INCONSISTENCY OF LEGAL PROVISIONS:
FAILURE IN INTRODUCING
THE CLAWBACK TAX ON THE
ROMANIAN MEDICINES MARKET

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Abstract

The performance of economic systems depends both on using resources with maximum efficiency and on society's income redistribution. Any socio-economic decision has to ensure Pareto efficiency or, according to the Kaldor-Hicks principle, to provide net benefit after the compensation of the involved social costs.

Health and education are main development vectors of all nations and funds oriented in these fields are major capital investments, for which recent utilities are ignored in favor of future ones that are much more important due to their major effects on the ostensible growth of society's capabilities. The constant insufficiency of financing the health system requires the search of new resources and their much more responsible and efficient management. The clawback tax, which theoretically withdraws a surplus part from the sales value of pharmaceutical companies, given the fact that the paying availability is estimated according to the involved opportunity costs, is a fiscal instrument practiced by many countries with beneficial consequences on the social surplus.

The three attempts (three normative acts in three years) of the Romanian national authorities to introduce the clawback tax may be considered failures, due to the absence of studies and tests that allow the implementation of accurate, sustainable and non-discriminatory rules and the highlight of compensatory measures.

Keywords: cost-benefit analysis, clawback, social surplus, consumer's surplus, producer's surplus, deadweight loss.

1. Introduction

The dynamic of major changes as well as the synergies of minor changes cause significant disturbances in economic systems, potentiated in a global environment by the preeminence of the mega-system which holistically wires extremely diversified components. While trying to find suitable models, interdependences and rules, in order to explain the changes, economists use more and more frequently concepts that are characteristic for other systems such as the social or biological one. Blaug quotes Marshal's statement, made almost a century ago, according to which 'the Mecca of the economist lies not in comparative statics, nor even in dynamic analysis, but rather in economic biology, which means that the economic system is a mechanism that develops in time' (Blaug, 1992, p. 454). The interventions in any field propagate and may occasionally induce severe mutations with repercussions on the ensemble. In the construction of economic models, the systemic theory interferes with the chaotic systems theory and the synergies.

In such a dynamic, complex and contradictory environment, economies are guided through state intervention, which has the responsibility to emphasize the goals that reach society's unanimous consensus and to establish those economic policies that finish up in growing welfare on the whole, '...welfare in the sense that all members of the collectivity must have a decent, common minimum stock of economic goods ...the optimal economic system is the one that provides the maximum of what people need' (Galbraith, 1982, p. 11).

The performance of a state depends on the economic results and on the policies of income redistribution as well, on their allocation according to the development capabilities, the real needs and targets of a society. Society's possibilities to provide and people's needs are in a relation of mutual stimulation. Including the axioms of human rights and access of all society members to a decent standard of living, facilitates the examination of the field and the separation of heteronomous elements and dysfunctionalities in any hypothesis of undertakings with socio-economic finality.

Policies should not be implemented unless a Pareto optimum is obtained, defined as 'the point that allows the improvement of a certain individual welfare, meaning his movement to a preferred position by adjusting goods or services through production or exchange without affecting someone else's welfare' (Blaug, 1992, p. 626.). Hicks states that 'a policy should be adopted if and only if those who would gain are capable of fully compensating those who would lose and yet remain better off' (Boardman *et al.*, 2004), which means getting a positive net benefit as the difference between necessary social costs and social benefits to come. Irrespective of the expression of these principles, the conclusion is that getting positive net benefits, namely the Pareto efficiency, is the only thing that could make possible the maximization of welfare on the whole.

The argument for certain socio-economic policies that maximize welfare implies a cost-benefit analysis, which takes into consideration these principles and is based on concepts such as paying availability and opportunity costs, the main indicators for

measuring costs and benefits. The limits of this method refer to the difficulties of monetary evaluation of benefits and the compensation of utility loss of some by the utility benefits of the others. As Boardman *et al.* (2004) argue 'while analysts evaluate the consequences of applying policies through the availability of the affected ones to pay and the resources necessary to its implementation through opportunity costs, the net benefit will indicate if those who pay might be adequately compensated and remain better off'. Any applied policy involves resource consumption, the opportunity cost, as a resource value in its best version, being a distinctive mark both for those who pay and for those who take measures.

In general, the main beneficiaries of redistributing society's income are the public services, given that their organization and finalities most adequately express the efficiency of the policies adopted by the authorities.

2. Research methodology

The purpose of this article is the analysis of the clawback tax impact within the policies of growth of the resources for medicines consumption support, in terms of anticipated net benefits, seen as positive evolution of the social surplus (consumer's surplus + producer's surplus), evaluated through monetary and non-monetary indicators. The aim is to indicate dysfunctionalities, inadvertences and errors generated by the implementation of regulations, as well as certain specific details that should illustrate the decisions of authorities together with the general principles of realism, and ensure the issuance of adequate regulations.

