Ministerial Decision No. ΔΥΓ3(α)/οικ.33013 (4)

Provisions on the pricing of medicinal products

THE MINISTER OF HEALTH AND SOCIAL SOLIDARITY

Having regard to:

(...)

We decide as follows:

Article 1

Definitions

1. "Maximum Wholesale Price" is the price at which medicinal products are sold to pharmacies. This price shall include the wholesale gross profit margin, calculated as a percentage of the net producer price or net import price.
2. "Maximum Retail Price" is the price at which medicinal products are sold by pharmacies to consumers, plus the pharmacy markup and VAT. Maximum retail prices shall be uniform across the country, excluding the regions where lower VAT rates apply.
3. "Net producer price or (ex factory) import price" is the price at which medicinal products are sold by importers, manufacturers, packers to wholesalers. The net price shall be derived by applying a percentage deduction on the wholesale price as follows: a) for non-prescription medicines (OTC), by 7.24%; b) for prescription medicines not reimbursed by social security funds, by 5.12%; and c) for prescription medicines reimbursed by social security funds, by 4.67%.
4. "Maximum hospital price" is the price at which medicinal products are sold by importers, manufacturers, packers to the central government, public hospitals, Social Care Units and the legal persons in public law referred to in para 1 of Article37 of Law 3918/2011, pharmacies of private hospitals with over 60 beds and the pharmacies and wholesalers referred to in para 2 of Article12 of Law 3816/2010. The maximum hospital price shall be derived by deducting 13% from the wholesale price.
5. In particular for medicinal products within the scope of para 2 of Article 12 of Law 3816/2010, the method for the calculation and determination of the retail price shall be as follows: a) a wholesale margin of 2% shall be added to the hospital price to obtain the Special Wholesale Price. On the resulting price, a regressive margin and a flat fee of €30 shall be added to obtain the retail price, as explained in the following article on profit margins. The final price shall be subject to VAT.
6. "Social Security Price (SSP)" is defined as the producer/import price reduced by 9%.
7. Medicinal products the active substance of which is protected by a national or European patent shall be referred to as "originator" products. Originator products shall be understood to include any medicines for which the manufacturer has acquired patent rights from the originator.
8. "Substantially similar" medicinal product shall mean a product which has the same active substance as the respective originator product and which has obtained a marketing authorisation.
9. The status of a medicinal product as an originator product or substantially similar shall be indicated in its marketing authorisation.

Comment [MSOffice1]: The words "and wholesale price" were deleted.

Article 2

Profit margins

1. For wholesalers, gross profit margins shall be determined as follows:

a) for non-prescription medicines (OTC), at 7.8% of the ex-factory price;
b) for prescription medicinal products not reimbursed by social security funds, at 5.4% of the ex-factory price;
c) for medicinal products reimbursed by social security funds, at 4.9% of the ex-factory price; and
d) for the medicinal products of para 2 of Article12 of Law 3816/2010, at 2% of the hospital price. The resulting price shall hereinafter be referred to as "special wholesale price".

Wholesalers	OTC	Negative list	Positive list	Law 3816, Article 12, para 2
Proportion of ex-factory price	7.8%	5.4%	4.9%	Special wholesale price = hospital price + 2%

2. For pharmacies, gross profit margins shall be determined as follows:
a) for non-prescription medicines (OTC), at 35% of the wholesale price;
b) for prescription medicinal products not reimbursed by social security funds, at 35% of the wholesale price;
c) for medicinal products reimbursed by social security funds and having a wholesale price of up to €200, at 32,4% of the wholesale price; and
d) for the medicinal products of para 2 of Article12 of Law 3816/2010 and for the first application of this Decision, as per the table below:

Medicinal products of para 2 of Article12 of Law 3816/2010

PRICE CATEGORY	ADD-ONS AND FINAL PRICE
Special wholesale price* of up to €500	Hospital price +2% + 8% + €30
Special wholesale price of €501-€1,000	Hospital price +2% + 7% + €30
Special wholesale price of over €1,001	Hospital price +2% + 6% + €30

*Special wholesale price = hospital price + 2%.

e) for the remaining medicinal products with a wholesale price of over €200, as per the table below:

Medicinal products, other than those of para 2 of Article 12 of Law 3816/2010, with a wholesale price of over €200

PRICE CATEGORY	ADD-ONS AND FINAL PRICE
Wholesale price of €200-€500	Wholesale price + 8% + €30
Wholesale price of €501-€1,000	Wholesale price + 7% + €30
Wholesale price over €1,001	Wholesale price + 6% + €30

In each subsequent re-pricing and as from 15 June at the latest, the pharmacy profit on medicinal products with a wholesale price and a special wholesale price of over €200, under points d and e of this paragraph and the respective tables, shall be a flat fee of €30.
For the medicinal products of paragraph 2 of article 12 of L. 3816/2010, which are included in the list due to the special controlled method of administration and whose wholesale price is lower than €200, the special method of determination of the retail price by private pharmacies results from the hospital price to which 2% as wholesaler's profit margin is added (Special Wholesale price) and on the resulting price the pharmacy's profit margin 16% is added. On the final price the VAT is added.

