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## **Claw-back Tax - a Fang of Romanian Health or a Moral Duty?**

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**Abstract:** This study belongs to the scientific field of economics, more precisely to finance area. The scientific challenges to which this approach tries to find answers are the so controversial claw-back tax. It is a fee that even if is applied to different fields of the economy, it succeeded to set up only the national health system from our country, and that is why, this approach try to clarify it. The obtained results of this work intends to bring more light in this dispute between the manufacturers of drugs and the state authority; in this matter, one part considers this claw-back tax as being a moral one, and the others think that it is something abusing their profits. The aim of this study is to clarify this matter, by objectively analyzing the problem from both sides, with their arguments, and with the scientific instruments. So, these are our objectives, treated with the qualitative scientific methods, trying to reach the results and getting the conclusions of this research.

**Keywords:** claw-back tax; health system; money; manufacturers of medicines; taxpayer

**JEL Classification:** G32, G34; J33; M41; M52; M55

### **1. Introduction**

The choice of this theme came from its importance and topicality of the subject. The scientific frame of this paper is circumscribed to the most present theme from time to time in our economic life. The scientific work is circumscribed economic area, specifically financial one, whose events and changes never ceases to amaze us, causing us to constantly seek new answers to other questions that always gives this area of research. The theme is both a challenge, and also a desire to add some more clarification to this matter. The research hypothesis is chosen from this multitude of taxes, and the reason is that this claw-back tax which affects the sanitary system in our country, the problem is: if this claw-back tax is a legal in sense of moral one, or not? This theme is important to be clarified, even if for its topicality, in our days, and of course for its implications in our life. As for the research methodology used in our work it is about a qualitative analysis. The paper proposes a theoretical and doctrine clarifying of the areas. The intuitive method used is because of the lack of data and qualitative approach to areas further research which implies a balanced approach and in terms of quantity. It is also used a prospect method of the impact of claw-back tax on the main undertakings involved: producers, consumers and the state.

Our paper begins with the clarifying the theoretical concept of claw-back fee, by iterating both the best respectful sources as international dictionaries, and also continuing with a pleiade of illustrious authors which have researched this area. After this starting presentation of the subject, this paper continues with the explanation of the topic applied from the theory into practice: that is in the medical system, with special mention to our country. It is fully explained the background of this fiscal measure in the

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Romanian sanitary system, and also the short “history” of this applying of the claw-back tax. It is also analyzed with details the impact of this fee on the health system, and on the public budget as well. Our study further presents the position both of the supporters of this claw-back fee, and also the critics of it. The final part of this paper shows the consequences of applying this tax for all the implied factors. As normally used, this approach ends with the conclusions of our research.

## 2. General Presentation

Accordingly to the basic definition, type claw-back fee is actually a financial penalty applied to companies that have violated certain provisions. In this case, however, it represents a surcharge revenues obtained from pharmaceutical companies that make sales over the state budget for medicines. First of all, we shall have a look to the different approaches of this topic in literature.

In the British & World English dictionary, the Claw-back tax is defined as two acceptors, as follows: “Money or benefits that are distributed and then taken back as a result of special circumstances, and the second acceptor is: a retraction of stock prices or of the market in general”. (British & World English Dictionary, 2015)

Oxford Advanced Learner's Dictionary explains claw-back as: “the act of getting money back from people it has been paid to; the money that is paid back”<sup>1</sup>.

Cambridge Dictionary precised: “A claw-back refers to the recovery of money which has been already paid to a person or company, typically because that payment should not have been made for legal (or occasionally moral) reasons. It can also refer to the recovered money itself. Claw-back provisions in a contract may entitle a party (e.g. the company’s shareholders or creditors) to claw-back (= recover) excessive salaries or bonuses paid to the company’s directors, for example, if it can be shown that those payments damaged the company’s ability to fulfill its commitments to that party. As the news headlines below suggest, the expression is usually used in a compound noun (e.g. claw-back provisions, claw-back clause) or as a phrasal verb (to claw something back)”<sup>2</sup>.

Investopedia explains “claw-back” both in two ways, like this: the first acceptor is: “purchasing certain investments provides taxable benefits contingent upon holding periods. When you sell these investments before they have reached maturity, the benefits must be returned; and the second acceptor is: in layman's terms, a fall in a stock's price right after an increase is called a claw-back of the price”<sup>3</sup>.

Farlex Financial Dictionary defines claw-back as: “a drop in a security's price after a previous rise, and the second acceptor is: “money that must be refunded or given back for some reason or other. The term especially applies to tax advantages extended to a taxpayer subject to certain conditions that the Eurostat taxpayer did not fulfill”<sup>4</sup>.