2.1. Definition of scope and used concepts

In order to avoid additional processing, useless for the purpose and objectives of this study, and to define the used terms, the following clarifications are provided:
– the evaluation of the clawback tax impact is made only for the segment in which the final beneficiaries purchase medicines directly from wholesale suppliers (hospitals, dialysis centers); the issued arguments are also valid for the field on the whole (including pharmacies that have not been included in order to reduce calculations);
– the producer's margin (PM) is the result of the operating profit, which can be substantially affected by the financial and extraordinary result, as well as by the income tax;
– the distributor's margin (DM) is also the result of the operating profit, as part of the trade markup to which he is entitled under regulations, and affected by the same factors;
– the consumer's surplus (CS) is graphically defined by the area between the demand curve and the price curve, being determined as the difference between the gross benefit (placed on the demand line) and the effectuated payments, represented by price. The fluctuation of the consumer's surplus is calculated according to the formula:

$$\Delta CS = (\Delta P)Q_0 + \tfrac{1}{2}(\Delta Q)(\Delta P), \text{ where: } P = \text{price}; Q = \text{quantity};$$

- the producer's surplus (PS), graphically defined by the area between the price line and the supply curve, is calculated as the difference between the revenues obtained by selling a quantity of the product and the costs necessary for the making of this quantity; in this undertaking we will consider the producer's surplus as a sum of the two components, even though the data presentation mentions the producer and the distributor separately: $PS = PM + DM$ and $\Delta PS = PSF - PSI$, where PSI is the surplus before the implementation of the clawback tax and PSF is the surplus after the implementation.

  The total producer's surplus (TPS) is the difference between income (I) and the total expenses (E) or the sum of the results from the operating (noted PM), financial (RF) and extraordinary activities (REX): $TPS = I - E = PM + [RF + REX]$;
- the social surplus (SS) is the sum of the consumer's surplus and the producer's surplus: $SS = CS + PS$;
- the clawback tax (CT) is generally defined as a deduction from a paid price or a market income, or from the distributed sums of money and benefits achieved in certain circumstances. The formulas used for the calculation of CT will be presented in the chapter related to it, as stipulated in the regulations;
- the deadweight loss (DL) is an effective cost for society or the negative net result defined as the producer's surplus decrease without any compensatory increase for the consumer's surplus. In this undertaking, the producer's surplus decrease is represented by the clawback tax and this relation may be written as follows: $DL = CT - \Delta CS$. DL results from the competitive market distortion and it may represent the loss of medicines suppliers who lost their ability to act on the market or other 'leaks', as they are called in the trade literature; and
- the conditions that the producers' surplus should fulfil in order for them to be able to commercialize medicines on the Romanian market are:
  * $PSF = (PSI - CT) > [Ie + \Sigma (eri^1 - eri^0)VAi + NP]$, for $eri^1 > eri^0$, $Ie > 0$, where: Ie are the interest expenses for both (producer and distributor), eri^0 and eri^1 are the exchange rates at the time of the acquisitions and, respectively, of their payment, at the level of the producer and distributor, VAi is the volume of acquisitions, i is the type of medicine, NP is the net operating result;
  * (2) $FNT_1 > [FNE_0 + FNF_0 + FNI_0]$, where: FNT = total cash flows, FNE = cash flows from operating activities, FNF = cash flows from financing activities, FNI, cash flows from investment activities.

As a result of the lack of fulfillment of these conditions, the pharmaceutical companies that provide medicines declare insolvency. These conditions are applicable for all the three versions of calculation for the clawback tax, issued by the authorities.

2.2. Research methodology

The research methodology is based on the cost-benefit analysis commonly used to evaluate the costs and benefits generated by the interventions of authorities, in some countries being brought by normative acts in the quantification of consequences and

adoption of social decisions that ensure the realization of a Pareto optimum, meaning the increase of general welfare. Moreover, we also used methods specific to the investigative process, phenomenologically oriented, comprehensively oriented (the study of normative documents, trade literature, participative observation, case study etc.), methods of intersection such as the combined quantitative and qualitative approach (document analysis), methods of data interpretation (deductive and comparative).

3. Considerations on medicines market and prices

'Generally, the medicines and health services market is not a free competitive market given that it only happens on very limited segments. The market entry restrictions and the reduced mobility of the production factors, the heterogeneity of the services, the strong asymmetry of information, the drastic limitation of the capacity of evaluating their own needs and the rational consumer behavior, the consideration of health as a worthy good, the unequal distribution of income and the inverse proportionality between these and needs lead to the market failure etc.' (Vlădescu, 2000).

The medicines market is strictly brought under regulation in that segment in which the medicines' cost is totally or partially paid by The National Health Insurance Fund (CNASS) or by The Ministry of Health (MS). This segment refers to 'the medicines included in the national healthcare programs, and for the medicines with or without personal contribution, used in ambulatory treatments based on medical prescription, via open circuit pharmacies, in hospital treatment and for medicines used in medical services provided in dialysis centers' (GEO no. 110/2011). The maximum price of these medicines is stipulated in the National Catalogue of prices for medicines of human use authorized to be put on the market in Romania (CaNaMed in short; National Health Insurance House, undated) approved, revised and corrected by order of the Minister of Health. The value added tax for medicines is established at 9% by the Romanian Fiscal Code.

In the presented examples, the producer's expenses (Tables 1 and 2) for the medicines with regulated price were grouped in three categories: research expenses (with a very large weight on the original products' price, even above 80%); direct expenses and other expenses (in which all the other indirect and management expenses were included). The price paid by the health network is based on the producer's price, accepted at the smallest level by comparison with the ones practiced in other 10-12 European countries, to which the trade markup is added according to types of commercialization and tranches. The markup for distributors varies between 14% (for the medicines that cost between 0 and 50 lei), 12% (>50-100 lei) and 10% (>100-300 lei), while for the medicines that cost more than 300 lei there is a fixed markup of 30 lei.

For example, Table 1 presents a medicine that has been commercialized at first as original (commercialized only by the producer that has patents for the product, substance, technology etc.) and subsequently as generic (produced by several producers, when taken out from under the protection of the patents of the original). Generally, the price of medicines is decreased during biddings, the only source being the producer's margin, given that the distribution markup is limited.

