitals. There are various forms of payback, governed by different regulations: 5% payback, 1.83% payback, payback by product, community budget payback, and hospital budget payback.

The different payback systems are all based on ratio and payment methods; however, they involve different rates, criteria and calculations. For the purposes that interest us here, the first twoe forms of payback (5% payback andv.1.83% payback) are exclusive of VAT while the other two (community budget payback and hospital budget payback) are inclusive of VAT.

In all forms of payback, regardless of the calculation system, the payments, gross of VAT, are made directly to the regional authorities that have run up deficits by overspending.

Before the Budget Law 2018, the VAT treatment of certain forms of paybacks from pharmaceutical companies to regional authorities was unclear.

(1) Law no. 205 of 27 December 2017, published in the Official Gazette on 29 December 2017.

Details of the new measure

The Budget Law 2018 has introduced the possibility of recovering the VAT included in paybacks. More specifically, paybacks are deemed to decrease, pursuant to article 26(2) of the VAT Law⁽²⁾, the tax base of sales of drugs; in other words, there is a sort of compulsory reduction in the sale price.

Consequently, pharmaceutical companies are entitled to recover the VAT paid on paybacks, by deducting it from subsequent payments.

The right to recover VAT arises because this tax becomes an extra burden for companies when they make a payback to a regional authority. It is at this moment that the pharmaceutical company, by refunding part of its profits on sales to a third party, actually decreases the tax base of the transactions involved.

From a timing perspective, the VAT is deductible upon cash payment, i.e. actual remittance of paybacks.

In terms of paperwork, for community budget and hospital budget paybacks, companies can make the adjustment themselves, based on an 'internal document' that makes specific reference to the Regulatory Authority (AIFA) notice indicating the amount to be paid and the due dates.

For the other forms of payback (5% payback and 1.83% payback) the recovery of the VAT is conditional on an equal amount being paid to the state, meaning that the final benefit is neutralized.

The Budget Law 2018 also specifies that, starting from 1 January 2018, all the different forms of payback must be inclusive of VAT. The 5% payback and 1.83% payback regulations have been changed accordingly.

With reference to remittances made before 1 January 2018 for community budget and hospital budget paybacks, the Budget Law 2018 stipulates that the VAT can be recovered by the deadline for the filing of the VAT return for 2018. Moreover, based on the literal wording of the Budget Law 2018, and pending any clarifications from the Tax Authority, at this stage it can be argued that there is no time limit on recovery of VAT of earlier years.

In the event that pharmaceutical companies have already deducted input VAT on 5% paybacks and 1.83% paybacks, a corresponding/equivalent amount of VAT should be posted in the output VAT ledger by 16 January 2018 and included in the January VAT settlement. The net output VAT for January will have to be paid by 16 February 2018.

The Budget Law 2018 also clarifies the direct tax impact of these measures. Without prejudice to accounting and tax approaches followed by companies before 1 January 2018, in relation to the deductibility of payback costs and related VAT, payback costs are deductible on a cash basis. Moreover, recouped VAT will give rise to a windfall gain subject to direct taxes under the ordinary rules. If VAT has been unduly recovered in the past, the new rules (for the 5% and 1.83% paybacks) state that a corresponding adjustment must now be made in the VAT ledger, resulting in an equivalent extraordinary cost that should be deducted for direct tax purposes in the tax year in progress on 1 January 2018.

The above measures also apply to drugs supplied to public bodies under the split-payment system.

(2) Presidential Decree no. 633 of 26 October 1972.

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