Webster's New World Finance and Investment Dictionary describes claw-back tax as follows: “a word used in the venture capital industry to describe a common term found in partnership agreements. A claw-back requires venture capitalists to refund fees to their investors if it turns out that the venture capitalists received more than their 20% share of a fund’s overall profits. Claw-backs became common in 2002, occurring when a venture capitalist took its 20% share of a fund’s early investment success, but the fund later lost money. Claw-backs also are used in other financing contexts, such as private equity”<sup>5</sup>. This matter was studied and deeply analyzed by some important researchers, among which we remind the followings: the adoption of a claw-back is followed by higher proportions of equity based pay and long-term pay. Firms with a greater proportion of equity based pay are more likely to suffer from managerial actions such as earnings manipulation (Burns and Kedia, 2006). They find that

<sup>1</sup> Oxford Advanced Learner's Dictionary, published by Oxford University Press, 2015.

<sup>2</sup> Cambridge Dictionary, printed by Cambridge University Press, 2015.

<sup>3</sup> <http://www.investopedia.com>.

<sup>4</sup> Farlex Financial Dictionary. © 2012 Farlex, Inc.

<sup>5</sup> Webster's New World Finance and Investment Dictionary - Copyright © 2010 by Wiley Publishing, Inc., Indianapolis, Indiana. Used by arrangement with John Wiley & Sons, Inc.

executives are more likely to manage earnings when they receive higher levels of equity-based pay. Efendi, Srivastava, and Swanson (2007) find that firms where the CEO has significant holdings of in-the-money options are more likely to restate earnings.

Levine and Smith (2010) theoretically explore the incentive properties of mechanisms that can retract previously awarded cash bonuses, but provide no empirical analysis. Chen, Greene, and Owers (2012) also develop a model of claw-back incentives.

Brown, Davis-Friday and Guler (2011) examine 252 claw-backs over 2005-2009 (Corporate Library data) and find that adopting firms are larger, have less influential CEOs, and have higher M&A bonuses and goodwill impairments.

Paquita Y. Davis-Friday, Abraham N. Fried and Abraham N. Fried (2011) examine whether the adoption of claw-back provisions in executive compensation contracts improves the informativeness of accounting information. Contrary to conventional wisdom, they find that claw-backs do not lead to improved financial reporting. Specifically, they also document a significant decline in the market's response to earnings surprises after the adoption of both fraud and performance based claw-back provisions. Their results provide a cautionary tale of how some types of claw-backs may produce an unintended consequence in terms of deteriorating the established relation between reported earnings and stock price.

Fried and Shilon (2011) provide information on usage rates for firms in 2010 in the S&P 500.

Some of the contemporaneous research on claw-back adoption often focuses on policies triggered by one specific event, such as accounting restatements (e.g., Chen, Green, and Owers (2012)).

This is consistent with the notion that a primary reason for adopting a recovery policy is concern over accounting or stock price manipulation by executives to increase bonus payments or increase the likelihood of clearing the performance hurdles defined in performance-based vesting provisions (Bettis, Bizjak, Coles and Kalpathy, 2012).

Ilona Babenko Benjamin Bennettb John M. Bizjakc Jeffrey L. Colesd, in their work named *Claw-back Provisions* (2012), contrary to some prior studies, they do not find that claw-back adoption lowers the incidence of financial restatements (Chan, Chen, Chen, and Yu, 2012) or reduces shareholder litigation or discretionary accruals. Nonetheless, on average the market reaction to report of a clawback policy prior to Dodd-Frank<sup>1</sup> is positive and significant, on the order of 0.5%.

### **3. From Theory to Practice: Applying Claw-Back Fee**

Claw-back is a tax applied in the pharmaceutical industry and assumed that all drug manufacturers to help fund public health system with an amount of money ranging between 5% and 11% of the income made by selling the products. The contribution shall be paid quarterly until the 25th of the month following the quarter in which delivery took place drugs in a special account opened at the Treasury on behalf of the Ministry of Health.

Claw-back tax, paid by drug manufacturers that have products on the list of compensated and free, was first introduced in 2009, but since then until now has suffered a series of changes. Given that GEO 104/2009 contained quite a lot of doubt about the calculation algorithm and the time you have paid this fee additions were made by WHO 928/2010. The new order brings certain clarifications regarding previous interpretations of the provisions relating to the declaration, calculation and payment of "claw-back". The most important changes concern:

- date on which the contribution ("claw-back" tax) becomes chargeable - only after receiving a fully revenues from sales related to a quarter;
- the date on which contributions must be paid - date of payment "claw-back" is set by the House

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<sup>1</sup>The Dodd-Frank Act: *Significant Impact on Public Companies*, Skadden, Arps, Slate, Meagher & Flom. Retrieved July 25, 2010.