Comment [MSOffice2]: New

Article 3
Price reductions

Manufacturers, packers and importers may offer additional price reductions, applied exclusively on the hospital price, for the central government, public hospitals, the Social Care Units of Article 37 of Law 3918/2011 and the pharmacies of EOPYY; any such reduction shall be indicated in the sale invoice.

Article 4
Pricing of originator products – Price verification

1. The prices of medicinal products legally marketed in the country shall be determined by decisions of the Minister of Health, in accordance with the provisions hereof, following elaboration and recommendation by the competent Service and an opinion of the Pricing Committee.
2. Before pricing an originator medicinal product, the competent Service shall undertake a survey in EU Member States in which the product is available and shall collect price data as reported by the competent authorities and agencies in the respective countries. Access to such data collection sources shall be ensured through dedicated websites of the official sources in each Member State of the EU. If access to such official websites is not possible or the data are insufficient, the Service may partly substitute data from other sources (reliable price research agencies), indicating the origin of data accordingly. Price research shall encompass any available price (ex-factory, wholesale, retail, hospital, insurance, etc.).
3. The following information shall be deemed essential for price-setting: a) name of medicinal product; b) active substance; c) strength; d) pharmaceutical form; e) pack size; f) ATC classification; g) the person responsible for placing the product on the market; and also the prices (wholesale and/or retail, and/or hospital and/or ex-factory) and the expiry date of the first patent of the active substance. The product must have been priced and must be marketed in at least three EU Member States.

Comment [MSOffice3]: The words "in the same form and strength" were deleted.

4. The prices of on-patent medicinal products are derived as the average of the three lowest prices of the respective products in EU Member States. Data reported by pharmaceutical companies via Price Verification Sheets may additionally be taken into consideration. Any sale invoices shall not be considered as eligible input in this respect.
5. An electronic template of the Price Verification Sheet shall be prepared by the Department of prices of medicines and forwarded to all pharmaceutical companies. It shall be completed and signed by the person responsible for placing each medicinal product on the market and shall be deemed a legally binding solemn declaration. The Price Bulletin shall include as mandatory fields: a) the EU Member States in which the product is marketed; b) the name of the product (same or different from the one used in Greece); the active substance, all the forms, pack sizes, strengths and their respective prices; ATC classification; the code assigned by EOF, as well as the start and expiry date of the first national or European patent for the active substance of the medicinal product. The Price Verification Sheet shall be completed twice a year; the exact dates shall be specified by a circular of the relevant Directorate of the Ministry of Health.
6. The Service shall verify the accuracy of the data contained in the Sheet by cross-checking with the EOF Register, as well as with any other available source of the European Union, individual Member States, official agencies and networks.

7. In the case of companies which withhold information or for any reason whatsoever fail to report or are found to have reported inaccurate data, the competent Service, following an opinion from the Pricing Committee, shall impose a fine, by decision of the Minister of Health in accordance with the provisions of Article 69 of Law 3984/2011.
6. The submission of applications, Price Verification Sheets, enquiries, data and any other communication between pharmaceutical companies and the Department of prices of medicines shall also be possible through the e-mail address: farmaka.times@yyka.gov.gr.

Article 5
Procedural matters regarding pricing

1. On the basis of the information set out in Article 4, the Department of prices of medicines shall assign prices to medicinal products taking into account, cumulatively, the criteria of paras 2 and 3, where possible. Otherwise, a correlation with strengths and pack sizes shall be carried out, by applying the provisions of Article12 hereof. For correlation with medicinal products of other EU countries, any pack sizes that are more than eight times larger than the Greek one shall not be taken into consideration, except for the medicinal products of para 2 of Article12 of Law 3816/2010. The provisions of the preceding sentence shall not apply to the correlation of prices of medicinal products in cases where the pack size of the medicinal product, as approved and priced in EU countries, is unique and equal to or larger than eight times the size of the Greek one.

