

CHAPTER 27

MEDICINES

Article 331

Determination of prices

1. Highest Wholesale price is the sale price to pharmacists. In the said price are included the profit of the wholesaler and the compulsory discounts.
2. The highest Retail Price of medicinal products shall be determined on the basis of the Wholesale price, increased by the legal profit of pharmacist and VAT.
Retail prices are the same throughout the country, with the exception of those areas where reduced VAT coefficient is applicable.
3. Net price is the sale price by pharmaceutical companies to wholesalers. The net price is determined on the basis of the wholesale price reduced by 7.78%.
4. Highest Hospital price for medicinal products is the sale price thereof to the State, Public Hospital Institutions, supervised by the Ministry of Health and Welfare and the Ministry of Employment and Social Protection and Private Clinics. The same price applies for the sale of the medicinal products of par. 2 of article 12 of L. 3816/2010 by the producer or packager or importer to private pharmacies. Hospital price is determined on the basis of the wholesale price reduced by 13%.
5. Highest price for Social Insurance funds is 96% of the net price of each medicinal product reduced by the percentage of contribution of the insured patient.
6. Original medicinal product is the product of the company which carried out the research and introduced worldwide the active ingredient in therapeutics, as well as the same medicinal product manufactured by other persons following legal transfer of the

relevant rights by the beneficiaries.

7. Essentially similar medicinal product is the medicinal product that has the same active ingredient as the respective original and for which a marketing authorization has been granted.
8. The designation of a medicinal product as original or as pharmaceutical product with the same active ingredient shall be indicated on the legal marketing authorization of the medicinal product, which is issued by EOF."

Article 332

Profit Margins

1. The gross profit for wholesalers is 8% calculated upon the net price of the producer or the importer. The above mentioned profit margin is granted as a compulsory discount.
2. For pharmacists, a gross profit of 35% is calculated upon the wholesale price.

Article 333

Discounts

1. In the case of sales to pharmacies, located out of the Prefecture and in cities with less than 5.000 inhabitants (with the exception of the Prefecture of Attica and Thessaloniki), manufacturers, packagers, importers and wholesalers shall be granted a compulsory discount of 4% upon the wholesale price. In order to enable wholesalers to grant the said discounts to pharmacies of paragraph 1 of the present article, producers, packagers and importers shall grant them a compulsory additional discount of 0,4% on the wholesale price for the overall sales.
2. Manufacturers, packagers and importers are allowed to grant: a) additional discount on the hospital price to the State, to public

Hospitals, to Institutions supervised by the Ministry of Health and Welfare and by the Ministry of Employment and Social Insurance and by private Clinics b) an additional discount of up to 5% on the wholesale price to wholesalers, pharmacies and cooperatives, under the condition to enter said discount in the invoice.

The same discount can be granted by wholesalers and cooperatives to pharmacies.

3. In case this limit of discount is exceeded, in addition to the sanctions provided for in the Market Decree Code, this will have as a consequence the reduction of the price by a rate proportional to the additional discount granted.

Article 335

Locally manufactured - packaged and ready-made imported medicinal products

The wholesale price of all locally manufactured, packaged and ready-made imported medicinal products may not exceed the price determined by the Department according to article 336, unless the Medicines Price Committee accepts that the specific price is lower than the cost, following comparison of the cost data submitted by the pharmaceutical company to the Department with the relevant data available to or collected by the competent Department.

Article 336

Investigation of prices - Determination of the price of medicinal products

1. The prices of the medicinal products in the internal market are determined by the competent Department of the General Secretariat of Commerce, following the conduct of an investigation in the member states of the European Union (E.U.) where the medicinal product is marketed. The sale price to wholesalers shall be taken into

account, resulting from the average of the three (3) lowest prices of the medicinal product in the member states of the European Union (E.U.) in which official data exist and which are officially announced by the competent authorities of these countries. The E.U. countries for which official data exist are announced in the 1st Price Bulletin each year. The medicinal product must have obtained a price in the same form and strength, in at least three (3) of the member states of the European Union. Especially for medicinal products designated as orphan in the marketing authorization, the Medicines Price Committee issues an opinion both on the method of determination of the price as well as on their price.

