

## 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 5<sup>th</sup>, 2014.

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

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