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 trader wholesaler and the compulsory discounts.
2. The highest Retail Price of medicinal products shall be determined on the grounds of the Wholesale price, increased by the legal profit of the medicinal products trader pharmacist and VAT.
   Retail prices are the same throughout the country, with the exception of those areas where reduced VAT coefficient is applicable.
3. Highest Hospital price for medicinal products is the sale price thereof to the State, Governmental Hospital Institutions, Institutions supervised by the Ministry of Health and Welfare and Occupation and Social Protection.
   Hospital price is determined on the basis of the wholesale price reduced by 13%.
4. Highest Insurance price of the Social Security fund is 96% of the net price of each medicinal product, as determined in article 332, reduced by the percentage of contribution of the insured patient.

Article 332
Profit Margins

1. For medicinal products traders wholesalers, the gross profits is 8% calculated upon the net price of the producer or the importer.
   Net price means the wholesale price reduced by the compulsory discounts.
   The above mentioned profits 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 provincial pharmacies, located out of the Prefecture and in cities with less than 5.000 inhabitants (with the exception of the

Prefecture of Attica and the former Municipality of Thessaloniki), manufacturers, packagers, importers and medicinal products traders wholesalers shall grant a compulsory discount of 4% upon the wholesale price.

In order to enable medicinal products traderswholesalers to grant the said discounts to provincial pharmacies, the producers, packagers and importers shall grant them a compulsory additional discount of 0,4% upon the wholesale price for the overall sales.

2. Manufacturers, packagers and importers are allowed to grant to the State, to public Hospitals, to Institutions supervised by the Ministry of Health and Welfare an additional (optional) discount upon hospital price without any restrictions, and also to Medicinal products traders wholesalers, pharmacies and cooperatives an additional (optional) discount up to 5% on the wholesale price, under the condition to enter said discount in the invoice.

The same range of discount can be granted by medicinal products traders wholesalers and cooperatives to pharmacies.

In case this limit of highest 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 334
Research Greek Original Medicinal products

1. Original medicinal products produced by Greek pharmaceutical industries, for which research has been carried out for the active ingredient or the pharmaceutical form and there is no equivalent medicinal product in another country, prices will be determined on the basis of the cost elements presented.

The said cost elements shall include production and packaging expenses for each form and package as well as Administration – Distribution – Propagation expenses as determined in the corresponding lists are updated every two years, calculated on the grounds of the average expenses of the sector.

Furthermore, new investments, the costs for the research and development of the active ingredient as well as the Greek know-how shall also be taken into consideration.

Cases of similar pharmaceutical forms are excluded.

The following are not considered as cost elements:

a. Moratory interests

b. Personal taxes (i.e. income taxes etc.)

c. Expenses due to the infringement of regulations in force.

d. The prices of active ingredients of any supplier (with the exception of the researcher) which are higher than the sale price of the research company.

e. Supplies from third parties and other expenses which are not related to the production and distribution of the medicinal products.

2. The highest net profit is set to 8,5% and is calculated on the overall cost with the exception of amortizations, interests and third parties profits for work on order under license manufacturing.

Article 335
Locally manufactured – packaged and ready - made imported medicinal products

1. The Wholesale price of all locally manufactured – packaged and ready – made imported medicinal products may not exceed the price of article 336, unless it is proven by the cost data that the specific price is under the cost.
2. The price of a medicinal product which is not marketed in the same pharmaceutical form and strength in at least three (3) of European Union member States shall not be approved.

