

To  
the Honourable  
Mr Adonis Georgiadis  
Minister of Health

Chalandri, November 6, 2013

Dear Minister,

In view of the filing of the Omnibus Law within the following days before the Greek Parliament, to our great surprise and disappointment we were informed that the provisions included therein have nothing to do with everything we discussed and have already agreed upon before summer. More specifically:

Subject	Commitments	Daft of Omnibus Law
<b>Patent:</b>	Protection of patent in force	Data protection period
<b>On-patent:</b>	Average of the 3 lower prices	Average of the 3 lowest, but prohibition of increases regardless of the price deriving from the average
<b>Off-patent:</b>	Reduction by 50% with observance of the average of the 3 lower prices in the EU countries	Reduction by 50% without observance of the 3 lower prices in the EU countries
<b>Generics</b>	Definition of a generic with the same qualitative and quantitative composition in active substances and same pharmacotechnical form with the reference product for which bioequivalence has been proven	The generic is only associated to the active substance
<b>Hospital Price:</b>	Non-publication of the hospital price	No provision
<b>Clawback:</b>	Calculation of clawback on the ex-factory price	No provision

In addition, there was, as you are aware, a convergence of opinions in the following issues which are not included in the manner agreed upon, in the Omnibus Law:

▫ **Voluntary reduction of prices (off-patent & generics):** while it was agreed to determine a threshold for the prices of medicinal products in order to avoid the price dumping, there is absolutely no relevant provision in the Omnibus Law.

▫ **Non-encumbrance of innovative medicinal products:** While it was agreed that no additional encumbrance on particularly innovative medicinal products/active substances that concern medicinal products which have been listed and occupy alone in a therapeutic category (ATC 5), the Omnibus Law provides for an additional rebate of 2% (9%+2%=11%) thus “punishing” innovation and products that have been listed and occupy alone a therapeutic category.

▫ **Products under law 3816:** while it was agreed that in case the Ministry insists on offering the medicinal products set out in Law 3816 also via private pharmacies, then freedom of selection of the distribution channel would be granted to pharmaceutical companies, provided that for these medicinal products, the hospital price would be equal to the ex-factory (average of the 3 lower prices in the EU countries), nevertheless the Omnibus Law makes no provision for the last two conditions that had been agreed upon and constitute prerequisites.

Dear Minister,

Being aware of your sensibility for Public Health, we kindly request that you incorporate the above amendments before the filing of the Omnibus Law to the Greek Parliament, in order to prevent the contingency of a highly risky and irreversible condition.

Yours sincerely,

Konstantinos M. Frouzis  
President

Nikos Kefalas  
Vice President