

## Pharma Sector under the Influence of the Parafiscal Mechanism: Clawback Tax

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### Abstract

*The authors of this paper address the issue of the „Clawback Tax” in the context of the desire to ensure an efficient and sustainable public health care system, but without affecting the legitimate interests of the Romanian Pharma Sector. Knowing what is meant by taxation and parafiscality, the penetration of the Clawback Tax substrata certainly requires a double approach: a legal one and an economic one (fiscal- budgetary). We consider the circumstances that led to the introduction of the Clawback Tax, the effects generated along the way and any changes that may be necessary, giving our work the following structure: Introduction; Theoretical Background; Research methodology focusing on the adoption of the Clawback Tax in Romania; Size and evolution regarding the financial source for the Single National Health Insurance Fund (FNUASS), based on the collection of the Clawback Tax; Adaptation of the regulatory framework on the Clawback Tax to the requirements of the Treaty on the Functioning of the European Union and Conclusions.*

**Key words:** Pharma sector; financing health; parafiscal mechanism; Clawback Tax; clarifications/assessments; necessary corrections

**J.E.L. classification:** H51, I15, I18, K34

### 1. Introduction

Before actually bringing the „Clawback Tax” into the debate, we feel it is necessary to present a few issues in relation to what parafiscality means. Thus, the concept in question refers to parafiscal contributions (taxes), which are nothing more than sums of money collected - either by the tax authorities or directly by the beneficiaries of the revenue in question - on the basis of legal rules adopted specifically for this purpose, but which are paid/transmitted to the accounts of certain public institutions or other public or (sometimes) private bodies (Beltrame & Mehl, 1997).

According to Professor Mircea Ștefan Minea, „the characteristic of parafiscal taxes is that they are - like taxes - compulsory (being established by law, they are pursued and collected either through tax administrations or directly by legally designated beneficiaries, in whose accounts they are concentrated, and constitute extra-budgetary income of legal persons of public or private law. The techniques and procedure for collecting/collecting parafiscal charges are very similar to those used in tax matters.” (Minea, 2011).

Parafiscal taxes come in a variety of forms, including, in the case of the Romanian tax system, the Clawback Tax. Obviously, from a legal point of view, no problems arise, as these special forms of constituting complementary financial resources at the disposal of public entities (CNAS - National Health Insurance House) are perfectly legal: „Even if they increase the burden placed on taxpayers, those taxes contribute - on the one hand - to the partial relief of the budget (in terms of bearing/covering certain expenses), and - on the other hand - the introduction of such special

(parafiscal) taxes is likely to ensure a fairer distribution of fiscal and non-tax burdens between the various categories of taxpayers, which is fully in line with constitutional principles.” (Minea, 2011).

In Romania, the legislator has tried to simplify the parafiscal system, adopting a normative act (RP/Romanian Parliament, 2017) which provides for the elimination of more than 100 taxes paid by citizens, aiming to „reduce waiting times, in front of counters, for their payment, but also to streamline the work of public institutions by simplifying and streamlining internal processes.” (RP, 2016). The eliminated taxes had a reduced budgetary impact, counting more on the time saved by citizens, which leads to increased consumption, trust in state institutions, and Romania's climb in the Doing Business world rankings.

Specifically, the changes introduced by the above-mentioned act concern the elimination of the following non-tax taxes (RP, 2016): (i) Radio and TV fees (which will be supported by the state budget, the institutions in question having the possibility to continue to finance themselves from the proceeds of advertising, donations or sponsorships); (ii) Stamp duty for motor vehicles; (iii) Fees charged by the National Office of the Commercial Registry when setting up a company and when registering entries; (iv) Fees for tax records and criminal records, which will be issued to applicants free of charge; (v) Consular fees levied at diplomatic missions and consular offices of Romania abroad; (vi) Fees for the apostille and super-legalisation of official documents, additional fee for the issue of passports; (vii) Fees for the payment of lost or amended documents for publication in the Official Gazette; (viii) Extra-judicial stamp duties; (ix) Fees for the issue of recreational/sports fishing permits.

Given the importance of the Clawback Tax for the financing of the public health system in Romania, the legislative changes in this respect have not been far-reaching. Knowing what taxation and parafiscality mean, including their importance for public budgets (Roş 2005, 2009, 2016; Drosu-Saguna & Tofan, 2010; Bostan, 2008, 2010; Costea, 2021; Costaş, 2019ab; Tofan, 2016), beyond legal considerations, the authors of this paper approach the issue of the Clawback Tax from other angles.