National Health Insurance by notification addressed to each payer;

- introduction of additional statements containing the details of the consideration medicines collected on a certain quarter;
- replacing “2010” by “year...” in the Annexes 1 to 5 of the Order 928/2010.

The Order of the Health Ministry no. 351/2011 changes the rules for calculation, declaration and payment of the claw-back fee. This becomes due only after receiving entirely by payers of income related to a quarter. Accordingly to the Order no. 928/591/2010, quarterly total revenue is the amount resulting from the sale in Romania by tax payers, as follows: medications included in national health programs that benefit the insured in outpatient treatment, with or without personal contribution, based on prescription, health insurance system, and medicinal insured persons in hospital treatment. Under the rules issued earlier, the persons liable to pay the tax declared National House Health Insurance drug sales by suppliers of drugs used in the outpatient treatment or medical units with beds, using the forms 2a, respectively 2b. The rules introduced by WHO 351/2011 is inserted and the obligation to declare, via new forms 2a1 and 2b1, full collection of these revenues corresponding quarterly sales previously reported. The new statements are submitted in the first 5 days of the month following the month in which they were fully collected revenues of a quarter.

As for the calculation of tax, Order no. 351/2011 clarifies the fact that the established percentage based on the total revenues from sales of medicines for outpatient and hospital use related to each quarter is applied to the proceeds from the sales of drugs for treatment outpatient and hospital use same quarter related (such as GEO 104/2009 also provides that introduced this contribution). Under the new provisions, and succession procedures for determining tax “claw-back” would take place as follows:

- in the first 5 days of the end of each quarter is still mandatory submission to the National Health Insurance House of the Declaration on the list of medicines sold in one quarter, for suppliers of drugs used in outpatient treatment (Form 2) and/or the Declaration on the list of medicines sold in one quarter for health facilities with beds (Form 2b). Maintain the health facilities with beds for compulsory transmission of health insurance houses lists of medicines purchased in that quarter;
- in the first 15 days of the end of each quarter is maintained for the National Health Insurance House mandatory transmission centralizer drugs purchased by the medical bed in the quarter;
- In the first 5 days of the month following the month in which they were entirely related revenues collected in a quarter (where income for that quarter were previously reported by Form 2a and/or 2b). Persons liable to pay tax are obliged to submit to the National House of Health Insurance, if applicable, the Declaration on the list of drugs used in outpatient treatment related to a quarter of the value of the services was collected (Form 2a1), and/or Declaration on drugs list used by health facilities with beds, relating to a quarter of the value of the services was collected (Form 2B1);
- within 15 days of filing Form and Form 2a1 2b1: National House of Health Insurance contribution due notice according to data reported;
- by the date specified in the notification received from the National House of Health Insurance, the persons liable to pay tax must make its remittance to the date specified in the notification (before payment is made until the 25th of the month following each quarter).

GEO 77/2011 was tried improvement and tax regulation “claw-back”, amid countless controversies and complaints that sparked a claw-back the old regulation, namely, GEO 104/2009, as amended and supplemented.

According to GEO 77/2011, quarterly contribution is calculated by applying a percentage “p” on the value of consumption of medicines, supported the National Fund for Health Insurance and the Ministry of Health budget, consumption related sales contribution of each payer. This percentage “p” is calculated by CNAS and communicates the marketing authorization holders of medicines following the expiration until the end of the quarter.

In turn, GEO 77/2011 has undergone some significant changes by GEO 110/2011 which again change the formula for calculating the contribution and the Ordinance 17/2012 regulating certain fiscal measures which came into force on August 24, 2012 which focuses on the following aspects:

- cancellation “delay penalties” for people who owe tax claw-back for the period between fourth quarter 2009 and third quarter 2011 are fulfilled cumulatively the following two conditions:

(1) people who owe claw-back declare and fully pay tax within 30 days from the date of entry into force of GO 17/2012

and

(2) pay the legal deadline for payment of interest due for principal obligations;

- the obligation of submission to the National Health Insurance House's updated list of drugs for which the claw-back tax is due until the 15th of the month following the quarter for which the tax is due;

- remove the value added tax (VAT) of the formula for calculating state budget incurred related to drugs, but only since the fourth quarter of 2012.

