

Tax & Legal Weekly Alert

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Tax Updates

Latest amendments regarding the claw-back tax in Romania

The Government amended the Emergency Ordinance 77/2011 regarding the claw-back tax. Based on the new provisions, the market authorizations holders/their legal representatives will pay a different claw-back tax for the medicines conditionally included in the list of compensated medicines for which cost-volume/cost-volume-result agreements were concluded – [page 2](#)



Latest amendments regarding the claw-back tax in Romania

The main amendments are:

- It is now clearly mentioned that the consumption of medicines communicated by the pharmacies to the National Health Insurance House includes VAT and that the claw-back tax due shall be computed after the VAT is deducted from the values of consumption communicated by the National Health Insurance House.
- A new mechanism for computing the claw-back tax is introduced. This applies only for the medicines admitted conditionally on the list of compensated medicines for which a cost-volume/cost-volume-result agreement is concluded between the market authorization holder, the National Health Insurance House and the Ministry of Health.
- The claw-back tax due for these medicines will be computed by applying a percentage "p" (mentioned in the cost-volume/cost-volume-result agreement) to the quarterly value of medicine consumption.
- The value of consumption will be established by taking into account the sale price, without VAT, and the volume of consumption of medicines, as established in the cost-volume/cost-volume-result agreement.
- If the consumption volume mentioned in the cost-volume/cost-volume- result is exceeded, the market authorization holder will pay the full amount of the exceeding consumption of medicines, excluded of VAT.
- The percentage "p" will be computed taking into consideration its value from the quarter prior to signing the cost-volume agreements plus 5 to 30 percentage points, depending on the number of contractible patients for each therapy compared to the number of eligible patients.

The above provisions come into effect starting November 5th, 2014.

Please do not hesitate to contact us if any clarification is needed:

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