Price structure	Original price		Generic price		Bidding price	
	Lei	%	Lei	%	Lei	%
Research expenses	200	57.14	0	0.00	0	0.00
Direct expenses	25	7.14	25	16.67	25	20.83
Other expenses	25	7.14	35	23.33	35	29.17
Total expenses	250	71.43	60	40.00	60	50.00
Producer's margin	70	20.00	76.35	50.90	49.09	40.91
Producer's price	320	91.43	136.35	90.90	109.09	90.91
Distribution	30	8.57	13.65	9.10	10.91	9.09
Wholesale medicine price	350	100.00	150.00	100.00	120.00	100.00
Pharmacy markup	35		18		14.4	
Pharmacy medicine price	385		168.00		134.40	

Source: Data gathered and processed by the authors

In Table 1 we can see the increased weight of the research expenses and the rather small weight of the other types of costs. Moreover, Figure 1 shows a large producer's margin.
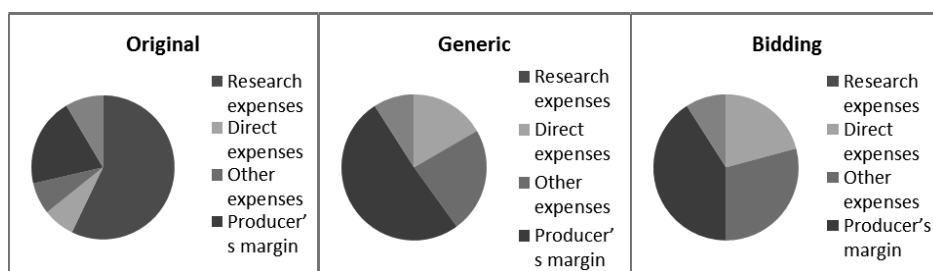

Figure 1: Medicine price structure

Source: The authors

Normally, after the recovery of the research expenses, if prices remain the same, their quantum changes into producer's profit and they become a significant fund for a future price decrease. At the same time, the loss from this accumulation that could be reinvested in research may affect the development of the sector. The failure of the medicine market does not allow any thorough view on the subject, thus the interest discrepancies are more or less harmonized through negotiations and regulations. It should be mentioned that, for the generic medicine in other expenses category there are certain expenses related to the bioequivalence with the original studies and promotion in competitive conditions, which increases them. In the case of medicines, examinations and market authorizations impose very large costs.

For the generic medicines with the main weight in the total sales, which are produced on a large scale by many operators, the price and producer's margin (Table 2) are much smaller, especially because of the competition.

Table 2: Price structure for a generic medicine

	Price structure	10 lei	%
generic ■ Research expenses ■ Direct expenses ■ Other expenses ■ Producer's margin ■ Distribution	Research expenses	0	0
	Direct expenses	3	30
	Other expenses	4	40
	Total expenses	7	70
	Producer's margin	1.77	17.7
	Producer's price	8.77	87.7
	Distribution	1.23	12.3
	Medicine price	10	100
	Pharmacy markup	2.4	
	Pharmacy price	12.4	

Source: The authors

It is also necessary that we mention the significant impact of the transportation expenses on the final price, since this sometimes happens under special conditions (cold, anti-break packages etc.). The constant increase of the transportation cost is an additional constraint in the evaluation of the redistribution policies of a part of the medicine producer's surplus.

The non-convergence between the authorities' interests that have to sustain the uncovered part of the medicines demand of FNUASS[1] and the state budget, and the producers' interests on one hand and the generics market competition on the other hand, determines the search for collateral solutions, including the decrease of producers' profits which frequently surpasses the average of other sectors.

The contracts between producers and distributors usually include substantial discounts after a certain sales limit considered as much as necessary to sustain the margin loss, through additional rollovers.

4. The clawback tax

Generally, the clawback tax represents the withdrawal of something distributed/ paid in excess or, more explicitly, clawback is a rule that allows the withdrawal of that part from a payment, which covers a performance that is not accurate or rightful. One of the most recent applications of the clawback tax is found in the case of the administrations of banks and other financial institutions responsible with the financial crisis, in order to prevent the phenomenon's recurrence. The motivation of introducing this type of tax is presented in the normative acts and consists in: (a) exceeding the limit settled for medicines within FNUASS and the budget of the Ministry of Health; (b) ensuring the uninterrupted access to medicines for the population, with or without

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1 Short form for Fondul Național Unic al Asigurărilor Sociale de Sănătate (En: Sole national fund of social health insurance).

personal contribution, used in ambulatory treatments within the national health programs and in the sanitary units with beds; and (c) the necessity of the implementation of a sustainable contribution system for the continuous supplementation of the financing sources of the health public system, under emergency regime.

In other words, without the contribution of the pharmaceutical sector, the authorities find themselves in the impossibility of providing the necessary medicines to the population. At the same time, this contribution is solicited as recognition of the benefits in excess of this sector in comparison to others, but also of the fact that the state is the prevailing client, without which the whole medicine market would collapse. The increased producers' margins, as well as the accumulations made in time, may represent significant reserves, a part from which may be withdrawn for financing the chronic deficits of resources, on condition of reasonability and compensation of these losses.

The constraint of obtaining a positive net social benefit by compensating the producers' losses, given that the consumer's surplus obviously grows by increasing the medicine acquisition resources, implies the correlated evaluation of paying availability of the holders of marketing authorizations, with the involved opportunity costs. The paying availability is conditioned by the request of maintaining the status quo of the holders of marketing authorizations. From an economic point of view, it may be assumed that a holder of marketing authorizations is inclined to pay if the total value of the margin realized until the introduction of the clawback tax remains relatively constant through the compensatory effect of the increase of the acquired quantities. In the evaluation of the paying availability there should be taken into account the opportunity costs involved by the medicines sale on other markets: the costs of withdrawal from the Romanian market and the costs of entrance on other markets. At the same time, the lawmaker should also take into consideration the potential own losses generated by the migration of some medicine suppliers, with severe incidences on population health and subsequent additional expenses.