On 5 February 2013, the Constitutional Court decided that the inclusion of value-added tax (VAT) in the formula for calculating the claw-back (for the period prior to the fourth quarter of 2012) is unconstitutional. Therefore, even if the GO 17/2012 removed VAT from the calculation formula claw-back just starting the fourth quarter of 2012, according to the decision of the Constitutional Court, VAT not to be taken into account even before the appearance of Ordinance 17/2012.

Conclusively, the calculation of “claw-back” is a laborious present case involves a close relationship between the taxpayer and the CNAS, preparing statements provided by the legislation listed above for each period they were in force, the calculation and payment contribution/tax coming as a consequently their data and communicate directly to the taxpayer by CNAS (market authorization holders of medicines).

Not least the calculation of “claw-back” involves taking certain decisions of the entity's legal representative on the interpretation and implementation of the legal framework applicable.

The latest version, which will come into force on October 1st 2011 brings the news eliminating value-added tax (VAT) of the calculation formula and increased the amount reference value of 1.42 billion lei 1,51 billion lei (without VAT). This reference amount is paid quarterly approved budget for medicinal National Unique Fund Health Insurance (FNUASS) and from the Ministry of Health (MOH). Generic Drugs Manufacturers Representatives Association of Romania (APMGR) argue that while the government eliminated the formula for calculating VAT, pharmaceutical companies are still required to pay a fee for the entire chain of distribution revenues, which include the additives applied by distributors and pharmacists. Moreover, the amount of reference, although it was raised, not the actual consumption of drugs in 2011. “Returning to the calculation formula of GEO 77/2011 which was widely criticized including by the IMF because of unfair character - similar charge applied to all producers, regardless of drug sales growth recorded by each company - and unpredictable (percentage “p” is calculated on the basis of erroneous non-transparent manner provided by CNAS and companies can not in any way anticipate the amount thereof)”, reads a release of APMGR.

Claw-back was adopted since October 2011 and now has begun to create problems for patients with serious diseases. The amount of an industry amounted to 400 million lei in the first three months of this year, i.e. 33.6% of the entire value of compensated drugs consumed during this period. The claw-back applies Romanian pharmaceutical industry for drug manufacturers to help fund public health system with a variable amount of money depending on the income. Although modified in order to be more friendly for the taxpayers, it remains rather controversial and the new project on claw-back public discussion launched by the authorities does not include requests from industry. But, four years after the introduction of this tax has not solved the health budget deficit, moreover, is, in the opinion of industry representatives, a brake on the development of generic drug companies by reducing local production, delaying investments in development and even reduction personal.

Although, for many seem like a visually impaired claw-back tax can be understood by a single word: claw. The main actors in health care - the state, manufacturers and retailers of medicines - are fighting to seize a larger part of the money those Romanians who contribute to National Health Insurance Fund. And as the stakes consistency, claw-back tax has become one of the most disputed legislative provisions of the last three years.

The underfunding of the health system threatens to impede the access of Romanians to new pharmaceutical treatments to eliminate from the market affordable medicines and the pharmaceutical industry to cancel investments in production and development.

Romanian authorities ask drug makers a review of the method of financing the deficit in the health system. Claw-back tax on producers to cover the difference between the state budget and actual consumption generated by drug treatment needs of patients Romanian, recorded in the last quarter of 2013 a significant increase of 30% compared to other quarters and reached a unsustainable level for the pharmaceutical industry.

Grand drug manufacturers complain that the fee claw-back corresponding first quarter of this year, in Romania represents about 30% of the sales of most drug manufacturers compensated. Curiously, small producers argue that the actual percentage is only 11%. Great producers of medicines, namely multinational companies, seeking annulment of the tax claw-back current form and asked the government to amend the law involved and the need for proper budgeting at national pharmaceutical, real consumption from 2013.

“Claw-back amount of the fee cannot be supported by the industry, it represents more than 400 million euro per year (calculated for 2011), averaging 33.6% of total sales of pharmaceutical manufacturers compensated over any company related taxes trade in this form unique in Europe”, reads a release of the Romanian Association member companies of International Medicine Manufacturers (EFPIA) and the Association of Generic Medicines Producers in Romania (APMGR). But what the medicines producers forget to say is that drugs manufacturers claw-back exists in all European Union countries and is designed to curb abusive consumption of drugs. Furthermore, fee has designed to help small producers in their fight with drug multinationals. The truth is that claw-back is good for small fee. It penalizes the major manufacturers offering huge discounts to pharmacies. Basically fee is charged to the final price at which the drug reaches the consumer. How multinationals offering 75% discounts at pharmacies, and they sell to the consumer medicines are now obliged to pay this tax and discounts. And this is not convenient. What they forget to say is that the major manufacturers in the European Union tax discounts offered to pharmacies are of 90%”, as declared a Romanian producer of drugs.