2. For converting into euro any prices of medicinal products denominated in other currencies, the Department of prices of medicines shall use the reference exchange rates published by the Bank of Greece as on the first business day of the calendar two-month period prior to the issuance of an Official Drug Price List.
3. Orphan medicines shall be priced in accordance with the provisions hereof and by the procedure laid down herein.
4. The transitional provision of Article 2 of Market Decree 8 – 2010 (setting a maximum limit on upward or downward adjustments to the prices of medicinal products) shall apply to those medicinal products the retail price of which is lower than €10 and which have obtained marketing authorisation before 2000. The provision shall also apply by analogy to substantially similar products.
5. Upon the completion of the pricing process, the competent Service shall recommend and the Minister of Health shall determine by Official Price Lists the prices of medicinal products, following an opinion from the Pricing Committee. The prices shall be updated on a quarterly basis and the Official Price lists shall be posted on the website of the Ministry of Health.

Article 6
Pricing of medicinal products after the expiry of the first patent of the active substance

1. The wholesale prices of medicinal products, after it has been verified by any appropriate method that the first national or European patent of their active substance has expired, shall be reduced to 50% by the competent Service, without an application by the marketing authorisation holder. Marketing Authorisation Holders may apply for a lower price, without any restriction.

2. Pharmaceutical companies shall indicate in the Price Verification Sheet the start and expiry date of the first national or European patent of the active substance. Failure to do so shall incur a fine, imposed by decision of the Minister of Health in accordance with the provisions of Law 3557/2007 and of Article 69 of Law 3984/2011.
3. For medicinal products the wholesale price of which is lower than €5, if after the expiry of the first national or European patent of their active substance and after the lapse of at least three years no substantially similar products exist, the Pricing Committee may recommend that a price increase be given beyond the levels specified in this Decision, provided that the MAH submits full cost data, and in accordance with the provisions of Article 8 hereof. The same shall apply to any substantially similar medicinal product that remains unique after the withdrawal of the originator product.

Article 7
Medicinal products of the same active substance (substantially similar) – Dynamic pricing

1. The wholesale prices of medicinal products of the same active substance, form and strength shall be determined at 40% of the price of the originator patented product; the reduction shall be effected by the competent Service without an application of the |marketing authorization holder (MAH). MAHs may apply for a lower price, without any restriction.
2. If the originator product comes in a different pack size, a correlation shall be carried out in accordance with the provisions of Article 12 hereof. A similar correlation shall also take place when the price of the originator product refers to a different form or strength. In this case, the other cost parameters shall also be considered.
3. When a substantially similar medicinal product corresponds to an originator product which is not marketed in the country, its price shall be determined in accordance with the provisions of Articles 5, 6 and 7 hereof.
4. For parenteral preparations, uniform prices shall be determined on the basis of the active substance, strength, pack size and other cost parameters.
5. For medicinal products of the same active substance authorised in Greece from 1 January 2012 onwards, the price reduction to 40% of the price of the originator patented product shall apply to the first three marketing authorisation applications to EOF for each form, strength and pack size. For each subsequent marketing authorisation and for the three subsequent products, the price shall be set at 10% below the price of the first three products of the same active substance for each form, strength and pack size. The same reduction shall apply respectively to the three subsequent three products with the same active substance to be authorized. The provision of this paragraph shall take effect following 1 October 2012.

Article 8
Medicinal products manufactured in Greece

1. For medicinal products authorised and marketed in Greece and not marketed in any other EU country, the prices shall be determined on the basis of a cost assessment that shall include the cost of production and packaging for each form and pack size, the cost of administration-marketing-distribution costs as determined by relevant tables updated every two years and reflecting the respective average costs in the industry.

2. The following shall not be considered as cost components: a) default interest expenses; b) personal taxes (income tax, etc.); c) cost of non-compliance with applicable provisions; d) any difference in the price of active substances charged by any supplier in excess of the price charged by the developing laboratory; e) third-party fees and other costs not related to the production or marketing of medicinal products.
3. In the case of Greek-patented medicinal products involving research on active substance or pharmaceutical form, for which there are clinical pharmacokinetics trials and a marketing authorisation by EOF, the cost assessment shall additionally take into account the value of new investment, the cost of research and development of the active substance or pharmaceutical form and a valuation of know-how. Similar pharmaceutical forms shall be exempted from this provision.
4. The maximum net profit margin shall be 8.5% of the total cost excluding depreciation, interest and third-party profits (contract manufacturing). In any event and for as long as the patent is valid, the price of the medicinal product may not be higher than three times the average of the prices of the medicinal products in the same ATC 4 category, compared with products of the same form and strength.

