



## Pricing of Pharmaceutical Products: The New Ministerial Decision no. 32535/2019

The new Ministerial Decision no. 32535/2019 followed up on the new pricing structure of the Law 4600/2019 that was adopted earlier this March. According to the Ministerial Decision:

1. In order to determine the price of pharmaceutical products for the first time, their pharmaceutical substances have to be priced in at least three (3) Member States of the European Union.
2. The upper limit of the ex-factory prices of the on-patent, off-patent, hybrid and biosimilar products as well as of pharmaceutical products based on the combination of known active substances is determined on the basis of the **average of the two lowest prices** inside Eurozone. If there is only one price in all Member-States, then this price is to be adopted.
3. The respective retail price should not be less than the Daily Treatment Costs, i.e. less than 0,20 euros.
4. In case of pharmaceutical products based on the combination of known active substances, if it is impossible to discover regulated prices in three Member States, their price can be determined according to the deduction doctrine.
5. The upper limit of the ex-factory price of pharmaceutical products of established medical use is determined either by the deduction doctrine or by the average of the two lowest Eurozone prices of the same or similar pharmaceutical substance.
6. The price of generic drugs is set at 65% of the price of the respective reference products in Greece or in any other Member-State and otherwise on the basis of the average of the two lowest prices inside Eurozone.
7. During each repricing, the pharmaceutical products' prices shall be **reduced** by up to 10% on the price of the immediately preceding price bulletin, if their value in the latter price bulletin is above the average of the two lowest prices inside Eurozone.
8. During each repricing, the prices of reference pharmaceutical products shall be **increased** by up to 10% on the price of the immediately preceding price bulletin, if their value in the latter price bulletin is below the lowest price of any Member-State inside Eurozone.
9. All prices will be revised **once** per year.



## Rebates for the Years 2006, 2007 and 2008

On May 17th 2019 Law 4611/19 (GG issue 73/A/17-05-2019) was passed, providing for the obligation of pharmaceutical companies to pay their respective rebates for the years 2006, 2007 and 2008.

These amounts were deemed previously not to be owed by the pharmaceutical companies, given the lack of legislative basis, as the Joint Ministerial Decision No.42000 / 14734/532 / 22.07.2008, which foreseen the relevant rebate, was canceled by virtue of the 4204/2014 decision of the Council of State, while the provisions of articles 2,3 and 4 of L. 3457/2006 and paragraph 3 of article 13 of Law 3408/2005, which also provided for the imposition of those rebates were abolished by virtue of article 35 of L. 3697/2008.

According to article 122 of the new Law, pharmaceutical companies are obliged to pay back the amount of 4% as a rebate on the actual pharmaceutical expenditure paid to them by the social security funds during the above mentioned three-year period.

The new Law authorises the Ministers of Finance and Health to issue a decision determining the relevant retention and reimbursement procedure, the conditions for repayment, the method of allocating the amount of the rebate per pharmaceutical company and all other necessary details, taking into account five criteria:

- A) The retail price of the pertinent pharmaceutical products for the years 2006, 2007 and 2008;
- B) The total sales of all packages, formulations and dosages of each pharmaceutical product per year and per pharmaceutical company;
- C) The reference price and the reimbursement price for the above three years;
- D) Any compulsory deductions/rebates applied;
- E) The insured patient's participation.

The collection of the amounts owed by each company is assigned to EOPYY and their payment can take place either in the form of payment in cash or by offsetting the amount with corresponding debts of EOPYY to pharmaceutical companies. The payment can be split

in up to 120 installments, following an application to EOPYY.

The same Law also provides that EOPYY is responsible for the collection of all rebates of the pharmaceutical companies for the years 2009 to 2011 and these may also be paid in installments.

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