Romanian health system is among the most poorly funded in the European Union, as Romania is among the last countries in Europe in terms of percentage of GDP allocated to health, with only 3.9% compared to the European average of 9%. Expenditure on drugs are only about 80€/year/capita, while even in neighbor countries - they start from 150€/year/capita.

The Romanian state has huge debts to suppliers of medicines, debt accumulated in recent years. One of the priority requirements of the International Monetary Fund was paying these debts (arrears) whose size threatens medical system crashes. In August 2010, the government allocated 1.9 billion lei to pay debts to suppliers of medicines, but after making payments, the IMF staff found that the absolute amount of arrears decreased by only 600 million lei. How was that possible? It seems that pharmacies have not submitted all the bills health insurance houses because they knew that the funds allocated were insufficient to compensate drugs. When new money appeared, the bills were reported. And as a story of bottomless pitcher began to rise incessantly new and new arrears. This situation was triggered in the 2008 election year, when the Health Ministry has eliminated the ceilings of pharmacies, which were kept under control with medication expenses compensated. To private reaction it was a natural one: both higher sales to make profits as large. In Romania, the main business partner pharmaceutical industry is the state, which totally or partially compensates for the price of a number of drugs.

As statistics reveal, only in 2012-2013 period, 2 of 10 patients were treated exclusively Romanian contributions from the pharmaceutical industry through claw-back. Manufacturers of drugs and APMGR gathered together in ARPIM associations point out that, under a budget well below the European average, as is currently updating the list in terms of compensated drugs, deficit financing exclusively to producers through claw-back it is impossible. In the last two years they have funded health system 2.8 billion lei, and the situation seems to change in 2014 as the authorities have allocated only 6.6 billion lei, while consumption amounted to 8 billion lei, without taking into account the updating of the list of free and subsidized medication. The amount of the claw-back tax reached 25.23% of the sales of subsidized drugs that manufacturers have had in the fourth quarter of 2014 showed Generic Medicines Industry Association in Romania (APMGR), which states that the National Insurance data health (CNAS) which was calculated based on the rate of duty are wrong.

#### **4. Technical Explanation of Claw-Back Tax**

Currently, all pharmaceutical companies pay to the State a claw-back fee amounting to about 14% of turnover (i.e. 14% of total company sales). The tax is paid only by the drug companies, but is calculated including distribution and pharmacy margins that you do not receive the drug companies. According to the Emergency Ordinance no. 77/2011, quarterly contribution (claw-back) is calculated by applying a percentage “p” on the value of drug consumption FNUASS budget support and that of MS, related sales contribution payer in each hand.

$$p = ((CTT - BAT) / CTT) * 100$$

in which CTT is total consumption of medicines paid from fund quarterly national unique health insurance and the Ministry of Health budget.

(CTT means total consumption of medicines paid quarterly budgets FNUASS and MS BAT quarterly approved budget for the drugs covered FNUASS and MS budgets, calculated by dividing the annual budget initially approved in April by state law).

The coefficient “p” shows APMGR in a statement, it rose to 25.23% in Q4 2014 compared to just 20.92% in quarter 3. Increased percentage “p” in calculating the claw-back tax to 26.1% in the 1st quarter of 2015, from 25.23% in Q4 2014 is a direct consequence of increased consumption of innovative medicines whose price was maintained at a very high level in recent years through violation of the laws on drug pricing. APMGR reiterates that the only solution that could make things normal, saving the insolvency generic manufacturers is the immediate implementation of a differentiated calculation of the tax claw-back for generics, based on the introduction of a maximum proportion of 65% in calculating the variable “p” the claw-back formula, thus correlating with the fiscal burden in the drug pricing policy.

