

GOVERNMENT GAZETTE OF THE HELLENIC REPUBLIC
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CONTENTS

Claw back for 2012

DECISIONS

No 110040

Claw back for the year 2013

THE ALTERNATE MINISTER OF HEALTH

Having Considered:

1. The provisions of article 11 of law 4052/2012 (Gov. Gazette 41/a/2012) as amended by Law 4093/2012 (Gov. Gazette 222/A/2012).
2. The Decision No Y47/3-07-12 of the Prime Minister 9Gov. Gazette 2105/B/12) “Assignment of competencies to the Alternate Minister of Health Marios Salmas” as amended by the Decision No ΔΥ1α/οικ. 78084/25-07-12 (Gov. Gazette 2339/B/2012).
3. The Ministerial Decision No ΔΥΓ3(α) ΓΥ 150/01-3-2012 (Gov. Gazette 681/B/2012).

4. The fact that no expense is generated against the State Budget from this Decision, we decide:

1. The budget for pharmaceutical expenses for all social insurance agencies cannot exceed the amount of Euro 2,440 m. including the Value Added Tax for 2013. The above amount is proportionally allocated to each Social Security Agency, in accordance with its approved budget. The monthly expenditure of each Agency cannot exceed 1/12 of the sum registered in the annual Budget thereof and corresponds to pharmaceutical care. Any amount in excess is calculated on a six-months basis. In case that at the end of each six-months period, the total pharmaceutical expenditure has exceeded the predetermined amount, the balance is sought to be paid and is paid by the pharmaceutical companies, in the special account suggested by each Agency.
2. Agencies using electronic prescribing services or the electronic scanning system, calculate the amount in excess that the pharmaceutical companies are obliged to reimburse, based on the actual sales data they have available. The amount to be reimbursed is calculated on a six-months basis, according to the amount that derives from the difference of the provided from the actual monthly pharmaceutical expenditure of each agency, after deducting the rebates, the reimbursements provided for by the relevant law, as well as the discounts.

3. For agencies not using electronic prescribing services or the electronic scanning system and until such systems are universally used, the calculation of the amounts the pharmaceutical companies are obliged to return, plus the rebate of 9% and the escalated rebate provided for by article 22 of law 4052/2012, is made based on the sales data for each company, as follows:

3.1 Based on the sales data the pharmaceutical companies register to the National Organisation for Medicines (EOF) each month (the submission thereof must have been concluded within the first week of the following month) which EOF verifies and confirms in order for this data to be used for the calculation of the claw back, allocation to each company is effected, based on the sum of the market shares of each medicine thereof in the therapeutic category of the positive list. Once the system of electronic prescribing will be universally used, the said data is extracted from the system.

3.2 The amount corresponding to parallel exports and sales to hospitals per company/medicine is deducted.

3.3 Based on the 80/20 proportion, the sales to Social Insurance Agencies are calculated and cross-checked with the data provided by HDIKA. Once the system of electronic prescribing will be universally used, the said data is extracted from the system.

3.4 Taking into account the respective data of cases 3.1, 3.2 and 3.3, the market shares per company/month for 2011 are defined. The sales data, per month and per company for 2011, constitute the reference base for the calculation of each amount in excess for each company in 2012.

4. For Agencies using electronic prescribing or electronic scanning system, the amount is defined that must be paid via the claw back mechanism for 2013, from each company based on the percentage of the actual participation of each pharmaceutical company in the formation of the pharmaceutical expenditure of each agency.

5. For Agencies where the determination of the participation as above is not possible, the market share of each company is used for the calculation, using 2012 as the reference year. Any amount in excess on the sales of each company per month, defines the amount that must be paid via the claw back mechanism for 2013.

