

Why do pharmaceutical companies in Romania oppose the claw-back tax?¹

By Oana Stratula (Partner)

The claw-back tax was first introduced in Romania in 2009 as an obligation for manufacturers of medicines to pay a quarterly contribution to reimbursed drugs. Given that in Romania the total quarterly consumption of reimbursed medicines is much higher than the approved budget for this type of medicine, drug producers consider the rate of the claw back tax very high and as such difficult for them to afford.

How is the claw-back tax calculated?

From the first quarter of 2012, a new calculation formula for the claw-back tax has been used, on the basis of an Emergency Ordinance amending Ordinance 77/2011. The claw-back tax includes two-thirds of the producer's market share and one-third of the manufacturer's growth in sales. The quarterly drug sales of an individual manufacturer itself covered by the National Unique Social Health Insurance Fund (FNUASS) and by the Health Ministry are settled by the CNAS.

What are pharma companies' objections to the claw-back tax?

In 2012 the claw-back tax rate was 22%, which led medicine manufacturers to the conclusion that its purpose is not to control excessive market growth, as would be normal, but to completely cover the healthcare budget deficit.

Another reason for their dissatisfaction is the fact that the tax is payable only by drug producers and is not shared by the whole distribution chain (from producers to pharmacies). Moreover, it is calculated by reference to the selling price of medicines in pharmacies, which also includes the mark-ups added to the original price by wholesalers and pharmacies, and hence drug producers end up paying a tax on incomes that they have not collected.

What is more, Government Emergency Ordinance 77/2012 illegally provided that the figure for drug sales on the basis of which the claw-back tax is calculated also includes VAT, which has prompted some drug producers to invoke exemption on the grounds of the unconstitutionality of this legal provision. The Constitutional Court of Romania found that the claw-back tax represents a percentage not only of the price of the medicine itself, but also of the value-added tax on the medicines, which equates to a tax on another tax. Consequently, since taxes and dues may be imposed only on incomes or assets, and not on other taxes,

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the Court decided that applying the claw-back tax on another tax is contrary to the constitutional provisions of fiscal duty.

For this reason, the Constitutional Court decided that inclusion of VAT in the total sales value of medicines in relation to which the claw-back tax is calculated is unconstitutional. The decision of the Constitutional Court is binding.

In spite of all the flaws reported by the drug producers, the claw-back tax continues to apply and the sanction for not paying it is the exclusion of medicines for which payment is not made from the list of reimbursed medicines.

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