Article 336
Investigation of the prices of medicinal products

1. Following investigation of the prices in EU countries where the medicinal product is marketed, the sale price to wholesaler shall be taken into account, resulting from the average of the three (3) lowest prices in the EU, plus the import expenses and the compulsory discounts.
2. The prices declared in the investigation and verification form by the interested parties (retail – wholesale – Ex factory price), either for the determination of the initial price or for the readjustment of the price of a marketed medicinal product, must be accompanied by a solemn declaration indicating that these prices are indeed the ones in force in the corresponding countries.
3. The approved price or each new medicinal product shall necessarily be verified by the Department, according to paragraph 1 of the present Article,

in the fifth (5th) consecutive price bulletin since the publication of its original price. The statutory and prerequisite price investigation forms for the medicinal products in question shall be submitted necessarily by the companies, at the latest 15 calendar days prior to the defined date of publication of the above bulletin, without prior notice by the Department

4. The competent Department shall necessarily investigate every year for four consecutive years following the year of first price determination of a medicinal product, whether the verification prices differentiated and shall proceed in the corresponding readjustments. For investigation purposes and upon notification of the Department, the companies are obliged to submit a corresponding investigation and verification form for their medicinal products, whose prices were approved during the under investigation period of time.

   The Department reserves the right, provided it is deemed necessary, to proceed with an investigation even after the four year period, on the grounds of objective criteria.

5. In case the above declarations under paragraphs 2 and 3 are inaccurate or disonest in addition to the reduction of price, a fine shall be imposed on the infringer, equal to ten times the value resulting from the calculation of the difference between the prices declared by the company and the prices which were ascertained by the Department for each country separately, multiplied by the quantities sold and for as long as the approved price was applied.

   Besides the above, the social security funds shall be entitled to claim damages for the resulting difference in price.

Article 337
Medicinal products with the same active ingredient

1. The prices of medicinal products with the same active ingredient and pharmaceutical form shall be set to 80% of the sale price of the corresponding original medicinal product, as determine each time until the application of the provisions article 338.

   In case the price of the original medicinal product has been reduced in compliance with the provisions of article 338, then the prices of the new medicinal products with the same active ingredient shall be set to the same level as those of the already approved medicinal products with the same active ingredient.

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. An original medicinal product is the product of pharmaceutical companies which performed the research and introduced world-wide the active ingredient in therapeutics, as well as the medicinal product produced by others pursuant to the assignment of the relevant rights by the owners.
3. The designation of a medicinal product as original (the product was approved pursuant to the filing of a complete application) or as a medicinal product with the same active ingredient (the product was approved pursuant to the filing of an abridged application) shall be indicated on the marketing authorisation, issued by the National Organisation for Medicines (EOF).
4. Uniform prices shall be determined for Analgesics and Parenteral solutions (sera), on the grounds of the prices of active ingredients and the rest of the cost data.

Article 338

The prices of original medicinal products shall be reduced by 20%, following certification by all available means of the expiration of the first National Patent for the active ingredient of the product and after one year of marketing of one or more medicinal products with the same active ingredient, provided they are marketed in a satisfactory degree in the Greek market in accordance with the data of the National Organisation for Medicines (EOF). In any case, the prices of original medicinal products should not be set at a level lower than those of essentially similar medicinal products (with the same active ingredient).

In the above case, and for four years, paragraph 1 of article 336 of the present shall not be applicable.

The procedure of the present article shall be applicable automatically (de Jure) by the Department of the Ministry of Development and shall be completed until June 30th of each year, for medicinal products for which the conditions of paragraph a' of the present article are applicable and the first National Patent for the active ingredient thereof has expired after December 31st 1997.

Medicinal products for which the conditions of paragraph a' of the present article are applicable and the first National Patent for their active ingredient expired before January 1st 1998, shall be examined on a case by case basis.

Article 339
Obligations of pharmaceutical companies

1. After the end of each administrative period, pharmaceutical companies are obliged to submit to the Department of Commerce of the Ministry of Development the following:

1.1 Within a one-month time limit, the sales per quantity and value for the administrative period in question.

1.2 Within a four-month time limit, balance sheet and the statements of expenditures (in detail and aggregated).

The submission of aforesaid documents constitutes an indispensable condition for the examination of any request for price approval or price reconsideration.

2. Cost elements control or partial control of documents of the companies shall be performed, if required, irrespective of tax or other controls, by employees of the Department of Commerce of the Ministry of Development at the seat of the company, which is obliged to put at their disposal all the books and documents kept.