We take into account the circumstances that led to the introduction of this contribution, the effects generated along the way and any changes that may be necessary.

## **2. Theoretical background**

The issue of financing the public health system is a very important one for the state and has been discussed in several specialist papers. The topic is still a current one, even if the specific germs are linked to 2008- 2009, when the Romanian government had high debts to drug suppliers, and „one of the International Monetary Fund's requirements, following Romania's accession to the European area, was the payment of arrears that threatened the state system.” (Costache, 2020).

Not many articles and books insist on the parafiscal components designed to provide budgetary resources to that system. Our documentation has identified such works (Petcu et al., 2014; Petrisor, 2020; Radu et al., 2016, 2018; Vladescu et al., 2016), which is why we refer to them, considering them more important.

In addition, we come up with some legislative developments and, on the other hand, we refer to some developments regarding the financial source „Clawback Tax” (for the Single National Health Insurance Fund) following the in-depth study of some reports prepared by prestigious institutions - the Court of Accounts of Romania, CNAS, MS, as well as by organizations that have researched similar issues, with remarkable results.

## **3. Research methodology focusing on the adoption of the Clawback Tax in Romania**

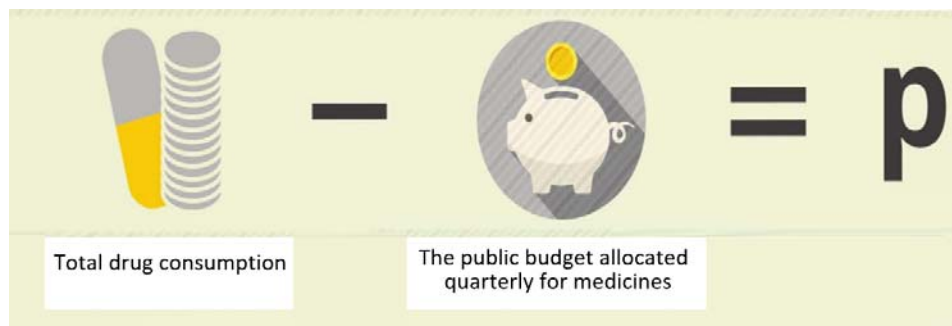
Entering into the Clawback Tax substrata certainly involves a twofold approach: one legal and one economic (fiscal-budgetary). Obviously in the context of the desire to ensure an efficient and sustainable public health protection system, but without affecting the legitimate interests of Pharma Sector.

The Romanian State established this compulsory contribution in 2009 (the mechanism is found in (RG/Romanian Government, 2009), representing in fact a tax applied in the pharmaceutical industry. Thus, all drug manufacturers contribute (through quarterly payments) to the financing of

the public health system with a share of the profit made from the sales of compensated medicines exceeding the amount allocated to them from the Single National Health Insurance Fund (FC/Fiscal Council, 2021).

In other words, these manufacturers bear the Clawback Tax based on a percentage „p” reflecting the difference between the total cost of the compensated medicines and the cost borne by the public budget each quarter (Figure no. 1).

Figure no. 1 Determination of the percentage „p” on which the Clawback Tax is based



Source: [https://apmgr.org/wp-content/uploads/2019/11/Infografic\\_ROI.pdf](https://apmgr.org/wp-content/uploads/2019/11/Infografic_ROI.pdf)

Although adopted in the context of a major crisis (RG, 2011), this tax is also applied in years of economic growth, due to the advantages in terms of ensuring the financing of health systems and the predictability of costs, knowing that there are risks related to the low availability of medicines, against the background of insufficient attractiveness of the market for local producers.

We therefore observe a remarkable continuity in the public health financing system, which has existed since 2011, for the quarterly contribution - calculated according to Article 3 of Government Emergency Ordinance No. 77/2011 (Clawback Tax) - there is an obligation to pay it quarterly by the holders of marketing authorizations for medicines. The obligation covers (RG, 2019): (i) those medicines included in the national health programmes; (ii) medicines with or without personal contribution, used in outpatient treatment on prescription through open circuit pharmacies; (iii) medicines used in hospital treatment; (iv) medicines used in medical services provided through dialysis centres, supported by the Single National Health Insurance Fund and the Ministry of Health budget.