Article 9
Obligations of pharmaceutical companies

1. After the end of each management period, pharmaceutical companies shall be required to submit to the Directorate of Medicines and Pharmacies, Department of Prices of Medicines, the following data:
1.1. Within a period of one month, volume and value data on their sales per code during the management period under review.
1.2. Within a period of four months, balance sheet and expenditure statement (detailed and in summary form).
The submission of the aforementioned data shall be a prerequisite for the consideration of any request for the approval or revision of a price.
2. A cost audit or audit of individual data of companies shall be carried out, where necessary, independently from any tax or other audit, by officers of Ministry of Health at the registered office of the company; the latter shall be required to provide auditors with access to all its accounting books and documents.
The competent Service, if it deems it necessary, may use data from similar companies and any other available data.
3. A company engaging in another line of business in addition to medicinal products, shall keep separate accounts for its pharmaceutical business. The same obligation shall apply to companies that manufacture or pack medicinal products on behalf of third parties (contract manufacturing) in respect of such products.
4. Pharmaceutical companies shall be required to keep a cost book for the medicinal products they manufacture or pack. Entries in the cost book shall reflect, for each form of medicinal product in detail and by batch, the quantities and cost of raw materials, additional materials and packing materials used, as well as the production/packaging costs of the medicinal products. Moreover, the cost book shall show the quantities produced and their value at ex-factory prices. At the end of the year, the General Industrial Costs corresponding to the production of each medicinal product shall be entered. Before its use, the cost book shall be authorized by the competent service. Companies which, under the Code on Tax Books and Documents or other legislation, are required to record these data in a book or in a card-based system shall be exempted from the obligation to keep a cost book.

Comment [MSOffice4]: New

Comment [MSOffice5]: The words "Market Control Police Department" were deleted.

5. Pharmaceutical companies, agents/importers, wholesalers and pharmacists shall be required to provide to the competent Service any relevant information as may be requested by the Service, in accordance with the provisions of Article30 of Legislative Decree 136/1946 (on the Market Control Code).
"6. At the first application of this Decision, pharmaceutical companies shall report to EOF, within a period of one month of the publication hereof, detailed data on all the medicinal products they have manufactured and/or packed at their facilities since 1 January 2008 and on behalf of which MAH they have done so. Thereafter, within the first quarter of each year, they shall report the same data, referring to the output of the preceding year. EOF shall cross-check the data with MAHs and record them in the file of each medicinal product together with any changes thereto."

Article 10

Submission of supporting documents and deadlines for pricing

1. For the purpose of determining or adjusting the prices of medicinal products for which a marketing authorisation has been granted by EOF or the European Medicines Agency (EMEA), an application shall be required. Applications shall be submitted at the competent Service or emailed to: farmaka.times@yyka.gov.gr, within forty-five (45) calendar days of the release of the latest Price Bulletin on the website of the Ministry of Health.
2. For all medicinal products of foreign origin (manufactured, packed, imported), a certificate by the foreign company, authenticated by the relevant authorities, shall be submitted to the competent Service, stating the ex-factory price, the wholesale and retail price of the medicinal product in its country of origin.
3. In the case of an application for the pricing of a new medicinal product, the competent Service shall issue a Price Bulletin within 90 days of receipt of the application.
If the information supporting the application is inadequate, the applicant shall be notified of what additional information is required, and the final decision shall be taken within 90 days of receipt of this additional information. If the decision results in a price that is significantly different from the price requested in the application, the Service shall justify its pricing decision to the applicant and the applicant may appeal the decision by submitting an application to the Minister of Health.
If the application for the pricing of a new medicinal product is not accompanied by the respective marketing authorisation, the application shall be archived without being processed.
4. In the case of an application for an increase in the price, the provisions of Articles 4, 5, 6, 7 and 8 hereof shall apply. The applicant shall provide adequate information including details of those events intervening since the price of the medicinal product was last determined which justify the price increase requested. In the event of an exceptional number of applications, the period may be extended once for a further 90 days.
5. In the event of a price freeze imposed for special reasons, marketing authorisation holders may apply for a derogation, the provisions of Articles 4, 5, 6, 7 and 8 hereof still being applicable. Any such derogation shall be granted for a limited number of medicinal products for which the price freeze entails significant losses for the company.
6. Marketing authorisation holders may request the deletion of their medicinal products from the Price Bulletin, provided they can prove that they have given to EOF

a three months' notice of discontinuation of the marketing of such products. In these cases, the provisions of Articles 6 and 7 hereof shall be taken into account.
7. For the determination of the price of medicines for which an authorization for parallel import has been issued by EOF, or for the change of their price, a relevant application must be submitted. These applications are submitted to the competent service or they are sent via e-mail to the following address: farmaka.times@yyka.gov.gr, within forty five (45) calendar days from the date of issuance of the respective Price Bulletin on the website of the Ministry of Health. Furthermore a Solemn Declaration is submitted, in which the purchase price by the supplier is mentioned and the certified sales invoice concerning the import volumes is attached.