The competent Department, should it deem necessary, may use information from related companies and other information it has at its disposal.

3. Companies producing or importing other products, besides medicinal products, must keep separate accounts for the sector of medicines. The same obligation applies to companies producing or packaging medicinal products on behalf of third parties (Contract manufacturing), as far as these medicinal products are concerned.

4. Pharmaceutical companies are obliged to keep books with respect to medicinal products they produce or pack. In the said book they shall enter, for each pharmaceutical form of the medicinal product in detail and per lot, the quantities and values of the raw ingredients and auxiliary ingredients, of the packaging materials used, as well as the production and packaging expenses of the medicinal products. Furthermore, the quantities produced and the value thereof shall be kept on the basis of their ex factory price. At the end of the year, the General Industrial Expenses corresponding to the production of the medicinal product shall be entered in the book. The book of cost elements shall be certified, before use, by the competent Market Police Department. Companies obliged by the Code on Tax information or another law to keep the said information in a book or account cards, are exempted from the obligation to keep books on cost elements.
5. The pharmaceutical companies, the representatives – importers, the wholesalers and the pharmacists are obliged to provide the competent Department every information requested with respect to the medicinal products, in accordance with the provisions of article 30 of Legislative Decree 136/46.

Article 340
Submission of Supporting documents and Deadlines for Price Determination

1. For the determination of the price of medicinal product for which a marketing authorization was issued by the National Organisation for Medicines (EOF) or the European Agency for Medicines (EMEA), or the changing of a price, an application must be filed with the information in support of the price requested.
2. The supporting documents required in each case shall be determined with a circular of the competent Department of the Ministry of Development.
3. For all medicinal products of foreign origin (manufactured, packaged, imported), a certificate of the foreign company, duly certified by the competent foreign authorities, must be submitted to the competent authorities, indicating the ex factory, wholesale and retail price of the medicinal product in the country of origin.
4. In the case of an application for the determination of price of a new medicinal product, the competent Department shall issue a Price Bulletin within 90 days following the submission of the application. If the documentation submitted with the application is insufficient, then the above

deadline shall begin on the date of submission by the interested party of all the documents provided for. If the determined price is significantly different from the requested price, the Department shall justify to the interested party the price set and the latter may submit to the Minister of Development an application for re-examination.

In case the corresponding marketing authorization is not submitted with the application for price determination of a new medicinal product, the application shall be put in the archives.

5. In case an application for price increase is filed, all the provisions of paragraph 4 are applicable. In his application the interested party must demonstrate the changes which occurred and justify the requested increase. In the case of large number of applications, the deadline may be extended by 60 days.
6. When, for specific reasons, the price of medicinal products must be frozen, the interested party may, in exceptional cases, request a deviation from friezing. The provisions of paragraphs 4 and 5 are also applicable in these cases. These specific cases of deviation from friezing concern a limited number of medicinal products resulting important losses to the company.

Article 341
General Provisions

1. Prices of medicinal products are set for packages approved by the National Organisation for Medicines (EOF) and the European Agency for Medicines (EMEA). Large (hospital) packages cannot be sold in parts by pharmacies.
2. Medicinal products, the marketing authorization of which bear the indication “FOR HOSPITAL USE ONLY”, must necessarily bear on the external packaging and on the enclosed package leaflet, clearly and within a special frame the indication “FOR HOSPITAL USE ONLY”. It is prohibited to sell through pharmacies such medicinal products to the public.
3. Retail prices must be indicated on the external packaging of medicinal products.
4. Transportation costs to the seat of provincial wholesalers and pharmacies, are born by pharmaceutical companies or by the importer. The same cost is born by wholesalers, with respect to their sales to provincial pharmacies.

Exceptionally, wholesalers shall not bear the transportation costs of an order when the value of the order does not exceed 10 Euros.