5. In case new companies with zero turnover (sales) in 2012, enter the market during the reference months, the market shares of all companies are recalculated based on the turnover (sales) of the companies that realised positive turnover (sales) in the preceding year, adding the extrapolated annual turnover of the new companies which enter the market in the reference months. In case companies with positive turnover (sales) in the preceding year, exit the market during the reference months, the market shares of all companies are recalculated based on the annual turnover (sales) of only the companies which realised positive turnover (sales) in the preceding year and during the reference months. This means that for the companies with positive turnover (sales) in the preceding year but with zero turnover (sales) during the reference months, the owed contribution is null.

6. All the data required is collected per month and payments are effected every six months, while the deadline for the payment of the amounts calculated is within one

month from certification. Any differences are offset in the intervals of the six-months periods.

7. EOPYY can set off the above amounts with equal debts thereof to the Marketing Authorisation Holders for pharmaceutical products, from the supply of pharmaceutical preparations for the needs of its pharmacies. The said off set is made only between the amounts of pharmaceutical products returned by the Marketing Authorisation Holders and the cleared debts of EOPYY to the said Marketing Authorisation Holders, which were generated within the same year.

8. A model for the application of the claw back mechanism follows, which constitutes an integral part of this decision.

BASIS OF CALCULATION OF CLAW BAK

It is noted that each agency will make use of the following calculations after taking into account the share of its - provided for - participation in the pharmaceutical expenditure, in accordance with the approved Budget thereof.

STAGE 1

DESCRIPTION OF STAGES

	Year 2013	
	Definition of Maximum limit of Budget for Expenditures	
Budget for expenditures	2.44	The maximum limit of the budget of defined for 2013, as well as for each month of the year
Monthly maximum limit of expenditure in billions of Euro	0.203	

STAGE 2

	Reference year for the calculation of the reference shares: 2011					We assume that there were four companies in the market in 2012. The annual and monthly turnover (sales) are calculated per company together with their market shares, which were calculated based on the sum of the market shares for medicines in the therapeutic category of the positive list.
	Turnover (sales) and market shares					
	Company 1	Company 2	Company 3	Company 4	Total	
Annual turnover (sales)	2.5	0.80	0.58	0.05	3.93%	
Market shares un 2011	64%	20%	15%	1%	100%	
Monthly turnover (sales)	0.21	0.07	0.05	0.00	0.33	

STAGE 3

Maximum limit for Jan 2013	End of January 2013					The data for the turnover (sales) for January 2013 per company are collected and the total turnover (sales) for the market is calculated. The difference between the monthly maximum limit and the actual turnover 0.(sales) defines the total consumption in excess.
	Collection of data					
	Company 1	Company 2	Company 3	Company 4	Total	
					0.203%	
January 2013						
Turnover (sales)	0.15	0.09	0.05	0.04	0.33	
Consumption in excess					0.127	

STAGE 4

End of February 2013					As in stage 3, but for February
Collection of data					
Company 1	Company 2	Company 3	Company 4	Total	
Maximum limit for Feb 2013				0.203%	
February 2013					
Turnover (sales)	0.18	0.05	0.01	0.02	0.26
Consumption in excess	The same procedure will be applied for the remaining months until 6/2013				0.02

STAGE 5

End of June 2013					
Calculation based on the amounts of the six-months claw backs					
Company 1	Company 2	Company 3	Company 4	Total	
Maximum limit for January and February 2013				Total amount	
Turnover (sales)	Total of monthly turnovers	Total of monthly turnovers	Total of monthly turnovers	Total of monthly turnovers	
Consumption in excess					Sum of individual totals

1. Claw back amount	Claw back amount per company	Claw back amount per company	Claw back amount per company	Claw back amount per company	Total claw back amount	It is calculated that the amount that must be automatically returned (claw back) based on the market shares in 2011 and the total consumption in excess
% of six-months excess which is automatically returned					100%	

9. This decision must be periodically reexamined with regard to the degree of target achievement with transgression of the fixed annual budget (for 2013 it has been fixed to Euro 2.440 million) for the pharmaceutical expenditure for all Social Insurance Agencies and the necessary corrective measures will be adopted.
This Decision must be published in the Government Gazette.

Athens, November 15, 2012

THE ALTERNATE MINISTER
MARIOS SALMAS