At the European level, „most countries have implemented some form of clawback/payback, including the five largest markets for medicines in Europe, averaging 8.6% of the value borne by health systems. In terms of value, Germany ranks first, with €5.5 billion in rebates and payback (13.3% of total healthcare expenditure on medicines), while Greece has the highest percentage level of clawback, 27.3%.” (RP, 2022).

In Hungary a similar (solidarity) tax has recently been introduced, but it is a maximum of 8% and only for very high turnover. In Romania, holders of marketing authorisations for medicines pay a disproportionately high 15% clawback tax (the highest in the EU), which prevents the Romanian medicines industry from progressing. As Romania is 80% dependent on imports, the effects are problems in the supply of season-specific medicines (PRIMER, 2023).

Compared to the original form of the law that adopted the Clawback Tax in Romania, a new law (RP, 2020) introduces several new features starting with the first quarter of 2020. For example, the quarterly contribution is calculated and due differentiated for type I, II, and III medicines (also regulating how to classify medicines by the three types).

The list of „type I, type II and type III medicines” is approved quarterly by order of the Minister of Health, by the 25th of the month following the end of a quarter, the contributions being calculated as follows: for „type I medicines”, the quarterly contribution is calculated by applying 25% to the value of their centralized consumption, communicated by the National Health Insurance House, after subtracting TVA; for „type II medicines”, the quarterly contribution is calculated by applying 15% to the base determined under the same conditions as above, and for „type III medicines”, 20%.

However, even if these measures have beneficial emphases, in the sense of capping and differentiated application of the percentage of the contribution due according to the classification of the medicines (innovative, generic/biosimilar/innovative off-patent, locally manufactured) - innovative medicines 25%, imported generics and biosimilars as well as off-patent innovators - 20% and locally manufactured medicines - 15%, the Association of Romanian Generic Medicines Manufacturers claims that the clawback tax is at a very high level (APMGR, 2022). According to the source mentioned, „In the case of generic drugs with full reimbursement, a 28% tax is paid according to Law 53/2020 for a drug priced between 5 and 50 Lei, with the mention that more than 2/3 of the generic drugs on the market in Romania belong to this category. In reality, the clawback tax is 28% because it is calculated on the retail price and thus includes the addition of distributors and pharmacies.” (APMGR, 2022). The table below (Table no. 1) is illustrative in this respect.

Table no. 1 - Price - Clawback Tax correlation under the application of Law 53/2020

	Manufacturer price [RON]	Wholesale price [RON]	Retail price [RON]	Clawback Producer [RON]	Clawback Retail [28.28%]
<b>Price 1</b>	5	5.7	7.07	1.41	<b>28%</b>
<b>Price 2</b>	10	11.4	14.14	2.83	<b>28%</b>
<b>Price 3</b>	25	28.5	35.34	7.07	<b>28%</b>
<b>Price 4</b>	50	57	70.68	14.14	<b>28%</b>
<b>Price 5</b>	100	112	129.92	25.98	<b>26%</b>
<b>Price 6</b>	300	330	369.6	73.92	<b>25%</b>
<b>Price 7</b>	3,000.00	3,030.00	3,065.00	613.00	20%
<b>Price 8</b>	10,000.00	10,030.00	10,065.00	2,013.00	20%

Source: <https://apmgr.org/wp-content/uploads/2022/10/APMGR-white-paper-2022-web.pdf>

## 4. Findings

### 4.1. Size and evolution of the financial source for the Single National Health Insurance Fund (FNUASS), based on the collection of the Clawback Tax

The Single National Health Insurance Fund (FNUASS), administered by the National Health Insurance House (CNAS), comprises revenues (54.85 billion lei in 2022, 10% higher than in 2021) made up of: (i) health insurance contributions (CASS) paid by employees and other insured persons who pay CASS; (ii) budget subsidies; (iii) clawback tax, paid by the subjects mentioned and under the conditions indicated above.

Regarding the clawback tax alone, CNAS collected 3.73 billion Lei in 2022, more than 4% more than in 2021 (Somanescu, 2023).

In previous years, there has been a fluctuating evolution of receipts from the trimonthly contribution (Clawback tax), increasing from the amount of 1,811 million lei recorded in 2012 to the amount of 2,129 million lei in 2019 (Figure no. 2).