The three attempts of instituting the clawback tax are presented in the following sections.

4.1. Government Emergency Ordinance no. 104/2009

In this first version, the clawback tax was a percentage tranche withdrawal from the sales income of the holders of marketing authorizations for medicines, according to the following table:

Table 3: Clawback tax according to GEO[2] no.104/2009

Quarterly receipts – thousands lei	>75000	50,001-75000	25001-50000	12501-25000	6251-12500	1251-6250	< 1250
Clawback tax - %	11	10	9	8	7	6	5

Source: GEO no.104/2009

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2   GEO stands for Government Emergency Ordinance.

An example of the application of this taxation method and its effects is presented in Table 4. In order to evaluate the impact of this tax on the producer's surplus (PS): $\Delta PS = PSF - PSI$, sales volumes from a single medicine were taken into consideration, framed in all the intervals mentioned in Table 3. The analysis was made for each of the prices detailed in Tables 1 and 2, keeping the producer's margin calculated in the structure of the price. The distributor's margin, as a result from exploitation, was set to 5% of its trade markup, being the same in all versions.

Table 4: Calculation of the evolution of producer's surplus

% clawback tax	5.0	6.0	7.0	8.0	9.0	10.0	11.0
Sales volume - thousands lei	600.0	1,251.0	6,251.0	12,501.0	25,001.0	50,001.0	75,001.0
Clawback tax - thousands lei	30.0	75.0	437.5	1,000.0	2,250.0	5,000.0	8,250.0
Acquisition price 8.77 lei, wholesale price 10 lei							
Quantity – thousands pieces	60.0	125.1	625.1	1,250.1	2,500.1	5,000.1	7,500.1
Acquisition value	526.2	1,097.1	5,482.1	10,963.4	21,925.9	43,850.9	65,775.9
Sales value	**600.0**	**1,251.0**	**6,251.0**	**12,501.0**	**25,001.0**	**50,001.0**	**75,001.0**
PM 17,7%	93.1	194.2	970.3	1,940.5	3,880.9	7,761.6	11,642.3
DM 5%	3.7	7.7	38.4	76.9	153.8	307.5	461.3
PSI – sum	96.8	201.9	1008.8	2017.4	4034.6	8069.1	12103.6
%	16.1	16.1	16.1	16.1	16.1	16.1	16.1
PSF - sum	66.8	126.8	571.2	1017.3	1784.5	3069	3853.5
%	11.1	10.1	9.1	8.1	7.1	6.1	5.1
Acquisition price 51 lei, wholesale price 57.1 lei							
Quantity – thousands pieces	10.5	21.9	109.4	218.8	437.7	875.4	1.313.0
Acquisition value	535.7	1,117.0	5,581.3	11,161.6	22,322.3	44,643.8	66,965.2
PM 20%	107.1	223.4	1,116.3	2,232.3	4,464.5	8,928.8	13,393.0
DM 5%	3.2	6.7	33.5	67.0	133.9	267.9	401.8
PSI – sum	110.4	230.1	1,149.7	2,299.3	4,598.4	9,196.6	13,794.8
%	18.4	18.4	18.4	18.4	18.4	18.4	18.4
PSF - sum	80.4	155.0	712.2	1,299.2	2,348.3	4,196.5	5,544.7
%	13.4	12.4	11.4	10.4	9.4	8.4	7.4
Acquisition price 109.1 lei, wholesale price 120 lei							
Quantity – thousands pieces	5.0	10.4	52.1	104.2	208.3	416.7	625.0
Acquisition value	545.5	1,137.3	5,682.7	11,364.5	22,728.0	45,455.1	68,182.2
PM 49,09	267.8	558.3	2,789.6	5,578.8	11,157.2	22,313.9	33,470.6
DM 5%	2.7	5.7	28.4	56.8	113.7	227.3	340.9
PSI – sum	270.5	564.0	2,818.0	5,635.6	11,270.8	22,541.2	33,811.6
%	45.1	45.1	45.1	45.1	45.1	45.1	45.1
PSF - sum	240.5	488.9	2,380.5	4,635.6	9,020.7	17,541.1	25,561.5
%	40.1	39.1	38.1	37.1	36.1	35.1	34.1
Acquisition price 320 lei, wholesale price 350 lei							
Quantity – thousands pieces	1.7	3.6	17.9	35.7	71.4	142.9	214.3
Acquisition value	548.6	1143.8	5715.2	11429.5	22858.1	45714.8	68572.3
PM 20%	109.7	228.8	1143.0	2285.9	4571.6	9143.0	13714.5
DM 0,05*30 lei	2.6	5.4	26.8	53.6	107.1	214.3	321.4
PSI – sum	112.3	234.1	1169.8	2339.5	4678.8	9357.3	14035.9
%	18.7	18.7	18.7	18.7	18.7	18.7	18.7
PSF - sum	82.3	159.1	732.3	1339.4	2428.7	4357.2	5785.8
%	13.7	12.7	11.7	10.7	9.7	8.7	7.7

Acquisition price 320 lei, wholesale price 350 lei							
PM 84%	460.8	960.8	4800.8	9600.8	19200.8	38400.4	57600.8
DM 0,05*30	2.6	5.4	26.8	53.6	107.1	214.3	321.4
PSI – sum	463.4	966.1	4827.6	9654.3	19307.9	38614.7	57922.2
%	77.2	77.2	77.2	77.2	77.2	77.2	77.2
PSF - sum	433.4	891.1	4390.0	8654.3	17057.8	33614.6	49672.1
%	72.2	71.2	70.2	69.2	68.2	67.2	66.2