2. For an investigation to be effected it is required that pharmaceutical companies submit to the competent Department of the General Secretariat of Commerce a price investigation form - solemn declaration that includes: a) the member states of the European Union (E.U.) in which the medicinal product for which a price determination is requested is marketed, b) the name, packaging, strength and form in which the medicinal product is marketed. The data are submitted in printed form to the above mentioned department and in electronic form at the email address: farmaka@gge.gr.
3. The price of the above mentioned medicinal products is re-examined and re-adjusted by the Department in the first, third and fifth Price Bulletin in accordance with paragraph 1 of the present article after taking into consideration paragraphs 3 and 4 of article 342. To this end, the interested companies submit in electronic form the price investigation form-solemn declaration, as described in paragraph 2 of the present article, without including the prices and send them to the competent Department to the electronic address farmaka@gge.gr at least 15 calendar days prior to the date of publication of the price bulletin, without prior notification of the Department.
4. Companies concealing or refusing to supply or supplying inaccurate or false data and information are punished by a fine equal to ten times the difference between the price deriving from the data submitted by the pharmaceutical company and the price determined

by the Department, multiplied by the quantity of the medicinal products sold for as long as the approved price applied. The imposition of the fine, according to this paragraph, is independent from the claim of Social Insurance funds for damages incurred from the above mentioned difference in the price of the medicinal product."

Article 337

Pricing of original medicinal products following expiration of the Patent

1. All the categories of prices of original medicinal products following certification by any appropriate means of the expiration of the first National or European Patent of the active ingredient of the respective products are reduced by at least 20%. The first six-month period following the expiration of the first National or European Patent of the active ingredient of the above mentioned medicinal products, the re-pricing of article 336 hereof is not applied.
2. Pharmaceutical companies are obliged to submit to the Department the number of the first National or European Patent of their medicinal products.
3. A fine according to L. 3557/2007 is imposed on the manufacturer or importer or packager who fails to notify the Department of the date of expiration of the first National or European Patent of their medicinal products by decision of the Minister of Economy, Competitiveness and Shipping.

Article 338

Medicinal products with the same active ingredient

1. The sale prices of medicinal products with the same active ingredient and pharmaceutical form, when marketed for the first time in the Greek market, are determined at a maximum percentage of seventy-two percent (72%) of the sale price of the respective original medicinal product during the validity period of the National or

European Patent.

The prices of medicinal products with the same active ingredient and pharmaceutical form are determined at a maximum percentage of ninety per cent (90%) of the sale price of the respective original medicinal product, as determined from time to time, according to the provisions in force after the expiration of the first National or European Patent of the active ingredient of the respective medicinal products.

Should the original medicinal product have a different packaging, then extrapolation is made of the packaging in accordance with article 342, par. 3, in order to determine the price of the medicinal product with the same active ingredient to 80% of the price resulting from the related extrapolation.

When the original medicinal product does not have an approved price for the same strength, the price of the medicinal product with the same active ingredient shall be calculated:

on the grounds of the price of the product with the closest strength of the same pharmaceutical form, co-estimating the relation in the other countries. When the original product does not have an approved price in the same pharmaceutical form, the price of the medicinal product with the same active ingredient shall be set to 80% of the price resulting from the application of the provisions of article 336.

2. If a medicinal product with the same active ingredient corresponds to an original medicinal product that is not marketed in the country but is marketed in a member state of the European Union (E.U.) its price is determined on the basis of the price of its original medicinal product in application of article 336 and paragraph 1 of this article.

If the essentially similar medicinal product corresponds to an original medicinal product that is not marketed in the country and in the European Union (E.U.), the essentially similar medicinal product is granted the average price of the respective essentially similar medicinal products with the same active ingredient.

3. For parenteral solutions (sera) single prices are determined on the basis of the prices of the active ingredients and the other cost data."

ARTICLE 2

1. At the time of entry into force hereof and until the 31/12/2010, the highest variations of the wholesale prices determined following the implementation of the market decree, may not exceed the percentage per price set in the following scale:

Wholesale Price of Medicinal Product	Maximum price reduction	Maximum price increase
Over € 50.01	According to the provisions of articles 336, 337, 338 and 342 of this market decree	0%
From € 20.01 to € 50	30%	0%
From € 5.01 to € 20	25%	0%
From 0 to € 5	3%	5%

2. The sale prices of the medicinal products applicable at the time of entry into force of this market decree shall continue to apply for a period of twenty-one (21) days for wholesalers and sixty (60) days for pharmacies as of the entry into force of the First Price Bulletin for their eventually existing stock.