In 2014 was published Government Emergency Ordinance no. 69/2014 on the establishment of financial measures in health and amending certain acts. GEO 69/2014 brings a number of changes and, especially, additions to the quarterly contribution regime (claw-back tax) regulated by Government Emergency Ordinance no. 77/2011 on the establishment of contributions to fund health spending, as amended, that have been instituted other financial measures applicable in regional or research and development. Quarterly total consumption value of drugs (CTT) used to determine the percentage “p” will be reported CNAS by health insurance funds on the basis of data recorded in the informatics platform of social health insurance; in turn, the value related to consumption of drugs centralized notified each taxpayer (tax base) will draw all the data recorded in the said platform, as follows:

- taxpayers, that authorization holders for medicines (“MAH”), Romanian legal persons and foreign legal representatives MAH will submit quarterly CNAS updated list of medicines for which the tax due according to a methodology and a format approved by order of the President of CNAS;
- tax payers will determine and calculate VAT excluding tax due from the volume of quarterly consumption of medicines notified by CNAS (in fact, regulation of current practice);

- appeals against consumption values will be notified by CNAS to see only the data for the first quarter for which they were communicated.

GEO no. 69/2014 supplements 77/2011, by establishing a separate tax regime for those drugs, as a result of the health technology assessment procedures, receiving conditional inclusion decisions DCI list. In short, the new rules thus established are:

For mentioned products may conclude price-volume/cost-volume-outcome (“CV Contracts”) with the funds obtained from the exclusion and/or compensation percentage change of medications included in the DCI list, as well as the implementation of policies pharmaceuticals (MAH interested potential elements apparently unknown); failure to conclude such contracts will attract unable to include relevant medicines DCI list.

CV contracts are qualifying as mechanisms to ensure the financial sustainability and predictability of costs in the public health system by which local MAH MAH foreign or local representative undertakes to supply medicinal products included conditioning DCI list under the rules of GEO no. 69/2014, for a certain category of patients and for a certain period of time;

Initiate contract negotiations CV is according to prioritization criteria and model contract expressly provided and methodology of the negotiation, conclusion and monitoring of the implementation of such contracts shall be determined by the Minister of Health and CNAS president;

Claw-back tax payable by taxpayers is determined by applying the CV based contracts provided these contracts to the value of consumption in individual quarterly statement of CNAS.

Consumption value is calculated by multiplying the quarterly retail price excluding VAT/wholesale price with the volume of medicines consumed quarterly volume limit set by contracts CV; and the percentage claw-back tax consists of the percentage value “p” for the previous quarter Contract conclusion CV, calculated according to the formula set out in art. 3 paragraph (2) of the Emergency Ordinance no. 77/2011 (the common percentage applicable fee unconditionally compensated medicines), plus between 5 and 30 percentage points in the proportion the number of patients for each therapy to shrink the number of eligible patients (percentage found in the relevant contract CV). If the cumulative excess volumes of drugs consumed volumes determined by contracts CV, taxpayers bear the full amount of the related drug consumption exceeded, excluding VAT; this value is not included in the calculation exceeded quarterly total consumption of drugs (CTT). Within 15 days of the issuance of conditional listing decision DCI list, foreign MAH must appoint a legal representative, Romanian legal person to negotiate and conclude contracts CV or to declare and pay claw-back payable; also, within 30 days from the date of conclusion CV MAH local or foreign legal representatives must register for tax purposes at the National Tax Administration Agency as contributors to claw-back.

Note that the rules on the submission of quarterly by CNAS, challenging them and the applicable payment terms relating to medicinal products included conditioning DCI list, although regulated distinct, are identical/similar to those for subsidized drugs without restrictions in the health insurance system, which is due to determine claw-back according to article 3 of GEO no. 77/2011. It also established the obligation of all foreigners holding MAH drugs included in the list DCI (including new products) that have not yet designated a legal representative, within 30 days of the entry into force of the ordinance, communicate CNAS data Identification of that representative, whilst tax recorded in the same period.

In essence, the new law establishes two tax regimes and determination of tax applicable claw-back drugs that are currently granted state social insurance system, i.e. new drugs conditioning included in the list comprising international common names for medicinal products for insured persons in the system health insurance or national health programs (“DCI List”). The Association states that the already high level of claw-back tax forced drug manufacturers only generics in Romania last year to lay off more than 300 employees and a decrease in production for the domestic market by 10% , and delay major investments in local production facilities. In addition, since 2011, when claw-back tax

was introduced, there have disappeared from the market more than 1,300 medications. GEO 69/2014<sup>1</sup> brings a number of changes and, especially, additions to the quarterly contribution regime (claw-back tax) regulated by Government Emergency Ordinance no. 77/2011 on the establishment of contributions to fund health spending, as amended, that have been instituted other financial measures applicable in regional or research and development.