Source: Data gathered and processed by the authors

We should mention that the sales value is kept in all the used price versions in order to emphasize the evolutions of the surplus for different price structures, according to the legal provisions. From the analysis of the data in Table 4, it results that:

- while the PSI sales rate is constant, the PSF rate decreases; the sale of increasing medicine quantities (at the same average price) becomes proportionally less profitable;
- firms with less significant sales are encouraged, which is beneficial for maintaining the competition level on the market;
- firms from the inferior limit of the interval are disadvantaged and they will be in the scope of a larger calculation percentage, at a level close to the previous one; if there is a limited number or just a supplier for certain medicines necessary in a volume from the interval limit, they will restrict the delivery;
- the deferred reimbursement of deliveries and the abrupt purchase payment for several semesters will disadvantage most of the suppliers who will try to minimize their losses;
- the expenses of firms that supply new state-of-the-art medicines (original and generic, in the first phase of life) are accepted, as long as they are commercialized in well-positioned volumes; and
- the commercialization of generic products (almost all of which come under the first approached group) becomes forbidden because of the unobserved conditions (1) and (2), presented above: (eri1 > eri0, Ie > 0), when the firms have unfavorable exchange rate differences and significant interest expenses, therefore a common producer's and distributor's surplus of under 10% is not sufficient to support them. It is known that sanitary units pay their acquisitions every 200 - 300 days and even after more than a year since their reception. This phenomenon creates conditions for unfavorable exchange rate differences and significant interest expenses (mainly small distributors tick in order to support their activity), while the producers' cash flow is permanently reduced.

4.2. Government Emergency Ordinance no. 77/2011

In the second version, the half-year contribution is calculated by applying a 'P' percentage on the medicine consumption (sales of each holder of marketing authorizations or their legal representatives) supported by FNUASS and the Ministry of Health budget. The percentage is calculated as follows: P = [(TCq-BAt)/TCq] x 100, where: TCq = total quarterly medicine consumption, Bat = ¼ of the annual approved budget.

We do not offer any examples as this calculation method cannot be viable. The client asks the supplier to finance all the consumption that exceeds the budget approved level, given the fact that this is constantly a great deal under the needs of the population.

4.3. Government Emergency Ordinance no. 110/2011

The last version establishes the calculation of the clawback tax as a quarterly contribution (oqc) of the medicines suppliers, according to the following formula: [(2/3)(Siq/STq) + (1/3)(Siq-Siqr)] (STq-STqr), with the following explanations:

– '(1) Siq = value of the quarterly individual medicine sales of each contribution payer, supported by the Sole national fund of social health insurances and the Ministry of Health budget; Siqr = value of the reference quarterly individual medicine sales of each contribution payer, supported by the Sole national fund of social health insurances and the Ministry of Health budget; STq = value of the quarterly total medicine sales supported by the Sole national fund of social health insurances and the Ministry of Health budget; STqr = value of the reference quarterly total medicine sales supported by the Sole national fund of social health insurances and the Ministry of Health budget.

– (2) The value of the reference quarterly total medicine sales supported by the Sole national fund of social health insurances and the Ministry of Health budget is of 1.425 billion lei. This value may be increased by the annual budget laws.

– (3) The value of the reference quarterly individual medicine sales of each contribution payer, supported by the Sole national fund of social health insurances and the Ministry of Health budget is established by the National Health Insurance Fund for each contribution payer. This value is calculated by relating the medicine sales of each contribution payer for the year 2011 to the total medicine sales, supported by the Sole national fund of social health insurances and the Ministry of Health budget, associated with the same year, and by multiplying the result by the value of the reference quarterly total sales of 1.425 billion lei.

– (4) The value stipulated at paragraph (3) is reported by the National Health Insurance Fund to each contribution payer until March 15, 2012. For the contribution payers who did not have medicine sales supported by the Sole national fund of social health insurances and the Ministry of Health budget until December 31, 2011, the value of the reference quarterly individual sales is zero.

– (5) According to paragraphs (1) - (3), the value of sales is, by law, the value of medicines supported by the Sole national fund of social health insurances and the Ministry of Health budget, which also includes the value added tax.' (GEO no. 110/2011)

As an example, we calculated the contribution owed by six pharmaceutical companies (Table 5). Evaluating the turnovers presented in the 'Report on the useful investigation regarding the study of the Romanian medicines wholesale market 2007-2009', drawn up by the Romanian Competition Council (2010), we assessed the reference quarterly sales and chosen the cases that represent the range of possible positions.

Calculations were made for two levels of the producers' margins, namely of 40% and 20%, and for three levels of distributors' markups. In order to remove any interpretations on the distributor's margin (frequently increased by the discounts subsequently given by the medicine producers), this was considered equal to the entire trade markup allowed by regulations.

We should mention that the obligation to pay a tax applied to another tax (according to this ordinance, the clawback tax is calculated on sales, including VAT) is not constitutional, as stated by the Constitutional Court, and that the 9% VAT institution was meant to increase the accessibility to medicines.

