Ministerial Decision ΔΥΓ3(α) /οικ. ΓΥ 150/01.03.2012

Automatic claw-back mechanism

THE MINISTER OF HEALTH AND SOCIAL SOLIDARITY

Having regard to:
1. the provisions of Article 11 of Law 4052/2012 (Government Gazette A 41);
2. the fact that this decision shall entail no expenditure under the government budget;
We decide as follows:
1. The pharmaceutical expenditure budget for the total of social security funds may not exceed the amount of €2,880 million, including VAT, for 2012, evenly allocated to two-month periods. If at the end of a two-month period the total pharmaceutical expenditure exceeds the specified ceiling, the overrun shall be demanded from pharmaceutical companies and shall be payable by them into an account to be designated by the Secretariat-General of Social Security in consultation with EOF and EOPYY.
2. Until the universal implementation of the e-prescription system or the scanning system for all prescriptions and for all social security funds, the amounts payable by pharmaceutical companies as an additional rebate, further to the standard 9% rebate and the escalated rebate of Article 22 of Law 4052/2012, shall be calculated as follows:
2.1 Within the first week of each month, pharmaceutical companies shall report monthly data on their sales during the preceding month; EOF shall verify and validate such data, before they can be used for the calculation of the rebate, which shall subsequently be allocated to the companies included in the positive list. Following the universal implementation of the e-prescription system, the relevant data shall be retrieved from the system.
2.2 For each company/each medicinal product, any sales amounts corresponding to parallel exports and sales to public hospitals shall be deducted for the rebate amount.
2.3 Sales to social security funds shall be imputed by applying a ratio of 80:20, and the result shall be cross-checked against the data of IDIKA (E-government of Social Security). Following the universal implementation of the e-prescription system, such data shall be retrieved from the system.
2.4 Taking into account the respective data under indents 2.1, 2.2 and 2.3 hereinabove on the sales per company and per month in 2011. The monthly turnover data for each company in respect of 2011 shall serve as a benchmark for calculating the overrun for each company in respect of 2012.
3. On the basis of the market share of each company, using 2011 as the reference year, the excess amount on the company's sales per month shall determine the amount payable by the company as automatic claw-back for 2012.
4. If, in any reference month, new companies with zero turnover in 2011 enter the market, the market shares of all the companies shall be re-calculated on the basis of the turnover (sales) of companies with positive turnover during the preceding year, adding the extrapolated annual turnover (sales) of new entrants during the reference months.
5. If companies with positive turnover (sales) during the preceding year exit the market in any reference month, the market shares of all companies shall be re-calculated, counting, in this case, the annual turnover (sales) of only these companies which exhibit positive turnover (sales) both in the preceding year and in the current reference months.

This implies that for companies with positive turnover (sales) in the preceding year and zero turnover in the reference months, the payable rebate shall be zero.

6. All necessary data shall be collected on a monthly basis and the amounts shall be payable every two months (by the end of the following month), offsetting any differences arising between the ends of the two-month periods.

7. The functioning of the automatic claw-back is illustrated in the Appendix below, which forms an integral part of this decision:

APPENDIX 1: Calculation of automatic claw-back based on a four-company model and which shall ba adjusted accordingly							
DATA		**CLAW BACK CALCULATION BASE**					
CALCULATIONS		**STEP 1**					**Description of STEPS**
		Year 2012					
		Maximum budgeted expenditure					
	Budgeted annual expenditure	2.88					Maximum budgeted expenditure is specified for 2012 and for each month of the year
	Monthly ceiling in € billions	**0.240**					
		STEP 2					
		Reference year for the calculation of market shares: 2011					
		Turnover (sales) and market shares					
		Company 1	**Company 2**	**Company 3**	**Company 4**	**All companies**	We assume that there were 4 companies in the market in 2011. The annual and monthly turnover (sales) for each company are calculated.
	Annual turnover (sales)	2.50	0.80	0.58	0.05	3.93	
	Market shares in 2011	64%	20%	15%	1%	100%	
	Monthly turnover (sales)	0.21	0.07	0.05	0.00	0.33	
		STEP 3					
		End-January 2012					
		Collection of data					
		Company 1	**Company 2**	**Company 3**	**Company 4**	**All companies**	
	Ceiling for Jan. 2012					**0.24**	Company-level turnover data for January 2012 are collected, and the total turnover (sales) of the market is calculated. The difference between the monthly ceiling and the actual turnover determines total excess consumption.
	January 2012						
	Turnover (sales)	0.15	0.09	0.05	0.04	0.33	
	Excess consumption					**0.09**	

<table>
<tr><td rowspan="20"></td><td rowspan="4"></td><td colspan="5">STEP 4</td><td rowspan="3"></td></tr>
<tr><td colspan="5">End-February 2012</td></tr>
<tr><td colspan="5">Collection of data</td></tr>
<tr><td>Company 1</td><td>Company 2</td><td>Company 3</td><td>Company 4</td><td>All companies</td><td>As in STEP 3, only different month (February)</td></tr>
<tr><td>Ceiling for Feb. 2012</td><td colspan="4"></td><td>0.24</td><td rowspan="9"></td></tr>
<tr><td>February 2012</td><td colspan="5"></td></tr>
<tr><td>Turnover (sales)</td><td>0.18</td><td>0.05</td><td>0.01</td><td>0.02</td><td>0.26</td></tr>
<tr><td>Overrun</td><td colspan="4"></td><td>0.02</td></tr>
<tr><td rowspan="4"></td><td colspan="5">STEP 5</td></tr>
<tr><td colspan="5">End-February 2012</td></tr>
<tr><td colspan="5">Calculation on the basis of bimonthly clawed back amount</td></tr>
<tr><td>Company 1</td><td>Company 2</td><td>Company 3</td><td>Company 4</td><td>All companies</td></tr>
<tr><td>Ceiling for Jan. and Feb. 2012</td><td colspan="4"></td><td>0.48</td><td rowspan="4">The cumulative budget ceiling for January and February 2012, the actual turnover(sales) and the overrun (excess consumption) are calculated</td></tr>
<tr><td>January and February 2012</td><td colspan="5"></td></tr>
<tr><td>Turnover (sales)</td><td>0.33</td><td>0.14</td><td>0.06</td><td>0.06</td><td>0.59</td></tr>
<tr><td>Overrun</td><td colspan="4"></td><td>0.110</td></tr>
<tr><td colspan="7"></td></tr>
<tr><td>1. Clawed back amount</td><td>0.0700</td><td>0.0224</td><td>0.0162</td><td>0.0014</td><td>0.110</td><td>The clawed back amount is calculated in the basis of market shares in 2011 and aggregate bimonthly overrun</td></tr>
<tr><td>Percentage bimonthly overrun automatically clawed back</td><td colspan="4"></td><td>100%</td><td rowspan="2"></td></tr>
<tr><td>Effective burden on total consumption</td><td>21%</td><td>16%</td><td>27%</td><td>2%</td><td>19%</td></tr>
</table>

8. This decision shall be reviewed regularly and, depending on the degree of achievement of the annual target for pharmaceutical expenditure (set at 2,880 million for 2012) for the total of social security funds, corrective action shall be taken as necessary.
We order that this decision be published in the Government Gazette.
Athens, 1 March 2012
THE MINISTER
ANDREAS LOVERDOS