In essence, the new law establishes two tax regimes and determination of claw-back tax applicable to drugs that are currently granted state social insurance system, i.e. new drugs conditioning included in the list comprising international common names for medicinal products for insured persons in the system health insurance or national health programs (“DCI List”). We note the following changes in applicable tax claw-back already compensated medicines in the public: quarterly total consumption value of drugs (CTT) used to determine the percentage “p” will be reported CNAS by health insurance funds on the basis of data recorded in the informatics platform of social health insurance; in turn, the value related to consumption of drugs centralized notified each taxpayer (tax base) will draw all the data recorded in the said platform.

The Association states that the already high level of tax claw-back forced drug manufacturers only generics in Romania last year to lay off more than 300 employees and a decrease in production for the domestic market by 10% and delay major investments in local production facilities. In addition, since 2011, when it was introduced claw-back, they have disappeared from the market more than 1,300 medications.

Generic Drugs Manufacturers Association of Romania (APMGR), the representative body of generic drug companies in Romania, announces that the claw-back tax on the 1st quarter of this year reached a new historic high of over 26% of sales to the public sector which will lead to the disappearance of several drugs and cheapest on the market and the collapse of the local pharmaceutical industry.

The tax is paid only by the drug companies, but is calculated including distribution and pharmacy margins that you do not receive the drug companies. And the producers of drugs accused that: Claw-back tax level in the fourth quarter of 2013 reached a level of 20% of the sales of medicines, it means that we pay, in addition to the flat 16%-20% of turnover. We are talking about higher taxation, somewhere at 40%. We have to stop all investments in 2014 until a solution is found for this claw-back tax.

Manufacturers, distributors and pharmacies selling drugs offset the debt: the state debt promptly honoring promises and citizen expect to receive subsidized drugs in payments that you make monthly to the National Health Insurance Fund, under the quiet approval of the State. If a manufacturer/importer of drugs cannot pay the quarterly fee (calculated based on a formula that takes into account the market share and sales growth), when products are withdrawn from the list of compensated and free of charge ones.

In this dispute, in Romania there are two different parties: one sustaining the claw-back tax, and another one rejecting and criticizing it, as follows: the Proponents of the tax say that, in Romania, the consumption of drugs crazy. They are right; CNAS spends a quarter of its funds with medicines, one of the highest percentages in Europe. 20 most prescribed medicines in Romania are new and expensive pharmaceuticals, which is unusual in Europe. Most often, they are part of national health programs - which recorded the largest increase in funding in recent years - and are usually prescribed total cleared and especially in poor districts and universities (according to World Bank experts). Manufacturers of generic drugs are required to pay for additions distributors and pharmacists as claw-back is calculated at retail price of drugs, which includes over producer prices and trade margins.

Maintaining reporting errors reported by member companies APMGR the National Health Insurance Fund (NHIF) and the total lack of transparency regarding the calculation of tax claw-back. Keeping the basis for calculating the tax claw-back of drugs purchased in hospitals are reimbursed twice by CNAS hospitals are funded under the DRG system. The existence of proven fraud and counterfeit

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<sup>1</sup> GEO – Government’s Emergency Ordinance.

medicines into the system, resulting in artificially raising the claw-back tax. Keeping prices above those of the rest of the EU for most settled 50 drugs, resulting in increased tax claw-back.

In the National Health Programs are recorded fact and the largest state debts to the pharmaceutical industry. Sometimes, even certain segments of state encourage such reckless spending. Process the lists of compensated drugs - entering the prerogative of the Ministry of Health committees - is "nontransparent, inconsistent and too little based on practical data" (IMF staff report). Thus, it follows that, in Romania, to compensate for treatment with extracts of ginkgo biloba, for example. In addition, sales of drugs on large international manufacturers which no longer have patent (so called generics) are not encouraged, their volume decreasing in recent years. When you asked last time the pharmacy "aspirin cheapest, not the most expensive"? As the opponents say that tax, in Romania, the consumption of drugs is much lower than in the rest of Europe. And they are right. Romania's per capita expenditure on drugs are the smallest, only 172 euro compared with the European average of EUR 376 maximum or registered in Greece (584 euro). As a percentage of GDP, expenditure on medicines Romania is 1.4%, below 1.7%, as is the European average (Eurostat)<sup>1</sup>.

Then the drugs trade is already overburdened in Romania, offset VAT on medicines being 9% compared to zero in the UK or Sweden.