Table 5: Examples of calculation of the contribution for a number of firms

Indicators		Firm 1	Firm 2	Firm 3	Firm 4	Firm 5	Firm 6
% individual annual sales within the annual total sales		0.04	0.01	0.21	0.07	0.10	
Reference total quarterly sales	STqr	1,425,000	1,425,000	1,425,000	1,425,000	1,425,000	0
Reference individual quarterly sales	Siqr	59,375	11,875	296,875	95,000	136,563	0
Total quarterly sales	STq	1,852,500	1,852,500	1,852,500	1,852,500	1,852,500	1,852,500
Individual quarterly sales	Siq	**83,125**	**10,688**	**237,500**	**190,000**	**136,563**	**5,600**
Total weight of individual quarterly sales	Siq/STq	0.04	0.01	0.13	0.10	0.07	0.00
Ref. total weight of ind. ref. quarterly sales	Siqr/STqr	0.04	0.01	0.21	0.07	0.10	0.00
Diff.ind.quart.salesandref.ind.quart.sales	Siq-Siqr	23,750	-1,188	-59,375	95,000	0	5,600
Diff. quart. total sales and ref. total sales	STq-STqr	427,500	427,500	427,500	427,500	427,500	427,500
Owed quarterly contribution	Oqc	**20,705**	**1,248**	**16,747**	**60,897**	**21,010**	**2,728**
% in sales		24.91	11.68	7.05	32.05	15.38	48.72
VAT (9%) – sum		6,864	882	19,610	15,688	11,276	462
owed taxes % (oqc + VAT)		33.91	20.68	16.05	41.05	24.38	57.72
Average PM - % in sales		40	40	40	40	40	40
% maximal trade markup in sales	case A	12.28	12.28	12.28	12.28	12.28	12.28
% average trade markup in sales	case B	10.71	10.71	10.71	10.71	10.71	10.71
% minimum trade markup in sales	case C	9.09	9.09	9.09	9.09	9.09	9.09
producer's surplus - %	case A	18.37	31.60	36.23	11.23	27.90	-5.44
producer's surplus - %	case B	16.80	30.03	34.66	9.66	26.33	-7.01
producer's surplus - %	case C	15.18	28.41	33.04	8.04	24.71	-8.63
average prod margin - % in sales		20.00	20.00	20.00	20.00	20.00	20.00
% maximal trade markup in sales	case A	12.28	12.28	12.28	12.28	12.28	12.28
% average trade markup in sales	case B	10.71	10.71	10.71	10.71	10.71	10.71
% minimum trade markup in sales	case C	9.09	9.09	9.09	9.09	9.09	9.09
producer's surplus - %	case A	-1.63	11.60	16.23	-8.77	7.90	-25.44
producer's surplus - %	case B	-3.20	10.03	14.66	-10.34	6.33	-27.01
producer's surplus - %	case C	-4.82	8.41	13.04	-11.96	4.71	-28.63

Source: Data gathered and processed by the authors

As for the table data, only the largest noticeable discrepancies are mentioned, regarding the proportionality between the sales volume and the calculated contribution, according to regulations: on a sale of 237,500 thousand lei the owed contribution is 16,747 thousand lei (7.05%), while on a sale of 83,125 thousand lei the calculated contribution is 20,705 thousand lei (24.91%), which reveals an extremely large penalty for surpassing the reference limit; on a sale 20% smaller (firm 4 in relation to firm 3)

the contribution owed is 3.64 times larger, especially because of the sales weight increase; according to the law, the last one (firm 6) owes almost half of the sales volume.

If we continue the analysis of the situations in which the pharmaceutical companies can be found, we notice that in the case of the producer's margin of 40% only the new firm is at loss, while in the case of the 20% margin, even though the margin is supplemented by the whole distributor's markup, half of the firms are at loss, distributors have no other markup to support their operational expenses, and producers use a negative margin. If these firms also have a negative financial result (from interest expenses and unfavorable exchange rate differences), the suppliers will certainly declare insolvency, given that the delivery payment is usually delayed by several months.

Moreover, there is an obvious and unprofitable lack of correlation between the owed contribution and medicine sales. In order to support this affirmation the following data are presented:

Table 6: Evolution of the contribution when modifying certain involved variables

	Siqr	Siq	STqr	STq	oqc	Comment
Siq=Siqr						On a sale equal to the reference one, the firm may owe 0 lei or 22 lei or 7.41 lei owed to it, according to what happens within the sector;
STq=STqr	100	100	10,000	10,000	0.00	
STq>STqr	100	100	10,000	15,000	22.22	
STq<STqr	100	100	10,000	9,000	-7.41	
Siq>Siqr						On a sale larger than the reference one, the firm may not owe anything, owe 50 lei (2.25 more than at the time of the merge) or only 5.56 lei;
STq=STqr	100	150	10,000	10,000	0.00	
STq>STqr	100	150	10,000	15,000	50.00	
STq<STqr	100	150	10,000	9,000	5.56	
Siq<Siqr						On a sale smaller than the reference one, the firm may not owe anything, owe 16.67 lei or 10 lei owed to it.
STq=STqr	100	90	10,000	10,000	0.00	
STq>STqr	100	90	10,000	15,000	16.67	
STq<STqr	100	90	10,000	9,000	-10.00	

Source: The authors

The unpredictability of the debts to the state and their random amount discourages the suppliers and determines them not to pay. In default of the impact studies and because of the superficial justification of regulations, there are delays in gathering resources in order to support the necessary medicine consumption, and the entire undertaking may even be compromised. The random establishment of certain parameters may generate entirely different situations for the same payer condition.

5. Evolution of social surplus when introducing the clawback tax and the deadweight losses

While evaluating the impact of governmental interventions (in this case justified by the failure of the health services market, including the pharmaceutical market) which affect private interests, the cost-benefit analysis allows the estimation of the benefits and social costs generated by the adopted social decision. In all the examples above, the evolution of the producer's surplus was examined as part of the social surplus (SS) that should increase by applying certain policies meant to enhance the

general welfare, observing the Pareto optimum. The producer's surplus expressed in monetary units is always diminished, sometimes even substantially, until their existence is put in jeopardy (it can't be admitted that in those cases where contribution is negative, the medicine suppliers will receive supplementations for the medicine payment, associated with those amounts).

