



American Chamber of Commerce  
in Romania

**American Chamber of Commerce in Romania**

Member of the AmCham Network

Union International Center - 11, Ion Campineanu St., 4<sup>th</sup> Floor, Bucharest

T: + 40 21 315 8694, + 40 21 312 4834, + 40 31 2amcham (262426)

F: + 40 21 312 4851 E: [amcham@amcham.ro](mailto:amcham@amcham.ro)

[www.amcham.ro](http://www.amcham.ro)

---

7 octombrie 2011

American Chamber of Commerce in Romania (AmCham Romania)

## **POSITION PAPER regarding the clawback tax adopted by GEO 77/2011**

AmCham Romania (American Chamber of Commerce in Romania) acknowledges Romanian Government's efforts to ensure a sustainable healthcare system and the need for a clawback mechanism to help better control the budget allocated to medicines. The implementation of this measure rises however major issues regarding the sustainability and viability of the business operations in the pharmaceutical industry.

In its current form, the clawback legislation (GEO 77/2011) sends a strong negative signal to the business environment about the unpredictable and volatile Romanian market, reducing investors' confidence.

The clawback tax approved by the Government on September 21 and enforced as of October 1 provides that the difference between the allocated budget for medicines and the actual consumption to be fully covered by producers.

The recently approved version of the clawback tax still preserves a series of measures that negatively impact the business environment on the long run, contributing to a decrease of Romania's attractiveness for foreign investments.

### **1. Annual Budget**

**The annual budget allocated by the authorities for medicines**, based on the State Budget Law is approved by the Parliament during **the last month of** the year. Obviously, this is the greatest unknown factor in calculating the value of the clawback tax and the impact on companies' businesses. A realistic budget would lead to an acceptable level of the clawback tax. Experience has proven that the healthcare budget has always been underfinanced, with an allocation of just 3.8% of GDP (significantly under the EU average - 8% and even below those of African countries - 5.2%). For instance, in 2010 the budget allocated to medicines was 4.4. bln RON, while the actual consumption went up to 5.3 bln RON. If the current legislation were to be applied, the industry would have entirely covered the 900 mln RON difference. Furthermore, in 2009, the amount the industry would have had to finance was 1.7 bln RON.

### **2. Pharmaceutical companies are taxed on incomes generated by other economic agents**

The current base used for calculating the clawback tax is the price reimbursed by CNAS. This includes the producer price, the distributor margins and pharmacy margins (on average 25%), plus 9% VAT. A taxable base that includes distributor and pharmacy margins, plus VAT is totally unsustainable for any business entity, regardless of the level of margins or the industry.

### **3. Producers of medicines are the only ones made accountable for budget control**

Market growth is not entirely controlled by producers. The consumption increase in real terms compared to the quarterly allocated budget is also influenced by other players in the market (pharmacy, distributors), in addition to system inefficiencies. Thus, authorities have no incentive to impose administrative measures, in order to control consumption.

#### **Recommendations:**

- 1.** Set an annual budget allocation for medicines based on the real needs of Romanian patients, taking into account the drug consumption in the previous year.
- 2.** Use the producer price as base for calculating the clawback tax OR have the producers cover maximum 60-70% of the difference between the real drug consumption and the allocated budget.
- 3.** Cap the “p” percent so that producers will not be made the only party responsible or covering the costs related to a potential exceeding of the initial budget allocated to drugs.

A final recommendation is the need to adopt this measure as part of a memorandum of understanding between the authorities and the pharmaceutical industry, which should settle in the near future areas of major interest towards a sustainable economic context for the pharmaceutical industry:

- Update the list of reimbursed drugs
- Set a sustainable pricing policy
- Gradually align to the payment terms provided by EU Directive 2011/7/UE.

\*\*\*

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

ALEXANDRA GĂTEJ, AmCham Romania President  
PASCAL PRIGENT, AmCham Healthcare Committee President  
ANCA HARASIM, Director Executiv

#### **Contact:**

E: [amcham@amcham.ro](mailto:amcham@amcham.ro)

T: 021 312 48 34, 031 22 624 26, F: 021312 48 51