Comment [MSOffice6]: New

Article 11
General provisions

1. The prices of medicinal products shall be determined for the pack sizes approved by EOF and the European Medicines Agency (EMEA). Large (hospital-size) packages may not be sold in parts by pharmacies.
2. Medicinal products designated by their marketing authorisation as being "exclusively for hospital use" shall be required to indicate clearly and in a special box on their outer package and in the enclosed leaflet the words "FOR HOSPITAL USE ONLY".
3. The outer package of medicinal products must indicate the retail price.
4. Transport costs for bringing medicinal products to the facilities of regional wholesalers and pharmacies shall be borne by manufacturers or importers. Such costs shall be borne by wholesalers in respect of products sold to regional pharmacies. By way of exception, wholesalers shall bear no transport costs for orders not exceeding €10 in value.
5. In the event of a price freeze, the Ministry of Health shall carry out a review, at least one a year, to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.
6. Pharmaceutical packages intended for export shall not be subject to controls by the Market Control Police.
7. Manufacturers, packers and importers of medicinal products shall be required to withhold a levy in favour of the National Pharmacy Association (0.4% of the wholesale price) for their sales to pharmacies. The levy shall be collected and transferred to the National Pharmacy Association through the Pension Fund for Health Professionals (TSAY). Wholesalers shall respectively withhold the levy from pharmacists. For medicinal products exported by wholesalers, the proportion of the levy corresponding to exports (and already withheld by pharmaceutical companies) shall be returned to wholesalers by the same procedure as in the case of other levies in favour of third parties under similar circumstances. This percentage shall fully borne by the purchasing pharmacies and shall be collected and transferred to the National Pharmacy Association by the aforementioned sellers/invoicers.
8. In case of co-marketed products, a single price shall be determined. If different prices are derived, the single price shall be the lowest of these different prices.

Article 12
Prices in the event of a change of the manufacturer or packer of a medicinal product

or of a replacement or addition of a pack size of a medicinal product, etc.

1. If the manufacturer and/or the packer of a medicinal product changes, the price of the product prior to the change shall be taken, as a maximum.

2. In the event of a replacement or addition of a pack size or strength of a medicinal product or an addition of a variation (provided that the variation refers to the same route of administration), the determination of the price shall involve a correlation with the prices determined as specified in the preceding articles hereof. For the correlation of medicinal products priced under Article 8 hereinabove, any change in packaging/standardisation costs shall be taken into account.

3. The conversion of packages and strengths shall take place as follows:

a) From a smaller to a larger pack/strength, the unit price shall diminish up to a maximum of 12%, as follows:

Percentage increase in pack size/strength	Percentage reduction in price
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
over 60	On a case-by-case basis, taking into account the available data

b) From a larger to a smaller pack size/strength, the unit price shall increase up to a maximum of 12%:

Percentage reduction in pack size/strength	Percentage increase in price
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 to 35	12.00

c) As an exception, the forms of single-dose injectable preparations, sachets and eye solutions shall be calculated pro rata.

4. When two or more strengths of the same medicinal product are priced and the prices derived are disproportional to each other, the lowest price shall be taken.

5. The approved prices shall be published in the Pharmaceutical Price Bulletin, following an opinion from the Pharmaceutical Price Committee. Interested parties may, within three (3) business days of the date after the meeting of the Pharmaceutical Price Committee, provide feedback on the resulting prices. This period shall be extended by two (2) business days in the case of Price Bulletins representing a general revision of the prices of medicinal products. The feedback from interested parties shall be reviewed and addressed by a Corrective Price Bulletin within twenty (20) days.

Article 13

Authenticity tag or barcode of medicinal products

The requirement to indicate the necessary data on the authenticity tag or barcode shall be without prejudice to the requirement to indicate such data on any other parts of the package in accordance with other provisions.

The Ministerial Decision DYG3(a)/oik.GY/151/12 (OJ 545/B/1-3-2012) as well as the decision DYG3(a)oik.128948 (OJ 2785/B/2-12-2011) are abolished.

Comment [MSOffice7]: New

This Decision shall enter into force as of its publication in the Government Gazette.

We order that this Decision be published in the Government Gazette.

Athens, 29 March 2012

THE MINISTER

ANDREAS LOVERDOS