



American Chamber of Commerce
in Romania

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American Chamber of Commerce in Romania (AmCham Romania)

POSITION PAPER ON CLAWBACK TAX PROJECT

The American Chamber of Commerce in Romania (AmCham Romania), through its Healthcare Committee, follows with keen interest the agenda of the Ministry of Health given that health policies are a critical factor not only for the well being of Romanian citizens but also for the economic performance of the country in general.

In this context, it has come to our attention that a legislative proposal regarding the clawback tax on pharmaceutical companies will be adopted by the Government in the coming days. AmCham is very concerned about the provisions of this legislative proposal in the latest draft we are aware of, attached to this letter.

This draft raises profound issues regarding the sustainability and viability of the pharmaceutical industry operating model for both our innovative pharma members and our generic pharma members. It will send a very negative message to all industries in terms of predictability and volatility of the Romanian marketplace and thus will risk significantly damaging investors' confidence.

AmCham believes that the following measures would specifically have a major negative impact on business operations:

- 1. Combination of aggressive tax on growth and tax on total sales:** a 70% tax on growth (50% for growth below 10%) and a 12% tax on total reimbursed sales (7% for generic) should be mutually exclusive. Indeed those two approaches follow different fiscal rationale; both have been considered in the different public consultations but never concomitantly. The aggressive tax on growth will totally eliminate growth prospects by making them non-economically viable while the tax on total sales will considerably deteriorate the profitability of the existing sales base. Simulations clearly demonstrate that applying the two approaches simultaneously will render the business models of both the innovative industry and the generic industry unsustainable.
- 2. 2009 as fixed reference point:** this will cap the market at the 2009 level in an arbitrary way. Since we are in 2011 and the market has grown since 2009 the current proposal will go beyond the stated objective of the claw back (keeping expenditures flat which means limiting the number of new patients) as it will mean a significant decrease and therefore the active discontinuation of current treatments. The fact that subsequent years will continue to be compared to 2009 eliminates future prospect for growth and as such de-incentivize any investments in the Romanian market. This could lead to heavy restructuring, program elimination and a halt in capital expenditures.
- 3. Sales base for the tax calculation:** the current base for the calculation of the taxes is the CNAS price. This price is the producer price, augmented by the distributor margins and the pharmacy margins. In effect, pharmaceuticals companies are being taxed on profits made by other economic entities. The combination of the double taxation described above AND a taxable base that includes distributor and pharmacy margins leads to incremental taxes being superior in absolute terms to incremental sales (see simulation attached). This obviously means a totally unsustainable position for any business, regardless of their margin structure.
- 4. Payment timing for the tax:** companies have to pay quarterly and the trigger is the CNAS receipt of invoice. In Romania, payment terms have almost reached the one year mark (over 330 days

on average). This has two consequences; first the industry is in effect financing the entire system (with significant working capital requirement). Second, the industry is facing a risky environment and that risk is of course compounded by the very long payment terms. The combination of a high risk, major exposure and expensive working capital requirement is already a source of significant concern. If on top of that the industry is now being asked to pay immediately a tax on money that it might recover (in full or only partially) a year from now, most companies will have no choice but asking their direct customers (distributors) to pay immediately. Since they will be unable to comply the entire system might be blocked.

AmCham recognizes the Romanian Government's efforts to meet the commitments under the IMF agreement and ensure the sustainability of the healthcare system to the benefit of Romanian patients. We also acknowledge the urgent character of these measures and the somewhat extraordinary economic conditions which could call for a set of temporary extraordinary measures. We believe that those priorities should be and could be met while at the same time maintaining an environment that will continue to be economically viable for the pharmaceutical industry (both innovative and generic companies) and ensure continued access to medicines.

We would therefore make the following recommendations:

- 1. Combination of aggressive tax on growth and tax on total sales:** a choice should be made between the two approaches. Since the commitment to the IMF has been a claw back tax and the objective is to control future expenditures we believe the focus should be on growth. AmCham would also like to point out that the current model focuses on company's growth where the authority concern should be more on total market growth. Indeed, a healthy competition on the marketplace will be beneficial for Romania and the current system will block the market shares at their current level, preventing for example a development of generics that could bring some cost benefits to the system.
- 2. 2009 as fixed reference point:** the more sensible approach should be to use the same period of the previous year as the reference. This is indeed the accepted way of evaluating growth and it should also be how the tax on growth is calculated.
- 3. Sales base for the tax calculation:** the base for the calculation of the taxes has to be the CIP price (or producer price). A different base cannot be acceptable as it will mean taxing the pharmaceutical industry on the distribution chain profits.
- 4. Payment timing for the tax:** companies cannot be asked to pay for money they have not collected and might never collect. We should therefore go back to a previous draft that was describing a payment becoming due after effective collection of sales.

AmCham wants to recognize the need for collecting revenues to the HC budget and is willing to discuss solutions for the short-term financing.

AmCham fully understands the Romanian Government's commitment to control healthcare costs, but wishes to alert you to the high likelihood of undesirable and unanticipated outcomes if the current draft is implemented as it is.

We have to take into account that the Romanian pharmaceutical industry already faces very significant challenges: very long payment terms, lowest prices in Europe, limited access to innovation because of the lack of recent reimbursement list update, TRP. We support the generic reference pricing on C2 products that has just been introduced but we need to acknowledge that it will also means an important loss of revenues for innovative companies. There is only so much an industry can support, introducing on top of the existing situation the measure described in the current draft will lead to a situation that proves economically unsustainable for pharmaceutical companies, both generic and innovative, with negative consequences for investment, employment, and ultimately the entire healthcare system in Romania.

AmCham reiterates its openness to dialogue and urges the Romanian authorities to consider its members as a resource and reasonable partners in helping them develop solutions that will achieve the authorities' objectives and be economically sustainable, for the clawback mechanism as well as the healthcare reforms in general.

For details or in view of meeting AmCham Romania representatives to discuss the above recommendations, please contact:

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