Romania is one of the European countries and origin of parallel trade, given the low price imposed by the Romanian producers. Parallel, trade occurs when a dealer buys drugs from manufacturers in countries with cheap medicines (Romania being one of the European countries with the cheapest drugs when put on the market) and exports them to countries with higher prices where they are sold directly pharmacies. This practice legal but immoral lowers the Romans access to certain drugs. The full truth is that the Romanian state invests far too little money in medication use compared with other European countries (Romania allocate health under 5% of GDP last place in the EU), and this consumption is not modeled in favor of the patient, but rather in favor the interests of the pharmaceutical industry.

It is a good measure taken by the government but whose application would be unfair for some players in the system that it encompasses manufacturers, distributors and pharmacies. Of these, only producers will bear the burden, because the difference will be charged (50 million in the example above) contains the profit margins of pharmacies and distributors. Romania is a special case here: the producer price of the drug enter the market, add distributor and the pharmacy margin, which grow (with VAT) acquisition final price to the patient. This price is settled by CNAS and taken as reference in calculating the claw-back, and distributors and pharmacies in Romania have among the highest margins in the European Union (Scrip Report).

Manufacturers of drugs warn that this claw-back tax increase is not supported by market developments. In addition, they fear that the growth trend will continue and even accelerate in coming quarters while the indicative budget for the calculation of the claw-back is as low medicine consumption in 2011.

The underfunding of the health system threatens to impede the access of Romanians to new pharmaceutical treatments to eliminate from the market affordable medicines and the pharmaceutical industry to cancel investments in production and development.

Romanian authorities ask drug makers a review of the method of financing the deficit in the health system. Claw-back tax on producers to cover the difference between the state budget and actual consumption generated by drug treatment needs of patients Romanian, recorded in the last quarter of 2013 – as example - a significant increase of 30% compared to other quarters and reached a unsustainable level for the pharmaceutical industry.

Every year, drug manufacturers cover the claw-back, the entire difference between the state budget and actual consumption generated by drug treatment needs of patients Romanian. In other words, the claw-back was transformed from a budget control measure in a tax burden which resulted in the creation of a business environment lacking transparency and predictability. The burden is even greater

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<sup>1</sup> www.eurostat.

as the list of compensated and free drugs has not been updated for six years, which means a negative economically and socially strong impact. As a consequence, they say that about a thousand of drugs will disappear from the market. Manufacturers of drugs warn that this claw-back tax increase is not supported by market developments. In addition, they fear that the growth trend will continue and even accelerate in coming quarters while the indicative budget for the calculation of the claw-back is as low medicine consumption in 2011. Keeping that tax in its present form, it can have serious economic and social consequences, primarily for population by the total disappearance from the market of medicines and inability to introduce new drugs and for drug companies, which will have to postpone or cancel investments in local production capacities.

In recent years, they say that the market disappeared almost 1.000 types of medicines in all therapeutic areas, both because of the claw-back, but also to the calculation. Head APMGR says that currently, there are 120 active trials of pharmaceutical companies on the claw-back, won at first instance, and if they will be won definitively, National Health Insurance must return differences and budgetary effort will be a huge one.

## **5. Conclusions**

The truth is that claw-back tax is good for small producers. It penalizes the major manufacturers offering huge discounts to pharmacies. Basically fee is charged to the final price at which the drug reaches the consumer. How multinationals offering 75% discounts at pharmacies, and they sell to the consumer medicines are now obliged to pay this tax and discounts. And this is not convenient. What they forget to say is that the major manufacturers in the European Union tax discounts offered to pharmacies is 90%. Note that if a manufacturer/importer of drugs cannot pay this quarterly fee (calculated based on a formula that takes into account the market share and sales growth), when products are withdrawn from the list of compensated and free.

But this claw-back tax is not a panacea for the Romanian medical system. If it is not matched by few essential measures such as rebuilding a new list of compensated drugs and the introduction of clear criteria for their therapeutic efficiency and economical, the claw-back will only be placed in a claw-back producers, that will improve the Balance Sheet State but not human health. That is why there are some problems that were pointed out by the Association of the manufacturers of the drugs in relation to claw-back: manufacturers of generic drugs are required to pay for additions distributors and pharmacists as claw-back is calculated at retail price of drugs, which includes over producer prices and trade margins; maintaining reporting errors reported by member companies APMGR the National Health Insurance Fund (NHIF) and the total lack of transparency regarding the calculation of tax claw-back; keeping the basis for calculating the tax claw-back of drugs purchased in hospitals are reimbursed twice by CNAS hospitals are funded under the DRG system; the existence of proven fraud and counterfeit medicines into the system, resulting in artificially raising the claw-back tax; keeping prices above those of the rest of the EU for most settled 50 drugs, resulting in an increased claw-back tax.

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