Figure no. 2 Evolution of receipts from the trimonthly contribution (Clawback tax, million lei/year, 2012-2019)



Source: Romanian Court of Accounts, 2020

[https://www.rfi.ro/sites/default/files/sinteza\\_raport\\_ap\\_cnas\\_cu\\_coperta\\_03092020.pdf](https://www.rfi.ro/sites/default/files/sinteza_raport_ap_cnas_cu_coperta_03092020.pdf)

On the other hand, CNAS expenditure (54.85 billion Lei in 2022) is intended to cover payments to hospitals for salary increases for medical and auxiliary staff, payments to doctors and other health service providers who have contracts with the Territorial Health Insurance Houses, payments for medical services, medicines and medical devices for patients.

The longer-term study on the dynamics of the share of the „subsidies” and „Clawback Tax” sources in the UNFSAF revenue shows that since 2019 „the two sources of funding have exchanged both places and in terms of volume of participation.” (Petrisor, 2020). The consequence of the Clawback Tax moving to the second place (moving up from the third place instead of subsidies) is that there is „a decrease in pressure on the state budget, but for the holders of marketing authorisations for medicines it means a worrying doubling of contributions from the clawback tax.” (Petrisor, 2020).

The risks that may arise are related to the quality of medicines (as production costs increase in this way too) or we may even have to deal with discontinuation of the supply of certain medicines that do not bear the kind of taxation referred to in this paper.

However, we cannot imagine that the Clawback Tax will be excluded for a period of 3-5 years, especially as it is mentioned in official reports (CCR, 2020) as a „strong point” of the management system of the Single National Health Insurance Fund.

#### 4.2. Adapting the regulatory framework on Clawback Tax to the requirements of the Treaty on the Functioning of the European Union

For reasons of European legislation, i.e. in order to eliminate the risk of an unfavourable ruling for Romania, it is considered necessary to amend and supplement the Emergency Ordinance No. 77/2011 on the establishment of certain contributions to finance certain health expenditure.

The European Commission's request concerns two issues, found in GEO No. 77/2011 (RP, 2023): (a) the compatibility of Art. 3<sup>7</sup> para. (2)(b) and of the percentage applied to this category, provided for in Art. (4) - being that it would favour the type II medicine (the one produced in Romania), regardless of whether by the way of authorisation it can be classified as a type I or a type III medicine - , with art. 110 of Treaty on the Functioning of the European Union; (b) the obligation for non-resident holders of marketing authorisations for such products to appoint a fiscal representative resident in Romania.

The draft law proposes to amend and supplement the Emergency Ordinance No. 77/2011 on the establishment of certain contributions to finance certain expenditure in the field of health, approved by Law No. 184/2015, with subsequent amendments and additions (RP, 2023), in order to eliminate

category III of medicines (medicines produced on a manufacturing line in Romania) for which a 15% contribution is due.

More specifically, starting with the third quarter of 2023, it is proposed to regulate a differentiated quarterly contribution for type I and II drugs, by applying fixed percentages of 25% (type I drugs) and 15% (type II drugs) respectively. The impact on the revenues collected to the UNFASS budget from the quarterly contribution, compared to the current formula, will be approximately -46.73 thousand lei/quarter.

Certainly, the new rule - as drafted - responds to the criticism made by the European Commission, establishing a uniform regime (15% for generic medicines and 25% for innovative medicines), regardless of whether the products are manufactured in Romania or come from other EU countries.

## 5. Conclusions

The Clawback Tax is an important element of parafiscality in Romania, and it appears in the public health financing system to be characterized by a remarkable continuity, which has existed since 2011. The legislative regulatory formula currently applied, to which we have briefly referred, gives functionality to the mechanism in place.

However, by the level of the tax and the way of calculation adopted, it is estimated in the studies and articles investigated by us that in Romania the tax is at the highest level in the European Union. Moreover, given that Romania is 80% dependent on imports, drug manufacturers claim that the clawback tax has blocked the domestic Pharma industry, not increasing for at least a decade.

This could lead to certain risks, related to the quality of medicines (as production costs increase in this way) or even to the discontinuation of certain medicines that do not bear the kind of taxation we have referred to in this paper.

Regarding the *limitations of the research*, even if we refer to the adaptation of the regulatory framework on Clawback Tax to the requirements of the Treaty on the Functioning of the European Union, we believe that the study should have included more elements (possibly parafiscal) of the public health financing systems found in the Member States of the European Union.

That is why we believe that this is the area to which *our future research* should be directed in relation to the theme dealt with in these pages.

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