5. In case of price friezing, the Ministry of Development shall examine at least once a year if the macroeconomic conditions justify continuation of friezing without any change.
6. The prices of medicinal products shall be determined with a Price Bulletin issued in accordance with the provisions of the Market Decree Code.
7. Sale prices which were published in Price Bulletins, or requested, or applied by the interested companies, may be decreased by the Ministry of Development provided there is a reason and evidence in support of the decrease.
8. Packages of medicinal products destined for export shall not be controlled by Market Decree.
9. Manufacturers, packagers and importers of medicinal products are obliged, for sales to wholesalers and pharmacies, to retain the contribution in favour of the Panhellenic Pharmaceutical Association (4 per thousand on the wholesale price). The contribution in favour of the PPA shall be collected and remitted to the latter via TSAY (Insurance and Pension Fund for Healthcare Professionals). Wholesalers shall retain the corresponding contribution from pharmacists. For the export of medicinal products by wholesalers, the corresponding amount of the contribution (which was already retained by pharmaceutical companies) shall be returned to the wholesalers according to the same procedure for the refund of other contributions in favour of third parties in similar cases.
10. In cases of Co-Marketing, the same price shall be set. Should different prices arise, the lowest price is taken into consideration.
11. The price resulting on the grounds of articles 334, 335, 336, and 341 shall be approved unless the price requested is lower.

Article 342
Price determination in case the manufacturer or the packager of a medicinal product change or in case of change or addition of a new package etc.

1. In case the manufacturer of a medicinal product, or the packagers thereof or both change, the price that the medicinal product had prior to the change shall be considered as highest price.
2. In case of change or addition of a new package or strength, as well as in the case of addition of a new similar pharmaceutical form (under the condition

that the new form shall have the same route of administration), in order to determine the price thereof, a correlation must be made with the prices determined in accordance with the provisions of articles 334, 335, 336, 337, 338 and 341 of the present decree or (in case prices have not been set in accordance with the aforesaid articles), with the prices in force.

With respect to the correlation of prices of medicinal products whose price was set in accordance with article 334, possible differentiation of the cost of packaging and production is taken into account.

3. The conversion of packaging and strength shall be performed as follows:

a) _From the small to the large package and strength unit, price shall be reduced, to a maximum limit of 12% as shown below:

Increase of Package (%)	Proportional price reduction (%)
Up to 5	1,67
From 5,01 to 10	3,18
From 10,01 to 15	4,56
From 15,01 to 20	5,83
From 20,01 to 25	7,00
From 25,01 to 30	8,08
From 30,01 to 35	9,07
From 35,01 to 40	10,00
From 40,01 to 45	10,86
From 45,01 to 50	11,67
From 50,01 to 60	12,00
From 60 and above	Examination on a case by case basis in relation with the information available

3.2 The unit price between the large and small package and strength shall be increased to a maximum limit of 12%:

Package reduction (%)	Proportional price increase (%)
Up to 5	1,32
From 5,01 to 10	2,78
From 10,01 to 15	4,41
From 15,01 to 20	6,25
From 20,01 to 25	8,33
From 25,01 to 30	10,71
From 30,01 and above	12,00

3.3 One dose injections, small sachets and ophthalmic solutions in a single dose, which are calculated proportionally, are excepted.

4. For price determination of two or more strengths of the same medicinal product, in case disproportional prices result, the lowest price shall be taken into consideration.

5. Paragraphs 2 and 4 of the present article shall not be applicable, at the discretion of the Ministry of Health and Welfare, to medicinal products which are unique, irreplaceable and absolutely necessary for Public Health.

6. Approved prices are published in a Price Bulletin, following the opinion of the Pricing Committee. Interested parties are entitled to be informed of the proposed prices within two (2) working days after the day following the session of the Pricing Committee. Should there be any request for the re-examination of prices, the price of these medicinal products will not be included in the Bulletin under publication but in a subsequent bulletin.

Article 343
Authenticity tag or bar code

The obligation to indicate on the authenticity tag or the bar code all the information provided for does not cancel the obligation to indicate this information on other parts of the packaging, as provided for in other regulations.