In order to evaluate the tax impact on the social surplus an example is presented, taken from Table 5 (firm 1) and completed with information from Table 7. For this undertaking, the particularization of sales as $\Sigma P_i Q_i$ (i = types of sold medicines) is not necessary, given that the tax is laid on sales in general and the particularization at the level of the medicine, according to the regulation principles, could create a situation that is not valid (see Table 6).

Table 7: Evolution of prices and sold quantities[3]

	Price - P	Quantity – Q	Sales -S
Before introducing CaNaMed	Pi = 11.4	Qi = 9,000	102,600
After introducing CaNaMed	Pk = 9.5	Qk = 8,750	83,125
Owed quarterly contribution (oqc)			20,705
Receipts after the tax deduction	P' = 7.13	Qk = 8,750	62,420
Configuration of variables on the supply curve, after the tax deduction	P' = 7.13	Q' = 8,438	60,195

Source: The authors

It is thought that firm 1 sold quarterly, before the issuance of the National Catalogue of prices for medicines, 9,000 thousand units of medicine X, at the price of 11.4 lei (Table 7), and afterwards it only sold 8,750 thousand units quarterly, at the established price of 9.5 lei, with a total value of 83,125 thousand lei. A contribution of 20,705 thousand lei (the clawback tax) (Table 5) was calculated for this sale (including VAT), according to the law. On a rough estimate, we could conclude that the social surplus remains constant. The producer's surplus is diminished by 20,705 thousand lei, while the consumer's surplus increases by the same amount:

$$\Delta CS = (\Delta P)Q_k + \tfrac{1}{2}(\Delta Q)(\Delta P) = 2.37 \times 8750 = 20,705 \text{ thousand lei,}$$

where $(\Delta P) = Pk - P' = 9.5 - 7.13$; Qk = 8,750 and $\Delta Q = 0$

$$\Delta SS = \Delta CS + \Delta PS = 20,705 - 20,705 = 0; \text{ therefore, SS = constant.}$$

Given that sales are known before and after introducing the CaNaMed prices, based on the data from Table 7, we could write the equation of the supply curve, considered linear:

$$Y = a + bx \text{ or } P = a + bQ$$

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3 The hypothesis of the quantity decrease on the terms of price drop off is based on the principles of the law of supply. An extension of the theoretical analysis would involve alternatives of the supply curve movement, which we did not consider being appropriate for this undertaking and might be the subject of a different research.

By solving the equation system:

$$\begin{cases} na + b\Sigma x_i = \Sigma y_i \\ a\Sigma x_i + b\Sigma x_i^2 = \Sigma x_i y_i; \quad \text{replacing data from Table 7:} \\ 2a + 17750\,b = 20.9 \\ 17750a + 157562500b = 185725 \text{ we find the values: } a = -57 \text{ and } b = 0.0076, \text{ the equation of the curve being: } P = -57 + 0.0076Q. \end{cases}$$

In the following figure the supply curve is drawn for firm 1 (for the generic products with mature markets, the supply curve laps over the marginal cost curve), which crosses over the demand curve in the equilibrium point 'C'. Conventionally, both curves were considered linear in order to simplify calculations.

According to the definitions of the terms previously mentioned and the graphic notations, it can be written that:

– the initial total surplus (PSTI) and the producer's final total surplus (PSTF) can be written as: PSTI = [OPkCQk - OACQk] = APkC; where: OPkCQk = sales/revenue and OACQk = expenses. PSTF = [OPkCQk - OACQk] - P'PkCE = [OPkCQk - OACQk] - CED] - P'PkCD; and

– the clawback tax (CT) is represented by the quadrilateral P'PkCE and it can be written as:

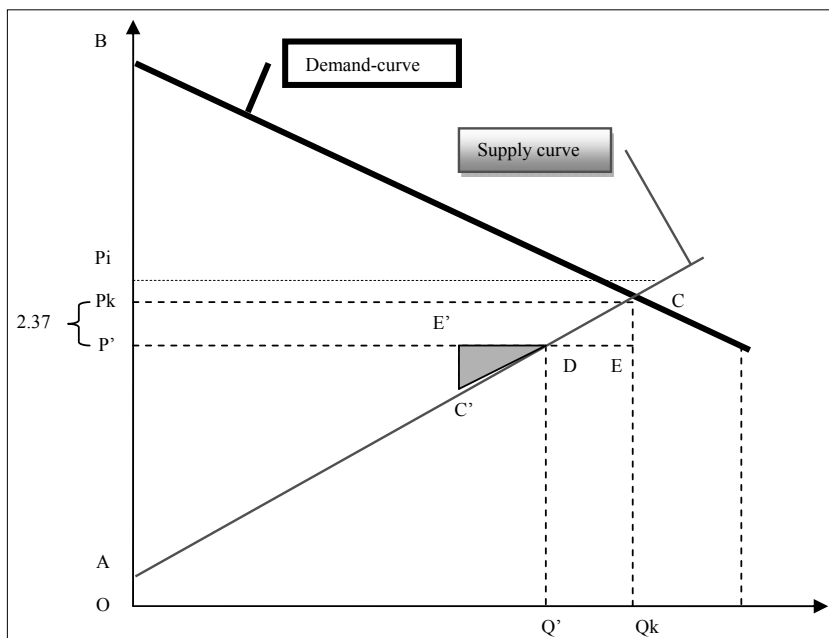CT = P'PkCE = P'PkCD + CED = 20,705 thousand lei.

Figure 2: Supply, demand and equilibrium

Source: The authors

If the mentioned equation of the supply curve is used, the coordinates of point D are found, for which: P'= 7.13 and from the equation 7.13 = -57+ 0.0076Q' it results that Q' = 8,438 thousand units and the surface of triangle CED will be calculated as CE = Pk-P'= 9.5 – 7.13 = 2.37 and DE = OQk-OQ' = 8,750 thousand – 8,438 thousand = 312 and the area CED = (2.37 x 312)/2 = 369 thousand lei, and P'PkCD = P'PkCE – CED = 20,705 thousand – 369 thousand = 20,336 thousand lei.

Hence, it can be written: ΔPS = PSTF - PSTI = - CED – P'PkCD = - 369 thousand – 20,336 thousand lei= -20,705 thousand lei.

However, it is noticed that CED is not deducted directly from PSTI but from OAC-Qk and it is re-projected inside AP'D, from where triangle C'E'D is literally lost.

Consumer's surplus (CS) before and after the implementation of the clawback tax, is represented on the axis as follows:

CSI = PkBC

CSF = P'BCD = PkBC + P'PkCD, hence: ΔCS = CSF - CSI = P'PkCD = 20,336 thousand lei.

Applying the formula of the surplus difference in point D we will get: ΔCS = (ΔP)Q' + ½(ΔQ)(ΔP) = (2.37 x 8438) + (2.37 x 312) = 19967 + 369 = 20,336 thousand lei, verifying the earlier calculations, according to the supply curve previously described.

The variation of the social surplus, as algebric sum of the variation of the two components becomes: ΔSS = ΔCS + ΔPS = 20,336 thousand – 20,705 thousand lei = - 369 thousand lei, because the area of triangle C'E'D is lost from the triangle ABC, which corresponds to the social surplus. This value that has an effect on the producer's surplus is not found in the consumer's surplus and, therefore, neither in the social surplus, thus representing a deadweight loss.

The deadweight loss (DL = CED) is a cost for society because it is not found in the social surplus (Boardman *et al.*, 2004). The authority takes over the clawback tax, but this is not entirely found in the final consumers' surplus (in the given example represented by hospitals and dialysis centers).

Starting from the definition of the deadweight loss as integral of the difference between benefits and social costs (Boardman *et al.*, 2004), which can be written as:

x1

DL = ∫ (MSB – MSC) dx if x0 <x1 (in this case: x=P and P'< Pk)

x0, where: MSB = marginal social benefit; MSC = marginal social cost, the variation of the deadweight loss when changing the price can be calculated according to the formula:

ΔDL = - ½ [PkQk (ΔP/Pk)^2 ε] where ε = the demand flexibility. For:

ε = 1 → ΔDL = -1/2 [60,195 (2.37/7.13)^2 1] = - 3,311.6 thousand lei
ε = 0.5 → ΔDL = - 1,655.8 thousand lei
ε = 0.0001 → ΔDL = - 0.33116 thousand lei.

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Therefore, the more flexible demand is, the larger deadweight loss is. In conclusion, the clawback tax, as any other tax that distorts the market, is not always beneficial for the social surplus, given that there are deadweight losses, which represent net social costs.

An evaluation of the two components of the social surplus, PS and CS, in non-monetary or monetarily unexpressed units, without considering that these unit increases are finished, emphasizes the following from Table 8.

Table 8: Consumer and producer surplus

Consumer surplus	Producer surplus
- increase of the medicines quantities purchased in the health system;	
- increase of the number of those who have access to treatments	- increase of the average price of medicines by requiring best quality medicines
- permanent provision of medicine treatment, without disruptions	- reduction of the reimbursement period for the sums owed to the medicines suppliers
- provision of a larger range of medicines	- increase of the required drug quantities, both due to additional resources, and to the more accelerated capital rotation, with beneficial repercussions on the use of the production capacities
- reduction of the treatment periods, due to the use of more efficient medicines	- decrease of the costs per product, by allocating the fixed costs on a larger amount
- increase of the last generation medicines weight, which are more effective in treating diseases	- certainty of receiving the appropriate sums for deliveries
- saving human lives in so far as the drug suppliers are inclined to pay to that effect.	

Source: The authors

6. Conclusions

The clawback tax is beneficial if it triggers the increase of social surplus and the minimization of the deadweight loss. In all methodologies issued by now there is an acceptable part, but the discrepancies it has induced partially inhibit the medicine supply.

The introduction of the clawback tax should be based on cost-benefit studies that underline the whole methodology, on elaborate simulations that validate all the parameters and all the included variables. The studies should be based on the medicine demand, according to the registered morbidity, the disease incidence, and the health programs supported by the state budget towards offer orientation and accurate evaluation of the demand. Furthermore, a cost-benefit study should take into consideration medicines for children, rare goods etc., which are exceptions from the general argument. The success of the implementation also depends on the common analysis authorities – medicine suppliers.

The fundamentation and the implementation of the clawback tax should circumscribe certain conditions: maintaining of the competition level through concentration barriers meant to encourage small suppliers, under satisfactory limits for the actual market structure; nondiscriminatory conditions for all market operators; determining the tax quantum, firstly according to the importance and necessity of those medicines, to the volume of individual deliveries, the type and prices of medicines and, as a sub-

ordinate factor only, to the conditions observed throughout the system; the payment of the medicines' counter value in reasonable terms; the withdrawal of the tax only from the payments that the system makes to the medicine suppliers; the removal of the discretionary involvement for promotion of physicians in the programs of firms; all specialists in the field should be involved and this should occur systematically, transparently and non-discriminatory; and by implementing penalties for not paying the medicine deliveries in time.

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